Human Medicines Authorised/Transfer Pending Products
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Please Note

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Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
0.18%w/v Sodium Chloride and 4.0% w/v Glucose Intravenous Infusion BP, (Viaflo Container	Baxter Holding B.V.	PA2299/008/005	Solution for infusion	- B05XA - B05XA31	- Anhydrous glucose - Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
0.9 % w/v Sodium Chloride Injection BP	B. Braun Medical Limited	PA0179/002/013	Solution for injection	- V07AB	- Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
0.9% Sodium Chloride Intravenous Infusion Solution	Laboratoire AGUETTANT	PA1968/018/001	Solution for infusion	- B05BB - B05BB01	- Sodium chloride		- Intravenous use
1% w/v Lidocaine Hydrochloride Injection BP	B. Braun Melsungen AG	PA0736/044/001	Solution for injection	- N01BB - N01BB02	- Lidocaine Hydrochloride Monohydrate		- Epidural use - Intradermal use - Intramuscular use - Intravenous use - Perineural use - Submucosal use
2% w/v Lidocaine Hydrochloride Injection BP	B. Braun Melsungen AG	PA0736/044/002	Solution for injection	- N01BB - N01BB02	- Lidocaine Hydrochloride Monohydrate		- Epidural use - Intradermal use - Intramuscular use - Intravenous use - Perineural use - Submucosal use
5% Glucose Intravenous Infusion Solution	Laboratoire AGUETTANT	PA1968/019/001	Solution for infusion	- B05BB - B05BB02	- Glucose		- Intravenous use
8.4% w/v Sodium Bicarbonate Intravenous Infusion BP	B. Braun Medical Limited	PA0179/006/001	Solution for infusion	- B05XA - B05XA02	- Sodium bicarbonate		- Intravenous use
A.Vogel Uva-ursi & Echinacea Cystitis oral drops	A.Vogel Ireland Limited	TR2309/021/001	Oral drops, solution			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Abacavir/Lamivudine Mylan 600 mg/300 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/193/001	Film-coated tablet	- J05AR - J05AR02	- Abacavir - Lamivudine		- Oral use
Abacavir/Lamivudine Mylan Pharma 600 mg/300 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/216/001	Film-coated tablet	- J05AR - J05AR02	- Abacavir sulfate - Lamivudine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Abasaglar	Eli Lilly Nederland B.V.	EU/1/14/944/001-004	Solution for injection in cartridge	- A10AE - A10AE04	- Insulin glargine	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Abasaglar	Eli Lilly Nederland B.V.	EU/1/14/944/005-008	Solution for injection in pre-filled pen	- A10AE - A10AE04	- Insulin glargine	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Abecma	Bristol-Myers Squibb Pharmaceuticals uc	EU/1/21/1539/001	Dispersion for infusion	- L01	- Idecabtagene Vicleucel	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Abevmy	Biosimilar Collaborations Ireland Limited	EU/1/20/1515/001-005	Concentrate for solution for infusion	- L01XC07	- Bevacizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Abidec Multivitamin Oral Drops Solution	Chefaro Ireland DAC	PA1186/001/001	Oral drops, solution	- A11BA	- Vitamin a palmitate - Ergocalciferol - Thiamine hydrochloride - Riboflavin sodium phosphate - Pyridoxine hydrochloride - Nicotinamide - Ascorbic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Abilify	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/001-005 Interchangeable List Code: IC0092-001-002	Tablet		- Aripiprazole	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ABILIFY	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/006-010 Interchangeable List Code: IC0092-002-056	Tablet		- Aripiprazole	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ABILIFY	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/011-015 Interchangeable List Code: IC0092-032-056	Tablet		- Aripiprazole	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ABILIFY	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/016-020 Interchangeable List Code: IC0092-033-056	Tablet		- Aripiprazole	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Abilify	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/024-026 Interchangeable List Code: IC0092-002-056	Orodispersible tablet		- Aripiprazole	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Abilify	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/027-029 Interchangeable List Code: IC0092-032-056	Orodispersible tablet		- Aripiprazole	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Abilify	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/030-032 Interchangeable List Code: IC0092-033-056	Orodispersible tablet		- Aripiprazole	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Abilify	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/033-035	Oral solution	- N05AX - N05AX12	- Aripiprazole	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Abilify	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/036	Solution for injection	- N05AX - N05AX12	- Aripiprazole	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Abilify Maintena	Otsuka Pharmaceutical Netherlands B.V.	EU/1/13/882/001,003	Powder and solvent for prolonged-release suspension for injection	- N05AX - N05AX12	- Aripiprazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Abilify Maintena	Otsuka Pharmaceutical Netherlands B.V.	EU/1/13/882/002,004	Powder and solvent for prolonged-release suspension for injection	- N05AX - N05AX12	- Aripiprazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Abiraterone 500 mg film-coated tablets	Rowex Ltd	PA0711/304/002 Interchangeable List Code: IC0123-117-003	Film-coated tablet		- Abiraterone acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Abiraterone Accord	Accord Healthcare S.L.U.	EU/1/20/1512/001 Interchangeable List Code: IC0123-130-002	Tablet		- Abiraterone acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Abiraterone Accord	Accord Healthcare S.L.U.	EU/1/20/1512/002-003 Interchangeable List Code: IC0123-117-003	Film-coated tablet		- Abiraterone acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Abiraterone Aristo 250 mg tablets	Aristo Pharma GmbH	PA1983/008/001 Interchangeable List Code: IC0123-130-002	Tablet		- Abiraterone acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Abiraterone Aristo 500 mg film-coated tablets	Aristo Pharma GmbH	PA1983/008/002 Interchangeable List Code: IC0123-117-003	Film-coated tablet		- Abiraterone acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Abiraterone Clonmel 500 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/336/001 Interchangeable List Code: IC0123-117-003	Film-coated tablet		- Abiraterone acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Abiraterone Krka	KRKA, d.d., Novo mesto	EU/1/21/1553/001-003 Interchangeable List Code: IC0123-117-003	Film-coated tablet		- Abiraterone acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Abiraterone Mylan	Mylan IRE Healthcare Limited	EU/1/21/1571/001-008 Interchangeable List Code: IC0123-117-003	Film-coated tablet		- Abiraterone acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Abiraterone Mylan	Mylan IRE Healthcare Limited	EU/1/21/1571/009-012	Film-coated tablet	- L02BX03	- Abiraterone acetate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Abiraterone Rowa 500 mg Film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/092/001 Interchangeable List Code: IC0123-117-003	Film-coated tablet		- Abiraterone acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Abiraterone Teva 500 mg film-coated tablets	Teva B.V.	PA1986/103/001 Interchangeable List Code: IC0123-117-003	Film-coated tablet		- Abiraterone acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Abraxane	Bristol-Myers Squibb Pharma EEIG	EU/1/07/428/001	Powder for concentrate for dispersion for infusion	- L01CD - L01CD01	- Paclitaxel (formulated as albumin bound nanoparticles)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Abrysvo powder and solvent for solution for injection Respiratory syncytial virus vaccine (bivalent, recombinant)	Pfizer Europe MA EEIG	EU/1/23/1752/001-006	Powder and solvent for solution for injection	- J07BX05	- Respiratory syncytial virus, subgroup A, stabilized prefusion F protein 847A - Respiratory syncytial virus, subgroup B, stabilized prefusion F protein 847B	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/021-22	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Epoetin alfa	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/023-24	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Epoetin alfa	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/025-26	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Epoetin alfa	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/11-12	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/1-2	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/13-14	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/15-16	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/3-4	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/5-6	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/7-8	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/9-10	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Abstral 100 microgram sublingual tablets	Kyowa Kirin Holdings B.V.	PA2288/004/002	Sublingual tablet	- N02AB - N02AB03	- Fentanyl	Full application (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Abstral 200 microgram sublingual tablets	Kyowa Kirin Holdings B.V.	PA2288/004/003	Sublingual tablet	- N02AB - N02AB03	- Fentanyl	Full application (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Abstral 300 microgram sublingual tablets	Kyowa Kirin Holdings B.V.	PA2288/004/004	Sublingual tablet	- N02AB - N02AB03	- Fentanyl	Full application (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Abstral 400 microgram sublingual tablets	Kyowa Kirin Holdings B.V.	PA2288/004/005	Sublingual tablet	- N02AB - N02AB03	- Fentanyl	Full application (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Abstral 600 microgram sublingual tablets	Kyowa Kirin Holdings B.V.	PA2288/004/006	Sublingual tablet	- N02AB - N02AB03	- Fentanyl	Full application (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Abstral 800 microgram sublingual tablets	Kyowa Kirin Holdings B.V.	PA2288/004/007	Sublingual tablet	- N02AB - N02AB03	- Fentanyl	Full application (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
ACARIZAX 12 SQ-HDM sublingual lyophilisate	ALK-Abello A/S	PA1255/010/001	Sublingual lyophilisate	- V01AA03	- Dermatophagoides Farinae Extract - Dermatophagoides Pteronyssinus Extract	Full application (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Accofil	Accord Healthcare S.L.U.	EU/1/14/943/003-004	Solution for injection in pre-filled syringe	- L03AA - L03AA02	- Filgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Accofil	Accord Healthcare S.L.U.	EU/1/14/946/001-002	Solution for injection in pre-filled syringe	- L03AA - L03AA02	- Filgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Accupro 10 mg film-coated tablets	Pfizer Healthcare Ireland	PA0822/007/002	Film-coated tablet	- C09AA - C09AA06	- Quinapril		- Oral use
Accupro 20 mg film-coated tablets	Pfizer Healthcare Ireland	PA0822/007/003	Film-coated tablet	- C09AA - C09AA06	- Quinapril		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Accupro 40 mg film-coated tablets	Pfizer Healthcare Ireland	PA0822/007/004	Film-coated tablet	- C09AA - C09AA06	- Quinapril		- Oral use
Accupro 5 mg film-coated tablets	Pfizer Healthcare Ireland	PA0822/007/001	Film-coated tablet	- C09AA - C09AA06	- Quinapril		- Oral use
Accuretic 20 mg/12.5 mg film-coated tablets	Pfizer Healthcare Ireland	PA0822/008/002	Film-coated tablet	- C09BA - C09BA06	- Quinapril - Hydrochlorothiazide		- Oral use
Accusol 35 Potassium 2 mmol/lSolution for haemofiltration, haemodialysis and haemodiafiltration	Nikkiso Belgium bvba	PA2021/002/001	Solution for haemodialysis/haemofiltration	- B05ZB	- Sodium chloride - Calcium chloride - Magnesium chloride - Sodium bicarbonate - Potassium chloride - Glucose anhydrous		- Haemodialysis - Intraarterial use
Accusol 35 Potassium 4 mmol/lSolution for haemofiltration, haemodialysis and haemodiafiltration	Nikkiso Belgium bvba	PA2021/002/002	Solution for haemodialysis/haemofiltration	- B05ZB	- Sodium chloride - Calcium chloride - Magnesium chloride - Sodium bicarbonate - Potassium chloride - Glucose anhydrous	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Haemodialysis - Intraarterial use
Accusol 35 Solution for haemofiltration, haemodialysis and haemodiafiltration	Nikkiso Belgium bvba	PA2021/001/001	Solution for haemofiltration	- B05ZB	- Sodium chloride - Calcium chloride - Magnesium chloride - Sodium bicarbonate		- Haemodialysis - Intraarterial use
Acerycal 10mg/10mg tablets	Les Laboratoires Servier	PA0568/018/004	Tablet	- C09BB	- Perindopril arginine - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Acerycal 5mg/10mg tablets	Les Laboratoires Servier	PA0568/018/002	Tablet	- C09BB	- Perindopril arginine - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Acerycal 10mg/5mg tablets	Les Laboratoires Servier	PA0568/018/003	Tablet	- C09BB	- Perindopril arginine - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Acerycal 5mg/5mg tablets	Les Laboratoires Servier	PA0568/018/001	Tablet	- C09BB	- Perindopril arginine - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Acetylcysteine Essential-Healthcare 600 mg effervescent tablets	Ascot Laboratories (Ireland) Limited	PA23163/003/001	Effervescent tablet	- R05CB - R05CB01	- Acetylcysteine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Acetylcysteine Stirling Anglian 600 mg effervescent tablets	Stirling Anglian Pharmaceuticals Ireland Limited	PA23138/003/001	Effervescent tablet	- R05CB - R05CB01	- Acetylcysteine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Acic 5% Cream	Rowex Ltd	PA0711/017/001	Cream	- D06BB - D06BB03	- Aciclovir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Topical
Acic Cold Sore 5% w/w Cream	Rowex Ltd	PA0711/017/006	Cream	- D06BB - D06BB03	- Aciclovir	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Cutaneous use
Aciclovir 200mg/5ml Oral Suspension	Syri Pharma Limited t/a Thame Laboratories	PA22697/001/001	Oral suspension	- J05AB - J05AB01	- Aciclovir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aciclovir 25mg/ml Concentrate for solution for infusion	Baxter Holding B.V.	PA2299/041/001	Concentrate for solution for infusion	- J05AB - J05AB01	- Aciclovir	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Aciclovir 25mg/ml concentrate for solution for infusion	Pfizer Healthcare Ireland	PA0822/215/001	Concentrate for solution for infusion	- J05AB - J05AB01	- Aciclovir sodium		- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Aciclovir 400mg/5ml Oral Suspension	Syri Pharma Limited t/a Thame Laboratories	PA22697/001/002	Oral suspension	- J05AB - J05AB01	- ACICLOVIR	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aciclovir Agepha 30 mg/g eye ointment	AGEPHA Pharma s.r.o.	PA22584/001/001	Eye ointment	- S01AD03	- Aciclovir	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Aciclovir Azevedos 250 mg Powder for solution for infusion	Laboratórios Azevedos - Indústria Farmacêutica S.A	PA1852/003/001	Powder for solution for infusion	- J05AB - J05AB01	- Aciclovir sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Acidex Oral Suspension, Sodium Alginate 500mg, Sodium Bicarbonate 267mg, Calcium Carbonate 160mg/10ml	Pinewood Laboratories Ltd	PA0281/075/001	Oral suspension	- B05CB - B05CB04	- Sodium alginate - Sodium bicarbonate - Calcium carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Aclasta	Sandoz Pharmaceuticals d.d.	EU/1/05/308/001	Solution for infusion	- M05BA - M05BA08	- Zoledronic acid	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Acnecide 5% w/w Ge	Galderma International	PA22743/001/001	Gel	- D10AE - D10AE01	- Benzoyl Peroxide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical use
Acnecide 5% w/w Ge	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/054/001	Gel	- D10AE - D10AE01	- Benzoyl Peroxide		- Topical use
Acnecide Wash 5 % w/w Gel	Galderma International	PA22743/001/002	Gel	- D10AE - D10AE01	- Benzoyl Peroxide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Cutaneous use - Topical use
Aconite	A. Nelson & Company Limited	HOR1149/001/001	Not assigned		- Aconitum napellus		- Oral use
ACTAIR 100 IR & 300 IR sublingual tablets	STALLERGENES	PA2113/002/002	Sublingual tablet	- V01AA03	- Dermatophagoides Pteronyssinus Extract - Dermatophagoides Farinae Extract	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
ACTAIR 100 IR sublingual tablets	STALLERGENES	PA2113/002/001	Sublingual tablet	- V01AA03	- Dermatophagoides Pteronyssinus Extract - Dermatophagoides Farinae Extract	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
ACTAIR 300 IR sublingual tablets	STALLERGENES	PA2113/002/003	Sublingual tablet	- V01AA03	- Dermatophagoides Pteronyssinus Extract - Dermatophagoides Farinae Extract	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Actelsar HCT 40 mg/12.5 mg tablets	Actavis Group hf	EU/1/13/817/001-013 Interchangeable List Code: IC0050-099-039	Tablet		- Hydrochlorothiazide - Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Actelsar HCT 80 mg/12.5 mg tablets	Actavis Group hf	EU/1/13/817/014-028 Interchangeable List Code: IC0050-081-039	Tablet		- Hydrochlorothiazide - Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Actelsar HCT 80 mg/25 mg tablets	Actavis Group hf	EU/1/13/817/029-041 Interchangeable List Code: IC0050-100-039	Tablet		- Hydrochlorothiazide - Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
ACTIFED 30mg/1.25mg per 5ml Syrup	JNTL Consumer Health I (Ireland) Limited	PA23490/029/001	Syrup	- R01BA - R01BA02	- PSEUDOEPHEDRINE HYDROCHLORIDE - TRIPROLIDINE HYDROCHLORIDE		- Oral use
Actifed 60mg/2.5mg Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/029/002	Tablet	- R01BA - R01BA02	- PSEUDOEPHEDRINE HYDROCHLORIDE - TRIPROLIDINE HYDROCHLORIDE		- Oral use
Actilyse 10 mg powder and solvent for solution for injection and infusion	Boehringer Ingelheim International GmbH	PA0775/011/001	Powder and solvent for solution for injection/infusion	- B01AD - B01AD02	- Alteplase	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Actilyse 20 mg powder and solvent for solution for injection and infusion	Boehringer Ingelheim International GmbH	PA0775/011/002	Powder and solvent for solution for injection/infusion	- B01AD - B01AD02	- Alteplase	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Actilyse 50 mg powder and solvent for solution for injection and infusion	Boehringer Ingelheim International GmbH	PA0775/011/003	Powder and solvent for solution for injection/infusion	- B01AD - B01AD02	- Alteplase	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Actilyse Cathflo 2 mg powder for solution for injection and infusion	Boehringer Ingelheim International GmbH	PA0775/011/004	Powder and solvent for solution for injection/infusion	- B01AD02	- Alteplase	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Actiprofen 200 mg tablets	Haleon Ireland Limited	PA0678/061/002	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen		- Oral use
Actiq 200 micrograms compressed lozenge with integral oromucosal applicator	Teva Pharma B.V.	PA0749/195/001	Compressed lozenge	- N02AB - N02AB03	- Fentanyl		- Oromucosal use
Actiq 200 micrograms compressed lozenge with integral oromucosal applicator	PCO Manufacturing Ltd.	PPA0465/407/001	Compressed lozenge	- N02AB03	- Fentanyl	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oromucosal use
Actiq 400 micrograms compressed lozenge with integral oromucosal applicator	PCO Manufacturing Ltd.	PPA0465/407/002	Compressed lozenge	- N02AB03	- Fentanyl	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oromucosal use
Actiq 400 micrograms compressed lozenge with integral oromucosal applicator	Teva Pharma B.V.	PA0749/195/002	Compressed lozenge	- N02AB - N02AB03	- Fentanyl		- Oromucosal use
Actiq 600 micrograms compressed lozenge with integral oromucosal applicator	Teva Pharma B.V.	PA0749/195/003	Compressed lozenge	- N02AB - N02AB03	- Fentanyl		- Oromucosal use
Activelle 1 mg/0.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/199/001	Film-coated tablet	- G03FA01	- Estradiol - Norethisterone acetate		- Oral use
Activelle 1 mg/0.5 mg film-coated tablets	Novo Nordisk A/S	PA0218/052/001	Film-coated tablet	- G03FA - G03FA01	- estradiol anhydrous - Norethisterone acetate		- Oral use
Actonel Plus Ca & D 35 mg film-coated tablets + 1000 mg/880 IU Effervescent Granules	PCO Manufacturing Ltd.	PPA0465/305/001	Effervescent granules + film-coated tablet	- M05BB04	- Risedronate sodium - Calcium carbonate - Colecalciferol	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Actos	CHEPLAPHARM Arzneimittel GmbH	EU/1/00/150/001	Tablet	- A10BG03	- Pioglitazone		- Oral use
Actos	CHEPLAPHARM Arzneimittel GmbH	EU/1/00/150/002	Tablet	- A10BG03	- Pioglitazone		- Oral use
Actos	CHEPLAPHARM Arzneimittel GmbH	EU/1/00/150/003	Tablet	- A10BG03	- Pioglitazone		- Oral use
Actos	CHEPLAPHARM Arzneimittel GmbH	EU/1/00/150/004	Tablet	- A10BG03	- Pioglitazone		- Oral use
Actos	CHEPLAPHARM Arzneimittel GmbH	EU/1/00/150/005	Tablet	- A10BG03	- Pioglitazone		- Oral use
Actos	CHEPLAPHARM Arzneimittel GmbH	EU/1/00/150/006	Tablet	- A10BG03	- Pioglitazone		- Oral use
Actos	Takeda Pharma A/S	EU/1/00/150/011	Tablet	- A10BG03	- Pioglitazone		- Oral use
Actraphane	Novo Nordisk A/S	EU/1/02/229/001-035	Solution for injection	- A10AD - A10AD01	- Insulin human		- Subcutaneous use
Actraphane 30	Novo Nordisk A/S	EU/1/02/229/036-037	Suspension for injection	- A10AD - A10AD01	- Insulin human - Insulin human		- Subcutaneous use
Actrapid	Novo Nordisk A/S	EU/1/02/230/001-015	Solution for injection	- A10AB - A10AB01	- Insulin human		- Subcutaneous use
Actrapid	Novo Nordisk A/S	EU/1/02/230/016-017	Solution for injection	- A10AB - A10AB01	- Insulin human		- Intravenous use - Subcutaneous use
ACULAR 0.5% w/v Eye drops, solution	PCO Manufacturing Ltd.	PPA0465/287/001	Eye drops, solution	- S01BC - S01BC05	- Ketorolac trometamol		- Ocular use
Acular 0.5% w/v Eye Drops, solution	IMED Healthcare Ltd.	PPA1463/200/001	Eye drops, solution	- S01BC - S01BC05	- Ketorolac trometamol		- Ocular use
Acular 0.5% w/v Eye Drops, solution	AbbVie Limited	PA1824/015/001	Eye drops, solution	- S01BC - S01BC05	- Ketorolac trometamol		- Ocular use
Adaluzis 500mg Powder for concentrate for solution for infusion	Correvio	PA2319/001/001	Powder for concentrate for solution for infusion	- J01DI - J01DI01	- CEFTOBIPROLE MEDOCARIL SODIUM	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Adasuve	Ferrer Internacional, S.A	EU/1/13/823/001	Inhalation powder, pre-dispensed	- N05AH - N05AH01	- Loxapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Adasuve	Ferrer Internacional, S.A	EU/1/13/823/002	Inhalation powder, pre-dispensed	- N05AH - N05AH01	- Loxapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Adcetris	Takeda Pharma A/S	EU/1/12/794/001	Powder for concentrate for solution for infusion	- L01XC - L01XC12	- Brentuximab vedotin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Adcirca	Eli Lilly Nederland B.V.	EU/1/08/476/005-06	Film-coated tablet	- G04BE08	- Tadalafil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Adcirca (previously Tadalafil Lilly)	Eli Lilly Nederland B.V.	EU/1/08/476/001-004	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Adcortyl Intra-articular/Intradermal Injection 10 mg/ml, Suspension for Injection, 5ml	Bristol-Myers Squibb Pharmaceuticals uc	PA0002/018/003	Suspension for injection	- H02AB - H02AB08	- Triamcinolone acetonide		- Intraarticular use - Intradermal use
Addiphos concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/024/001	Concentrate for solution for infusion	- B05XA - B05XA30	- Potassium dihydrogen phosphate - Potassium hydroxide - Disodium phosphate dihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Additrace N concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/023/002	Concentrate for solution for infusion	- B05XA - B05XA31	- Chromic chloride hexahydrate - Copper chloride dihydrate - Ferric chloride hexahydrate - Manganese chloride tetrahydrate - Potassium iodide - Sodium fluoride - Sodium molybdate dihydrate - Sodium selenite anhydrous - Zinc chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Adempas	Bayer AG	EU/1/13/907/001-003	Film-coated tablet	- C02KX - C02KX05	- Riociguat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Adempas	Bayer AG	EU/1/13/907/004-006	Film-coated tablet	- C02KX - C02KX05	- Riociguat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Adempas	Bayer AG	EU/1/13/907/007-009	Film-coated tablet	- C02KX - C02KX05	- Riociguat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Adempas	Bayer AG	EU/1/13/907/010-012	Film-coated tablet	- C02KX - C02KX05	- Riociguat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Adempas	Bayer AG	EU/1/13/907/013-015	Film-coated tablet	- C02KX - C02KX05	- Riociguat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Adenocor 3 mg/ml solution for injection	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/139/001	Solution for injection	- C01EB - C01EB10	- Adenosine		- Intravenous use
Adenosine 3 mg/ml solution for injection in pre-filled syringe	Fresenius Kabi Deutschland GmbH	PA2059/004/001	Solution for injection in pre-filled syringe	- C01EB - C01EB10	- Adenosine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Adenuric	Menarini International Operations Luxembourg S.A.	EU/1/08/447/001-002	Film-coated tablet	- M04AA - M04AA03	- Febuxostat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Adenuric	Menarini International Operations Luxembourg S.A.	EU/1/08/447/003-004	Film-coated tablet	- M04AA - M04AA03	- Febuxostat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Adizem-SR 120 mg Prolonged Release Capsules	Mundipharma Pharmaceuticals Limited	PA1688/001/002	Prolonged-release capsule, hard	- C08DB - C08DB01	- Diltiazem hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Adizem-SR 180 mg Prolonged Release Capsules	Mundipharma Pharmaceuticals Limited	PA1688/001/003	Prolonged-release capsule, hard	- C08DB - C08DB01	- Diltiazem hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Adizem-SR 90 mg Prolonged Release Capsules	Mundipharma Pharmaceuticals Limited	PA1688/001/001	Prolonged-release capsule, hard	- C08DB - C08DB01	- Diltiazem hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ADIZEM-XL 120mg prolonged release capsules	Mundipharma Pharmaceuticals Limited	PA1688/001/004	Prolonged-release capsule, hard	- C08DB - C08DB01	- Diltiazem hydrochloride		- Oral use
ADIZEM-XL 180mg prolonged release capsules	Mundipharma Pharmaceuticals Limited	PA1688/001/005	Prolonged-release capsule, hard	- C08DB - C08DB01	- Diltiazem hydrochloride		- Oral use
ADIZEM-XL 240 mg prolonged release capsules	Mundipharma Pharmaceuticals Limited	PA1688/001/006	Prolonged-release capsule, hard	- C08DB - C08DB01	- Diltiazem hydrochloride		- Oral use
ADIZEM-XL 300 mg prolonged release capsules	Mundipharma Pharmaceuticals Limited	PA1688/001/007	Prolonged-release capsule, hard	- C08DB - C08DB01	- Diltiazem hydrochloride		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Adjupanrix	GlaxoSmithKline Biologicals S.A.	EU/1/09/578/001	Emulsion and suspension for emulsion for injection	- J07BB - J07BB02	- Purified antigen fractions of inactivated split virions a/vietnam/1194/2004 nibrg-14 (h5n1)		- Intramuscular use
Adrenaline (Epinephrine) 1 mg/10 ml (1:10,000) Solution for Injection in Pre-Filled Syringe	Laboratoire AGUETTANT	PA1968/002/001	Solution for injection in pre-filled syringe	- C01CA - C01CA24	- Adrenaline tartrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Adrenaline (Epinephrine) 1:1,000 Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/035/001	Solution for injection	- C01CA - C01CA24	- Adrenaline (epinephrine)		- Intramuscular use - Intravenous use - Subcutaneous use
Adrovance 70 mg/2800 IU tablets	N.V. Organon	EU/1/06/364/001-004 Interchangeable List Code: IC0052-102-002	Tablet		- Vitamin D3 - Alendronic acid	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Adrovance 70 mg/5600 IU tablets	N.V. Organon	EU/1/06/364/006-008 Interchangeable List Code: IC0052-103-002	Tablet		- Vitamin D3 - Alendronic acid	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Adtralza	LEO Pharma A/S	EU/1/21/1554/001	Solution for injection in pre-filled syringe	- D11AH07	- Tralokinumab	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Adtralza	LEO Pharma A/S	EU/1/21/1554/001-003	Solution for injection in pre-filled syringe	- D11AH07	- Tralokinumab	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Adtralza	LEO Pharma A/S	EU/1/21/1554/004-005	Solution for injection	- D11AH07	- Tralokinumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Advagraf	Astellas Pharma Europe BV	EU/1/07/387/11-13	Prolonged-release capsule, hard	- L04AD - L04AD02	- Tacrolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Advagraf	Astellas Pharma Europe BV	EU/1/07/387/1-2	Prolonged-release capsule, hard	- L04AD - L04AD02	- Tacrolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Advagraf	Astellas Pharma Europe BV	EU/1/07/387/3-6	Prolonged-release capsule, hard	- L04AD - L04AD02	- Tacrolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Advagraf	Astellas Pharma Europe BV	EU/1/07/387/7-8	Prolonged-release capsule, hard	- L04AD - L04AD02	- Tacrolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ADVATE	Takeda Manufacturing Austria AG	EU/1/03/271/001	Powder and solvent for solution for injection	- B02BD - B02BD02	- Recombinant coagulation fviii (octocog alfa)		- Intravenous use
Advate	Takeda Manufacturing Austria AG	EU/1/03/271/002	Powder and solvent for solution for injection	- B02BD - B02BD02	- Recombinant coagulation fviii (octocog alfa)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Advate	Takeda Manufacturing Austria AG	EU/1/03/271/003	Powder and solvent for solution for injection	- B02BD - B02BD02	- Recombinant coagulation fviii (octocog alfa)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Advate	Takeda Manufacturing Austria AG	EU/1/03/271/004	Powder and solvent for solution for injection	- B02BD - B02BD02	- Recombinant coagulation fviii (octocog alfa)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
ADVATE	Takeda Manufacturing Austria AG	EU/1/03/271/005	Powder and solvent for solution for injection	- B02BD - B02BD02	- Recombinant coagulation fviii (octocog alfa)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
ADVATE	Takeda Manufacturing Austria AG	EU/1/03/271/006	Powder and solvent for solution for injection	- B02BD - B02BD02	- Recombinant coagulation fviii (octocog alfa)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Advate	Takeda Manufacturing Austria AG	EU/1/03/271/007	Powder and solvent for solution for injection	- B02BD - B02BD02	- Recombinant coagulation fviii (octocog alfa)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Advate	Takeda Manufacturing Austria AG	EU/1/03/271/008	Powder and solvent for solution for injection	- B02BD - B02BD02	- Recombinant coagulation fviii (octocog alfa)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Advate	Takeda Manufacturing Austria AG	EU/1/03/271/009	Powder and solvent for solution for injection	- B02BD - B02BD02	- Recombinant coagulation fviii (octocog alfa)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Advil Cold & Flu Coated TabletsIbuprofen 200mgPseudoephedrine Hydrochloride 30mg	Haleon Ireland Limited	PA0678/147/001	Coated tablet	- M01AE - M01AE51	- Ibuprofen - PSEUDOEPHEDRINE HYDROCHLORIDE		- Oral use
Advil Cold & Flu Relief Soft Capsules Ibuprofen 200mg Pseudoephedrine Hydrochloride 30mg	Haleon Ireland Limited	PA0678/147/002	Capsule, soft	- M01AE - M01AE51	- Ibuprofen - PSEUDOEPHEDRINE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Advil Liquid 200mg Soft capsules	Haleon Ireland Limited	PA0678/146/001	Capsule, soft	- M01AE - M01AE01	- Ibuprofen		- Oral use
ADYNOVI	Baxalta Innovations GmbH	EU/1/17/1247/001-004	Powder and solvent for solution for injection	- B02BD - B02BD02	- Rurioctocog alfa pegol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
ADYNOVI	Baxalta Innovations GmbH	EU/1/17/1247/005-008	Powder and solvent for solution for injection	- B02BD - B02BD02	- Rurioctocog alfa pegol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
ADYNOVI	Baxalta Innovations GmbH	EU/1/17/1247/010-012	Powder and solvent for solution for injection	- B02BD - B02BD02	- Rurioctocog alfa pegol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
ADYNOVI	Baxalta Innovations GmbH	EU/1/17/1247/013-014	Powder and solvent for solution for injection	- B02BD - B02BD02	- Rurioctocog alfa pegol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Adynovi	Baxalta Innovations GmbH	EU/1/17/1247/015-016	Powder for solution for injection	- B02BD02	- Rurioctocog alfa pegol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Aerinaze	N.V. Organon	EU/1/07/399/001-006	Modified-release tablet	- R01BA - R01BA52	- Desloratidine - Pseudoephedrine sulfate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
AERIUS	N.V. Organon	EU/1/00/160/001	Film-coated tablet	- R06AX - R06AX27	- Desloratidine		- Oral use
AERIUS	N.V. Organon	EU/1/00/160/001-013	Film-coated tablet	- R06AX - R06AX27	- Desloratidine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Aerius	N.V. Organon	EU/1/00/160/61-69	Oral solution	- R06AX - R06AX27	- Desloratadine, micronized		- Oral use
Afinitor	Novartis Europharm Limited	EU/1/09/538/001	Tablet	- L01XE - L01XE10	- Everolimus		- Oral use
Afinitor	Novartis Europharm Limited	EU/1/09/538/004	Tablet	- L01XE - L01XE10	- Everolimus		- Oral use
Afinitor	Novartis Europharm Limited	EU/1/09/538/009-010	Tablet	- L01XE - L01XE10	- Rad n bht	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Aflunov	Seqirus S.r.l.	EU/1/10/658/001-002	Suspension for injection in pre-filled syringe	- J07BB - J07BB02	- H5n1 (a/vietnam/1194/2004)		- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Afstyla	CSL Behring GmbH	EU/1/16/1158/001	Powder and solvent for solution for injection	- B02BD - B02BD02	- Lonoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Afstyla	CSL Behring GmbH	EU/1/16/1158/002	Powder and solvent for solution for injection	- B02BD - B02BD02	- Lonoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Afstyla	CSL Behring GmbH	EU/1/16/1158/003	Powder and solvent for solution for injection	- B02BD - B02BD02	- Lonoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Afstyla	CSL Behring GmbH	EU/1/16/1158/004	Powder and solvent for solution for injection	- B02BD - B02BD02	- Lonoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Afstyla	CSL Behring GmbH	EU/1/16/1158/005	Powder and solvent for solution for injection	- B02BD - B02BD02	- Lonoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Afstyla	CSL Behring GmbH	EU/1/16/1158/006	Powder and solvent for solution for injection	- B02BD - B02BD02	- Lonoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Afstyla	CSL Behring GmbH	EU/1/16/1158/007	Powder and solvent for solution for injection	- B02BD - B02BD02	- Lonoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
After Bite 3.5% w/v Cutaneous Emulsion	Zenview Limited	PA22919/001/001	Cutaneous emulsion		- Ammonia		- Cutaneous use
AGAMREE	Santhera Pharmaceuticals (Deutschland) GmbH	EU/1/23/1776/001	Oral suspension	- H02AB18	- Vamorolone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Agerdex 1 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/088/001 Interchangeable List Code: IC0011-039-003	Film-coated tablet		- Anastrozole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Agnus castus oral drops	A. Vogel Ireland Ltd,	TR2309/017/001	Oral drops, solution		- Tincture from agnus castus fruits	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Agomelatine Mylan 25 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/189/001 Interchangeable List Code: IC0136-022-003	Film-coated tablet		- Agomelatine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aimovig	Novartis Europharm Limited	EU/1/18/1293/001-003	Solution for injection	- N02CX	- ERENUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	
Aimovig	Novartis Pharma GmbH	EU/1/18/1293/004-006	Solution for injection in pre-filled syringe	- N02CX07	- ERENUMAB	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
AirBuFo Forspiro 160 microgram/4.5 microgram/dose inhalation powder, pre-dispensed	Rowex Ltd	PA0711/284/001	Inhalation powder, pre-dispensed	- R03AK - R03AK07	- Budesonide - Formoterol fumarate dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
AirBuFo Forspiro 320 microgram/9 microgram/dose inhalation powder, pre-dispensed	Rowex Ltd	PA0711/284/002	Inhalation powder, pre-dispensed	- R03AK07	- Budesonide - Formoterol fumarate dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
AirFluSal Forspiro 50 microgram/500 microgram/dose, inhalation powder, predispensed	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/004/002	Inhalation powder, pre-dispensed	- R03AK - R03AK06	- SALMETEROL XINAFOATE - Fluticasone propionate		- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
AirFluSal MDI 25 microgram/125 microgram/dose pressurised inhalation, suspension	Rowex Ltd	PA0711/270/001 Interchangeable List Code: IC0128-176-053	Pressurised inhalation, suspension		- SALMETEROL XINAFOATE - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
AirFluSal MDI 25 microgram/250 microgram/dose pressurised inhalation, suspension	Rowex Ltd	PA0711/270/002 Interchangeable List Code: IC0128-177-053	Pressurised inhalation, suspension		- SALMETEROL XINAFOATE - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
AirFluSal® Forspiro® 50 microgram/250 microgram/dose, inhalation powder, predispensed	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/004/001	Inhalation powder, pre-dispensed	- R03AK - R03AK06	- Salmeterol - FLUTICASONE PROPIONATE		- Inhalation use
AirFluSal® Forspiro® 50 microgram/250 microgram/dose, inhalation powder, predispensed	Rowex Ltd	PA0711/237/001	Inhalation powder, pre-dispensed	- R03AK - R03AK06	- Salmeterol - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
AirFluSal® Forspiro® 50 microgram/500 microgram/dose, inhalation powder, predispensed	Rowex Ltd	PA0711/237/002	Inhalation powder, pre-dispensed	- R03AK - R03AK06	- Salmeterol - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
AJOVY	TEVA GmbH	EU/1/19/1358/001-002	Solution for injection in pre-filled syringe	- N02CD03	- FREMANEZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Akeega	Janssen-Cilag International NV	EU/1/23/1722/001	Film-coated tablet	- L01	- Niraparib Tosilate Monohydrate - Abiraterone acetate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Akeega	Janssen-Cilag International NV	EU/1/23/1722/002	Film-coated tablet	- L01	- Niraparib Tosilate Monohydrate - Abiraterone acetate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Akineton 2 mg tablets	Laboratorio Farmaceutico S.I.T.	PA1253/001/001	Tablet	- N04AA - N04AA02	- Biperiden hydrochloride		- Oral use
Akineton 2mg Tablet	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/010/001	Tablet	- N04AA - N04AA02	- Biperiden hydrochloride		- Oral use
Akineton Retard 4 mg prolonged release tablets	Laboratorio Farmaceutico S.I.T.	PA1253/002/001	Prolonged-release tablet	- N04AA - N04AA02	- Biperiden hydrochloride		- Oral use
Aklief 50 microgram/g Cream	Galderma International	PA22743/017/001	Cream	- D10AD06	- Trifarotene	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Akynzeo	Helsinn Birex Pharmaceuticals Limited	EU/1/15/1001/003	Powder for concentrate for solution for infusion	- A04AA55	- FOSNETUPITANT CHLORIDE HYDROCHLORIDE - Palonosetron hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Akynzeo	Helsinn Birex Pharmaceuticals Limited	EU/1/15/1001/004	Concentrate for solution for infusion	- A04AA55	- FOSNETUPITANT CHLORIDE HYDROCHLORIDE - Palonosetron hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Akynzeo 300 mg/0.5 mg hard capsules	Helsinn Birex Pharmaceuticals Limited	EU/1/15/1001/001	Capsule, hard	- A04AA - A04AA05	- Netupitant - Palonosetron (as hydrochloride)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Alacare 8 mg medicated plaster	Photonamic GmbH & Co. KG	PA2071/001/001	Medicated plaster	- L01XD - L01XD04	- 5-aminolevulinic acid hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Albunorm 20%, 200g/l, solution for infusion	Octapharma (IP) SPRL	PA2219/007/002	Solution for infusion	- B05AA - B05AA01	- Human plasma protein not containing less than 96% human albumin		- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Albunorm 5%, 50 g/l, solution for infusion	Octapharma (IP) SPRL	PA2219/007/001	Solution for infusion	- B05AA - B05AA01	- Human plasma protein not containing less than 96% human albumin		- Intravenous use
Alburex 20, 200 g/l, solution for infusion	CSL Behring GmbH	PA0800/008/002	Solution for infusion	- B05AA - B05AA01	- Human albumin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Alburex 5, 50 g/l, solution for infusion	CSL Behring GmbH	PA0800/008/001	Solution for infusion	- B05AA - B05AA01	- Human albumin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Albutein, 200 gram(s)/litre, solution for infusion	Instituto Grifols S.A.	PA0849/006/002	Solution for infusion	- B05AA01	- Human albumin solution	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Albutein, 50 gram(s)/litre, solution for infusion	Instituto Grifols S.A.	PA0849/006/001	Solution for infusion	- B05AA01	- Human albumin solution	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Aldactone 100 mg Film-coated tablet	IMED Healthcare Ltd.	PPA1463/223/002	Film-coated tablet	- C03DA01	- Spironolactone		- Oral use
Aldactone 100 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/418/002	Film-coated tablet	- C03DA01	- Spironolactone		- Oral use
Aldactone 100 mg Film-coated tablets	Pfizer Healthcare Ireland	PA0822/110/003	Film-coated tablet	- C03DA - C03DA01	- Spironolactone		- Oral use
Aldactone 25 mg Film-coated Tablets	Pfizer Healthcare Ireland	PA0822/110/001	Film-coated tablet	- C03DA - C03DA01	- Spironolactone		- Oral use
Aldactone 25 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/418/001	Film-coated tablet	- C03DA01	- Spironolactone		- Oral use
Aldactone 25 mg Film-coated Tablets	IMED Healthcare Ltd.	PPA1463/223/001	Film-coated tablet	- C03DA01	- Spironolactone	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Aldactone 25 mg Film-coated Tablets	Primecrown 2010 Limited	PPA1633/030/001	Film-coated tablet	- C03DA - C03DA01	- Spironolactone		- Oral use
Aldactone 25 mg Film-coated Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/043/001	Film-coated tablet	- C03DA - C03DA01	- Spironolactone		- Oral use
Aldactone 50 mg Film-coated tablets	Pfizer Healthcare Ireland	PA0822/110/002	Film-coated tablet	- C03DA - C03DA01	- Spironolactone		- Oral use
ALDARA	Viatris Healthcare Limited	EU/1/98/080/001	Cream	- D06BB - D06BB10	- Imiquimod	Full application (Article 8(3) of Directive No 2001/83/EC)	
Aldomet 250 mg Film-coated Tablets	Aspen Pharma Trading Limited	PA1691/012/001	Film-coated tablet	- C02AB - C02AB01	- Methyldopa		- Oral use
Aldomet 500 mg Film-coated Tablets	Aspen Pharma Trading Limited	PA1691/012/002	Film-coated tablet	- C02AB - C02AB01	- Methyldopa		- Oral use
ALDURAZYME	Genzyme Europe B.V.	EU/1/03/253/01-3	Concentrate for solution for infusion	- A16AB - A16AB05	- Laronidase		- Intravenous use
Alecensa	Roche Registration GmbH	EU/1/16/1169/001	Capsule, hard	- L01ED03	- Alectinib hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Alendronate/Colecalciferol Teva 70 mg/2800 IU tablets	Teva Pharma B.V.	PA0749/196/001 Interchangeable List Code: IC0052-102-002	Tablet		- Vitamin d3 - Alendronic acid	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Alendronate/Colecalciferol Teva 70 mg/5600 IU tablets	Teva Pharma B.V.	PA0749/196/002 Interchangeable List Code: IC0052-103-002	Tablet		- Vitamin d3 - Alendronic acid	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Alendronic Acid Bluefish Once weekly 70 mg tablets	Bluefish Pharmaceuticals AB	PA1436/004/001 Interchangeable List Code: IC0051-101-002	Tablet		- Sodium alendronate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Alendronic Acid Once Weekly 70 mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/032/001 Interchangeable List Code: IC0051-101-002	Tablet		- Alendronic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Alendronic acid/Cholecalciferol Accord 70 mg/5600 IU tablets	Accord Healthcare Ireland Ltd.	PA2315/020/002 Interchangeable List Code: IC0052-103-002	Tablet		- Vitamin d3 - Alendronic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Alendronic acid/Cholecalciferol Accord 70mg/2800IU tablets	Accord Healthcare Ireland Ltd.	PA2315/020/001 Interchangeable List Code: IC0052-102-002	Tablet		- Alendronic acid - Vitamin d3	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Alendronic acid/Colecalciferol Rowex 70 mg/2 800 IU tablets	Rowex Ltd	PA0711/319/001	Tablet	- M05BB03	- Alendronate sodium trihydrate - Colecalciferol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Alendronic acid/Colecalciferol Rowex 70 mg/5 600 IU tablets	Rowex Ltd	PA0711/319/002	Tablet	- M05BB03	- Alendronate sodium trihydrate - Colecalciferol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Alexette 0.02mg/3mg film-coated tablets	Gedeon Richter Plc	PA1330/009/001	Film-coated tablet	- G03AA - G03AA12	- Drospirenone - Ethinylestradiol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Alfentanil 500 micrograms/ml solution for injection/infusion	AS Kalceks	PA2165/006/001	Solution for injection/infusion	- N01AH02	- Alfentanil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Alfu 10 mg Prolonged-release Tablets	Aurobindo Pharma (Malta) Limited	PA1445/018/001	Prolonged-release tablet	- G04CA - G04CA01	- Alfuzosin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
ALIMTA	Eli Lilly Nederland B.V.	EU/1/04/290/001	Powder for concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed		- Intravenous use
Alimta	Eli Lilly Nederland B.V.	EU/1/04/290/002	Powder for concentrate for solution for infusion	- L01BA04	- Pemetrexed		
Alka-Seltzer Effervescent Tablets Acetylsalicylic Acid (Aspirin) 324mg Sodium Hydrogen Carbonate 1744mg Citric Acid 965mg	Bayer Limited	PA1410/032/001	Effervescent tablet	- N02BA - N02BA01	- Sodium hydrogen carbonate - Aspirin - Citric acid anhydrous		- Oral use
Alkeran 2 mg Film-coated Tablets	Aspen Pharma Trading Limited	PA1691/004/002	Film-coated tablet	- L01AA - L01AA03	- Melphalan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Alkeran 50mg, Powder and Solvent for Solution for Infusion	Aspen Pharma Trading Limited	PA1691/004/001	Powder and solvent for solution for infusion	- L01AA - L01AA03	- Melphalan	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Alkindi	Diurnal Europe B.V.	EU/1/17/1260/001	Granules	- H02AB - H02AB09	- Hydrocortisone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Alkindi	Diurnal Europe B.V.	EU/1/17/1260/002	Granules	- H02AB - H02AB09	- Hydrocortisone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Alkindi	Diurnal Europe B.V.	EU/1/17/1260/003	Granules	- H02AB - H02AB09	- Hydrocortisone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Alkindi	Diurnal Europe B.V.	EU/1/17/1260/004	Granules	- H02AB - H02AB09	- Hydrocortisone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Alli	GlaxoSmithKline Dungarvan Limited	EU/1/07/401/12-15	Capsule, hard	- A08AB - A08AB01	- Orlistat	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Alli	GlaxoSmithKline Dungarvan Limited	EU/1/07/401/1-6	Capsule, hard	- A08AB - A08AB01	- Orlistat	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Alli	GlaxoSmithKline Dungarvan Limited	EU/1/07/401/7-11	Capsule, hard	- A08AB - A08AB01	- Orlistat	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Allopurinol 100 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/219/001	Tablet	- M04AA - M04AA01	- Allopurinol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Allopurinol 300 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/219/002	Tablet	- M04AA - M04AA01	- Allopurinol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Allopurinol Teva 100 mg tablets	Teva Pharma B.V.	PA0749/099/001	Tablet	- M04AA - M04AA01	- Allopurinol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Allopurinol Teva 300 mg tablets	Teva Pharma B.V.	PA0749/099/003	Tablet	- M04AA - M04AA01	- Allopurinol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Alluzience, 200 Speywood units/mL, solution for injection	Ipsen Pharma	PA1613/004/001	Solution for injection	- M03AX01	- Botulinum Toxin A - Haemagglutinin Complex	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Almogran 12.5 mg film-coated tablet	Almirall, S.A.	PA0968/001/001	Film-coated tablet	- N02CC - N02CC05	- Almotriptan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Alofisel	Takeda Pharma A/S	EU/1/17/1261/001	Suspension for injection	- L04	- Expanded human allogeneic mesenchymal adult stem	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intralesional use
Alopur 100 mg Tablets	Rowex Ltd	PA0711/154/001	Tablet	- M04AA - M04AA01	- Allopurinol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Alopur 300 mg Tablets	Rowex Ltd	PA0711/154/002	Tablet	- M04AA - M04AA01	- Allopurinol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
ALOXI	Helsinn Birex Pharmaceuticals Limited	EU/1/04/306/2-3	Capsules, Soft	- A04AA05	- PALONOSETRON (AS HYDROCHLORIDE)		- Oral use
ALOXI	Helsinn Birex Pharmaceuticals Limited	EU/1/04/306/001	Solution for injection	- A04AA - A04AA05	- Palonosetron (as hydrochloride)		- Intravenous use
Aloxi 500 micrograms soft capsules	Helsinn Birex Pharmaceuticals Limited	EU/1/04/306/002-003	Capsule, soft	- A04AA - A04AA05	- Palonosetron (as hydrochloride)		- Oral use
Alphagan 0.2% w/v (2 mg/ml) eye drops, solution	AbbVie Limited	PA1824/007/001	Eye drops, solution	- S01EA - S01EA05	- Brimonidine tartrate		- Ocular use
Alphagan 0.2% w/v (2 mg/ml) eye drops, solution	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/007/001	Eye drops, solution	- S01EA05	- Brimonidine tartrate		- Ocular use
Alphagan 0.2% w/v (2 mg/ml) eye drops, solution	PCO Manufacturing Ltd.	PPA0465/413/001	Eye drops, solution	- S01EA05	- Brimonidine tartrate		- Ocular use
Alprazolam 0.25 mg Tablets	Rowex Ltd	PA0711/140/001 Interchangeable List Code: IC0094-145-002	Tablet		- Alprazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Alprazolam 0.5 mg Tablets	Rowex Ltd	PA0711/140/002 Interchangeable List Code: IC0094-040-002	Tablet		- Alprazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Alprazolam Krka 1 mg tablets	KRKA, d.d., Novo mesto	PA1347/097/003 Interchangeable List Code: IC0094-039-002	Tablet		- Alprazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Alprazolam Krka 250 microgram tablets	KRKA, d.d., Novo mesto	PA1347/097/001 Interchangeable List Code: IC0094-145-002	Tablet		- Alprazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Alprazolam Krka 500 microgram tablets	KRKA, d.d., Novo mesto	PA1347/097/002 Interchangeable List Code: IC0094-040-002	Tablet		- Alprazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Alprolix	Swedish Orphan Biovitrum AB	EU/1/16/1098/001	Powder and solvent for solution for injection	- B02BD - B02BD04	- Eftrenonacog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Alprolix	Swedish Orphan Biovitrum AB	EU/1/16/1098/002	Powder and solvent for solution for injection	- B02BD - B02BD04	- Eftrenonacog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Alprolix	Swedish Orphan Biovitrum AB	EU/1/16/1098/003	Powder and solvent for solution for injection	- B02BD - B02BD04	- Eftrenonacog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Alprolix	Swedish Orphan Biovitrum AB	EU/1/16/1098/004	Powder and solvent for solution for injection	- B02BD - B02BD04	- Eftrenonacog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Alprolix	Swedish Orphan Biovitrum AB	EU/1/16/1098/005	Powder and solvent for solution for injection	- B02BD - B02BD04	- Eftrenonacog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Altavita D3 50,000 IU oral solution	Consilient Health Limited	PA1876/002/001	Oral solution	- A11CC - A11CC05	- Cholecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
altavitaD3 1,000 IU soft capsules	Consilient Health Limited	PA1876/005/001	Capsule, soft	- A11CC - A11CC05	- Cholecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
altavitaD3 25,000 IU soft capsules	Consilient Health Limited	PA1876/004/003	Capsule, soft	- A11CC - A11CC05	- Cholecalciferol (02)	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
AltavitaD3 25,000IU oral solution	Consilient Health Limited	PA1876/002/002	Oral solution	- A11CC - A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
altavitaD3 50,000 IU soft capsules	Consilient Health Limited	PA1876/004/004	Capsule, soft	- A11CC - A11CC05	- Cholecalciferol (02)	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
altavitaD3 7,000 IU soft capsules	Consilient Health Limited	PA1876/005/002	Capsule, soft	- A11CC - A11CC05	- Cholecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Alunbrig	Takeda Pharma A/S	EU/1/18/1264/001-004	Film-coated tablet	- L01XE43	- Brigatinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Alunbrig	Takeda Pharma A/S	EU/1/18/1264/005-008	Film-coated tablet	- L01XE43	- Brigatinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Alunbrig	Takeda Pharma A/S	EU/1/18/1264/009-010	Film-coated tablet	- L01XE43	- Brigatinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ALUTARD SQ Bee 100 000 SQ-U/ml suspension for injection	ALK-Abello A/S	PA1255/008/001	Suspension for injection	- V01AA07	- Apis mellifera	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
ALUTARD SQ Bee Initial Pack (100 SQ-U/ml, 1 000 SQ-U/ml, 10 000 SQ-U/ml and 100 000 SQ-U/ml) suspension for injection	ALK-Abello A/S	PA1255/008/002	Suspension for injection	- V01AA07	- Apis mellifera - Apis mellifera - Apis mellifera - Apis mellifera	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
ALUTARD SQ Wasp 100 000 SQ-U/ml suspension for injection	ALK-Abello A/S	PA1255/009/001	Suspension for injection	- V01AA07	- Vespula spp.	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
ALUTARD SQ Wasp Initial Pack (100 SQ-U/ml, 1 000 SQ-U/ml, 10 000 SQ-U/ml and 100 000 SQ-U/ml) suspension for injection	ALK-Abello A/S	PA1255/009/002	Suspension for injection	- V01AA07	- Vespula spp. - Vespula spp. - Vespula spp. - Vespula spp.	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Alverine Mayoly Spindler 60mg Hard Capsules	Laboratoires Mayoly Spindler	PA1993/001/001	Capsule, hard	- A03AX - A03AX08	- ALVERINE CITRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Alvesco 160 micrograms pressurised inhalation, solution	IMED Healthcare Ltd.	PPA1463/175/001	Pressurised inhalation, solution	- R03BA - R03BA08	- Ciclesonide		- Inhalation use
Alvesco 160 micrograms pressurised inhalation, solution	Covis Pharma Europe B.V.	PA22986/001/002	Pressurised inhalation, solution	- R03BA - R03BA08	- Ciclesonide		- Inhalation use
Alvesco 80 micrograms pressurised inhalation, solution	Covis Pharma Europe B.V.	PA22986/001/001	Pressurised inhalation, solution	- R03BA - R03BA08	- Ciclesonide		- Inhalation use
Alymsys	Mabxience Research, S.L.	EU/1/20/1509/001-002	Concentrate for solution for infusion	- L01XC07	- Bevacizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Amantadine hydrochloride Renata 100 mg Capsules, hard	Renata Pharmaceuticals (Ireland) Limited	PA22865/005/001	Capsule, hard	- N04BB01	- AMANTADINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ambirix	GlaxoSmithKline Biologicals S.A.	EU/1/02/224/001	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis b surface antigen (hbs ag) - Hepatitis a virus		- Intramuscular use
Ambirix	GlaxoSmithKline Biologicals S.A.	EU/1/02/224/002	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis b surface antigen (hbs ag) - Hepatitis a virus		- Intramuscular use
Ambirix	GlaxoSmithKline Biologicals S.A.	EU/1/02/224/003	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis a virus - Hepatitis b surface antigen (hbs ag)		- Intramuscular use
Ambirix	GlaxoSmithKline Biologicals S.A.	EU/1/02/224/004	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis a virus - Hepatitis b surface antigen (hbs ag)		- Intramuscular use
Ambirix	GlaxoSmithKline Biologicals S.A.	EU/1/02/224/005	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis b surface antigen (hbs ag) - Hepatitis a virus		- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
AmBisome Liposomal Amphotericin B 50 mg Powder for Concentrate for Dispersion for Infusion	Gilead Sciences Ireland UC	PA2322/001/001	Concentrate for solution for infusion	- J02AA - J02AA01	- Amphotericin b	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ambrisentan Accord 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/235/002	Film-coated tablet	- C02KX - C02KX02	- Ambrisentan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ambrisentan Accord 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/235/001	Film-coated tablet	- C02KX - C02KX02	- Ambrisentan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ambrisentan Mylan	Mylan Pharmaceuticals Limited	EU/1/19/1368/001-002	Film-coated tablet	- C02KX - C02KX02	- Ambrisentan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ambrisentan Mylan	Mylan S.A.S.	EU/1/19/1368/003-004	Film-coated tablet	- C02KX - C02KX02	- Ambrisentan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ameluz	Biofrontera Bioscience GmbH	EU/1/11/740/001	Gel	- L01XD - L01XD04	- 5-aminolevulinic acid hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Ametop 40 mg/g Gel	Alliance Pharma (Ireland) Limited	PA2325/002/001	Gel	- N01BA - N01BA03	- Tetracaine base	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Amgevita	Amgen Europe B.V.	EU/1/16/1164/001	Solution for injection in pre-filled syringe	- L04AB - L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Amgevita	Amgen Europe B.V.	EU/1/16/1164/002-009	Solution for injection	- L04AB - L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
AMGLIDIA	AMMTek	EU/1/18/1279/001-002	Oral suspension	- A10BB - A10BB01	- Glibenclamide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
AMGLIDIA	AMMTek	EU/1/18/1279/003-004	Oral suspension	- A10BB - A10BB01	- Glibenclamide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Amidex 1 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/189/001 Interchangeable List Code: IC0011-039-003	Film-coated tablet		- Anastrozole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
AMIFAMPRIDINE SERB	SERB S.A.,	EU/1/22/1646/001-003	Tablet	- N07XX05	- Amifampridine Phosphate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amikacin 5 mg/ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/072/001	Solution for infusion	- J01GB - J01GB06	- Amikacin	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Amikacin Caragen 250 mg/ml solution for injection/infusion	Caragen Limited	PA22939/001/001	Solution for injection/infusion	- J01GB06	- Amikacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Aminophylline Hydrate 25mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/099/001	Solution for injection	- R03DA - R03DA05	- AMINOPHYLLINE HYDRATE		- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Aminoven 16, solution for infusion, bottle	Fresenius Kabi Deutschland GmbH	PA2059/025/002	Solution for infusion	- B05BA - B05BA01	- Isoleucine - Leucine - Lysine acetate - Methionine - Phenylalanine - Threonine - Tryptophan - Valine - Arginine - Histidine - Alanine - Glycine - Proline - Serine - Tyrosine - Taurine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Aminoven 25, solution for infusion, bottle	Fresenius Kabi Deutschland GmbH	PA2059/025/003	Solution for infusion	- B05BA - B05BA01	- Isoleucine - Leucine - Lysine acetate - Methionine - Phenylalanine - Threonine - Tryptophan - Valine - Arginine - Histidine - Alanine - Glycine - Proline - Serine - Tyrosine - Taurine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Aminoven 8, solution for infusion, bottle	Fresenius Kabi Deutschland GmbH	PA2059/025/001	Solution for infusion	- B05BA - B05BA01	- Isoleucine - Leucine - Lysine acetate - Methionine - Phenylalanine - Threonine - Tryptophan - Valine - Arginine - Histidine - Alanine - Glycine - Proline - Serine - Tyrosine - Taurine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Amisulpride 200 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/182/002	Tablet	- N05AL - N05AL05	- Amisulpride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amisulpride 50 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/182/001	Tablet	- N05AL - N05AL05	- Amisulpride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amitriptyline 25 mg Film-Coated Tablets	Clonmel Healthcare Ltd	PA0126/041/001	Film-coated tablet	- N06AA - N06AA09	- Amitriptyline hydrochloride		- Oral use
Amitriptyline hydrochloride 10mg/5ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/002/001	Oral solution	- N06AA - N06AA09	- Amitriptyline hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Amitriptyline Hydrochloride 25 mg/ 5 ml Oral Solution	Pinewood Laboratories Ltd	PA0281/233/001	Oral solution	- N06AA - N06AA09	- Amitriptyline hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amitriptyline hydrochloride 25mg/5ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/002/002	Oral solution	- N06AA - N06AA09	- Amitriptyline hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Amitriptyline Hydrochloride 50 mg/ 5 ml Oral Solution	Pinewood Laboratories Ltd	PA0281/233/002	Oral solution	- N06AA - N06AA09	- Amitriptyline hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Amitriptyline hydrochloride 50mg/5ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/002/003	Oral solution	- N06AA - N06AA09	- Amitriptyline hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Amlode 10 mg Tablets	Rowex Ltd	PA0711/138/002 Interchangeable List Code: IC0045-002-008	Tablet		- Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlode 5 mg tablets	Rowex Ltd	PA0711/138/001 Interchangeable List Code: IC0045-001-008	Tablet		- Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine 10 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/075/002	Tablet	- C08CA - C08CA01	- Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine 5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/075/001	Tablet	- C08CA - C08CA01	- Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine Bluefish 10 mg tablets	Bluefish Pharmaceuticals AB	PA1436/016/002 Interchangeable List Code: IC0045-002-008	Tablet		- Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine Bluefish 5 mg tablets	Bluefish Pharmaceuticals AB	PA1436/016/001 Interchangeable List Code: IC0045-001-008	Tablet		- Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine Clonmel 10 mg tablets	Clonmel Healthcare Ltd	PA0126/258/002 Interchangeable List Code: IC0045-002-008	Tablet		- Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine Clonmel 5 mg tablets	Clonmel Healthcare Ltd	PA0126/258/001 Interchangeable List Code: IC0045-001-008	Tablet		- Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine Fair-Med 10mg Tablets	Pharmsol Europe Limited	PA25291/001/002 Interchangeable List Code: IC0045-002-008	Tablet		- Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine Fair-Med 5mg Tablets	Pharmsol Europe Limited	PA25291/001/001 Interchangeable List Code: IC0045-001-008	Tablet		- Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine Krka 10 mg Tablets	KRKA, d.d., Novo mesto	PA1347/034/002 Interchangeable List Code: IC0045-002-008	Tablet		- Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine Krka 5 mg Tablets	KRKA, d.d., Novo mesto	PA1347/034/001 Interchangeable List Code: IC0045-001-008	Tablet		- Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine Pinewood 10 mg tablets	Pinewood Laboratories Ltd	PA0281/165/002	Tablet	- C08CA - C08CA01	- Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine Pinewood 5 mg Tablets	Pinewood Laboratories Ltd	PA0281/165/001	Tablet	- C08CA - C08CA01	- Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine Teva 10 mg Tablets	Teva Pharma B.V.	PA0749/067/002 Interchangeable List Code: IC0045-002-008	Tablet		- Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Amlodipine Teva 5 mg Tablets	Teva Pharma B.V.	PA0749/067/001 Interchangeable List Code: IC0045-001-008	Tablet		- Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine Thame 10mg/5ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/003/002	Oral solution	- C08CA - C08CA01	- Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine Thame 5mg/5ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/003/001	Oral solution	- C08CA01	- Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine Upjohn 10 mg tablets	Upjohn EESV	PA23055/013/002 Interchangeable List Code: IC0045-002-008	Tablet		- Amlodipine	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Amlodipine Upjohn 5 mg tablets	Upjohn EESV	PA23055/013/001 Interchangeable List Code: IC0045-001-008	Tablet		- Amlodipine	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Amlodipine Viatris 10 mg tablets	Viatris Limited	PA23266/002/002 Interchangeable List Code: IC0045-002-008	Tablet		- Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine Viatris 5 mg tablets	Viatris Limited	PA23266/002/001 Interchangeable List Code: IC0045-001-008	Tablet		- Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan Clonmel 10 mg/160 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/274/003 Interchangeable List Code: IC0042-084-003	Film-coated tablet		- Amlodipine - Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan Clonmel 5 mg/160 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/274/002 Interchangeable List Code: IC0042-086-003	Film-coated tablet		- Amlodipine - Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan Clonmel 5 mg/80 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/274/001 Interchangeable List Code: IC0042-087-003	Film-coated tablet		- Amlodipine - Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan Krka 10 mg / 160 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/055/003 Interchangeable List Code: IC0042-084-003	Film-coated tablet		- Amlodipine - Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan Krka 10 mg / 320 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/055/005	Film-coated tablet	- C09DB01	- Amlodipine - Valsartan	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan Krka 5 mg / 320 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/055/004	Film-coated tablet	- C09DB01	- Amlodipine - Valsartan	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan Krka 5 mg/ 160 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/055/002 Interchangeable List Code: IC0042-086-003	Film-coated tablet		- Amlodipine - Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan Krka 5 mg/ 80 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/055/001 Interchangeable List Code: IC0042-087-003	Film-coated tablet		- Amlodipine - Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Amlodipine/Valsartan Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1092/001-013 Interchangeable List Code: IC0042-087-003	Film-coated tablet		- Amlodipine besilate - Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1092/014-026 Interchangeable List Code: IC0042-086-003	Film-coated tablet		- Amlodipine besilate - Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1092/027-039 Interchangeable List Code: IC0042-084-003	Film-coated tablet		- Amlodipine besilate - Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan/Hydrochlorothiazide Clonmel 10 mg/160 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/303/002	Film-coated tablet	- C09DX - C09DX01	- Amlodipine besilate - Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan/Hydrochlorothiazide Clonmel 10 mg/160 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/303/004	Film-coated tablet	- C09DX - C09DX01	- Amlodipine besilate - Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan/Hydrochlorothiazide Clonmel 10 mg/320 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/303/005	Film-coated tablet	- C09DX - C09DX01	- Amlodipine besilate - Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan/Hydrochlorothiazide Clonmel 5 mg/160 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/303/001	Film-coated tablet	- C09DX - C09DX01	- Amlodipine besilate - Valsartan - Hydrochlorothiazide	Complete application (stand-alone) - Council Directive 81/851/EEC	- Oral use
Amlodipine/Valsartan/Hydrochlorothiazide Clonmel 5 mg/160 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/303/003	Film-coated tablet	- C09DX - C09DX01	- Amlodipine besilate - Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan/Hydrochlorothiazide Krka 10 mg/160 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/106/002	Film-coated tablet	- C09DX01	- Amlodipine - Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan/Hydrochlorothiazide Krka 5 mg/160 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/106/001	Film-coated tablet	- C09DX01	- Amlodipine - Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlodipine/Valsartan/Hydrochlorothiazide Krka 5 mg/160 mg/25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/106/003	Film-coated tablet	- C09DX01	- Amlodipine - Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlotan 10 mg tablet	Athlone Pharmaceuticals Limited	PA1418/003/002 Interchangeable List Code: IC0045-002-008	Tablet		- Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amlotan 5 mg tablet	Athlone Pharmaceuticals Limited	PA1418/003/001 Interchangeable List Code: IC0045-001-008	Tablet		- Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
AMMONAPS	Immedica Pharma AB	EU/1/99/120/001	Tablet	- A16AX03	- Sodium phenylbutyrate		- Oral use
AMMONAPS	Immedica Pharma AB	EU/1/99/120/002	Tablet	- A16AX03	- Sodium phenylbutyrate		- Oral use
AMMONAPS	Immedica Pharma AB	EU/1/99/120/003	Granules	- A16AX03	- Sodium phenylbutyrate		- Oral use
AMMONAPS	Immedica Pharma AB	EU/1/99/120/004	Granules	- A16AX03	- Sodium phenylbutyrate		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Amoclav 125mg/31.25mg per 5ml Powder for Oral Suspension	Rowex Ltd	PA0711/162/001 Interchangeable List Code: IC0037-071-034	Powder for oral suspension		- potassium clavulanate - Amoxicillin trihydrate		- Oral use
Amoclav 250mg/125mg Film-coated Tablets	Rowex Ltd	PA0711/162/002 Interchangeable List Code: IC0037-074-003	Film-coated tablet		- Amoxicillin trihydrate - potassium clavulanate		- Oral use
Amoclav 500mg/125mg Film-coated tablets	Rowex Ltd	PA0711/162/003 Interchangeable List Code: IC0037-073-003	Film-coated tablet		- potassium clavulanate - Amoxicillin trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amorolfine 5 % w/v medicated nail lacquer	Rowex Ltd	PA0711/309/001	Medicated nail lacquer	- D01AE16	- Amorolfine hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Amorolfine 5% w/v medicated nail lacquer	Bluefish Pharmaceuticals AB	PA1436/029/001	Medicated nail lacquer	- D01AE16	- Amorolfine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Amoxicillin 125 mg/5 ml powder for oral suspension	Clonmel Healthcare Ltd	PA0126/282/003	Powder for oral suspension	- J01CA - J01CA04	- Amoxicillin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Amoxicillin 250 mg hard capsules	Clonmel Healthcare Ltd	PA0126/282/001	Capsule, hard	- J01CA - J01CA04	- Amoxicillin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Amoxicillin 250 mg/5 ml powder for oral suspension	Clonmel Healthcare Ltd	PA0126/282/004	Powder for oral suspension	- J01CA - J01CA04	- Amoxicillin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Amoxicillin 500 mg hard capsules	Clonmel Healthcare Ltd	PA0126/282/002	Capsule, hard	- J01CA - J01CA04	- Amoxicillin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Amoxicillin Delbert 500 mg, powder for solution for injection or infusion	Laboratoires DELBERT	PA23217/001/001	Powder for solution for injection/infusion	- J01CA - J01CA04	- Amoxicillin sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Amoxicillin DSM Sinochem Pharmaceuticals 500 mg hard capsules	Centrient Pharmaceuticals Netherlands B.V	PA1832/001/002	Capsule, hard	- J01CA - J01CA04	- Amoxicillin (as trihydrate)	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amoxicillin/clavulanic acid Krka 500 mg/125 mg Film-Coated Tablets	KRKA, d.d., Novo mesto	PA1347/044/001 Interchangeable List Code: IC0037-073-003	Film-coated tablet		- Amoxicillin - Clavulanic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ampres 10mg/ml solution for injection	B. Braun Melsungen AG	PA0736/043/001	Solution for injection	- N01BA - N01BA04	- CHLOROPROCAINE HYDROCHLORIDE		- Intrathecal use
Ampres 20 mg/ml solution for injection	B. Braun Melsungen AG	PA0736/043/002	Solution for injection	- N01BA - N01BA04	- Chloroprocaine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Perineural use
Amsalyo 75 mg powder for concentration for solution infusion	Eurocept International BV	PA1591/003/001	Powder for solution for infusion	- L01XX01	- Amsacrine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Amsidine 75 mg/1.5 ml Concentrate and Solvent for Concentrate for Solution for Infusion	Eurocept International BV	PA1591/002/001	Concentrate and solvent for concentrate for solution for infusion	- L01XX - L01XX01	- Amsacrine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Amsparity	Pfizer Service Company BVBA	EU/1/19/1415/001	Solution for injection in pre-filled syringe	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Amsparity	Pfizer Service Company BVBA	EU/1/19/1415/002	Solution for injection	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Amsparity	Pfizer Service Company BVBA	EU/1/19/1415/003-006	Solution for injection in pre-filled syringe	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Amsparity	Pfizer Service Company BVBA	EU/1/19/1415/007-010	Solution for injection in pre-filled pen	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Amversio	SERB S.A.,	EU/1/22/1640/001	Oral powder	- A16AA06	- Betaine anhydrous	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Amvuttra	Alnylam Netherlands B.V.	EU/1/22/1681/001	Solution for injection in pre-filled syringe	- N07XX - N07XX18	- Vutrisiran Sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan 0.6 mg/1.2 mg honey & lemon lozenges	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/192/001	Lozenge	- R02AA - R02AA03	- 2,4 DICHLOROBENZYL ALCOHOL - Amylmetacresol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oromucosal use
Amylmetacresol/2,4-Dichlorobenzyl alcohol Mylan 0.6 mg/1.2 mg mint lozenges	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/192/002	Lozenge	- R02AA - R02AA03	- Amylmetacresol - 2,4 DICHLOROBENZYL ALCOHOL	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oromucosal use
AMYViD	Eli Lilly Nederland B.V.	EU/1/12/805/001-002	Solution for injection	- V09AX - V09AX05	- Florbetapir (18f)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
AMYViD	Eli Lilly Nederland B.V.	EU/1/12/805/003-004	Solution for injection	- V09AX - V09AX05	- Florbetapir (18f)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Anadin Analgesic Film-coated Tablets Aspirin 325mg Caffeine 15mg	GlaxoSmithKline Consumer Healthcare (Ireland) Limited	PA0678/148/001	Film-coated tablet	- N02BA - N02BA51	- Aspirin - Caffeine		- Oral use
Anadin Maximum Strength Hard Capsules Aspirin 500mg, caffeine 32mg	GlaxoSmithKline Consumer Healthcare (Ireland) Limited	PA0678/148/002	Capsule, hard	- N02BA - N02BA51	- Caffeine - Aspirin		- Oral use
Anafranil SR 75 mg Prolonged-release Tablets	zr pharma& GmbH	PA23086/001/001	Prolonged-release tablet	- N06AA - N06AA04	- Clomipramine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Anagrelide 0.5 mg Hard Capsules	Athlone Pharmaceuticals Limited	PA1418/006/001	Capsule, hard	- L01XX - L01XX35	- Anagrelide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Anagrelide Mylan	Mylan Pharmaceuticals Limited	EU/1/17/1253/002	Capsule, hard	- L01XX - L01XX35	- Anagrelide hydrochloride monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Anagrelide Mylan	Mylan Pharmaceuticals Limited	EU/1/17/1256/001	Capsule, hard	- L01XX - L01XX35	- Anagrelide hydrochloride monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Anapen 300 micrograms in 0.3ml solution for injection in a pre-filled syringe	Bioprojet Pharma	PA22580/001/002	Solution for injection in pre-filled syringe	- C01CA - C01CA24	- Epinephrine		- Intramuscular use
Anapen 500 micrograms / 0.3ml solution for injection in a pre-filled syringe	Bioprojet Pharma	PA22580/001/003	Solution for injection in pre-filled syringe	- C01CA - C01CA24	- Epinephrine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Anapen Junior 150 micrograms in 0.3ml solution for injection in a pre- filled syringe	Bioprojet Pharma	PA22580/001/001	Solution for injection in pre-filled syringe	- C01CA - C01CA24	- Epinephrine		- Intramuscular use
Anastrozole 1 mg Film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/068/001 Interchangeable List Code: IC0011-039-003	Film-coated tablet		- Anastrozole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Anastrozole 1mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/076/001 Interchangeable List Code: IC0011-039-003	Film-coated tablet		- Anastrozole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Anastrozole Bluefish 1 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/010/001 Interchangeable List Code: IC0011-039-003	Film-coated tablet		- Anastrozole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Anastrozole Synthon 1 mg, film-coated tablets	Synthon BV	PA0840/004/001 Interchangeable List Code: IC0011-039-003	Film-coated tablet		- Anastrozole	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Anastrozole Teva 1 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/028/001 Interchangeable List Code: IC0011-039-003	Film-coated tablet		- Anastrozole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Anbesol Anaesthetic Antiseptic Oromucosal Solution	Alliance Pharma (Ireland) Limited	PA2325/003/001	Oromucosal solution	- N01BB - N01BB52	- Lidocaine hydrochloride - Chlorocresol - Cetylpyridinium chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oromucosal use
Andrews Liver Salts Effervescent Powder	Haleon Ireland Limited	PA0678/043/001	Effervescent powder	- A06AD - A06AD04 - A09AB - A09AB04	- Sodium hydrogen carbonate - Citric acid - Magnesium sulphate dihydrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Androcur 100 mg Tablets	Bayer Limited	PA1410/001/001	Tablet	- G03HA01	- Cyproterone acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Androgel 25 mg, transdermal gel in sachet	Laboratoires Besins International	PA1054/001/001	Transdermal gel in sachet	- G03BA - G03BA03	- Testosterone		- Topical use
Androgel 50 mg, transdermal gel in sachet	Laboratoires Besins International	PA1054/001/002	Transdermal gel in sachet	- G03BA - G03BA03	- Testosterone		- Topical use
Anexate 500 micrograms/5ml, solution for injection or infusion	Cheplapharm Arzneimittel GmbH	PA1868/002/001	Solution for injection/infusion	- V03AB - V03AB25	- Flumazenil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Angeliq 1 mg/2 mg film-coated tablets	Bayer Limited	PA1410/013/001	Film-coated tablet	- G03FA - G03FA17	- Estradiol - Drospirenone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Angusta 25 microgram tablets	Norgine B.V.	PA1336/010/001	Tablet	- G02AD06	- Misoprostol	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Anhydrol Forte 20% w/v Cutaneous Solution	Dermal Laboratories (Ireland) Limited	PA23128/004/001	Cutaneous solution	- D11AA	- Aluminium chloride hexahydrate		- Cutaneous use
Anidulafungin 100 mg powder for concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/021/001	Powder for concentrate for solution for infusion	- J02AX06	- Anidulafungin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Anidulafungin 100 mg Powder for concentrate for solution for infusion	Rowex Ltd	PA0711/278/001	Powder for concentrate for solution for infusion	- J02AX06	- Anidulafungin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Anidulafungin Teva 100 mg Powder for Concentrate for Solution for Infusion	Teva B.V.	PA1986/045/001	Powder for concentrate for solution for infusion	- J02AX - J02AX06	- Anidulafungin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Anoro Ellipta	GlaxoSmithKline (Ireland) Limited	EU/1/14/898/001-003	Inhalation powder, pre-dispensed	- R03AL03	- Vilanterol trifenatate - Umeclidinium bromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Antabuse 400 mg Effervescent Tablets	Teva B.V.	PA1986/110/001	Effervescent tablet	- N07BB - N07BB01	- Disulfiram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Anthisan Cream 2% w/w	Phoenix Labs	PA1113/024/001	Cream	- D04AA - D04AA02	- Mepyramine maleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Anti-Hist Allergy 10mg Film-coated tablets	Clonmel Healthcare Ltd	PA0126/267/001	Film-coated tablet	- R06AE - R06AE07	- Cetirizine dihydrochloride		- Oral use
Anti-Hist Allergy 1mg/ml Oral Solution	Clonmel Healthcare Ltd	PA0126/267/002	Oral solution	- R06AE - R06AE07	- Cetrizine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Anusol Cream	SOFIBEL	PA22647/001/001	Cream	- C05AX - C05AX04	- Bismuth oxide - Balsam peru - Zinc oxide		- Topical use
Anusol HC Ointment	SOFIBEL	PA22647/002/001	Ointment	- D07BA	- HYDROCORTISONE ACETATE - Benzyl benzoate - Bismuth subgallate - Bismuth oxide - Balsam peru - Zinc oxide		- Topical
Anusol HC Suppositories	SOFIBEL	PA22647/002/002	Suppository	- C05AA - C05AA01	- HYDROCORTISONE ACETATE - Benzyl benzoate - Bismuth oxide - Balsam peru - Zinc oxide - Bismuth subgallate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Rectal use
Anusol Ointment	SOFIBEL	PA22647/001/002	Ointment	- C05AX - C05AX04	- Bismuth subgallate - Bismuth oxide - Balsam peru - Zinc oxide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical
Anusol Suppositories	SOFIBEL	PA22647/001/003	Suppository	- C05AX - C05AX04	- Bismuth oxide - Zinc oxide - Balsam peru - Bismuth subgallate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Rectal use
Anxicalm 10 mg Tablets	Clonmel Healthcare Ltd	PA0126/011/003	Tablet	- N05BA - N05BA01	- Diazepam		- Oral use
Anxicalm 2 mg Tablets	Clonmel Healthcare Ltd	PA0126/011/001	Tablet	- N05BA - N05BA01	- Diazepam		- Oral use
Anxicalm 5 mg Tablets	Clonmel Healthcare Ltd	PA0126/011/002	Tablet	- N05BA - N05BA01	- Diazepam		- Oral use
Apeneta 100 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/105/002	Prolonged-release tablet	- N02AX06	- Tapentadol maleate hemihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apeneta 150 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/105/003	Prolonged-release tablet	- N02AX06	- Tapentadol maleate hemihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apeneta 200 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/105/004	Prolonged-release tablet	- N02AX06	- Tapentadol maleate hemihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apeneta 250 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/105/005	Prolonged-release tablet	- N02AX06	- Tapentadol maleate hemihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Apeneta 50 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/105/001	Prolonged-release tablet	- N02AX06	- Tapentadol maleate hemihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apexxnar	Pfizer Europe MA EEIG	EU/1/21/1612/001-006	Suspension for injection	- J07AL02	- Pneumococcal polysaccharide serotype 1 - Pneumococcal Polysaccharide Serotype 3 - Pneumococcal polysaccharide serotype 4 - Pneumococcal polysaccharide serotype 5 - Pneumococcal Polysaccharide Serotype 6A - Pneumococcal polysaccharide serotype 7f - Pneumococcal Polysaccharide Serotype 8 - Pneumococcal polysaccharide serotype 9v - Pneumococcal Polysaccharide Serotype 10A - Pneumococcal Polysaccharide Serotype 11A - Pneumococcal Polysaccharide Serotype 12F - Pneumococcal polysaccharide serotype 14 - Pneumococcal Polysaccharide Serotype 15B - Pneumococcal polysaccharide serotype 18c - Pneumococcal Polysaccharide Serotype 19A - Pneumococcal polysaccharide serotype 19f - Pneumococcal Polysaccharide Serotype 22F - Pneumococcal polysaccharide serotype 23f - Pneumococcal Polysaccharide Serotype 33F	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Apidra	Sanofi-Aventis Deutschland GmbH	EU/1/04/285/021-036	Solution for injection	- A10AB - A10AB06	- Insulin glulisine		- Intravenous use
APIDRA	Aventis Pharma Deutschland GmbH	EU/1/04/285/1-20	Solution for injection	- A10AB	- Insulin glulisine		
Apixaban 2.5 mg film-coated tablets	Norton Waterford	PA0436/049/001 Interchangeable List Code: IC0124-018-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apixaban 2.5 mg film-coated tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/009/001 Interchangeable List Code: IC0124-018-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Apixaban 5 mg film-coated tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/009/002 Interchangeable List Code: IC0124-001-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apixaban 5 mg film-coated tablets	Norton Waterford	PA0436/049/002 Interchangeable List Code: IC0124-001-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apixaban Accord 2.5 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/20/1458/001-020 Interchangeable List Code: IC0124-018-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apixaban Accord 5 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/20/1458/021-046 Interchangeable List Code: IC0124-001-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apixaban Clonmel 2.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/328/001 Interchangeable List Code: IC0124-018-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apixaban Clonmel 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/328/002 Interchangeable List Code: IC0124-001-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apixaban Krka 2.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/107/001 Interchangeable List Code: IC0124-018-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apixaban Krka 5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/107/002 Interchangeable List Code: IC0124-001-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apixaban Mylan 2.5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/233/001 Interchangeable List Code: IC0124-018-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apixaban Mylan 5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/233/002 Interchangeable List Code: IC0124-001-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apixaban Pinewood 2.5 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/259/001 Interchangeable List Code: IC0124-018-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apixaban Pinewood 5 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/259/002 Interchangeable List Code: IC0124-001-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apixaban Rowex 2.5 mg film-coated tablets	Rowex Ltd	PA0711/303/001 Interchangeable List Code: IC0124-018-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apixaban Rowex 5 mg film-coated tablets	Rowex Ltd	PA0711/303/002 Interchangeable List Code: IC0124-001-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Apixaban Teva 2.5 mg film-coated tablets	Norton Waterford	PA0436/052/001 Interchangeable List Code: IC0124-018-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Apixaban Teva 5 mg film-coated tablets	Norton Waterford	PA0436/052/002 Interchangeable List Code: IC0124-001-003	Film-coated tablet		- Apixaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
APO-go AMPOULES 10 mg/ml Solution for Injection or Infusion *Abbreviated to APO-go in the text	Stada Arzneimittel AG	PA0593/043/002	Solution for injection/infusion	- N04BC - N04BC07	- Apomorphine hydrochloride		- Subcutaneous use
APO-go POD 5 mg/ml solution for infusion in cartridge	Stada Arzneimittel AG	PA0593/042/004	Solution for infusion in cartridge	- N04BC07	- Apomorphine hydrochloride hemihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
APO-go® PEN 10 mg/ml Solution for Injection** Abbreviated to APO-go in the text	Stada Arzneimittel AG	PA0593/043/001	Solution for injection	- N04BC - N04BC07	- Apomorphine hydrochloride		- Subcutaneous use
APO-go® PFS 5mg/ml Solution for Infusion in Pre-filled Syringe*Abbreviated to APO-go in the text	Stada Arzneimittel AG	PA0593/043/003	Solution for infusion in pre-filled syringe	- N04BC - N04BC07	- Apomorphine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Aprepitant Accord 125 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/148/002	Capsule, hard	- A04AD12	- Aprepitant	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aprepitant Accord 125 mg/80 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/148/003	Capsule, hard	- A04AD12	- Aprepitant - Aprepitant	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aprepitant Accord 80 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/148/001	Capsule, hard	- A04AD12	- Aprepitant	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
APRETUDE	ViiV Healthcare BV	EU/1/23/1760/001	Film-coated tablet	- J05AJ04	- Cabotegravir Sodium - cabotegravir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Aprok 50mg powder for solution for injection	Laboratoires Thea	PA1107/006/001	Powder for solution for injection	- S01AA - S01AA27	- Cefuroxime Sodium	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intraocular use
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/001	Tablet	- C09CA - C09CA04	- Irbesartan		
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/001-003	Tablet	- C09CA - C09CA04	- Irbesartan	Full application (Article 8(3) of Directive No 2001/83/EC)	
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/004	Tablet	- C09CA - C09CA04	- Irbesartan		
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/004-006	Tablet	- C09CA - C09CA04	- Irbesartan	Full application (Article 8(3) of Directive No 2001/83/EC)	
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/007	Tablet	- C09CA - C09CA04	- Irbesartan		
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/007-009	Tablet	- C09CA - C09CA04	- Irbesartan	Full application (Article 8(3) of Directive No 2001/83/EC)	
Aptivus	Boehringer Ingelheim International GmbH	EU/1/05/315/001	Capsule, soft	- J05AE - J05AE09	- Tipranavir		

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Aptivus	Boehringer Ingelheim International GmbH	EU/1/05/315/002	Oral solution	- J05AE	- Tipranavir		- Oral use
Aqueous Cream Emulsifying Wax 9% w/w, White Soft Parafin 15% w/w, Liquid Paraffin 6% w/w	Ovelle Limited	PA0206/021/001	Cream	- D02AX	- Emulsifying wax - White soft paraffin - Liquid paraffin		- Topical
AQUIPTA	AbbVie Deutschland GmbH & Co. KG	EU/1/23/1750/001-002	Tablet	- N02C - N02CD07	- Atogepant monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
AQUIPTA	AbbVie Deutschland GmbH & Co. KG	EU/1/23/1750/003-004	Tablet	- N02C - N02CD07	- Atogepant monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Aqumeldi	Proveca Pharma Limited	EU/1/23/1717/001-003	Orodispersible tablet	- C09AA02	- Enalapril maleate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
ARANESP	Amgen Europe B.V.	EU/1/01/185/001-002	Solution for injection in pre-filled syringe	- B03XA - B03XA02	- Darbepoetin alfa		- Intravenous use - Subcutaneous use
Aranesp	Amgen Europe B.V.	EU/1/01/185/003-004	Solution for injection in pre-filled syringe	- B03XA02	- Darbepoetin alfa		- Intravenous use - Subcutaneous use
Aranesp	Amgen Europe B.V.	EU/1/01/185/005-006	Solution for injection in pre-filled syringe	- B03XA02	- Darbepoetin alfa		- Intravenous use - Subcutaneous use
Aranesp	Amgen Europe B.V.	EU/1/01/185/007-008	Solution for injection in pre-filled syringe	- B03XA02	- Darbepoetin alfa		- Intravenous use - Subcutaneous use
Aranesp	Amgen Europe B.V.	EU/1/01/185/009-010	Solution for injection in pre-filled syringe	- B03XA - B03XA02	- Darbepoetin alfa		- Intravenous use - Subcutaneous use
Aranesp	Amgen Europe B.V.	EU/1/01/185/011-012	Solution for injection in pre-filled syringe	- B03XA02	- Darbepoetin alfa		- Intravenous use - Subcutaneous use
Aranesp	Amgen Europe B.V.	EU/1/01/185/013-014	Solution for injection in pre-filled syringe	- B03XA02	- Darbepoetin alfa		- Intravenous use - Subcutaneous use
Aranesp	Amgen Europe B.V.	EU/1/01/185/015-016	Solution for injection in pre-filled syringe	- B03XA02	- Darbepoetin alfa		- Intravenous use - Subcutaneous use
Aranesp	Amgen Europe B.V.	EU/1/01/185/017-018	Solution for injection in pre-filled syringe	- B03XA02	- Darbepoetin alfa		- Intravenous use - Subcutaneous use
Aranesp	Amgen Europe B.V.	EU/1/01/185/019-020	Solution for injection in pre-filled syringe	- B03XA02	- Darbepoetin alfa		- Intravenous use - Subcutaneous use
Aranesp	Amgen Europe B.V.	EU/1/01/185/021-022	Solution for injection in pre-filled syringe	- B03XA	- Darbepoetin alfa		- Intravenous use - Subcutaneous use
Aranesp	Amgen Europe B.V.	EU/1/01/185/031-032	Solution for injection in pre-filled syringe	- B03XA	- Darbepoetin alfa		- Intravenous use - Subcutaneous use
ARAVA	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/001	Film-coated tablet	- L04AA - L04AA13	- Leflunomide		- Oral use
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/002	Film-coated tablet	- L04AA13	- Leflunomide		- Oral use
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/003	Film-coated tablet	- L04AA13	- Leflunomide		- Oral use
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/004	Film-coated tablet	- L04AA13	- Leflunomide		- Oral use
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/005	Film-coated tablet	- L04AA13	- Leflunomide		- Oral use
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/006	Film-coated tablet	- L04AA13	- Leflunomide		- Oral use
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/007	Film-coated tablet	- L04AA13	- Leflunomide		- Oral use
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/008	Film-coated tablet	- L04AA13	- Leflunomide		- Oral use
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/009	Film-coated tablet	- L04AA13	- Leflunomide		- Oral use
Arcoxia 120 mg film-coated tablets	NV Organon	PA0964/009/004 Interchangeable List Code: IC0108-167-003	Film-coated tablet		- Etoricoxib	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Arcoxia 30 mg film-coated tablets	NV Organon	PA0964/009/001 Interchangeable List Code: IC0108-033-003	Film-coated tablet		- Etoricoxib	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Arcoxia 30 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/176/004 Interchangeable List Code: IC0108-033-003	Film-coated tablet		- Etoricoxib		- Oral use
Arcoxia 60 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/176/001 Interchangeable List Code: IC0108-127-003	Film-coated tablet		- Etoricoxib		- Oral use
Arcoxia 60 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/041/001 Interchangeable List Code: IC0108-127-003	Film-coated tablet		- Etoricoxib	ZZZ PPA	- Oral use
Arcoxia 60 mg film-coated tablets	NV Organon	PA0964/009/002 Interchangeable List Code: IC0108-127-003	Film-coated tablet		- Etoricoxib	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Arcoxia 90 mg film-coated tablets	NV Organon	PA0964/009/003 Interchangeable List Code: IC0108-166-003	Film-coated tablet		- Etoricoxib	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Arcoxia 90 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/041/002 Interchangeable List Code: IC0108-166-003	Film-coated tablet		- Etoricoxib	ZZZ PPA	- Oral use
Arcoxia 90 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/176/002 Interchangeable List Code: IC0108-166-003	Film-coated tablet		- Etoricoxib		- Oral use
Areloger 15 mg tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/057/002	Tablet	- M01AC - M01AC06	- Meloxicam		- Oral use
Areloger 7.5 mg tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/057/001	Tablet	- M01AC - M01AC06	- Meloxicam		- Oral use
AREXVY	GlaxoSmithKline Biologicals	EU/1/23/1740/001-002	Powder and suspension for suspension for injection	- J07	- Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
ARICEPT 10 mg film coated tablets	Pfizer Healthcare Ireland	PA0822/002/002 Interchangeable List Code: IC0062-002-015	Film-coated tablet		- Donepezil hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ARICEPT 5 mg film coated tablets	Pfizer Healthcare Ireland	PA0822/002/001 Interchangeable List Code: IC0062-001-015	Film-coated tablet		- Donepezil hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ARICEPT EVESS 10 mg orodispersible tablet	Pfizer Healthcare Ireland	PA0822/002/004 Interchangeable List Code: IC0062-002-015	Orodispersible tablet		- Donepezil hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ARICEPT EVESS 5 mg orodispersible tablet	Pfizer Healthcare Ireland	PA0822/002/003 Interchangeable List Code: IC0062-001-015	Orodispersible tablet		- Donepezil hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ARIKAYCE liposomal	Insmed Netherlands B.V.	EU/1/20/1469/001	Nebuliser dispersion	- J01GB06	- AMIKACIN SULFATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Arimidex 1 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/218/001 Interchangeable List Code: IC0011-039-003	Film-coated tablet		- Anastrozole	ZZZ PPA	- Oral use
Arimidex 1 mg Film-coated Tablets	IMED Healthcare Ltd.	PPA1463/070/001 Interchangeable List Code: IC0011-039-003	Film-coated tablet		- Anastrozole	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Arimidex 1 mg film-coated tablets	Originalis B.V.	PPA2306/017/001 Interchangeable List Code: IC0011-039-003	Film-coated tablet		- Anastrozole		- Oral use
Arimidex 1mg Film-coated Tablets	Laboratoires Juvise Pharmaceuticals	PA23154/001/001 Interchangeable List Code: IC0011-039-003	Film-coated tablet		- Anastrozole		- Oral use
Aripil 10 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/099/002 Interchangeable List Code: IC0062-002-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripil 5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/099/001 Interchangeable List Code: IC0062-001-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole 10 mg tablets	Brillpharma (Ireland) Limited	PA22749/016/002 Interchangeable List Code: IC0092-002-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole 15 mg tablets	Brillpharma (Ireland) Limited	PA22749/016/003 Interchangeable List Code: IC0092-032-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole 20 mg tablets	Brillpharma (Ireland) Limited	PA22749/016/004 Interchangeable List Code: IC0092-003-002	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole 30 mg tablets	Brillpharma (Ireland) Limited	PA22749/016/005 Interchangeable List Code: IC0092-033-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole 5 mg tablets	Brillpharma (Ireland) Limited	PA22749/016/001 Interchangeable List Code: IC0092-001-002	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Accord	Accord Healthcare S.L.U.	EU/1/15/1045/001-006 Interchangeable List Code: IC0092-001-002	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Accord	Accord Healthcare S.L.U.	EU/1/15/1045/007-012 Interchangeable List Code: IC0092-002-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Accord	Accord Healthcare S.L.U.	EU/1/15/1045/013-018 Interchangeable List Code: IC0092-032-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Aripiprazole Accord	Accord Healthcare S.L.U.	EU/1/15/1045/019-022 Interchangeable List Code: IC0092-033-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Clonmel 10 mg tablets	Clonmel Healthcare Ltd	PA0126/266/002 Interchangeable List Code: IC0092-002-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Clonmel 15 mg tablets	Clonmel Healthcare Ltd	PA0126/266/003 Interchangeable List Code: IC0092-032-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Clonmel 30 mg tablets	Clonmel Healthcare Ltd	PA0126/266/004 Interchangeable List Code: IC0092-033-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Clonmel 5 mg tablets	Clonmel Healthcare Ltd	PA0126/266/001 Interchangeable List Code: IC0092-001-002	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Krka 10mg Tablets	KRKA, d.d., Novo mesto	PA1347/089/002 Interchangeable List Code: IC0092-002-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Krka 15mg Tablets	KRKA, d.d., Novo mesto	PA1347/089/003 Interchangeable List Code: IC0092-032-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Krka 30mg Tablets	KRKA, d.d., Novo mesto	PA1347/089/004 Interchangeable List Code: IC0092-033-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Krka 5mg Tablets	KRKA, d.d., Novo mesto	PA1347/089/001 Interchangeable List Code: IC0092-001-002	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Mylan Pharma	Mylan S.A.S.	EU/1/15/1005/001-003 Interchangeable List Code: IC0092-001-002	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Mylan Pharma	Mylan S.A.S.	EU/1/15/1005/004-006 Interchangeable List Code: IC0092-002-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Mylan Pharma	Mylan S.A.S.	EU/1/15/1005/007-009 Interchangeable List Code: IC0092-032-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Mylan Pharma	Mylan S.A.S.	EU/1/15/1005/010-012 Interchangeable List Code: IC0092-033-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Pinewood 10 mg tablets	Pinewood Laboratories Ltd	PA0281/214/002 Interchangeable List Code: IC0092-002-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Aripiprazole Pinewood 15 mg tablets	Pinewood Laboratories Ltd	PA0281/214/003 Interchangeable List Code: IC0092-032-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Pinewood 30 mg tablets	Pinewood Laboratories Ltd	PA0281/214/004 Interchangeable List Code: IC0092-033-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Pinewood 5 mg tablets	Pinewood Laboratories Ltd	PA0281/214/001 Interchangeable List Code: IC0092-001-002	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Sandoz	Sandoz GmbH	EU/1/15/1029/001-014 Interchangeable List Code: IC0092-001-002	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Sandoz	Sandoz GmbH	EU/1/15/1029/015-028 Interchangeable List Code: IC0092-002-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Sandoz	Sandoz GmbH	EU/1/15/1029/029-042 Interchangeable List Code: IC0092-032-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Sandoz	Sandoz GmbH	EU/1/15/1029/043-047 Interchangeable List Code: IC0092-003-002	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Sandoz	Sandoz GmbH	EU/1/15/1029/048-061 Interchangeable List Code: IC0092-033-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Teva 10 mg tablets	Teva B.V.	PA1986/019/002 Interchangeable List Code: IC0092-002-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Teva 15 mg tablets	Teva B.V.	PA1986/019/003 Interchangeable List Code: IC0092-032-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Teva 30 mg tablets	Teva B.V.	PA1986/019/004 Interchangeable List Code: IC0092-033-056	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Aripiprazole Teva 5 mg tablets	Teva B.V.	PA1986/019/001 Interchangeable List Code: IC0092-001-002	Tablet		- Aripiprazole	Complete application (stand-alone) - Council Directive 81/851/EEC	- Oral use
Aripiprazole Zentiva	Zentiva k.s.	EU/1/15/1009/001-005 Interchangeable List Code: IC0092-001-002	Tablet		- Aripiprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
ARIPIPRAZOLE ZENTIVA	Zentiva k.s.	EU/1/15/1009/006-010 Interchangeable List Code: IC0092-002-056	Tablet		- ARIPIPRAZOLE	Article 10(1) - Generic Application	- Oral use
ARIPIPRAZOLE ZENTIVA	Zentiva k.s.	EU/1/15/1009/011-015 Interchangeable List Code: IC0092-032-056	Tablet		- ARIPIPRAZOLE	Article 10(1) - Generic Application	- Oral use
ARIPIPRAZOLE ZENTIVA	Zentiva k.s.	EU/1/15/1009/016-020 Interchangeable List Code: IC0092-033-056	Tablet		- ARIPIPRAZOLE	Article 10(1) - Generic Application	- Oral use
ARIPIPRAZOLE ZENTIVA	Zentiva k.s.	EU/1/15/1009/021-023 Interchangeable List Code: IC0092-002-056	Orodispersible Tablet		- ARIPIPRAZOLE	Article 10(1) - Generic Application	- Oral use
ARIPIPRAZOLE ZENTIVA	Zentiva k.s.	EU/1/15/1009/024-026 Interchangeable List Code: IC0092-032-056	Orodispersible Tablet		- ARIPIPRAZOLE	Article 10(1) - Generic Application	- Oral use
ARIPIPRAZOLE ZENTIVA	Zentiva k.s.	EU/1/15/1009/027-029 Interchangeable List Code: IC0092-033-056	Orodispersible Tablet		- ARIPIPRAZOLE	Article 10(1) - Generic Application	- Oral use
ARIXTRA	Viatris Healthcare Limited	EU/1/02/206/001-004	Solution for injection in pre-filled syringe	- B01AX - B01AX05	- Fondaparinux sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Arixtra	Viatris Healthcare Limited	EU/1/02/206/005-008	Solution for injection in pre-filled syringe	- B01AX - B01AX05	- Fondaparinux sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Arixtra	Viatris Healthcare Limited	EU/1/02/206/009-011	Solution for injection in pre-filled syringe	- B01AX - B01AX05	- Fondaparinux sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Arixtra	Viatris Healthcare Limited	EU/1/02/206/012-014	Solution for injection in pre-filled syringe	- B01AX - B01AX05	- Fondaparinux sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Arixtra	Viatris Healthcare Limited	EU/1/02/206/015-017	Solution for injection in pre-filled syringe	- B01AX - B01AX05	- Fondaparinux sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	
Arixtra	Viatris Healthcare Limited	EU/1/02/206/018	Solution for injection in pre-filled syringe	- B01AX - B01AX05	- Fondaparinux sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	
Arixtra	Viatris Healthcare Limited	EU/1/02/206/031-032	Solution for injection in pre-filled syringe	- B01AX - B01AX05	- Fondaparinux sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Arlevert 20 mg/40 mg tablets	Hennig Arzneimittel GmbH & Co KG	PA1238/001/001	Tablet	- N07CA - N07CA52	- Cinnarizine - Dimenhydrinate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Armisarte (Previosuly Pemetrexed Actavis)	Actavis Group hf	EU/1/15/1063/001-003	Concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed diacid	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Arnica	A. Nelson & Company Limited	HOR1149/031/001	Tablet		- Arnica montana (ghp)		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Arnica	Nelsons GmbH	HOR22892/002/001	Pillules		- Arnica montana	Simplified Registration for a Homeopathic Medicinal Product (Article 14, Directive 2001/83/EC)	- Oral use
Arnica	Weleda AG	HOR23380/001/001	Tablet		- Arnica planta tota 30X dilution	Simplified Registration for a Homeopathic Medicinal Product (Article 14, Directive 2001/83/EC)	- Oral use
Aromasin 25 mg coated tablets	Pfizer Healthcare Ireland	PA0822/111/001 Interchangeable List Code: IC0142-022-040	Coated tablet		- Exemestane	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Aromasin 25 mg coated tablets	Originalis B.V.	PPA2306/015/001 Interchangeable List Code: IC0142-022-040	Coated tablet		- Exemestane	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Aromasin 25 mg coated tablets	IMED Healthcare Ltd.	PPA1463/069/001 Interchangeable List Code: IC0142-022-040	Coated tablet		- Exemestane	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Aromasin 25 mg coated tablets	PCO Manufacturing Ltd.	PPA0465/236/001 Interchangeable List Code: IC0142-022-040	Coated tablet		- Exemestane	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Arovi 10,000 IU (100 mg)/1 mL solution for injection in pre-filled syringe	Laboratorios Farmacéuticos ROVI, S.A.	PA1995/001/001	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Haemodialysis - Intravenous use - Subcutaneous use
Arovi 2,000 IU (20 mg)/0.2 mL solution for injection in pre-filled syringe	Laboratorios Farmacéuticos ROVI, S.A.	PA1995/001/002	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Haemodialysis - Intravenous use - Subcutaneous use
Arovi 4,000 IU (40 mg)/0.4 mL solution for injection in pre-filled syringe	Laboratorios Farmacéuticos ROVI, S.A.	PA1995/001/003	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Haemodialysis - Intravenous use - Subcutaneous use
Arovi 6,000 IU (60 mg)/0.6 mL solution for injection in pre-filled syringe	Laboratorios Farmacéuticos ROVI, S.A.	PA1995/001/004	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Haemodialysis - Intravenous use - Subcutaneous use
Arovi 8,000 IU (80 mg)/0.8 mL solution for injection in pre-filled syringe	Laboratorios Farmacéuticos ROVI, S.A.	PA1995/001/005	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Haemodialysis - Intravenous use - Subcutaneous use
Arquist 125 microgram per actuation pressurised inhalation, suspension	Cipla Europe NV	PA1963/012/001	Pressurised inhalation, suspension	- R03BA - R03BA05	- Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Arquist 250 microgram per actuation pressurised inhalation, suspension	Cipla Europe NV	PA1963/012/002	Pressurised inhalation, suspension	- R03BA - R03BA05	- Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Arret 2 mg Hard Capsules	PCO Manufacturing Ltd.	PPA0465/155/001	Capsule, hard	- A07DA - A07DA03	- Loperamide hydrochloride		- Oral use
Arret 2mg Hard Capsules	Johnson & Johnson (Ireland) Limited	PA0330/042/001	Capsule, hard	- A07DA - A07DA03	- Loperamide hydrochloride		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Arsenic Trioxide Accord	Accord Healthcare S.L.U.	EU/1/19/1398/001-003	Concentrate for solution for infusion	- L01XX27	- Arsenic Trioxide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Arsenic trioxide medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/20/1475/001	Concentrate for solution for infusion	- L01XX27	- Arsenic Trioxide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Arsenic Trioxide Mylan	Mylan IRE Healthcare Limited	EU/1/20/1427/001-002	Concentrate for solution for infusion	- L01XX27	- Arsenic Trioxide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Artelac 3.2 mg/ml Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/004/001	Eye drops, solution	- S01XA - S01XA20	- Hypromellose	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Ocular use
Artelac Preservative Free Single Dose Unit	Bausch + Lomb Ireland Limited	PA23259/004/002	Eye drops, solution in single-dose container	- S01XA - S01XA20	- Hypromellose	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Ocular use
Artelac Preservative Free Single Dose Unit	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/023/001	Eye drops, solution in single-dose container	- S01XA - S01XA20	- Hypromellose		- Ocular use
Artelac Preservative Free Single Dose Unit 3.2 mg/ml Eye Drops Solution	IMED Healthcare Ltd.	PPA1463/099/001	Eye drops, solution in single-dose container	- S01XA - S01XA20	- Hypromellose		- Ocular use
Artelac Preservative Free Single Dose Unit 3.2 mg/ml eye drops, solution	PCO Manufacturing Ltd.	PPA0465/454/001	Eye drops, solution in single-dose container	- S01XA20	- Hypromellose		- Ocular use
Artesunate Amivas	Amivas Ireland Limited	EU/1/21/1582/001-002	Powder and solution for solution for injection	- P01BE03	- Artesunate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Arthrimel 1500mg Film Coated Tablets	Phoenix Labs	PA1113/011/003	Film-coated tablet	- M01AX - M01AX05	- Glucosamine sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Arthrimel 500 mg Film-Coated Tablets	Phoenix Labs	PA1113/011/001	Film-coated tablet	- M01AX - M01AX05	- Glucosamine sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Arthrimel 750mg Film Coated Tablets	Phoenix Labs	PA1113/011/002	Film-coated tablet	- M01AX - M01AX05	- Glucosamine sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Arthrotec 50 modified-release tablets	Pfizer Healthcare Ireland	PA0822/112/001 Interchangeable List Code: IC0058-109-021	Modified-release tablet		- Diclofenac sodium - Misoprostol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Arthrotec 50 modified-release tablets	PCO Manufacturing Ltd.	PPA0465/114/001 Interchangeable List Code: IC0058-109-021	Modified-release tablet		- Misoprostol - DICLOFENAC SODIUM		- Oral use
Arthrotec 75 modified-release tablets	PCO Manufacturing Ltd.	PPA0465/114/002 Interchangeable List Code: IC0058-113-021	Modified-release tablet		- Diclofenac sodium - Misoprostol		- Oral use
Arthrotec 75 modified-release tablets	IMED Healthcare Ltd.	PPA1463/159/001 Interchangeable List Code: IC0058-113-021	Modified-release tablet		- Diclofenac sodium - Misoprostol		- Oral use
Arthrotec 75 modified-release tablets	Pfizer Healthcare Ireland	PA0822/112/002 Interchangeable List Code: IC0058-113-021	Modified-release tablet		- Diclofenac sodium - Lactose monohydrate - Misoprostol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Artichoke-Milk Thistle Complex Tablets	A.Vogel Ireland Limited	TR2309/015/001	Tablet		- Dry extract from fresh cynara scolymus l. leaves (1:30-31) extraction solvent:ethanol 65% v/v - Dry extract from silybum marianum l. gaertn fruits (1:2.0-2.1) extration solvent ethanol 58% v/v - Dry extract from fresh dandelion root&herb(taraxacum officinalis web) (1:17-18) extraction solvent:ethanol 51% - Dry extract from peumus boldus molina (1:10-11) extraction solvent:ethanol 70% v/v	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
ARTISS Solutions for Sealant, deep frozen	Baxter Holding B.V.	PA2299/026/001	Solution for sealant	- B02BC - V03AK	- Human fibrinogen - Human thrombin - Calcium chloride - Aprotinin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Epilesional use - Topical use
ASACARD 162.5 mg prolonged release hard capsules	New Haven Pharma (UK) Limited	PA1966/001/001	Prolonged-release capsule, hard	- B01AC - B01AC06	- Acetylsalicylic acid		- Oral use
Asacolon 1000 mg Suppository	Tillotts Pharma GmbH	PA2018/005/001	Suppository	- A07EC02	- Mesalazine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Rectal use
Asacolon 1600 mg modified-release tablets	Tillotts Pharma GmbH	PA2018/004/001	Modified-release tablet	- A07EC - A07EC02	- Mesalazine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Asacolon 400mg Gastro-Resistant Tablets	Tillotts Pharma GmbH	PA2018/001/001	Gastro-resistant tablet	- A07EC - A07EC02	- Mesalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Asacolon 500 mg Suppositories	Tillotts Pharma GmbH	PA2018/001/003	Suppository	- A07EC - A07EC02	- Mesalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Rectal use
Asacolon 800 mg Gastro-resistant Tablets	PCO Manufacturing Ltd.	PPA0465/465/001	Gastro-resistant tablet	- A07EC - A07EC02	- Mesalazine		- Oral use
Asacolon 800mg Gastro-resistant Tablets	Tillotts Pharma GmbH	PA2018/001/002	Gastro-resistant tablet	- A07EC - A07EC02	- Mesalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Asmanex Twisthaler 200 micrograms Inhalation Powder	Organon Pharma (Ireland) Limited	PA23198/012/001	Inhalation powder	- R03BA - R03BA07	- Mometasone furoate		- Inhalation use
Asmanex Twisthaler 400 micrograms Inhalation Powder	Organon Pharma (Ireland) Limited	PA23198/012/002	Inhalation powder	- R03BA - R03BA07	- Mometasone furoate		- Inhalation use
Aspaveli	Apellis Ireland Limited	EU/1/21/1595/001-002	Solution for infusion	- L04AA54	- Pegcetacoplan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Aspirin 300mg Effervescent tablets	Bayer Limited	PA1410/037/001	Effervescent tablet	- N02BA - N02BA01	- Aspirin		- Oral use
Aspirin 75mg gastro-resistant tablets	Clonmel Healthcare Ltd	PA0126/246/001	Gastro-resistant tablet	- B01AC - B01AC06	- Acetyl salicylic acid	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Aspirin Krka 75 mg gastro-resistant tablets	KRKA, d.d., Novo mesto	PA1347/070/001	Gastro-resistant tablet	- B01AC - B01AC06	- Acetylsalicylic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Astepro 1.5 mg/ml nasal spray, solution	Mylan IRE Healthcare Limited	PA2010/045/001	Nasal spray, solution	- R01AC - R01AC03	- Azelastine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Astilin 10 mg film-coated tablets	Ascot Laboratories (Ireland) Limited	PA23163/001/001	Film-coated tablet	- N06AA - N06AA09	- Amitriptyline	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Astilin 25 mg film-coated tablets	Ascot Laboratories (Ireland) Limited	PA23163/001/002	Film-coated tablet	- N06AA - N06AA09	- Amitriptyline hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Atacand 16 mg tablets	PCO Manufacturing Ltd.	PPA0465/116/002 Interchangeable List Code: IC0009-038-002	Tablet		- Candesartan cilexetil		- Oral use
Atacand 16 mg tablets	IMED Healthcare Ltd.	PPA1463/031/002 Interchangeable List Code: IC0009-038-002	Tablet		- Candesartan cilexetil		- Oral use
Atacand 16 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/010/003 Interchangeable List Code: IC0009-038-002	Tablet		- Candesartan cilexetil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Atacand 4 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/010/001 Interchangeable List Code: IC0009-008-002	Tablet		- Candesartan cilexetil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Atacand 8 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/010/002 Interchangeable List Code: IC0009-009-002	Tablet		- Candesartan cilexetil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Atacand 8 mg tablets	IMED Healthcare Ltd.	PPA1463/031/001 Interchangeable List Code: IC0009-009-002	Tablet		- Candesartan cilexetil		- Oral use
Atacand 8 mg tablets	PCO Manufacturing Ltd.	PPA0465/116/001 Interchangeable List Code: IC0009-009-002	Tablet		- Candesartan cilexetil	ZZZ PPA	- Oral use
Atacand Plus 16 mg/12.5 mg tablets	PCO Manufacturing Ltd.	PPA0465/117/001 Interchangeable List Code: IC0029-036-002	Tablet		- Candesartan cilexetil - Hydrochlorothiazide		- Oral use
Atacand Plus 16 mg/12.5 mg tablets	IMED Healthcare Ltd.	PPA1463/053/001 Interchangeable List Code: IC0029-036-002	Tablet		- Candesartan cilexetil - Hydrochlorothiazide	ZZZ PPA	- Oral use
Atacand Plus 16 mg/12.5 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/011/002 Interchangeable List Code: IC0029-036-002	Tablet		- Candesartan cilexetil - Hydrochlorothiazide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Atacand Plus 8 mg/12.5 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/011/001 Interchangeable List Code: IC0029-058-002	Tablet		- Hydrochlorothiazide - Candesartan cilexetil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Atazanavir Krka	KRKA, d.d., Novo mesto	EU/1/19/1353/001	Capsule, hard	- J05AE - J05AE08	- Atazanavir sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Atazanavir Krka	KRKA, d.d., Novo mesto	EU/1/19/1353/002	Capsule, hard	- J05AE - J05AE08	- Atazanavir sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atazanavir Krka	KRKA, d.d., Novo mesto	EU/1/19/1353/003-004	Capsule, hard	- J05AE - J05AE08	- Atazanavir sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atazanavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1091/001-003	Capsule, hard	- J05AE - J05AE08	- Atazanavir sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atazanavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1091/004-006	Capsule, hard	- J05AE - J05AE08	- Atazanavir sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atazanavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1091/007-010	Capsule, hard	- J05AE - J05AE08	- Atazanavir sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atazanavir Rowex 300 mg Capsules hard	Rowex Ltd	PA0711/287/004	Capsule, hard	- J05AE08	- Atazanavir sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atecor 100mg Tablets	Rowex Ltd	PA0711/003/003	Film-coated tablet	- C07AB - C07AB03	- Atenolol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Not Currently Available
Atecor 25mg Tablets	Rowex Ltd	PA0711/003/001	Film-coated tablet	- C07AB - C07AB03	- Atenolol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Not Currently Available
Atecor 50mg Tablets	Rowex Ltd	PA0711/003/002	Film-coated tablet	- C07AB - C07AB03	- Atenolol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Not Currently Available
Atecor CT 100 mg/25 mg Film-coated tablets	Rowex Ltd	PA0711/020/002	Film-coated tablet	- C07CB - C07CB03	- Chlortalidone - Atenolol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atecor CT 50 mg/12.5 mg Film-coated tablets	Rowex Ltd	PA0711/020/001	Film-coated tablet	- C07CB - C07CB03	- Chlortalidone - Atenolol		- Oral use
Atectura Breezhaler 125 micrograms/127.5 micrograms inhalation powder, hard capsules	Novartis Europharm Limited	EU/1/20/1439/005-008	Inhalation powder, hard capsule	- R03AK14	- Indacaterol acetate - Mometasone furoate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Atectura Breezhaler 125 micrograms/260 micrograms inhalation powder, hard capsules	Novartis Europharm Limited	EU/1/20/1439/009-012	Inhalation powder, hard capsule	- R03AK14	- Indacaterol acetate - Mometasone furoate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Atectura Breezhaler 125 micrograms/62.5 micrograms inhalation powder, hard capsules	Novartis Europharm Limited	EU/1/20/1439/001-004	Inhalation powder, hard capsule	- R03AK14	- Indacaterol acetate - Mometasone furoate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Atenolol 5mg/ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/004/001	Oral solution	- C07AB - C07AB03	- Atenolol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atenomel 100 mg Tablets	Clonmel Healthcare Ltd	PA0126/069/002	Tablet	- C07AB - C07AB03	- Atenolol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atenomel 25 mg Tablets	Clonmel Healthcare Ltd	PA0126/069/003	Tablet	- C07AB - C07AB03	- Atenolol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atenomel 50 mg Tablets	Clonmel Healthcare Ltd	PA0126/069/001	Tablet	- C07AB - C07AB03	- Atenolol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Atgam 50 mg/ml concentrate for solution for infusion	Pfizer Healthcare Ireland	PA0822/238/001	Concentrate for solution for infusion	- L04AA03	- Anti-T Lymphocyte Immunoglobulin for Human Use, Horse	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ativan 1 mg Tablets	Pfizer Healthcare Ireland	PA0822/090/001	Tablet	- N05BA - N05BA06	- Lorazepam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Atomoxetine Accord 10 mg Hard Capsule	Accord Healthcare Ireland Ltd.	PA2315/019/001	Capsule, hard	- N06BA09	- Atomoxetine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atomoxetine Accord 100 mg Hard Capsules	Accord Healthcare Ireland Ltd.	PA2315/019/007	Capsule, hard	- N06BA09	- Atomoxetine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atomoxetine Accord 18 mg Hard Capsule	Accord Healthcare Ireland Ltd.	PA2315/019/002	Capsule, hard	- N06BA09	- Atomoxetine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atomoxetine Accord 25 mg Hard Capsule	Accord Healthcare Ireland Ltd.	PA2315/019/003	Capsule, hard	- N06BA09	- Atomoxetine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atomoxetine Accord 40 mg Hard Capsule	Accord Healthcare Ireland Ltd.	PA2315/019/004	Capsule, hard	- N06BA09	- Atomoxetine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atomoxetine Accord 60 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/019/005	Capsule, hard	- N06BA09	- Atomoxetine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atomoxetine Accord 80 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/019/006	Capsule, hard	- N06BA09	- Atomoxetine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvas 10 mg film-coated tablets	Rowex Ltd	PA0711/180/001 Interchangeable List Code: IC0001-002-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvas 20 mg film-coated tablets	Rowex Ltd	PA0711/180/002 Interchangeable List Code: IC0001-003-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvas 40 mg film-coated tablets	Rowex Ltd	PA0711/180/003 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvas 80 mg film-coated tablets	Rowex Ltd	PA0711/180/004 Interchangeable List Code: IC0001-005-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin 10 mg Film-Coated Tablets	Pinewood Laboratories Ltd	PA0281/236/001 Interchangeable List Code: IC0001-002-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin 10 mg film-coated tablets	Dexcel Pharma GmbH	PA2261/004/001 Interchangeable List Code: IC0001-002-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin 10 mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/195/001 Interchangeable List Code: IC0001-002-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin 10mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/003/001 Interchangeable List Code: IC0001-002-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Atorvastatin 20 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/003/002 Interchangeable List Code: IC0001-003-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin 20 mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/195/002 Interchangeable List Code: IC0001-003-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin 20 mg film-coated tablets	Dexcel Pharma GmbH	PA2261/004/002 Interchangeable List Code: IC0001-003-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin 20 mg Film-Coated Tablets	Pinewood Laboratories Ltd	PA0281/236/002 Interchangeable List Code: IC0001-003-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin 40 mg Film-Coated Tablets	Pinewood Laboratories Ltd	PA0281/236/003 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin 40 mg film-coated tablets	Dexcel Pharma GmbH	PA2261/004/003 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin 40 mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/195/003 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin 40 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/003/003 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin 80 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/003/004 Interchangeable List Code: IC0001-005-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin 80 mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/195/004 Interchangeable List Code: IC0001-005-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin 80 mg Film-Coated Tablets	Pinewood Laboratories Ltd	PA0281/236/004 Interchangeable List Code: IC0001-005-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Accord 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/277/001	Film-coated tablet	- C10AA05	- Atorvastatin calcium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Accord 20 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/277/002	Film-coated tablet	- C10AA05	- Atorvastatin calcium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Accord 40 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/277/003	Film-coated tablet	- C10AA05	- Atorvastatin calcium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Bluefish 10 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/027/001 Interchangeable List Code: IC0001-002-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Atorvastatin Bluefish 20 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/027/002 Interchangeable List Code: IC0001-003-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Bluefish 30 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/027/003	Film-coated tablet	- C10AA - C10AA05	- Atorvastatin calcium trihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Bluefish 40 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/027/004 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Bluefish 60 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/027/005	Film-coated tablet	- C10AA - C10AA05	- Atorvastatin calcium trihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Bluefish 80 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/027/006 Interchangeable List Code: IC0001-005-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Clonmel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/271/001 Interchangeable List Code: IC0001-002-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/271/002 Interchangeable List Code: IC0001-003-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Clonmel 40 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/271/003 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Clonmel 80 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/271/004 Interchangeable List Code: IC0001-005-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/023/001 Interchangeable List Code: IC0001-002-003	Film-coated tablet		- Atorvastatin	ZZZ --Unknown--	- Oral use
Atorvastatin Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/023/002 Interchangeable List Code: IC0001-003-003	Film-coated tablet		- Atorvastatin	ZZZ --Unknown--	- Oral use
Atorvastatin Krka 40 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/023/003 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin	ZZZ --Unknown--	- Oral use
Atorvastatin Krka 80 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/009/004 Interchangeable List Code: IC0001-005-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Liconsa 10 mg film-coated tablets	Laboratorios LICONSA, S.A.	PA1239/028/001 Interchangeable List Code: IC0001-002-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Liconsa 20 mg film-coated tablets	Laboratorios LICONSA, S.A.	PA1239/028/002 Interchangeable List Code: IC0001-003-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Atorvastatin Liconsa 40 mg film-coated tablets	Laboratorios LICONSA, S.A.	PA1239/028/003 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Liconsa 80 mg film-coated tablets	Laboratorios LICONSA, S.A.	PA1239/028/004 Interchangeable List Code: IC0001-005-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin OPKO 40 mg film coated tablets	Opko Health Spain S.L.U.	PA23271/001/001 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Pinewood 10 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/218/001 Interchangeable List Code: IC0001-002-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Pinewood 20 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/218/002 Interchangeable List Code: IC0001-003-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Pinewood 40 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/218/003 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Pinewood 80 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/218/004 Interchangeable List Code: IC0001-005-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Rowa 10 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/079/001 Interchangeable List Code: IC0001-002-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Rowa 20 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/079/002 Interchangeable List Code: IC0001-003-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Rowa 40 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/079/003 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Rowa 80 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/079/004 Interchangeable List Code: IC0001-005-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Teva 10 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/110/001 Interchangeable List Code: IC0001-002-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Teva 20 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/110/002 Interchangeable List Code: IC0001-003-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Teva 40 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/110/003 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Teva 80 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/110/004 Interchangeable List Code: IC0001-005-003	Film-coated tablet		- Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Atorvastatin Viatris 10 mg film-coated tablets	Viatris Limited	PA23266/001/001 Interchangeable List Code: IC0001-002-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Viatris 20 mg film-coated tablets	Viatris Limited	PA23266/001/002 Interchangeable List Code: IC0001-003-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Viatris 40 mg film-coated tablets	Viatris Limited	PA23266/001/003 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atorvastatin Viatris 80 mg film-coated tablets	Viatris Limited	PA23266/001/004 Interchangeable List Code: IC0001-005-003	Film-coated tablet		- Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atosiban SUN	Sun Phamaceutical Industries Europe B.V.	EU/1/13/852/001	Solution for injection	- G02CX - G02CX01	- Atosiban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
ATOSIBAN SUN	Sun Phamaceutical Industries Europe B.V.	EU/1/13/852/002	Concentrate for solution for infusion	- G02CX01	- ATOSIBAN	Article 10(1) - Generic Application	- Intra-venous
Atovaquone/Proguanil Hydrochloride 250 mg /100 mg film-coated tablets	Glenmark Arzneimittel GmbH	PA22645/006/001	Film-coated tablet	- P01BB - P01BB51	- Atovaquone - PROGUANIL HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atovaquone/Proguanil Hydrochloride 250 mg/100 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/209/001	Film-coated tablet	- P01BB - P01BB51	- Atovaquone - PROGUANIL HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Atozet 10 mg/10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/470/001 Interchangeable List Code: IC0118-017-003	Film-coated tablet		- Atorvastatin - Ezetimibe		- Oral use
Atozet 10 mg/20 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/470/002 Interchangeable List Code: IC0118-051-003	Film-coated tablet		- Ezetimibe - Atorvastatin		- Oral use
Atozet 10 mg/40 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/470/003 Interchangeable List Code: IC0118-059-003	Film-coated tablet		- Ezetimibe - Atorvastatin		- Oral use
Atozet 10 mg/40 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/215/001 Interchangeable List Code: IC0118-059-003	Film-coated tablet		- Ezetimibe - Atorvastatin	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Atozet 10 mg/40 mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/022/003 Interchangeable List Code: IC0118-059-003	Film-coated tablet		- Ezetimibe - Atorvastatin	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Atozet 10 mg/80 mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/022/004 Interchangeable List Code: IC0118-060-003	Film-coated tablet		- Ezetimibe - Atorvastatin	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Atozet 10 mg/80 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/215/002 Interchangeable List Code: IC0118-060-003	Film-coated tablet		- Ezetimibe - Atorvastatin	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Atozet 10 mg/80 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/470/004 Interchangeable List Code: IC0118-060-003	Film-coated tablet		- Ezetimibe - Atorvastatin		- Oral use
Atozet 10mg/10mg Film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/022/001 Interchangeable List Code: IC0118-017-003	Film-coated tablet		- Ezetimibe - Atorvastatin	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Atozet 10mg/20mg Film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/022/002 Interchangeable List Code: IC0118-051-003	Film-coated tablet		- Ezetimibe - Atorvastatin	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Atracurium 10 mg/ml solution for injection/infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/011/001	Solution for injection/infusion	- M03AC - M03AC04	- Atracurium besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Atracurium besilate 10 mg/ml solution for injection/infusion	AS Kalceks	PA2165/001/001	Solution for injection/infusion	- M03AC - M03AC04	- Atracurium besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
ATRIANCE 5mg/ml Solution for Infusion	Sandoz Pharmaceuticals d.d.	EU/1/07/403/001	Solution for infusion	- L01BB - L01BB07	- Nelarabine		- Intravenous use
Atrogel Arnica Gel	A. Vogel Ireland Ltd,	TR2309/001/001	Gel		- Arnica montana l. flowers (der 1:20)	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Cutaneous use
Atropine Sulfate Aguettant 0.1 mg/ml solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/003/001	Solution for injection in pre-filled syringe	- A03BA - A03BA01	- Atropine Sulfate Monohydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Atropine Sulfate Aguettant 0.2mg/ml Solution for Injection in Pre-Filled Syringe	Laboratoire AGUETTANT	PA1968/003/002	Solution for injection in pre-filled syringe	- A03BA - A03BA01	- Atropine sulfate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Atrosan Devil's Claw film-coated tablets	A.Vogel Ireland Limited	TR2309/003/001	Film-coated tablet		- Devil's claw extract (as dry root)	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Atrovent 250 UDVs 250 micrograms/ 1ml Nebuliser Solution	Boehringer Ingelheim International GmbH	PA0775/012/002	Nebuliser solution	- R03BB - R03BB01	- Ipratropium bromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Atrovent 500 UDVs, 500 micrograms/ 2ml Nebuliser Solution	Boehringer Ingelheim International GmbH	PA0775/012/003	Nebuliser solution	- R03BB - R03BB01	- Ipratropium bromide		- Inhalation use
Atrovent Inhaler CFC-Free 20 micrograms per metered dose pressurised inhalation solution	Boehringer Ingelheim International GmbH	PA0775/012/001	Pressurised inhalation, solution	- R03BB - R03BB01	- Ipratropium bromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Aubagio	Sanofi Winthrop Industrie	EU/1/13/838/001-005	Film-coated tablet	- L04AA - L04AA31	- Teriflunomide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Aubagio	Sanofi Winthrop Industrie	EU/1/13/838/006	Film-coated tablet	- L04AA31	- Teriflunomide	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Audax Ear Drops Solution Choline Salicylate 20%w/v Glycerol 12.6%w/v	LanesHealth (Ireland) Limited	PA22702/003/001	Ear drops, solution	- S02DA	- Choline salicylate - Glycerol		- Topical

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Augmentin 250 mg/125 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/093/007 Interchangeable List Code: IC0037-074-003	Film-coated tablet		- Amoxicillin trihydrate - potassium clavulanate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Augmentin 500 mg/125 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/019/003 Interchangeable List Code: IC0037-073-003	Film-coated tablet		- Amoxicillin - Clavulanic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Augmentin 875 mg/125 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/019/005 Interchangeable List Code: IC0037-072-003	Film-coated tablet		- Amoxicillin - Clavulanic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Augmentin 875 mg/125 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/017/001 Interchangeable List Code: IC0037-072-003	Film-coated tablet		- Amoxicillin trihydrate - Clavulanic acid		- Oral use
Augmentin Duo Mixed Fruit 400 mg/57 mg/5 ml Powder for Oral Suspension	GlaxoSmithKline (Ireland) Limited	PA1077/019/006 Interchangeable List Code: IC0037-076-034	Powder for oral suspension		- Amoxicillin - Clavulanic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Augmentin Paediatric 125 mg/31.25 mg per 5 ml Powder for Oral Suspension	GlaxoSmithKline (Ireland) Limited	PA1077/093/004 Interchangeable List Code: IC0037-071-034	Powder for oral suspension		- Amoxicillin - Clavulanic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Avamys	GlaxoSmithKline (Ireland) Limited	EU/1/07/434/001-003	Nasal spray, suspension	- R01AD - R01AD12	- Fluticasone furoate		- Intranasal use
AVASTIN	Roche Registration GmbH	EU/1/04/300/001-002	Concentrate for solution for infusion	- L01FG01	- Bevacizumab		- Intravenous use
AVAXIM, suspension for injection in a pre-filled syringe Hepatitis A vaccine (inactivated, adsorbed)	Sanofi Pasteur	PA2131/002/001	Suspension for injection in pre-filled syringe	- J07BC - J07BC02	- Hepatitis a virus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Not Currently Available
Avelox 400 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/118/001	Film-coated tablet	- J01MA - J01MA14	- Moxifloxacin		- Oral use
Avelox 400 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/230/001	Film-coated tablet	- J01MA - J01MA14	- Moxifloxacin hydrochloride		- Oral use
AvenaCalm Avena sativa oral drops	A. Vogel Ireland Ltd,	TR2309/012/001	Oral drops, solution		- Tincture from pressed juice from avena sativa l, herba rec (fresh oat herb),(1:1.2)	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Avodart 0.5 mg soft capsules	PCO Manufacturing Ltd.	PPA0465/211/001 Interchangeable List Code: IC0140-040-001	Capsule, soft		- Dutasteride	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Avodart 0.5 mg soft capsules	IMED Healthcare Ltd.	PPA1463/149/001 Interchangeable List Code: IC0140-040-001	Capsule, soft		- Dutasteride	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Avodart 0.5 mg soft capsules	GlaxoSmithKline (Ireland) Limited	PA1077/104/001 Interchangeable List Code: IC0140-040-001	Capsule, soft		- Dutasteride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Avonex	Biogen Netherlands B.V.	EU/1/97/033/003	Solution for injection in pre-filled syringe	- L03AB - L03AB07	- Interferon beta - 1a		- Intramuscular use
Axhidrox 2.2 mg/pump actuation cream	Dr. August Wolff GmbH & Co. KG Arzneimittel	PA0988/003/001	Cream	- D11AA	- Glycopyrronium bromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Axsain 0.075% w/w Cream	Teva B.V.	PA1986/088/001	Cream	- M02AB01	- Capsaicin		- Topical
Axumin	Blue Earth Diagnostics Ireland Ltd	EU/1/17/1186/001	Solution for injection	- V09IX - V09IX12	- Fluciclovine (18f)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Axumin	Blue Earth Diagnostics Ireland Ltd	EU/1/17/1186/002	Solution for injection	- V09IX - V09IX12	- Fluciclovine (18f)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Axura	Merz Pharmaceuticals GmbH	EU/1/02/218/1-3 Interchangeable List Code: IC0022-002-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE		- Oral use
Axura	Merz Pharmaceuticals GmbH	EU/1/02/218/16 Interchangeable List Code: IC0022-106-003	Film-coated tablet		- Memantine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Axura	Merz Pharmaceuticals GmbH	EU/1/02/218/17-22 Interchangeable List Code: IC0022-003-003	Film-coated tablet		- Memantine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Axura 5 mg/pump actuation oral solution	Merz Pharmaceuticals GmbH	EU/1/02/218/5-6 Interchangeable List Code: IC0022-107-019	Oral solution		- MEMANTINE HYDROCHLORIDE		- Oral use
Aybintio	Samsung Bioepis NL B.V.	EU/1/20/1454/001	Concentrate for solution for infusion	- L01XC07	- Bevacizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Aybintio	Samsung Bioepis NL B.V.	EU/1/20/1454/001-002	Concentrate for solution for infusion	- L01XC07	- Bevacizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Aybintio	Samsung Bioepis NL B.V.	EU/1/20/1454/002	Concentrate for solution for infusion	- L01XC07	- Bevacizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Aybintio	Samsung Bioepis NL B.V.	EU/1/20/1451/002	Concentrate for solution for infusion	- L01XC07	- Bevacizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Aybintio	Samsung Bioepis NL B.V.	EU/1/20/1451/001	Concentrate for solution for infusion	- L01XC07	- Bevacizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
AYVAKYT	Blueprint Medicines (Netherlands) B.V.	EU/1/20/1473/001	Film-coated tablet	- L01EX18 - L01XE	- Avapritinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
AYVAKYT	Blueprint Medicines (Netherlands) B.V.	EU/1/20/1473/002	Film-coated tablet	- L01EX18 - L01XE	- Avapritinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
AYVAKYT	Blueprint Medicines (Netherlands) B.V.	EU/1/20/1473/003	Film-coated tablet	- L01EX18 - L01XE	- Avapritinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
AYVAKYT	Blueprint Medicines (Netherlands) B.V.	EU/1/20/1473/004	Film-coated tablet	- L01EX18	- Avapritinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
AYVAKYT	Blueprint Medicines (Netherlands) B.V.	EU/1/20/1473/005	Film-coated tablet	- L01EX18	- Avapritinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Azacitidine 25 mg/ml powder for suspension for injection	Clonmel Healthcare Ltd	PA0126/362/001	Powder for suspension for injection	- L01BC07	- Azacitidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Azacitidine Accord	Accord Healthcare S.L.U.	EU/1/19/1413/001	Powder for suspension for injection	- L01BC07	- Azacitidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Azacitidine betapharm	Betapharm Arzneimittel GmbH	EU/1/19/1416/001	Powder for suspension for injection	- L01BC07	- Azacitidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Azacitidine Clonmel 25 mg/ml powder for suspension for injection	Clonmel Healthcare Ltd	PA0126/316/001	Powder for suspension for injection	- L01BC07	- Azacitidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Azacitidine EVER Pharma 25 mg/ml powder for suspension for injection	EVER Valinject GmbH	PA1774/003/001	Powder for suspension for injection	- L01BC07	- Azacitidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Azacitidine Mylan	Mylan IRE Healthcare Limited	EU/1/20/1426/001-002	Powder for suspension for injection	- L01BC07	- Azacitidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Azacitidine Rowex 25 mg/ml Powder for suspension for injection	Rowex Ltd	PA0711/297/001	Powder for suspension for injection	- L01BC07	- Azacitidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Azacitidine Seacross 25 mg/ml powder for suspension for injection	Seacross Pharma (Europe) Limited	PA22766/005/001	Powder for suspension for injection	- L01BC07	- Azacitidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Azactam 1 g Powder for Solution for Injection or Infusion	Bristol-Myers Squibb Pharmaceuticals uc	PA0002/052/002	Powder for solution for injection/infusion	- J01DF - J01DF01	- Aztreonam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Azactam 2 g Powder for Solution for Injection or Infusion	Bristol-Myers Squibb Pharmaceuticals uc	PA0002/052/003	Powder for solution for injection/infusion	- J01DF - J01DF01	- Aztreonam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Azalia 75 microgram film-coated tablets	Gedeon Richter Plc	PA1330/010/001	Film-coated tablet	- G03AC - G03AC09	- Desogestrel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
AZARGA	Novartis Europharm Limited	EU/1/08/482/1-2	Eye drops, suspension	- S01ED - S01ED51	- TIMOLOL MALEATE - Brinzolamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Azecort 137 micrograms/50 micrograms per actuation nasal spray, suspension	Mylan IRE Healthcare Limited	PA2010/061/001	Nasal spray, suspension	- R01AD - R01AD58	- Azelastine hydrochloride - Fluticasone propionate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Nasal use
Azelastine Eye Drops, 0.5 mg/ml, Eye Drops, solution	Mylan IRE Healthcare Limited	PA2010/046/001	Eye drops, solution	- S01GX - S01GX07	- Azelastine hydrochloride		- Ocular use
Azelastine hydrochloride /Fluticasone propionate Rowex 137 micrograms/50 micrograms per actuation, nasal spray suspension	Rowex Ltd	PA0711/324/001	Nasal spray, suspension	- R01AD58	- Azelastine hydrochloride - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Nasal use
AZILECT 1 mg tablets	Teva B.V.	EU/1/04/304/1-7 Interchangeable List Code: IC0112-039-002	Tablet		- Rasagiline	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Azilsartan medoxomil/Chlortalidone 40 mg /12.5 mg Film-coated Tablets	Takeda Pharma A/S	PA2167/001/001	Film-coated tablet	- C09DA - C09DA09	- AZILSARTAN MEDOXOMIL POTASSIUM - Chlortalidone	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Azilsartan medoxomil/Chlortalidone 40 mg/25 mg Film-coated tablets	Takeda Pharma A/S	PA2167/001/002	Film-coated tablet	- C09DA - C09DA09	- AZILSARTAN MEDOXOMIL POTASSIUM - Chlortalidone	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Azithromycin Clonmel 250 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/150/001 Interchangeable List Code: IC0113-130-009	Film-coated tablet		- Azithromycin dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Azithromycin Krka 250 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/047/001 Interchangeable List Code: IC0113-130-009	Film-coated tablet		- Azithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Azithromycin Teva 250 mg film-coated tablets	Teva Pharma B.V.	PA0749/039/002 Interchangeable List Code: IC0113-130-009	Film-coated tablet		- Azithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Azomyr	N.V. Organon	EU/1/00/157/001	Film-coated tablet	- R06AX - R06AX27	- Desloratidine		- Oral use
Azomyr	N.V. Organon	EU/1/00/157/001-013	Film-coated tablet	- R06AX - R06AX27	- Desloratidine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Azomyr	N.V. Organon	EU/1/00/157/59-67	Oral solution	- R06AX - R06AX27	- Desloratadine, micronized		- Oral use
Azopt	Novartis Europharm Limited	EU/1/00/129/002	Eye drops, suspension	- S01EC - S01EC04	- Brinzolamide		- Ocular use
Azopt Eye Drops	Novartis Europharm Limited	EU/1/00/129/001	Eye drops, suspension	- S01EC - S01EC04	- Brinzolamide		- Ocular use
Azromax 250 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/122/001 Interchangeable List Code: IC0113-130-009	Film-coated tablet		- Azithromycin dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Azuzote 30 mg film-coated tablets	Azure Pharmaceuticals Ltd	PA22871/001/001	Film-coated tablet	- N02BG06	- NEFOPAM HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Azyter 15 mg/g eye drops, solution, in single-dose container	Laboratoires Thea	PA1107/004/001	Eye drops, solution	- S01AA - S01AA26	- Azithromycin dihydrate	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Azzalure, 125 Speywood units, powder for solution for injection	Ipsen Pharma	PA1613/001/001	Powder for solution for injection	- M03AX - M03AX01	- Clostridium botulinum toxin type a haemagglutinin complex	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Baclofen 5mg/5ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/005/001	Oral solution	- M03BX - M03BX01	- Baclofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Baclopar 10 mg Tablets	Viatris Limited	PA23266/019/001	Tablet	- M03BX - M03BX01	- Baclofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bactroban 2% w/w Nasal Ointment	PCO Manufacturing Ltd.	PPA0465/312/001	Nasal ointment	- D06AX - D06AX09	- Mupirocin		- Nasal use
Bactroban 2% w/w Nasal Ointment	GlaxoSmithKline (Ireland) Limited	PA1077/094/002	Nasal ointment	- D06AX - D06AX09	- Mupirocin calcium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Bactroban 2% w/w Ointment	GlaxoSmithKline (Ireland) Limited	PA1077/094/001	Ointment	- D06AX - D06AX09	- Mupirocin		- Cutaneous use
Bactroban 2% w/w Ointment	PCO Manufacturing Ltd.	PPA0465/312/002	Ointment	- D06AX - D06AX09	- Mupirocin		- Cutaneous use
BAQSIMI	Amphastar France Pharmaceuticals, S.A.S.	EU/1/19/1406/001-002	Nasal powder in single-dose container	- H04AA - H04AA01	- GLUCAGON	Full application (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Baraclude	Bristol-Myers Squibb Pharma EEIG	EU/1//06/343/01	Film-coated tablet	- J05AF - J05AF10	- Entecavir		- Oral use
Baraclude	Bristol-Myers Squibb Pharma EEIG	EU/1/06/343/02,04,07	Film-coated tablet	- J05AF10	- Entecavir		- Oral use
Baraclude	Bristol-Myers Squibb Pharma EEIG	EU/1/06/343/05	Oral solution	- J05AF10	- Entecavir		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Bavencio	Merck Europe B.V.	EU/1/17/1214/001	Concentrate for solution for infusion	- L01XC	- Avelumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
BCG medac, powder and solvent for intravesical suspension	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/004/001	Powder and solvent for intravesical suspension	- L03AX - L03AX03	- Bacillus Calmette Guérin (BCG)	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravesical use
BCG VACCINE AJV	AJ Vaccines A/S	PA2160/003/001	Powder and solvent for suspension for injection	- J07AN - J07AN01	- Mycobacterium bovis (bcg) stam 1331	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intradermal use
Beclazone 100 micrograms CFC-Free Inhaler Pressurised Inhalation Solution	Norton Waterford	PA0436/021/010	Pressurised inhalation, solution	- R03BA - R03BA01	- Beclometasone dipropionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Beclazone 100 micrograms Easi-Breathe CFC-Free Inhaler Pressurised Inhalation Solution	Norton Waterford	PA0436/021/014	Pressurised inhalation, solution	- R03BA - R03BA01	- Beclometasone dipropionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Beclazone 200 micrograms CFC-Free Inhaler, Pressurised Inhalation Solution	Norton Waterford	PA0436/021/011	Pressurised inhalation, solution	- R03BA - R03BA01	- Beclometasone dipropionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Beclazone 200 micrograms Easi-Breathe CFC-Free Inhaler, Pressurised Inhalation Solution	Norton Waterford	PA0436/021/015	Pressurised inhalation, solution	- R03BA - R03BA01	- Beclometasone dipropionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Beclazone 250 micrograms CFC-Free Inhaler Pressurised Inhalation Solution	Norton Waterford	PA0436/021/012	Pressurised inhalation, solution	- R03BA01	- Beclometasone dipropionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Beclazone 250 micrograms Easi-Breathe CFC-Free Inhaler Pressurised Inhalation Solution	Norton Waterford	PA0436/021/016	Pressurised inhalation, solution	- R03BA - R03BA01	- Beclometasone dipropionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Beclazone 50 micrograms CFC-Free Inhaler Pressurised Inhalation Solution	Norton Waterford	PA0436/021/009	Pressurised inhalation, solution	- R03BA - R03BA01	- Beclometasone dipropionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Becloneb 400 micrograms/1 ml nebuliser suspension	Chiesi Farmaceutici S.p.A.	PA0584/003/001	Nebuliser suspension	- R03BA - R03BA01	- Beclometasone dipropionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Becloneb 800 micrograms/2 ml nebuliser suspension	Chiesi Farmaceutici S.p.A.	PA0584/003/002	Nebuliser suspension	- R03BA - R03BA01	- Beclometasone dipropionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Beclospin 400 micrograms/1 ml nebuliser suspension	Chiesi Farmaceutici S.p.A.	PA0584/004/001	Nebuliser suspension	- R03BA - R03BA01	- Beclometasone dipropionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Beclospin 800 micrograms/2 ml nebuliser suspension	Chiesi Farmaceutici S.p.A.	PA0584/004/002	Nebuliser suspension	- R03BA - R03BA01	- Beclometasone dipropionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Beconase Hayfever nasal spray 50 micrograms per spra	Chefaro Ireland DAC	PA1186/008/001	Nasal spray, suspension	- R01AD - R01AD01	- Beclometasone dipropionate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Nasal use
Becotide Evohaler 100 micrograms, Pressurised Inhalation Solution	GlaxoSmithKline (Ireland) Limited	PA1077/042/007	Pressurised inhalation, solution	- R03BA - R03BA01	- Beclometasone dipropionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Becotide Evohaler 250 micrograms, Pressurised Inhalation Solution	GlaxoSmithKline (Ireland) Limited	PA1077/042/009	Pressurised inhalation, solution	- R03BA - R03BA01	- Beclometasone dipropionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Becotide Evohaler 50 micrograms, Pressurised Inhalation Solution	GlaxoSmithKline (Ireland) Limited	PA1077/042/006	Pressurised inhalation, solution	- R03BA - R03BA01	- Beclometasone dipropionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Bekemv	Amgen Technology (Ireland) UC	EU/1/23/1727/001	Concentrate for solution for infusion	- L04AA25	- Eculizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Belkyra 10mg/ml solution for injection	AbbVie Limited	PA1824/021/001	Solution for injection	- D11AX	- Deoxycholic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Belladonna	A. Nelson & Company Limited	HOR1149/006/001	Not assigned		- Atropa belladonna		- Oral use
Belladonna 0.25% w/w Medicated Plaster	Cuxson Gerrard Healthcare Limited	PA23188/002/001	Medicated plaster	- M02AX - M02AX10	- Belladonna alkaloids		- Topical use
Bemfola	Gedeon Richter Plc	EU/1/13/909/001-005	Solution for injection	- G03GA - G03GA05	- Follitropin alfa	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Bemrist Breezhaler 125 micrograms/127.5 micrograms inhalation powder, hard capsules	Novartis Europharm Limited	EU/1/20/1441/005-008	Inhalation powder, hard capsule	- R03AK14	- Indacaterol acetate - Indacaterol - Mometasone furoate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Bemrist Breezhaler 125 micrograms/260 micrograms inhalation powder, hard capsules	Novartis Europharm Limited	EU/1/20/1441/009-012	Inhalation powder, hard capsule	- R03AK14	- Indacaterol acetate - Indacaterol - Mometasone furoate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Bemrist Breezhaler 125 micrograms/62.5 micrograms inhalation powder, hard capsules	Novartis Europharm Limited	EU/1/20/1441/001-004	Inhalation powder, hard capsule	- R03AK14	- Indacaterol acetate - Indacaterol - Mometasone furoate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Bendamustine 100 mg powder for concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/077/002	Powder for concentrate for solution for infusion	- L01AA - L01AA09	- Bendamustine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Bendamustine 100 mg Powder for Concentrate for Solution for Infusion	Teva B.V.	PA1986/121/002	Powder for concentrate for solution for infusion	- L01AA - L01AA09	- Bendamustine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Bendamustine 25 mg Powder for Concentrate for Solution for Infusion	Teva B.V.	PA1986/121/001	Powder for concentrate for solution for infusion	- L01AA - L01AA09	- Bendamustine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Bendamustine 25 mg powder for concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/077/001	Powder for concentrate for solution for infusion	- L01AA - L01AA09	- Bendamustine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Bendamustine 25 mg/ml concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/077/003	Concentrate for solution for infusion	- L01AA09	- Bendamustine hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Bendamustine HCl 100 mg Powder for Concentrate for Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/028/002	Powder for concentrate for solution for infusion	- L01AA - L01AA09	- Bendamustine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Bendamustine HCl 25 mg Powder for Concentrate for Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/028/001	Powder for concentrate for solution for infusion	- L01AA - L01AA09	- Bendamustine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Bendroflumethiazide 2.5 mg Tablets	Brillpharma (Ireland) Limited	PA22749/021/001	Tablet	- C03AA01	- Bendroflumethiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bendroflumethiazide 5 mg Tablets	Brillpharma (Ireland) Limited	PA22749/021/002	Tablet	- C03AA01	- Bendroflumethiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
BENEFIX	Pfizer Europe MA EEIG	EU/1/97/047/001	Powder and solvent for solution for injection	- B02BD - B02BD04	- Factor ix, human recombinant		- Intravenous use
BeneFIX	Pfizer Europe MA EEIG	EU/1/97/047/002	Powder and solvent for solution for injection	- B02BD - B02BD04	- Factor ix, human recombinant		- Unknown
BeneFIX	Pfizer Europe MA EEIG	EU/1/97/047/003	Powder and solvent for solution for injection	- B02BD - B02BD04	- Factor ix, human recombinant		- Unknown
Benefix	Pfizer Europe MA EEIG	EU/1/97/047/004	Powder and solvent for solution for injection	- B02BD - B02BD04	- Nonacog alfa		- Intravenous use
Benefix	Pfizer Europe MA EEIG	EU/1/97/047/005	Powder and solvent for solution for injection	- B02BD - B02BD04	- Nonacog alfa		- Intravenous use
Benefix	Pfizer Europe MA EEIG	EU/1/97/047/006	Powder and solvent for solution for injection	- B02BD - B02BD04	- Nonacog alfa		- Intravenous use
Benefix	Pfizer Europe MA EEIG	EU/1/97/047/007	Powder and solvent for solution for injection	- B02BD - B02BD04	- Nonacog alfa		- Intravenous use
BeneFIX	Pfizer Europe MA EEIG	EU/1/97/047/008	Powder and solvent for solution for injection	- B02BD - B02BD04	- Nonacog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
BeneFIX	Pfizer Europe MA EEIG	EU/1/97/047/009	Powder and solvent for solution for injection	- B02BD - B02BD09	- Nonacog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Benepali	Samsung Bioepis NL B.V.	EU/1/15/1074/001	Solution for injection in pre-filled syringe	- L04AB - L04AB01	- Etanercept	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Benepali	Samsung Bioepis NL B.V.	EU/1/15/1074/002	Solution for injection in pre-filled pen	- L04AB - L04AB01	- Etanercept	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Benepali	Samsung Bioepis NL B.V.	EU/1/15/1074/005-007	Solution for injection in pre-filled syringe	- L04AB - L04AB01	- Etanercept	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Benlysta	GlaxoSmithKline (Ireland) Limited	EU/1/11/700/001-002	Powder for concentrate for solution for infusion	- L04AA - L04AA26	- Belimumab		- Intravenous use
Benlysta	GlaxoSmithKline (Ireland) Limited	EU/1/11/700/003-005	Solution for injection in pre-filled pen	- L04AA - L04AA26	- Belimumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Benlysta	GlaxoSmithKline (Ireland) Limited	EU/1/11/700/006-007	Solution for injection in pre-filled syringe	- L04AA - L04AA26	- Belimumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Benylin Children's Chesty Cough 50mg/5ml Syrup	JNTL Consumer Health I (Ireland) Limited	PA23490/011/001	Syrup	- R05CA - R05CA03	- Guaifenesin	ZZZ Article 8.3(i)	- Oral use
Benylin Children's Dry Coughs Syrup Diphenhydramine Hydrochloride 7mg/5ml Levomenthol 0.55mg/5ml	JNTL Consumer Health I (Ireland) Limited	PA23490/008/001	Syrup	- R06AA - R06AA02	- Levomenthol - Diphenhydramine hydrochloride		- Oral use
Benylin Cough Medicine Syrup Diphenhydramine hydrochloride 14mg/5ml Levomenthol 1.1mg/5ml	JNTL Consumer Health I (Ireland) Limited	PA23490/005/001	Syrup	- R06AA - R06AA02	- Diphenhydramine hydrochloride - Levomenthol		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
BENYLIN Day & Night Tablets, 500mg/60mg tablets and 500/25mg film-coated tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/006/001	Film-coated tablet	- N02BE51	- Paracetamol - PSEUDOEPHEDRINE HYDROCHLORIDE - Paracetamol - Diphenhydramine hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Benylin Dry Coughs Syrup Diphenhydramine hydrochloride 14mg/5ml Dextromethorphan hydrobromide 6.5mg/5ml Levomenthol 2mg/5ml	JNTL Consumer Health I (Ireland) Limited	PA23490/004/001	Syrup	- R06AA - R06AA52	- Diphenhydramine hydrochloride - Dextromethorphan hydrobromide - Levomenthol	ZZZ --Unknown--	- Oral use
Benylin Dual Action Dry Syrup, Pseudoephedrine 30mg, Dextromethorphan 10mg, Triprolidine 1.25mg	JNTL Consumer Health I (Ireland) Limited	PA23490/002/001	Syrup	- R01BA - R01BA52	- Dextromethorphan hydrobromide - PSEUDOEPHEDRINE HYDROCHLORIDE - TRIPROLIDINE HYDROCHLORIDE	Competence of personnel (Article 23 of Directive No 2010/63/EU)	- Oral use
Benylin Four Flu Film-Coated Tablets. Paracetamol 500mg Diphenhydramine hydrochloride 12.5mg Pseudoephedrine hydrochloride 22.5mg	JNTL Consumer Health I (Ireland) Limited	PA23490/013/001	Film-coated tablet	- N02BE - N02BE51	- Paracetamol - PSEUDOEPHEDRINE HYDROCHLORIDE - Diphenhydramine hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup	JNTL Consumer Health I (Ireland) Limited	PA23490/041/001	Syrup	- R05CA03	- Guaifenesin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Benylin Mucus Relief 250mg/5ml Syrup	McNeil Healthcare (Ireland) Ltd	PA0823/035/001	Syrup	- R05CB - R05CB03	- Carbocisteine		- Oral use
Benylin Non-Drowsy Dry Coughs, Syrup Dextromethorphan hydrobromide 7.5mg/5ml	JNTL Consumer Health I (Ireland) Limited	PA23490/010/001	Syrup	- R05DA - R05DA09	- Dextromethorphan hydrobromide		- Oromucosal use
BENYLIN Non-drowsy for Chesty Coughs Syrup Guaifenesin 100mg/5ml Levomenthol 1.1mg/5ml	JNTL Consumer Health I (Ireland) Limited	PA23490/007/001	Syrup	- R05CA - R05CA03	- Levomenthol - Guaifenesin	Competence of personnel (Article 23 of Directive No 2010/63/EU)	- Oral use
Benylin Phlegm Cough Menthol 100 mg/5 ml oral solution	McNeil Healthcare (Ireland) Ltd	PA0823/066/001	Oral solution	- R05CA - R05CA03	- Guaifenesin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Benylin Phlegm Cough plus Decongestant SyrupGuaifenesin 100mg/5mlPseudoephedrine Hydrochloride 30mg/5ml	Johnson & Johnson (Ireland) Limited	PA0330/032/001	Syrup	- R01BA - R01BA52	- PSEUDOEPHEDRINE HYDROCHLORIDE - Guaifenesin		- Oral use
Benylin Phlegm Cough Syrup Guaifenesin 100 mg/5ml Levomenthol 1.1 mg/ 5ml Syrup	JNTL Consumer Health I (Ireland) Limited	PA23490/031/001	Syrup	- R05CA - R05CA03	- Levomenthol - Guaifenesin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Benzyl Benzoate 25% w/v Application Cutaneous Emulsion	Ovelle Limited	PA0206/023/001	Cutaneous emulsion	- P03AX - P03AX01	- Benzyl benzoate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Cutaneous use - Topical use
Benzylpenicillin sodium 3000 mg Powder for Solution for Injection/Infusion	Rowex Ltd	PA0711/310/002	Powder for solution for injection/infusion	- J01CE01	- Benzylpenicillin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Benzylpenicillin sodium 600 mg Powder for Solution for Injection/Infusion	Rowex Ltd	PA0711/310/001	Powder for solution for injection/infusion	- J01CE01	- Benzylpenicillin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Beovu	Novartis Europharm Limited	EU/1/19/1417/001-002	Solution for injection	- S01LA06	- Brolucizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravitreal use
Bepantiseptic First Aid Cream	Bayer Limited	PA1410/047/001	Cream	- D08AC - D08AC52	- Phenol - Chlorhexidine digluconate	Full application (Article 8(3) of Directive No 2001/83/EC)	
Berinert 1500 IU Powder and solvent for solution for injection	CSL Behring GmbH	PA0800/013/002	Powder and solvent for solution for injection	- B06AC01	- C1 Esterase Inhibitor (Human)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Berinert 2000 IU Powder and solvent for solution for injection	CSL Behring GmbH	PA0800/013/003	Powder and solvent for solution for injection	- B06AC01	- C1 Esterase Inhibitor (Human)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Berinert 3000 IU Powder and solvent for solution for injection	CSL Behring GmbH	PA0800/013/004	Powder and solvent for solution for injection	- B06AC01	- C1 Esterase Inhibitor (Human)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Berinert 500 IU Powder and solvent for solution for injection/infusion.	CSL Behring GmbH	PA0800/013/001	Powder and solvent for solution for injection	- B06AC01	- C1 Esterase Inhibitor (Human)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Beriplex P/N 1000 IU, powder and solvent for solution for injection	CSL Behring GmbH	PA0800/010/003	Powder and solvent for solution for injection	- B02BD - B02BD01	- Factor ii activity - Factor vii activity - Factor x activity - Factor ix activity - Protein c activity - Protein s antigen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Beriplex P/N 250 IU, powder and solvent for solution for injection	CSL Behring GmbH	PA0800/010/001	Powder and solvent for solution for injection	- B02BD - B02BD01	- Factor ii activity - Factor vii activity - Factor x activity - Factor ix activity - Protein c activity - Protein s antigen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Beriplex P/N 500 IU, powder and solvent for solution for injection	CSL Behring GmbH	PA0800/010/002	Powder and solvent for solution for injection	- B02BD - B02BD01	- Factor ii activity - Factor vii activity - Factor x activity - Factor ix activity - Protein c activity - Protein s antigen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
BEROMUN	Belpharma S.A.	EU/1/99/097/001	Powder for solution for infusion	- L03AX - L03AX11	- Tumour necrosis factor alfa 1a		- Unknown
BESPONSA 1 mg powder for concentrate for solution for infusion	Pfizer Europe MA EEIG	EU/1/17/1200/001	Powder for concentrate for solution for infusion	- L01XC26	- Inotuzumab ozogamicin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Besremi	AOP Orphan Pharmaceuticals AG	EU/1/18/1352/001	Solution for injection in pre-filled pen	- L03AB15	- Ropeginterferon alfa-2b	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Besremi	AOP Orphan Pharmaceuticals AG	EU/1/18/1352/002	Solution for injection in pre-filled syringe	- L03AB15	- Ropeginterferon alfa-2b	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Betacap Scalp Application 0.1 % w/w cutaneous solution	Dermal Laboratories (Ireland) Limited	PA23128/010/001	Cutaneous solution	- D07AC - D07AC01	- Betamethasone valerate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Topical use
Betaferon	Schering AG	EU/1/95/003/001	Powder and solvent for solution for injection	- L03AB - L03AB08	- Interferon beta-1b		- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Betaferon	Schering AG	EU/1/95/003/002	Powder and solvent for solution for injection	- L03AB - L03AB08	- Interferon beta-1b		- Subcutaneous use
Betaferon	Bayer AG	EU/1/95/003/003	Powder and solvent for solution for injection	- L03AB - L03AB08	- Interferon beta-1b		- Subcutaneous use
Betaferon	Schering AG	EU/1/95/003/004	Powder and solvent for solution for injection	- L03AB - L03AB08	- Interferon beta-1b		- Subcutaneous use
Betagan 0.5% w/v Unit Dose Eye Drops, Solution	AbbVie Limited	PA1824/012/001	Eye drops, solution	- S01ED - S01ED03	- Levobunolol hydrochloride		- Ocular use
Betahistine dihydrochloride 16 mg Tablets	Azure Pharmaceuticals Ltd	PA22871/017/002 Interchangeable List Code: IC0084-038-002	Tablet		- Betahistine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Betahistine dihydrochloride 16mg tablets	Accord Healthcare Ireland Ltd.	PA2315/078/002 Interchangeable List Code: IC0084-038-002	Tablet		- Betahistine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Betahistine dihydrochloride 24 mg Tablets	Azure Pharmaceuticals Ltd	PA22871/017/003	Tablet	- N07CA01	- Betahistine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Betahistine dihydrochloride 8 mg Tablets	Azure Pharmaceuticals Ltd	PA22871/017/001 Interchangeable List Code: IC0084-009-002	Tablet		- Betahistine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Betahistine dihydrochloride 8mg tablets	Accord Healthcare Ireland Ltd.	PA2315/078/001 Interchangeable List Code: IC0084-009-002	Tablet		- Betahistine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Betaloc 1 mg/ml solution for injection	Recordati Ireland Limited	PA1404/007/001	Solution for injection	- C07AB - C07AB02	- METOPROLOL TARTRATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Beta-Prograne 160mg Prolonged-Release Capsules	Tillomed Pharma GmbH	PA22720/002/001	Prolonged-release capsule, hard	- C07AA - C07AA05	- Propranolol hydrochloride		- Oral use
Betmiga	Astellas Pharma Europe BV	EU/1/12/809/001-007	Prolonged-release tablet	- G04BD - G04BD12	- Mirabegron (ym178)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Betmiga	Astellas Pharma Europe BV	EU/1/12/809/008-014	Prolonged-release tablet	- G04BD - G04BD12	- Mirabegron (ym178)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Betnesol 0.1% w/v Eye, Ear and Nasal Drops, solution	RPH Pharmaceuticals AB	PA1638/001/001	Ear/eye/nasal drops, solution	- S02BA - S02BA07	- BETAMETHASONE SODIUM PHOSPHATE		- Ocular use
Betnesol-N 0.1% w/v, 3500 IU/ml Eye, Ear and Nasal Drops, solution	RPH Pharmaceuticals AB	PA1638/002/001	Ear/eye/nasal drops, solution	- S03CA - S03CA06	- Neomycin sulfate - BETAMETHASONE SODIUM PHOSPHATE		- Auricular use - Nasal use - Ocular use
Betnovate Cream 0.1% w/w	GlaxoSmithKline (Ireland) Limited	PA1077/001/001	Cream	- D07AC - D07AC01	- Betamethasone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Betnovate Ointment 0.1% w/w	GlaxoSmithKline (Ireland) Limited	PA1077/001/002	Ointment	- D07AC - D07AC01	- Betamethasone valerate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical
Betnovate RD (Ready Diluted) 0.025% w/w Cream	GlaxoSmithKline (Ireland) Limited	PA1077/001/004	Cream	- D07AC - D07AC01	- Betamethasone valerate		- Topical
Betnovate RD (Ready Diluted) 0.025% w/w Ointment	GlaxoSmithKline (Ireland) Limited	PA1077/001/005	Ointment	- D07AC - D07AC01	- Betamethasone valerate		- Topical

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Betnovate Scalp Application 0.1% w/v Cutaneous Solution	GlaxoSmithKline (Ireland) Limited	PA1077/001/003	Cutaneous solution	- D07AC - D07AC01	- Betamethasone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical
Betnovate-C 0.1% / 3% w/w Cream	GlaxoSmithKline (Ireland) Limited	PA1077/002/001	Cream	- D07BC - D07BC01	- Betamethasone - Clioquinol		- Topical use
Bettamousse 1mg/g (0.1%) cutaneous foam	RPH Pharmaceuticals AB	PA1638/009/001	Cutaneous foam	- D07AC - D07AC01	- Betamethasone valerate		- Cutaneous use
Bevespi Aerosphere	AstraZeneca AB	EU/1/18/1339/001	Pressurised inhalation, suspension	- R03AL07	- Formoterol fumarate dihydrate - GLYCOPYRRONIUM	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Bexsero	GSK Vaccines S.r.l.	EU/1/12/812/001-004	Suspension for injection in pre-filled syringe	- J07AH09	- Recombinant neisseria meningitidis serogroup b nhba fusion protein - Recombinant neisseria meningitidis serogroup b nada fusion protein - Recombinant neisseria meningitidis serogroup b fhbp fusion protein - Outer rmembrane vesicles (omv)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Beyfortus	Sanofi Winthrop Industrie	EU/1/22/1689/001-003	Solution for injection in pre-filled syringe	- J06B - J06BD08	- Nirsevimab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Beyfortus	Sanofi Winthrop Industrie	EU/1/22/1689/004-006	Solution for injection in pre-filled syringe	- J06BD08	- Nirsevimab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Bicalutamide 50 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/079/001 Interchangeable List Code: IC0137-023-003	Film-coated tablet		- Bicalutamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bicalutamide 50 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/038/001 Interchangeable List Code: IC0137-023-003	Film-coated tablet		- Bicalutamide	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Bicalutamide Fair-Med 150mg Film-coated Tablets	Fairmed Healthcare GmbH	PA1789/001/002	Film-coated tablet	- L02BB - L02BB03	- Bicalutamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bicalutamide Fair-Med 50 mg film-coated tablets	Fairmed Healthcare GmbH	PA1789/001/001 Interchangeable List Code: IC0137-023-003	Film-coated tablet		- Bicalutamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bicalutamide Teva 50 mg film-coated tablets	Teva Pharma B.V.	PA0749/032/001 Interchangeable List Code: IC0137-023-003	Film-coated tablet		- Bicalutamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Biktarvy	Gilead Sciences Ireland UC	EU/1/18/1289/001-002	Film-coated tablet	- J05AR - J05AR20	- BICTEGRAVIR - Emtricitabine - Tenofovir alafenamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Biktarvy	Gilead Sciences Ireland UC	EU/1/18/1289/005-006	Film-coated tablet	- J05AR20	- Bictegravir Sodium - Emtricitabine - Tenofovir alafenamide fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Biluta 50 mg film-coated tablets	Rowex Ltd	PA0711/100/001 Interchangeable List Code: IC0137-023-003	Film-coated tablet		- Bicalutamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
BIMERVAX	Hipra Human Health S.L.	EU/1/22/1709/001	Emulsion for injection	- J07BX03	- SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Bimzelx	UCB Pharma S.A.	EU/1/21/1575/001-004	Solution for injection in pre-filled syringe	- L04AC21	- Bimekizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Bimzelx	UCB Pharma S.A.	EU/1/21/1575/005-008	Solution for injection in pre-filled pen	- L04AC21	- Bimekizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Binocrit	Sandoz GmbH	EU/1/07/410/11-12	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Binocrit	Sandoz GmbH	EU/1/07/410/1-2	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Binocrit	Sandoz GmbH	EU/1/07/410/13-014	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Binocrit	Sandoz GmbH	EU/1/07/410/15-16	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Binocrit	Sandoz GmbH	EU/1/07/410/21-22	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Epoetin alfa	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Binocrit	Sandoz GmbH	EU/1/07/410/23-24	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Epoetin alfa	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Binocrit	Sandoz GmbH	EU/1/07/410/25-26	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Epoetin alfa	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Binocrit	Sandoz GmbH	EU/1/07/410/3-4	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Binocrit	Sandoz GmbH	EU/1/07/410/5-6	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Binocrit	Sandoz GmbH	EU/1/07/410/7-8	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Binocrit	Sandoz GmbH	EU/1/07/410/9-10	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Binosto Once Weekly 70 mg effervescent tablets	Clonmel Healthcare Ltd	PA0126/280/001	Effervescent tablet	- M05BA - M05BA04	- Alendronic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Biopoin	TEVA GmbH	EU/1/09/565/11-16	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use
Biopoin	TEVA GmbH	EU/1/09/565/1-2	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use
Biopoin	TEVA GmbH	EU/1/09/565/17-22	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use
Biopoin	TEVA GmbH	EU/1/09/565/23-28	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use
Biopoin	TEVA GmbH	EU/1/09/565/3-4	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Biopoin	TEVA GmbH	EU/1/09/565/5-6	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use
Biopoin	TEVA GmbH	EU/1/09/565/7-8	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use
Biopoin	TEVA GmbH	EU/1/09/565/9-10	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use
Biphozyl Solution for haemodialysis / haemofiltration	Baxter Holding B.V.	PA2299/055/001	Solution for haemodialysis/haemofiltration	- B05ZB	- Magnesium chloride hexahydrate - Sodium chloride - Sodium hydrogen carbonate - Potassium chloride - Disodium phosphate dihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Bisocor 10 mg Tablets	Unichem Laboratories Ltd	PA22654/003/002 Interchangeable List Code: IC0065-002-014	Tablet		- Bisoprolol hemifumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisocor 5 mg Tablets	Unichem Laboratories Ltd	PA22654/003/001 Interchangeable List Code: IC0065-001-014	Tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisodol Antacid Chewable TabletsCalcium Carbonate 522mgMagnesium Carbonate Light 68mgSodium Hydrogen Carbonate 64mg	Teva B.V.	PA1986/071/001	Chewable tablet	- A02AC - A02AC01	- Sodium hydrogen carbonate - Calcium carbonate - Light magnesium carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Bisolvon 4mg/5ml Oral Solution	Opella Healthcare France SAS T/A Sanofi	PA23180/015/001	Oral solution	- R05CB - R05CB02	- Bromhexine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Bisop 1.25 mg film-coated tablets	Rowex Ltd	PA0711/159/001 Interchangeable List Code: IC0065-044-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisop 10 mg film-coated tablets	Rowex Ltd	PA0711/159/006 Interchangeable List Code: IC0065-002-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisop 2.5 mg film-coated tablets	Rowex Ltd	PA0711/159/002 Interchangeable List Code: IC0065-018-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisop 3.75 mg film-coated tablets	Rowex Ltd	PA0711/159/003 Interchangeable List Code: IC0065-108-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisop 5 mg film-coated tablets	Rowex Ltd	PA0711/159/004 Interchangeable List Code: IC0065-001-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisop 7.5 mg film-coated tablets	Rowex Ltd	PA0711/159/005 Interchangeable List Code: IC0065-041-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/194/003 Interchangeable List Code: IC0065-002-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Bisoprolol 2.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/194/001 Interchangeable List Code: IC0065-018-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/194/002 Interchangeable List Code: IC0065-001-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Fumarate 1.25mg Tablets	Chanelle Medical Unlimited Company	PA0688/014/001 Interchangeable List Code: IC0065-044-014	Tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Fumarate 10 mg Tablets	Chanelle Medical Unlimited Company	PA0688/014/005 Interchangeable List Code: IC0065-002-014	Tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Fumarate 2.5 mg Tablets	Chanelle Medical Unlimited Company	PA0688/014/002 Interchangeable List Code: IC0065-018-014	Tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Fumarate 2.5 mg tablets	Unichem Laboratories Ltd	PA22654/002/001 Interchangeable List Code: IC0065-018-014	Tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Fumarate 3.75 mg Tablets	Chanelle Medical Unlimited Company	PA0688/014/003 Interchangeable List Code: IC0065-108-014	Tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Fumarate 5 mg Tablets	Chanelle Medical Unlimited Company	PA0688/014/004 Interchangeable List Code: IC0065-001-014	Tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol fumarate Pinewood 1.25 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/264/001	Film-coated tablet	- C07AB07	- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol fumarate Pinewood 10 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/264/006	Film-coated tablet	- C07AB07	- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol fumarate Pinewood 2.5 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/264/002	Film-coated tablet	- C07AB07	- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol fumarate Pinewood 3.75 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/264/003	Film-coated tablet	- C07AB07	- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol fumarate Pinewood 5 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/264/004	Film-coated tablet	- C07AB07	- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol fumarate Pinewood 7.5 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/264/005	Film-coated tablet	- C07AB07	- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/031/003 Interchangeable List Code: IC0065-002-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Krka 2.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/031/001 Interchangeable List Code: IC0065-018-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Bisoprolol Krka 5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/031/002 Interchangeable List Code: IC0065-001-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Mylan 1.25 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/153/001 Interchangeable List Code: IC0065-044-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Mylan 10 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/153/006 Interchangeable List Code: IC0065-002-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Mylan 2.5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/153/002 Interchangeable List Code: IC0065-018-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Mylan 3.75 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/153/003 Interchangeable List Code: IC0065-108-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Mylan 5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/153/004 Interchangeable List Code: IC0065-001-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Mylan 7.5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/153/005 Interchangeable List Code: IC0065-041-014	Film-coated tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Zentiva 1.25mg tablets	Zentiva k.s.	PA1701/010/001 Interchangeable List Code: IC0065-044-014	Tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Zentiva 10 mg tablets	Zentiva k.s.	PA1701/010/006 Interchangeable List Code: IC0065-002-014	Tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Zentiva 2.5mg tablets	Zentiva k.s.	PA1701/010/002 Interchangeable List Code: IC0065-018-014	Tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Zentiva 3.75mg tablets	Zentiva k.s.	PA1701/010/003 Interchangeable List Code: IC0065-108-014	Tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Zentiva 5mg tablets	Zentiva k.s.	PA1701/010/004 Interchangeable List Code: IC0065-001-014	Tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprolol Zentiva 7.5mg tablets	Zentiva k.s.	PA1701/010/005 Interchangeable List Code: IC0065-041-014	Tablet		- BISOPROLOL FUMARATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprololhemifumaraat Genthon 10 mg, film-coated tablets	Genthon B.V.	PA0740/007/002 Interchangeable List Code: IC0065-002-014	Film-coated tablet		- Bisoprolol hemifumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bisoprololhemifumaraat Genthon 5 mg film-coated tablets	Genthon B.V.	PA0740/007/001 Interchangeable List Code: IC0065-001-014	Film-coated tablet		- Bisoprolol hemifumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Bitifrin 0.3 mg/ml + 5 mg/ml eye drops, solution	Farmaprojects S.A.	PA1391/005/001	Eye drops, solution	- S01ED51	- Bimatoprost - Timolol Maleate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Blenrep	GlaxoSmithKline (Ireland) Limited	EU/1/20/1474/001	Powder for concentrate for solution for infusion	- L01XC39	- Belantamab Mafodotin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Blincyto	Amgen Europe B.V.	EU/1/15/1047/001	Powder for concentrate and solution for solution for infusion	- L01XC19	- Blinatumomab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Blissel 50 micrograms/g vaginal gel	Italfarmaco S.A.	PA2102/001/001	Vaginal gel	- G03CA - G03CA04	- Estriol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Blitzima	Celltrion Healthcare Hungary Kft.	EU/1/17/1205/001-002	Concentrate for solution for infusion	- L01XC - L01XC02	- Rituximab		- Intravenous use
Blomensy 10 mg film-coated tablets	EGIS Pharmaceuticals PLC	PA1470/006/002	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Blomensy 15 mg film-coated tablets	EGIS Pharmaceuticals PLC	PA1470/006/003	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Blomensy 2.5 mg film-coated tablets	EGIS Pharmaceuticals PLC	PA1470/006/001	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Blomensy 20 mg film-coated tablets	EGIS Pharmaceuticals PLC	PA1470/006/004	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Blopress 16 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/014/004 Interchangeable List Code: IC0009-038-002	Tablet		- Candesartan cilexetil		- Oral use
Blopress 32 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/014/005 Interchangeable List Code: IC0009-037-002	Tablet		- Candesartan cilexetil		- Oral use
Blopress 4 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/014/002 Interchangeable List Code: IC0009-008-002	Tablet		- Candesartan cilexetil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Blopress 8 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/014/003 Interchangeable List Code: IC0009-009-002	Tablet		- Candesartan cilexetil		- Oral use
Blopress Plus 16 mg/12.5 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/015/002 Interchangeable List Code: IC0029-036-002	Tablet		- Candesartan cilexetil - Hydrochlorothiazide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Blopress Plus 32 mg/12.5 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/015/003 Interchangeable List Code: IC0029-035-002	Tablet		- Candesartan cilexetil - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Blopress Plus 32 mg/25 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/015/004 Interchangeable List Code: IC0029-034-002	Tablet		- Candesartan cilexetil - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Blopress Plus 8 mg/12.5 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/015/001 Interchangeable List Code: IC0029-058-002	Tablet		- Candesartan cilexetil - Hydrochlorothiazide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
BOCOUTURE 100 units powder for solution for injection	Merz Pharmaceuticals GmbH	PA1907/003/002	Powder for solution for injection	- M03AX01	- CLOSTRIDIUM BOTULINUM NEUROTOXIN TYPE A (150KD), FREE OF COMPLEXING PROTEINS	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
BOCOUTURE 50 units powder for solution for injection	Merz Pharmaceuticals GmbH	PA1907/003/001	Powder for solution for injection	- M03AX01	- CLOSTRIDIUM BOTULINUM NEUROTOXIN TYPE A (150KD), FREE OF COMPLEXING PROTEINS	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Bonasol Once Weekly 70 mg Oral Solution	Xeolas Pharmaceuticals Limited	PA1572/001/001	Oral solution	- M05BA - M05BA04	- Alendronic acid	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Bondronat	Atnahs Pharma Netherlands B.V.	EU/1/96/012/011-13	Concentrate for solution for infusion	- M05BA06	- Ibandronic acid		- Intravenous use
Bondronat	Atnahs Pharma Netherlands B.V.	EU/1/96/012/001	Concentrate for solution for infusion	- M05BA - M05BA06	- Ibandronic acid monosodium monohydrate		- Intravenous use
Bondronat	Atnahs Pharma Netherlands B.V.	EU/1/96/012/002	Concentrate for solution for infusion	- M05BA	- Ibandronic acid monosodium monohydrate		- Intravenous use
Bondronat	Atnahs Pharma Netherlands B.V.	EU/1/96/012/003	Concentrate for solution for infusion	- M05BA	- Ibandronic acid monosodium monohydrate		- Intravenous use
Bondronat	Atnahs Pharma Netherlands B.V.	EU/1/96/012/004	Concentrate for solution for infusion	- M05BA	- Ibandronic acid monosodium monohydrate		- Intravenous use
Bondronat 50 mg film-coated tablets	Atnahs Pharma Netherlands B.V.	EU/1/96/012/009-010 Interchangeable List Code: IC0141-023-003	Film-coated tablet		- Ibandronic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Bonjela Oromucosal GelCholine Salicylate 8.714%Cetalkonium Chloride 0.010%	Reckitt Benckiser Ireland Ltd	PA0979/001/001	Oromucosal gel	- N02BA - N02BA03	- Choline salicylate - Cetalkonium chloride		- Topical use
Bonjela Teething Gel Oromucosal GelCholine Salicylate 8.714%Cetalkonium Chloride 0.010%	Reckitt Benckiser Ireland Ltd	PA0979/001/003	Oromucosal gel	- N02BA - N02BA03	- Choline salicylate - Cetalkonium chloride	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Bonviva	Atnahs Pharma Netherlands B.V.	EU/1/03/265/5-6	Solution for injection	- M05BA - M05BA06	- Ibandronic acid		
Bonviva 150 mg film-coated tablets	Atnahs Pharma Netherlands B.V.	EU/1/03/265/3-4 Interchangeable List Code: IC0141-062-003	Film-coated tablet		- Ibandronic acid	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Boostrix suspension for injection in pre-filled syringe Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content)	GlaxoSmithKline (Ireland) Limited	PA1077/020/001	Suspension for injection in pre-filled syringe	- J07AJ52	- Diphtheria toxoid - Tetanus toxoid - Pertussis toxoid - Filamentous haemagglutinin - Pertactin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Boots Ibuprofen and Codeine 200mg / 12.8 mg film-coated tablets	Taw Pharma (Ireland) Limited	PA23081/004/001	Film-coated tablet	- N02AJ - N02AJ08	- Ibuprofen - Codeine phosphate hemihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bortezomib 1 mg powder for solution for injection	Morningside Healthcare (Malta) Limited	PA23142/012/001	Powder for solution for injection	- L01XX - L01XX32	- Bortezomib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Bortezomib 2.5 mg powder for solution for injection	Morningside Healthcare (Malta) Limited	PA23142/012/003	Powder for solution for injection	- L01XX32	- Bortezomib	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Bortezomib 2.5 mg/ml solution for injection	EVER Valinject GmbH	PA1774/008/001	Solution for injection	- L01XX32	- Bortezomib	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Bortezomib 3.5 mg powder for solution for injection	Morningside Healthcare (Malta) Limited	PA23142/012/002	Powder for solution for injection	- L01XX - L01XX32	- Bortezomib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Bortezomib 3.5 mg powder for solution for injection	Reddy Holding GmbH	PA23092/003/001	Powder for solution for injection	- L01XX32	- Bortezomib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Bortezomib 3.5 mg powder for solution for injection	Baxter Holding B.V.	PA2299/057/001	Powder for solution for injection	- L01XX32	- Bortezomib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Bortezomib 3.5 mg powder for solution for injection	MSN Labs Europe Limited	PA23250/003/001	Powder for solution for injection	- L01XX32	- Bortezomib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Bortezomib Accord	Accord Healthcare S.L.U.	EU/1/15/1019/001	Powder for solution for injection	- L01XX - L01XX32	- Bortezomib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Bortezomib Accord	Accord Healthcare S.L.U.	EU/1/15/1019/002	Powder for solution for injection	- L01XX - L01XX32	- Bortezomib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Bortezomib Accord	Accord Healthcare S.L.U.	EU/1/15/1019/003-006	Solution for injection	- L01XX32	- Bortezomib	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Bortezomib Biotech Pharma 3.5 mg powder for solution for injection	Target Healthcare Limited	PA25233/001/001	Powder for solution for injection	- L01XX32	- Bortezomib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Bortezomib Clonmel 2.5 mg/ml Solution for Injection	Clonmel Healthcare Ltd	PA0126/297/001	Solution for injection	- L01XX - L01XX32	- Bortezomib	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Bortezomib Fresenius Kabi	Fresenius Kabi Deutschland GmbH	EU/1/19/1397/001	Powder for solution for injection	- L01XX32	- Bortezomib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Bortezomib Hospira	Pfizer Europe MA EEIG	EU/1/16/1114/001	Powder for solution for injection	- L01XX - L01XX32	- Bortezomib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Bortezomib medac 3.5 mg powder for solution for injection	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/018/001	Powder for solution for injection	- L01XX - L01XX32	- Bortezomib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Bortezomib Mylan 3.5 mg powder for solution for injection	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/191/001	Powder for solution for injection	- L01XX - L01XX32	- Bortezomib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Bortezomib Rowex 3.5 mg Powder for solution for injection	Rowex Ltd	PA0711/288/001	Powder for solution for injection	- L01XG01	- Bortezomib (as mannitol boronic ester)	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Bortezomib SUN	Sun Phamaceutical Industries Europe B.V.	EU/1/16/1102/001	Powder for solution for injection	- L01XX - L01XX32	- Bortezomib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Bosentan Zentiva 125 mg film-coated tablets	Zentiva k.s.	PA1701/011/002	Film-coated tablet	- C02KX01	- Bosentan monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Bosentan Zentiva 62.5 mg film-coated tablets	Zentiva k.s.	PA1701/011/001	Film-coated tablet	- C02KX01	- Bosentan monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bosulif	Pfizer Europe MA EEIG	EU/1/13/818/001-002	Film-coated tablet	- L01XE - L01XE14	- Bosutinib monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Bosulif	Pfizer Europe MA EEIG	EU/1/13/818/003-004	Film-coated tablet	- L01XE - L01XE14	- Bosutinib monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
BOSULIF	Pfizer Europe MA EEIG	EU/1/13/818/006-007	Film-coated tablet	- L01XE - L01XE14	- Bosutinib monohydrate		- Oral use
Bosutinib Clonmel 100 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/369/001	Film-coated tablet	- L01XE14	- Bosutinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bosutinib Clonmel 400 mg film coated tablets	Clonmel Healthcare Ltd	PA0126/369/002	Film-coated tablet	- L01XE14	- Bosutinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bosutinib Clonmel 500 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/369/003	Film-coated tablet	- L01XE14	- Bosutinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
BOTOX 200 Allergan UnitsPowder for solution for injection	AbbVie Limited	PA1824/017/003	Powder for solution for injection	- M03AX - M03AX01	- Botulinum Toxin Type A	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
BOTOX 50 Allergan Units Powder for solution for injection	AbbVie Limited	PA1824/017/002	Powder for solution for injection	- M03AX - M03AX01	- Botulinum Toxin Type A	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Botox100 Allergan Units Powder for solution for injection	AbbVie Limited	PA1824/017/001	Powder and solvent for solution for injection	- M03AX - M03AX01	- Botulinum Toxin Type A	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Brabio 20 mg/ml solution for injection, pre-filled syringe	Viatris Limited	PA23266/010/001	Solution for injection in pre-filled syringe	- L03AX - L03AX13	- Glatiramer acetate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Brabio 40 mg/ml solution for injection in pre-filled syringe	Viatris Limited	PA23266/011/001	Solution for injection in pre-filled syringe	- L03AX - L03AX13	- Glatiramer acetate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Braftovi	Pierre Fabre Medicament	EU/1/18/1314/001	Capsule, hard	- L01XE	- ENCORAFENIB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Braftovi	Pierre Fabre Medicament	EU/1/18/1314/002	Capsule, hard	- L01XE	- ENCORAFENIB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Braltus 10 microgram per delivered dose inhalation powder, hard capsule	Teva B.V.	PA1986/006/001	Inhalation powder, hard capsule	- R03BB - R03BB04	- Tiotropium bromide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Bramitob 300mg/4ml Nebuliser Solution	Chiesi Farmaceutici S.p.A.	PA0584/007/001	Nebuliser solution	- J01GB - J01GB01	- Tobramycin		- Inhalation use
Bretaris Genuair	Covis Pharma Europe B.V.	EU/1/12/781/001-003	Inhalation powder	- R03BB - R03BB05	- Micronized aclidinium bromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Brevibloc Premixed 10 mg/ml solution for Infusion	Baxter Holding B.V.	PA2299/021/002	Solution for infusion	- C07AB - C07AB09	- Esmolol Hydrochloride		- Intravenous use
Brevibloc Premixed 10 mg/ml Solution for Injection	Baxter Holding B.V.	PA2299/021/001	Solution for injection	- C07AB - C07AB09	- Esmolol Hydrochloride		- Intravenous use
Brevoxyl 40mg/g cream	Avianta Pharma EU Limited	PA23354/001/001	Cream	- D10AE - D10AE01	- Benzoyl peroxide		- Topical use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Breyanzi	Celgene Europe B.V.	EU/1/22/1631/001	Dispersion for infusion	- L01	- Lisocabtagene Maraleucel	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Bricanyl 500 micrograms/ml solution for injection or infusion	AstraZeneca AB	PA1019/007/001	Solution for injection/infusion	- R03CC - R03CC03	- Terbutaline sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
Bricanyl Turbohaler 500 micrograms per metered dose, inhalation powder	AstraZeneca AB	PA1019/007/002	Inhalation powder	- R03AC - R03AC03	- Terbutaline sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Bridion 100 mg/ml solution for injection	Merck Sharp & Dohme BV	EU/1/08/466/1-2	Solution for injection	- V03AB - V03AB35	- Sugammadex	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Brilique	AstraZeneca AB	EU/1/10/655/001-006	Film-coated tablet	- B01AC24	- Ticagrelor	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Brilique	AstraZeneca AB	EU/1/10/655/007-011	Film-coated tablet	- B01AC24	- Ticagrelor	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Brilique	AstraZeneca AB	EU/1/10/655/012-014	Orodispersible tablet	- B01AC24	- Ticagrelor	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Brillphalac 3.335 g/5 ml oral solution	Brillpharma (Ireland) Limited	PA22749/011/001	Oral solution	- A06AD - A06AD11	- Lactulose	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Brimica Genuair	Covis Pharma Europe B.V.	EU/1/14/963/001-003	Inhalation powder	- R03AL - R03AL05	- Micronized formoterol fumarate dihydrate - Micronized aclidinium bromide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Brinavess	Correvio	EU/1/10/645/001-002	Concentrate for solution for infusion	- C01BG - C01BG11	- Vernakalant hydrochloride	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Brineura	BioMarin International Limited	EU/1/17/1192/001	Solution for infusion	- A16AB	- Cerliponase	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intracerebral use
Brintellix	H. Lundbeck A/S	EU/1/13/891/001-007	Film-coated tablet	- N06AX - N06AX26	- Vortioxetine hydrobromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Brintellix	H. Lundbeck A/S	EU/1/13/891/008-017	Film-coated tablet	- N06AX26	- Vortioxetine hydrobromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Brintellix	H. Lundbeck A/S	EU/1/13/891/018-026	Film-coated tablet	- N06AX26	- Vortioxetine hydrobromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Brintellix	H. Lundbeck A/S	EU/1/13/891/027-035	Film-coated tablet	- N06AX26	- Vortioxetine hydrobromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Brintellix	H. Lundbeck A/S	EU/1/13/891/036	Oral drops, solution	- N06AX26	- Vortioxetine-dl-lactate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Brinzolamide 10 mg/ml eye drops, Suspension	Accord Healthcare Ireland Ltd.	PA2315/149/001	Eye drops, suspension	- S01EC - S01EC04	- Brinzolamide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Brinzolamide Sandoz 10mg/ml eye drops, suspension	Rowex Ltd	PA0711/226/001	Eye drops, suspension	- S01EC - S01EC04	- Brinzolamide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Briumvi	Neuraxpharm Pharmaceuticals S.L.	EU/1/23/1730/001	Concentrate for solution for infusion	- L04 - L04AG14	- Ublituximab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Briviact	UCB Pharma SA	EU/1/15/1073/001-004	Film-coated tablet	- N03AX - N03AX23	- Brivaracetam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Briviact	UCB Pharma SA	EU/1/15/1073/005-008	Film-coated tablet	- N03AX - N03AX23	- Brivaracetam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Briviact	UCB Pharma SA	EU/1/15/1073/009-012	Film-coated tablet	- N03AX - N03AX23	- Brivaracetam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Briviact	UCB Pharma SA	EU/1/15/1073/013-016	Film-coated tablet	- N03AX - N03AX23	- Brivaracetam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Briviact	UCB Pharma SA	EU/1/15/1073/017-020	Film-coated tablet	- N03AX - N03AX23	- Brivaracetam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Briviact	UCB Pharma SA	EU/1/15/1073/021	Oral solution	- N03AX - N03AX23	- Brivaracetam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Briviact	UCB Pharma SA	EU/1/15/1073/022	Solution for injection/infusion	- N03AX - N03AX23	- Brivaracetam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Brodilaten 1.25 mg/2.5 ml Nebuliser solution	Noridem Enterprises Limited	PA1122/024/001	Nebuliser solution	- R03AC02	- SALBUTAMOL SULFATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Brodilaten 2.5 mg/2.5 ml nebuliser solution	Noridem Enterprises Limited	PA1122/024/002 Interchangeable List Code: IC0078-137-052	Nebuliser solution		- SALBUTAMOL SULFATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Brodilaten 5.0 mg/2.5 ml Nebuliser solution	Noridem Enterprises Limited	PA1122/024/003 Interchangeable List Code: IC0078-139-052	Nebuliser solution		- SALBUTAMOL SULFATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Brolene 0.1% w/v Eye Drops Solution	Clonmel Healthcare Ltd	PA0126/357/001	Eye drops, solution	- S01AX - S01AX15	- Propamidine isetionate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Ocular use
Brolene 0.15 % w/w Eye Ointment	Clonmel Healthcare Ltd	PA0126/357/002	Eye ointment	- S01AX - S01AX14	- Dibrompropamidine isetionate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Ocular use
Bronchitol	Pharmaxis Europe Limited	EU/1/12/760/001-002	Inhalation powder, hard capsule	- R05CB - R05CB16	- Mannitol		- Inhalation use
Bronchoforce chesty cough oral drops	A. Vogel Ireland Ltd,	TR2309/010/001	Oral drops, solution		- Tincture from fresh ivy herb (hedera helix l.) (1:5.7-6.0) extraction solvent: ethanol 51% v/v. - Tincture from fresh aerial parts of thyme (thymus vulgaris l.) (1:8.0-8.2) extraction solvent: ethanol 51% v/v - Tincture from liquorice root (glycyrrhiza glabra l.) (1:10-11) extraction solvent: ethanol 51% v/v.	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Bronchosan dry, tickly cough syrup	A. Vogel Ireland Ltd,	TR2309/008/001	Syrup			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Bronx Airmaster 50 microgram/100 microgram/ dose inhalation powder, pre-dispensed	Neutec Inhaler Ireland Limited	PA23030/001/001	Inhalation powder, pre-dispensed	- R03AK06	- Salmeterol - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Bronx Airmaster 50 microgram/250 microgram/ dose inhalation powder, pre-dispensed	Neutec Inhaler Ireland Limited	PA23030/001/002	Inhalation powder, pre-dispensed	- R03AK06	- Salmeterol - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Bronx Airmaster 50 microgram/500 microgram/ dose inhalation powder, pre-dispensed	Neutec Inhaler Ireland Limited	PA23030/001/003	Inhalation powder, pre-dispensed	- R03AK06	- Salmeterol - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
BroPair® Spiromax®	Teva B.V.	EU/1/21/1534/001-002	Inhalation powder	- R03AK06	- SALMETEROL XINAFOATE - Fluticasone propionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
BroPair® Spiromax®	Teva B.V.	EU/1/21/1534/003-004	Inhalation powder	- R03AK06	- SALMETEROL XINAFOATE - Fluticasone propionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Brufen 400mg film-coated tablets	Viatris Healthcare Limited	PA23355/012/001	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Brufen 600mg film-coated tablets	Viatris Healthcare Limited	PA23355/012/002	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Brufen Paediatric 100mg/5ml Oral Suspension	Viatris Healthcare Limited	PA23355/012/003	Oral suspension	- M01AE01	- Ibuprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Brufen Retard 800mg prolonged release tablets	Viatris Healthcare Limited	PA23355/012/004	Prolonged-release tablet	- M01AE - M01AE01	- Ibuprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Brukinsa	BeiGene Ireland Limited	EU/1/21/1576/001	Capsule, hard	- L01 - L01EL03	- Zanubrutinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Brupro 200mg Film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/067/001	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Brupro Cold & Flu 200 mg/30 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/067/006	Film-coated tablet	- R05X	- Ibuprofen - PSEUDOEPHEDRINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Brupro for Children 100 mg/5 ml oral suspension	Rowa Pharmaceuticals Limited	PA0074/067/004	Oral suspension	- M01AE01	- Ibuprofen	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Brupro for Children Six Plus 200 mg/5 ml oral suspension	Rowa Pharmaceuticals Limited	PA0074/067/005	Oral suspension	- M01AE01	- Ibuprofen	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Brupro Max 400mg Film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/067/002	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Brupro Rx 600mg Film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/067/003	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Bryonia	A. Nelson & Company Limited	HOR1149/007/001	Pillules		- Bryonia cretica		- Oral use
Buccolam	Laboratorios Lesvi, S.L.	EU/1/11/709/001	Oromucosal solution	- N05CD - N05CD08	- Midazolam		- Oromucosal use
Buccolam	Laboratorios Lesvi, S.L.	EU/1/11/709/002	Oromucosal solution	- N05CD - N05CD08	- Midazolam	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oromucosal use
Buccolam	Laboratorios Lesvi, S.L.	EU/1/11/709/003	Oromucosal solution	- N05CD - N05CD08	- Midazolam		- Oromucosal use
Buccolam	Laboratorios Lesvi, S.L.	EU/1/11/709/004	Oromucosal solution	- N05CD - N05CD08	- Midazolam		- Oromucosal use
Budenofalk 2mg/dose rectal foam	Dr. Falk Pharma GmbH	PA0573/002/002	Rectal foam	- A07EA - A07EA06	- Budesonide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Rectal use
Budenofalk 3 mg gastro-resistant capsules	Dr. Falk Pharma GmbH	PA0573/002/001	Gastro-resistant capsule, hard	- A07EA - A07EA06	- Budesonide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Budenofalk 4 mg suppositories	Dr. Falk Pharma GmbH	PA0573/008/001	Suppository	- A07EA06	- Budesonide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Rectal use
Budenofalk® 9mg gastro-resistant granules	Dr. Falk Pharma GmbH	PA0573/002/003	Gastro-resistant granules	- A07EA - A07EA06	- Budesonide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Budesonide Teva Pharma 0.5 mg/2 ml Nebuliser Suspension	Teva Pharma B.V.	PA0749/207/002	Nebuliser suspension	- R03BA - R03BA02	- Budesonide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Budesonide Teva Pharma 1 mg/2 ml Nebuliser Suspension	Teva Pharma B.V.	PA0749/207/003	Nebuliser suspension	- R03BA - R03BA02	- Budesonide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Bufomix Easyhaler, 160 micrograms/4.5 micrograms/inhalation, inhalation powder	Orion Corporation	PA1327/015/002	Inhalation powder	- R03AK - R03AK07	- Budesonide - Formoterol fumarate dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Bufomix Easyhaler, 320 micrograms/9 micrograms/inhalation, inhalation powder	Orion Corporation	PA1327/015/003	Inhalation powder	- R03AK - R03AK07	- Budesonide - Formoterol fumarate dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Bufomix Easyhaler, 80 micrograms/4.5 micrograms/inhalation, inhalation powder	Orion Corporation	PA1327/015/004	Inhalation powder	- R03AK - R03AK07	- Budesonide - Formoterol fumarate dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Bupivacaine 2.5 mg / mL Solution for injection	Noridem Enterprises Limited	PA1122/029/001	Solution for injection	- N01BB01	- Bupivacaine hydrochloride, anhydrous	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use - Infiltration - Intraarticular use
Bupivacaine 2.5 mg/ml Solution for Injection	Baxter Holding B.V.	PA2299/035/001	Solution for injection	- N01BB - N01BB10	- Bupivacaine hydrochloride, monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use - Intraarticular use - Perineural use - Subcutaneous use
Bupivacaine 5 mg / mL Solution for injection	Noridem Enterprises Limited	PA1122/029/002	Solution for injection	- N01BB01	- Bupivacaine hydrochloride, anhydrous	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use - Infiltration - Intraarticular use
Bupivacaine 5 mg/ml Solution for Injection	Baxter Holding B.V.	PA2299/035/002	Solution for injection	- N01BB - N01BB10	- Bupivacaine hydrochloride, monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use - Intraarticular use - Perineural use - Subcutaneous use
Bupivacaine Heavy 5 mg/ml Solution for Injection	Panpharma	PA2272/001/001	Solution for injection	- N01BB - N01BB01	- BUPIVACAINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intratracheal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Bupivacaine Hydrochloride 0.25% w/v Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/091/001	Solution for injection	- N01BB - N01BB01	- Bupivacaine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use - Intraarticular use
Bupivacaine Hydrochloride 0.5% w/v Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/091/002	Solution for injection	- N01BB - N01BB01	- Bupivacaine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use - Intraarticular use
Buplex 200mg film-coated tablets	Teva B.V.	PA1986/116/001	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Buplex 400mg film-coated tablets	Teva B.V.	PA1986/116/002	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Buplex 400mg film-coated tablets	Teva B.V.	MISPA1986/116/001 _MISTAKE	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Buplex Rx 200 mg film-coated tablets	Teva B.V.	PA1986/117/001	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Buplex Rx 400 mg film-coated tablets	Teva B.V.	PA1986/117/002	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Buplex Rx 600 mg film-coated tablets	Teva B.V.	PA1986/117/003	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Buprenorphine 0.4 mg Sublingual Tablets	Activase Pharmaceuticals Limited	PA1567/001/001	Sublingual tablet	- N07BC - N07BC01	- Buprenorphine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Sublingual use
Buprenorphine 2 mg Sublingual Tablets	Activase Pharmaceuticals Limited	PA1567/001/002	Sublingual tablet	- N07BC - N07BC01	- Buprenorphine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Sublingual use
Buprenorphine 2 mg Sublingual Tablets	Morningside Healthcare (Malta) Limited	PA23142/003/001	Sublingual tablet	- N02AE - N02AE01	- Buprenorphine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Buprenorphine 8 mg Sublingual Tablets	Morningside Healthcare (Malta) Limited	PA23142/003/002	Sublingual tablet	- N02AE - N02AE01	- Buprenorphine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Buprenorphine 8 mg Sublingual Tablets	Activase Pharmaceuticals Limited	PA1567/001/003	Sublingual tablet	- N07BC - N07BC01	- Buprenorphine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Sublingual use
Burinex 1 mg Tablets	KARO PHARMA AB	PA22650/001/001	Tablet	- C03CA - C03CA02	- Bumetanide		- Oral use
Burinex 5 mg Tablets	KARO PHARMA AB	PA22650/001/002	Tablet	- C03CA - C03CA02	- Bumetanide		- Oral use
Buscopan 10 mg Coated Tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/016/002	Coated tablet	- A03BB - A03BB01	- Hyoscine butylbromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Buscopan Ampoules 20 mg/ml Solution for Injection	Opella Healthcare France SAS T/A Sanofi	PA23180/016/001	Solution for injection	- A03BB - A03BB01	- Hyoscine butylbromide		- Intramuscular use - Intravenous use
Buscopan Rx 10mg Coated Tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/022/001	Coated tablet	- A03BB - A03BB01	- Hyoscine butylbromide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Busulfan Fresenius Kabi	Fresenius Kabi Deutschland GmbH	EU/1/14/951/001	Concentrate for solution for infusion	- L01AB - L01AB01	- Busulfan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
BuTrans 10 micrograms/hour transdermal patch	Mundipharma Pharmaceuticals Limited	PA1688/002/002	Transdermal patch	- N02AE - N02AE01	- Buprenorphine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
BuTrans 15 microgram/hour transdermal patch	Mundipharma Pharmaceuticals Limited	PA1688/002/004	Transdermal patch	- N02AE - N02AE01	- Buprenorphine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Transdermal use
BuTrans 20 micrograms/hour transdermal patch	Mundipharma Pharmaceuticals Limited	PA1688/002/003	Transdermal patch	- N02AE - N02AE01	- Buprenorphine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
BuTrans 5 micrograms/hour transdermal patch	Mundipharma Pharmaceuticals Limited	PA1688/002/001	Transdermal patch	- N02AE - N02AE01	- Buprenorphine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Buttercup Bronchostop Berry Flavour Cough Pastilles	Kwizda Pharma GmbH	TR2006/001/002	Pastille	- R05CA - R05CA10	- Thyme herb dry extract 7-13:1, native extraction solvent: water	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Buttercup Bronchostop Cough Syrup	Kwizda Pharma GmbH	TR2006/001/001	Syrup	- R05CA - R05CA10	- Thyme herb extract der 7-13:1, extraction medium: water, native - Marshmallow liquid extract der 1:12-14, extraction medium: water, native	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Buttercup Bronchostop Day & Night Oral Solution	Kwizda Pharma GmbH	TR2006/002/001	Oral solution	- R05X		Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Buvidal	Camurus AB	EU/1/18/1336/001	Prolonged-release solution for injection	- N07BC01	- Buprenorphine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Buvidal	Camurus AB	EU/1/18/1336/002	Prolonged-release solution for injection	- N07BC - N07BC01	- Buprenorphine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Buvidal	Camurus AB	EU/1/18/1336/003	Prolonged-release solution for injection	- N07BC - N07BC01	- Buprenorphine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Buvidal	Camurus AB	EU/1/18/1336/004	Prolonged-release solution for injection	- N07BC - N07BC01	- Buprenorphine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Buvidal	Camurus AB	EU/1/18/1336/005	Prolonged-release solution for injection	- N07BC - N07BC01	- Buprenorphine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Buvidal	Camurus AB	EU/1/18/1336/006	Prolonged-release solution for injection	- N07BC - N07BC01	- Buprenorphine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Buvidal	Camurus AB	EU/1/18/1336/007	Prolonged-release solution for injection	- N07BC - N07BC01	- Buprenorphine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Buvidal	Camurus AB	EU/1/18/1336/009	Prolonged-release solution for injection	- N07BC01	- Buprenorphine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Byannli	Janssen-Cilag International NV	EU/1/20/1453/007	Prolonged-release suspension for injection	- N05AX13	- Paliperidone palmitate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
Byannli	Janssen-Cilag International NV	EU/1/20/1453/008	Prolonged-release suspension for injection	- N05AX13	- Paliperidone palmitate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Bydureon	AstraZeneca AB	EU/1/11/696/001-004	Powder and solvent for prolonged-release suspension for injection in pre-filled pen	- A10BX - A10BX04	- Exenatide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Bydureon	AstraZeneca AB	EU/1/11/696/005-006	Prolonged-release suspension for injection in pre-filled pen	- A10BJ01	- Exenatide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Byetta	AstraZeneca AB	EU/1/06/362/1-2	Solution for injection in pre-filled pen	- A10BJ01	- Exenatide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Byetta	AstraZeneca AB	EU/1/06/362/3-4	Solution for injection in pre-filled pen	- A10BJ01	- Exenatide	Full application (Article 8(3) of Directive No 2001/83/EC)	
Byfavo	Paion Deutschland GmbH	EU/1/20/1505/001	Powder for solution for injection/infusion	- N05CD	- Remimazolam besilate - Remimazolam (in house)	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Byfavo	Paion Netherlands B.V.	EU/1/20/1505/002	Powder for concentrate for solution for injection/infusion	- N05CD14	- Remimazolam besilate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Bylvay	Ipsen Pharma	EU/1/21/1566/001	Capsule, hard	- A05AX05	- Odevixibat sesquihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Bylvay	Ipsen Pharma	EU/1/21/1566/002	Capsule, hard	- A05AX05	- Odevixibat sesquihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Bylvay	Ipsen Pharma	EU/1/21/1566/003	Capsule, hard	- A05AX05	- Odevixibat sesquihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Bylvay	Ipsen Pharma	EU/1/21/1566/004	Capsule, hard	- A05AX05	- Odevixibat sesquihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
By-Madol SR 100 mg prolonged-release capsules, hard	Ethypharm	PA0549/016/002 Interchangeable List Code: IC0074-024-030	Prolonged-release capsule, hard		- Tramadol hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
By-Madol SR 150 mg prolonged-release capsules, hard	Ethypharm	PA0549/016/003 Interchangeable List Code: IC0074-062-030	Prolonged-release capsule, hard		- Tramadol hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
By-Madol SR 200 mg prolonged-release	Ethypharm	PA0549/016/004 Interchangeable List Code: IC0074-067-030	Prolonged-release capsule, hard		- Tramadol hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
By-Madol SR 50 mg prolonged-release capsules, hard	Ethypharm	PA0549/016/001 Interchangeable List Code: IC0074-023-030	Prolonged-release capsule, hard		- Tramadol hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Byooviz	Samsung Bioepis NL B.V.	EU/1/21/1572/001	Solution for injection	- S01LA04	- Ranibizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravitreal use
Cabaser 1 mg Tablet	Pfizer Healthcare Ireland	PA0822/114/001	Tablet	- N04BC - N04BC06	- Cabergoline	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cabazitaxel Accord	Accord Healthcare S.L.U.	EU/1/20/1448/001	Concentrate for solution for infusion	- L01CD04	- Cabazitaxel	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Cabazitaxel EVER Pharma 10 mg/ml concentrate for solution for infusion	EVER Valinject GmbH	PA1774/004/001	Concentrate for solution for infusion	- L01CD04	- Cabazitaxel	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Cabazitaxel Fresenius Kabi 20 mg/ml concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/082/001	Concentrate for solution for infusion	- L01CD04	- Cabazitaxel	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Cabazitaxel MSN 60 mg concentrate and solvent for solution for infusion	MSN Labs Europe Limited	PA23250/002/001	Concentrate and solvent for solution for infusion	- L01CD04	- Cabazitaxel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Cabergoline 1 mg Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/011/001	Tablet	- N04BC06	- Cabergoline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cabergoline 2 mg Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/011/002	Tablet	- N04BC06	- Cabergoline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cablivi	Ablynx NV	EU/1/18/1305/001	Powder and solvent for solution for injection	- B01AX07	- caplacizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Cabometyx	Ipsen Pharma	EU/1/16/1136/001-002	Film-coated tablet	- L01XE - L01XE26	- Cabozantinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cabometyx	Ipsen Pharma	EU/1/16/1136/003-004	Film-coated tablet	- L01XE - L01XE26	- Cabozantinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cabometyx	Ipsen Pharma	EU/1/16/1136/005-006	Film-coated tablet	- L01XE - L01XE26	- Cabozantinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cadelius 600 mg / 2000 IU orodispersible tablets	Italfarmaco S.A.	PA2102/002/002	Orodispersible tablet	- A12AX	- Calcium carbonate - Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Cadelius 600mg/1000 IU ordispersible tablet	Italfarmaco S.A.	PA2102/002/001	Orodispersible tablet	- A12AX	- Calcium carbonate - Cholecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Caelyx	Baxter Holding B.V.	EU/1/96/011/001	Concentrate for solution for infusion	- L01DB - L01DB01	- DOXORUBICIN HYDROCHLORIDE		- Intravenous use
Caelyx	Baxter Holding B.V.	EU/1/96/011/002	Concentrate for solution for infusion	- L01DB - L01DB01	- DOXORUBICIN HYDROCHLORIDE		- Intravenous use
Calamine Lotion, cutaneous suspension	Ovelle Limited	PA0206/016/002	Cutaneous suspension	- D02AB	- Zinc oxide - Calamine		- Topical use
Calcichew 500 mg chewable tablets	PCO Manufacturing Ltd.	PPA0465/156/001	Chewable tablet	- A12AA - A12AA04	- Calcium		- Oral use
Calcichew 500mg Chewable Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/013/001	Chewable tablet	- A12AA - A12AA04	- Calcium carbonate		- Oral use
Calcichew-D3 Forte 500 mg/400 IU Chewable Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/013/002	Chewable tablet	- A12AX	- Cholecalciferol - Calcium carbonate		- Oral use
Calcichew-D3 Forte 500 mg/400 IU Chewable Tablets	PCO Manufacturing Ltd.	PPA0465/156/003	Chewable tablet	- A12AA04	- Calcium carbonate - Colecalciferol		- Oral use
Calcichew-D3 Forte Double Strength 1000 mg / 800 IU Chewable Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/013/003	Chewable tablet	- A12AX	- Calcium carbonate - Cholecalciferol concentrate (powder form)		- Oral use
Calcipotriol/Betamethasone 50 microgram/g + 0.5 mg/g gel	Aristo Pharma GmbH	PA1983/005/001	Gel	- D05AX52	- Betamethasone - Calcipotriol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Calcipotriol/Betamethasone Rowex 50 microgram/g + 0.5 mg/g Ointment	Rowex Ltd	PA0711/254/001	Ointment	- D05AX - D05AX52	- Calcipotriol - Betamethasone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Calcium Acetate 500mg Tablets	Pinewood Laboratories Ltd	PA0281/063/001	Tablet	- A12AA - A12AA12	- Calcium acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Calcium Resonium 99.934 % Powder for oral or rectal suspension	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/141/001	Powder for oral/rectal suspension	- V03AE - V03AE01	- Calcium polystyrene sulphonate		- Oral use - Rectal use
Calciup D3 500 mg/440 IU chewable tablet	Rowex Ltd	PA0711/217/002	Chewable tablet	- A12AX	- Calcium carbonate - Cholecalciferol concentrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Calciup D3 Forte 1000mg/880 IU Chewable Tablets	Rowex Ltd	PA0711/217/001	Chewable tablet	- A12AX	- Calcium carbonate - Cholecalciferol concentrate (powder form)	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Caldease 15% w/w Medicated Ointment	Clonmel Healthcare Ltd	PA0126/153/001	Ointment	- D02AB	- Zinc oxide		- Topical use
Caldesene 10% w/w Medicated Powder	Clonmel Healthcare Ltd	PA0126/152/001	Cutaneous powder	- D01AE - D01AE54	- Calcium undecylenate		- Cutaneous use
Caldesene Adult 10% w/w Medicated Powder	Clonmel Healthcare Ltd	PA0126/247/001	Cutaneous powder	- D01AE - D01AE04	- Calcium undecylenate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Topical
Calmurid HC 10%/5%/1% w/w Cream	Galderma International	PA22743/003/001	Cream	- D07XA - D07XA01	- Hydrocortisone - Urea - Lactic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Cutaneous use
Calpol 120 mg/ 5 ml Sugar Free Infant Oral Suspension	Johnson & Johnson (Ireland) Limited	PA0330/017/004	Oral suspension	- N02BE - N02BE01	- Paracetamol	ZZZ --Unknown--	- Oral use
Calpol 120 mg/5 ml Infant Oral Suspension	Johnson & Johnson (Ireland) Limited	PA0330/017/001	Oral suspension	- N02BE - N02BE01	- Paracetamol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Calpol Six Plus 250mg/5ml Oral Suspension	Johnson & Johnson (Ireland) Limited	PA0330/017/002	Oral suspension	- N02BE - N02BE01	- Paracetamol		- Oral use
Calpol Six Plus 250mg/5ml Sugar/Colour Free Oral Suspension	Johnson & Johnson (Ireland) Limited	PA0330/017/003	Oral suspension	- N02BE - N02BE01	- Paracetamol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Calpol Six Plus Fastmelts 250 mg Paracetamol orodispersible tablets	Johnson & Johnson (Ireland) Limited	PA0330/017/005	Orodispersible tablet	- N02BE - N02BE01	- Paracetamol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Calquence	AstraZeneca AB	EU/1/20/1479/001-002	Capsule, hard	- L01XE - L01XE51	- Acalabrutinib	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Calquence	AstraZeneca AB	EU/1/20/1479/001-004	Film-coated tablet	- L01 - L01EL02	- Acalabrutinib maleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Calrecia 100 mmol/l, solution for infusion	Fresenius Medical Care Deutschland GmbH	PA1350/006/001	Solution for infusion	- B05XA - B05XA07	- Calcium chloride dihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Caltrate 600 mg/400 IU, Film-coated Tablets	Haleon Ireland Limited	PA0678/156/001	Film-coated tablet	- A12AX	- Calcium carbonate - Cholecalciferol concentrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Calvepen 250 mg/5 ml Powder for Oral Suspension	Clonmel Healthcare Ltd	PA0126/137/003	Powder for oral suspension	- J01CE - J01CE02	- PHENOXYMETHYL PENICILLIN CALCIUM		- Oral use
Calvepen 333 mg Tablets	Clonmel Healthcare Ltd	PA0126/137/001	Film-coated tablet	- J01CE - J01CE02	- Phenoxymethylpenicillin calcium		- Oral use
Calvepen 666 mg Tablets	Clonmel Healthcare Ltd	PA0126/137/002	Film-coated tablet	- J01CE - J01CE02	- PHENOXYMETHYL PENICILLIN CALCIUM		- Oral use
CALVIDIN® 600 mg/400 I.U. chewable tablets	Mylan IRE Healthcare Limited	PA2010/038/001	Chewable tablet	- A12AX	- Calcium carbonate - Cholecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Camcevi	Accord Healthcare S.L.U.	EU/1/22/1647/001	Prolonged-release suspension for injection	- L02AE02	- Leuprorelin Mesilate - Leuprorelin	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
CAMCOLIT 250 mg film-coated tablets	Essential Pharma (M) Limited	PA22644/001/001	Film-coated tablet	- N05AN - N05AN01	- Lithium carbonate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
CAMCOLIT 400 mg film-coated tablets	Essential Pharma (M) Limited	PA22644/001/002	Film-coated tablet	- N05AN - N05AN01	- Lithium carbonate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Campral EC 333 mg Gastro-resistant tablets	IMED Healthcare Ltd.	PPA1463/177/001	Gastro-resistant tablet	- N07BB - N07BB03	- Acamprosate calcium		- Oral use
Campral EC 333mg Gastro-resistant tablets	PCO Manufacturing Ltd.	PPA0465/504/001	Gastro-resistant tablet	- N07BB03	- Acamprosate calcium	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Campral EC 333mg Gastro-resistant tablets	Merck Serono (Ireland) Limited	PA2286/007/001	Gastro-resistant tablet	- N07BB - N07BB03	- Acamprosate calcium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
CAMPTO 20 mg/mL concentrate for solution for infusion	Pfizer Healthcare Ireland	PA0822/212/001	Concentrate for solution for infusion	- L01XX - L01XX19	- Irinotecan hydrochloride trihydrate		- Intravenous use
Camzyos	Bristol-Myers Squibb Pharma EEIG	EU/1/23/1716/001-002/009	Capsule, hard	- C01EB - C01EB24	- Mavacamten	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Camzyos	Bristol-Myers Squibb Pharma EEIG	EU/1/23/1716/003-004/010	Capsule, hard	- C01EB - C01EB24	- Mavacamten	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Camzyos	Bristol-Myers Squibb Pharma EEIG	EU/1/23/1716/005-006/011	Capsule, hard	- C01EB - C01EB24	- Mavacamten	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Camzyos	Bristol-Myers Squibb Pharma EEIG	EU/1/23/1716/007-008/012	Capsule, hard	- C01EB - C01EB24	- Mavacamten	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
CANCIDAS	Merck Sharp & Dohme BV	EU/1/01/196/001	Powder for concentrate for solution for infusion	- J02AX - J02AX04	- Caspofungin		- Intravenous use
Cancidas	Merck Sharp & Dohme BV,	EU/1/01/196/002	Powder for solution for infusion		- Caspofungin		- Intravenous use
Cancidas	Merck Sharp & Dohme BV	EU/1/01/196/003	Powder for concentrate for solution for infusion	- J02AX - J02AX04	- Caspofungin		- Intravenous use
Candesartan 16 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/150/003 Interchangeable List Code: IC0009-038-002	Tablet		- Candesartan cilexetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Candesartan 4 mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/150/001 Interchangeable List Code: IC0009-008-002	Tablet		- Candesartan cilexetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Candesartan 8 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/150/002 Interchangeable List Code: IC0009-009-002	Tablet		- Candesartan cilexetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Candesartan Hydrochlorothiazide 16 mg/12.5 mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/151/001 Interchangeable List Code: IC0029-036-002	Tablet		- Candesartan cilexetil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Candesartan Hydrochlorothiazide Krka 16mg/12.5mg tablets	KRKA, d.d., Novo mesto	PA1347/011/002 Interchangeable List Code: IC0029-036-002	Tablet		- Candesartan cilexetil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Candesartan Hydrochlorothiazide Krka 32mg/12.5mg tablets	KRKA, d.d., Novo mesto	PA1347/011/003 Interchangeable List Code: IC0029-035-002	Tablet		- Candesartan cilexetil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Candesartan Hydrochlorothiazide Krka 32mg/25mg Tablets	KRKA, d.d., Novo mesto	PA1347/011/004 Interchangeable List Code: IC0029-034-002	Tablet		- Candesartan cilexetil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Candesartan Hydrochlorothiazide Krka 8mg/12.5mg tablets	KRKA, d.d., Novo mesto	PA1347/011/001 Interchangeable List Code: IC0029-058-002	Tablet		- Candesartan cilexetil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Candesartan Krka 16 mg tablets	KRKA, d.d., Novo mesto	PA1347/026/003 Interchangeable List Code: IC0009-038-002	Tablet		- Candesartan cilexetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Candesartan Krka 32 mg Tablets	KRKA, d.d., Novo mesto	PA1347/026/004 Interchangeable List Code: IC0009-037-002	Tablet		- Candesartan cilexetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Candesartan Krka 4 mg tablets	KRKA, d.d., Novo mesto	PA1347/026/001 Interchangeable List Code: IC0009-008-002	Tablet		- Candesartan cilexetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Candesartan Krka 8 mg tablets	KRKA, d.d., Novo mesto	PA1347/026/002 Interchangeable List Code: IC0009-009-002	Tablet		- Candesartan cilexetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Candist 16 mg Tablets	Clonmel Healthcare Ltd	PA0126/206/003 Interchangeable List Code: IC0009-038-002	Tablet		- Candesartan cilexetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Candist 4 mg Tablets	Clonmel Healthcare Ltd	PA0126/206/001 Interchangeable List Code: IC0009-008-002	Tablet		- Candesartan cilexetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Candist 8 mg Tablets	Clonmel Healthcare Ltd	PA0126/206/002 Interchangeable List Code: IC0009-009-002	Tablet		- Candesartan cilexetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Candist Plus 16 mg/12.5 mg Tablets	Clonmel Healthcare Ltd	PA0126/207/002 Interchangeable List Code: IC0029-036-002	Tablet		- Candesartan cilexetil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Caneclear 150 mg hard capsule	Phoenix Labs	PA1113/013/001	Capsule, hard	- J02AC - J02AC01	- Fluconazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Canespor 10 mg/g cream	Bayer Limited	PA1410/083/001	Cream	- D01AC - D01AC10	- Bifonazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Canesten 10 mg/g Cream	PCO Manufacturing Ltd.	PPA0465/048/001	Cream	- D01AC - D01AC01	- Clotrimazole	ZZZ PPA	- Topical use
Canesten 100mg Pessary	Bayer Limited	PA1410/039/007	Pessary	- G01AF - G01AF02	- Clotrimazole		
Canesten 200mg Pessary	Bayer Limited	PA1410/039/008	Pessary	- G01AF - G01AF02	- Clotrimazole		- Vaginal use
Canesten 500 mg Pessary	Bayer Limited	PA1410/039/009	Pessary	- G01AF - G01AF02	- Clotrimazole		- Vaginal use
Canesten 500 mg Pessary.	PCO Manufacturing Ltd.	PPA0465/048/002	Pessary	- G01AF02	- Clotrimazole	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Vaginal use
Canesten 500mg Soft Vaginal Capsule	Bayer Limited	PA1410/039/010	Vaginal capsule, soft	- G01AF - G01AF02	- Clotrimazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Canesten Athlete's Foot Cream	Bayer Limited	PA1410/039/013	Cream	- D01AC - D01AC01	- Clotrimazole	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Topical
Canesten Combi Pessary & Cream	Bayer Limited	PA1410/039/001	Cream + pessary	- G01AF - G01AF02	- Clotrimazole - Clotrimazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Canesten Combi Soft Vaginal Capsule & Cream 500 mg Soft Vaginal Capsule and 2 % w/w Cream	Bayer Limited	PA1410/039/014	Cream + vaginal capsule, soft	- G01AF - G01AF02	- Clotrimazole - Clotrimazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use - Vaginal use
Canesten Cream	Bayer Limited	PA1410/039/002	Cream	- D01AC - D01AC01	- Clotrimazole		- Topical use
Canesten Cream Combi Internal & External Creams	Bayer Limited	PA1410/039/003	Vaginal cream	- G01AF - G01AF02	- Clotrimazole - Clotrimazole		- Cutaneous use - Vaginal use
Canesten Duopak	Bayer Limited	PA1410/039/005	Cream + pessary	- G01AF - G01AF02	- Clotrimazole - Clotrimazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use - Vaginal use
Canesten HC 1% w/w + 1% w/w Cream	Bayer Limited	PA1410/040/002	Cream	- D01AC - D01AC20	- Clotrimazole - HYDROCORTISONE ACETATE	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Topical
Canesten HC CreamClotrimazole 1.0% w/w Hydrocortisone 1.0% w/w	Bayer Limited	PA1410/040/001	Cream	- D01AC - D01AC20	- Clotrimazole - Hydrocortisone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Canesten Internal Cream	Bayer Limited	PA1410/039/006	Vaginal cream	- G01AF - G01AF02	- Clotrimazole		- Vaginal use
Canesten Thrush Cream	Bayer Limited	PA1410/039/012	Vaginal cream	- G01AF - G01AF02	- Clotrimazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Canesten Thrush Cream	PCO Manufacturing Ltd.	PPA0465/048/004	Vaginal cream	- G01AF02	- Clotrimazole		- Cutaneous use - Topical - Topical use
Canesten Thrush Cream	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/061/001	Vaginal cream	- G01AF - G01AF02	- Clotrimazole		- Topical use
CanOral 150mg Capsule	Bayer Limited	PA1410/041/001	Capsule, hard	- J02AC - J02AC01	- Fluconazole	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Capasal Therapeutic Shampoo	Dermal Laboratories (Ireland) Limited	PA23128/008/001	Shampoo	- D05AA	- Salicylic acid - Coconut oil - Coal tar		- Cutaneous use
Capecitabine	Accord Healthcare S.L.U.	EU/1/12/762/001-006 Interchangeable List Code: IC0079-062-003	Film-coated tablet		- Capecitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Capecitabine	Accord Healthcare S.L.U.	EU/1/12/762/007-012 Interchangeable List Code: IC0079-029-003	Film-coated tablet		- Capecitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Capecitabine	Accord Healthcare S.L.U.	EU/1/12/762/013-018 Interchangeable List Code: IC0079-117-003	Film-coated tablet		- Capecitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Capecitabine medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/12/802/001-014 Interchangeable List Code: IC0079-062-003	Film-coated tablet		- Capecitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Capecitabine medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/12/802/015-028 Interchangeable List Code: IC0079-029-003	Film-coated tablet		- Capecitabine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Capecitabine medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/12/802/029-042 Interchangeable List Code: IC0079-117-003	Film-coated tablet		- Capecitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Capecitabine Teva 150 mg film-coated tablets	Teva B.V.	EU/1/12/761/001 Interchangeable List Code: IC0079-062-003	Film-coated tablet		- Capecitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Capecitabine Teva 500 mg film-coated tablets	Teva B.V.	EU/1/12/761/002 Interchangeable List Code: IC0079-117-003	Film-coated tablet		- Capecitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Caprelsa	Genzyme Europe B.V.	EU/1/11/749/001	Film-coated tablet	- L01XE - L01XE12	- Vandetanib		- Oral use
Caprelsa	Genzyme Europe B.V.	EU/1/11/749/002	Film-coated tablet	- L01XE - L01XE12	- Vandetanib		- Oral use
Carbaglu Dispersible	Recordati Rare Diseases	EU/1/02/246/1-2	Dispersible tablet	- A16AA - A16AA05	- Carglumic acid		- Oral use
Carbamazepine 100 mg Tablets	Azure Pharmaceuticals Ltd	PA22871/010/001	Tablet	- N03AF01	- Carbamazepine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carbamazepine 200 mg Tablets	Azure Pharmaceuticals Ltd	PA22871/010/002	Tablet	- N03AF01	- Carbamazepine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carbamazepine 400 mg Tablets	Azure Pharmaceuticals Ltd	PA22871/010/003	Tablet	- N03AF01	- Carbamazepine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carbamazepine Essential Pharma 125 mg Suppositorie	Essential Pharma (M) Limited	PA22644/003/001	Suppository	- N03AF01	- Carbamazepine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Rectal use
Carbamazepine Essential Pharma 250 mg Suppositorie	Essential Pharma (M) Limited	PA22644/003/002	Suppository	- N03AF - N03AF01	- Carbamazepine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Rectal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Carbidopa/Levodopa Fair-Med 10 mg/100 mg Tablets	Fairmed Healthcare GmbH	PA1789/007/002	Tablet	- N04BA - N04BA02	- Carbidopa - Levodopa	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carbidopa/Levodopa Fair-Med 12.5mg/50mg Tablet	Fairmed Healthcare GmbH	PA1789/007/001	Tablet	- N04BA - N04BA02	- Levodopa - Carbidopa	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carbidopa/Levodopa Fair-Med 25 mg/100 mg Tablets	Fairmed Healthcare GmbH	PA1789/007/003	Tablet	- N04BA - N04BA02	- Carbidopa - Levodopa	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carbidopa/Levodopa Fair-Med 25 mg/250 mg Tablets	Fairmed Healthcare GmbH	PA1789/007/004	Tablet	- N04BA - N04BA02	- Carbidopa - Levodopa	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carbidopa/Levodopa Orion 12.5 mg/50 mg tablets	Orion Corporation	PA1327/021/001	Tablet	- N04BA02	- Carbidopa monohydrate - Levodopa	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carbidopa/Levodopa Orion 25 mg/100 mg tablets	Orion Corporation	PA1327/021/002	Tablet	- N04BA02	- Carbidopa monohydrate - Levodopa	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carbimazole 20 mg Tablets	Essential-Healthcare Ltd.	PA2130/001/002	Tablet	- H03BB - H03BB01	- Carbimazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carbimazole 20 mg Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/006/002	Tablet	- H03BB01	- Carbimazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carbimazole 5 mg Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/006/001	Tablet	- H03BB01	- Carbimazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carbimazole 5 mg Tablets	Essential-Healthcare Ltd.	PA2130/001/001	Tablet	- H03BB - H03BB01	- Carbimazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carbocisteine 375mg Hard Capsules	Chanelle Medical Unlimited Company	PA0688/045/001	Capsule, hard	- R05CB - R05CB03	- Carbocisteine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carbomix 50 g Granules for Oral Suspension	Athlone Pharmaceuticals Limited	PA1418/007/001	Granules for oral suspension	- A07BA - A07BA01	- Charcoal, activated	Competence of personnel (Article 23 of Directive No 2010/63/EU)	- Oral use
Carboplatin 10 mg/ml concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/032/001	Concentrate for solution for infusion	- L01XA - L01XA02	- Carboplatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Carboplatin 10 mg/ml Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/080/001	Concentrate for solution for infusion	- L01XA - L01XA02	- Carboplatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Carboplatin-Teva 10 mg/ml Concentrate for Solution for Infusion	Teva Pharma B.V.	PA0749/004/001	Concentrate for solution for infusion	- L01XA - L01XA02	- Carboplatin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Carbosan 2% w/w Gel	Rowa Pharmaceuticals Limited	PA0074/011/001	Gel	- A02BX01	- CARBENOXOLONE SODIUM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Cutaneous use
Carbosylane 140mg/45mg Capsules	Laboratoires Grimberg	PA0345/001/001	Capsule	- A02DA - A02DA01	- Simeticone - Charcoal, activated	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Cardicor 1.25 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/004/001 Interchangeable List Code: IC0065-044-014	Film-coated tablet		- Bisoprolol hemifumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Cardicor 10 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/004/006 Interchangeable List Code: IC0065-002-014	Film-coated tablet		- Bisoprolol hemifumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cardicor 2.5 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/004/002 Interchangeable List Code: IC0065-018-014	Film-coated tablet		- Bisoprolol hemifumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cardicor 3.75 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/004/003 Interchangeable List Code: IC0065-108-014	Film-coated tablet		- Bisoprolol hemifumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cardicor 5 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/004/004 Interchangeable List Code: IC0065-001-014	Film-coated tablet		- Bisoprolol hemifumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cardicor 7.5 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/004/005 Interchangeable List Code: IC0065-041-014	Film-coated tablet		- Bisoprolol hemifumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
CARDURA 1mg Tablets	Viatris Healthcare Limited	PA23355/003/001 Interchangeable List Code: IC0021-039-002	Tablet		- Doxazosin		- Oral use
CARDURA 2mg Tablets	Viatris Healthcare Limited	PA23355/003/002 Interchangeable List Code: IC0021-006-002	Tablet		- Doxazosin		- Oral use
Cardura XL 4 mg Prolonged-release tablets	Viatris Healthcare Limited	PA23355/001/001 Interchangeable List Code: IC0021-008-024	Prolonged-release tablet		- Doxazosin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cardura XL 8 mg Prolonged-release tablets	Viatris Healthcare Limited	PA23355/001/002 Interchangeable List Code: IC0021-009-024	Prolonged-release tablet		- Doxazosin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cariban 10 mg/10 mg modified-release hard capsules	Italfarmaco S.p.A.	PA1776/002/001	Modified-release capsule, hard	- R06AA59	- DOXYLAMINE SUCCINATE - Pyridoxine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carmustine 100 mg powder and solvent for concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/239/001	Powder and solvent for concentrate for solution for infusion	- L01AD01	- Carmustine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Carmustine 100 mg powder and solvent for concentrate for solution for infusion	Tillomed Pharma GmbH	PA22720/003/001	Powder and solvent for concentrate for solution for infusion	- L01AD - L01AD01	- Carmustine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Carmustine 300 mg powder and solvent for concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/250/002	Powder and solvent for concentrate for solution for infusion	- L01AD01	- Carmustine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Carmustine 50 mg powder and solvent for concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/250/001	Powder and solvent for concentrate for solution for infusion	- L01AD01	- Carmustine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Carmustine medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/18/1278/001	Powder and solvent for concentrate for solution for infusion	- L01AD01	- Carmustine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Carnation Callous Caps 40% w/w Medicated plasters	Cuxson Gerrard Healthcare Limited	PA23188/001/002	Medicated plaster	- D11AF	- Salicylic acid		- Route of administration not applicable
Carnation Corn Caps 40% w/w Medicated plasters	Cuxson Gerrard Healthcare Limited	PA23188/001/001	Medicated plaster	- D11AF	- Salicylic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Route of administration not applicable

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Carnation Vericap Verruca Treatment 10% w/w medicated plaster	Cuxson Gerrard Healthcare Limited	PA23188/001/003	Medicated plaster	- D02AF	- Salicylic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Carvedilol Krka 12.5 mg Tablets	KRKA, d.d., Novo mesto	PA1347/037/003	Tablet	- C07AG - C07AG02	- Carvedilol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carvedilol Krka 25 mg Tablets	KRKA, d.d., Novo mesto	PA1347/037/004	Tablet	- C07AG - C07AG02	- Carvedilol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carvedilol Krka 3.125 mg Tablets	KRKA, d.d., Novo mesto	PA1347/037/001	Tablet	- C07AG - C07AG02	- Carvedilol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carvedilol Krka 6.25 mg tablets	KRKA, d.d., Novo mesto	PA1347/037/002	Tablet	- C07AG - C07AG02	- Carvedilol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Carvykti	Janssen Pharmaceutica NV	EU/1/22/1648/001	Dispersion for infusion	- L0XX	- Ciltacabtagene autoleucel	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Casacol Expectorant SyrupMethoxyphenamine hydrochloride 20 mg/5 ml Guaiphenesin 100 mg/5 ml Sodium Citrate 200 mg/5 ml	Phoenix Labs	PA1113/007/001	Syrup	- R05CA - R05CA10	- Methoxyphenamine hydrochloride - Sodium citrate - Guaiphenesin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Casodex 50 mg film-coated tablets	Laboratoires Juvise Pharmaceuticals	PA23154/002/001 Interchangeable List Code: IC0137-023-003	Film-coated tablet		- Bicalutamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Casodex 50 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/144/001 Interchangeable List Code: IC0137-023-003	Film-coated tablet		- Bicalutamide	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Casodex 50 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/107/001 Interchangeable List Code: IC0137-023-003	Film-coated tablet		- Bicalutamide	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Casodex 50 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/037/001 Interchangeable List Code: IC0137-023-003	Film-coated tablet		- Bicalutamide	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Caspofungin 50mg powder for concentrate for solution for infusion	Flynn Pharma Limited	PA1226/013/001	Powder for concentrate for solution for infusion	- J02AX - J02AX04	- Caspofungin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Caspofungin 50mg powder for concentrate for solution for infusion	Demo S.A.	PA1989/001/001	Powder for concentrate for solution for infusion	- J02AX - J02AX04	- Caspofungin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Caspofungin 50mg powder for concentrate for solution for infusion	Pinewood Laboratories Ltd	PA0281/246/001	Powder for concentrate for solution for infusion	- J02AX - J02AX04	- Caspofungin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Caspofungin 70mg powder for concentrate for solution for infusion	Pinewood Laboratories Ltd	PA0281/246/002	Powder for concentrate for solution for infusion	- J02AX - J02AX04	- Caspofungin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Caspofungin 70mg powder for concentrate for solution for infusion	Demo S.A.	PA1989/001/002	Powder for concentrate for solution for infusion	- J02AX - J02AX04	- Caspofungin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Caspofungin 70mg powder for concentrate for solution for infusion	Flynn Pharma Limited	PA1226/013/002	Powder for concentrate for solution for infusion	- J02AX - J02AX04	- Caspofungin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Caspofungin Accord	Accord Healthcare S.L.U.	EU/1/15/1081/001	Powder for concentrate for solution for infusion	- J02AX - J02AX04	- Caspofungin acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Caspofungin Accord	Accord Healthcare S.L.U.	EU/1/15/1081/002	Powder for concentrate for solution for infusion	- J02AX - J02AX04	- Caspofungin acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Caspofungin Clonmel 50 mg powder for concentrate for solution for infusion	Clonmel Healthcare Ltd	PA0126/341/001	Powder for concentrate for solution for infusion	- J02AX04	- Caspofungin acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Caspofungin Clonmel 70 mg powder for concentrate for solution for infusion	Clonmel Healthcare Ltd	PA0126/341/002	Powder for concentrate for solution for infusion	- J02AX04	- Caspofungin acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Caspofungin Fresenius Kabi 50 mg powder for concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/005/001	Powder for concentrate for solution for infusion	- J02AX - J02AX04	- Caspofungin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Caspofungin Fresenius Kabi 70 mg powder for concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/005/002	Powder for concentrate for solution for infusion	- J02AX - J02AX04	- Caspofungin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Cataflam 50mg Coated Tablets	Novartis Ireland Limited	PA0896/004/001	Coated tablet	- M01AB - M01AB05	- Diclofenac potassium		- Oral use
Catapres Ampoules 150 micrograms in 1 ml Solution for Injection	Glenwood GmbH	PA2256/002/001	Solution for injection	- C02AC - C02AC01	- Clonidine hydrochloride		- Intravenous use
Catapres Tablets 100 micrograms	Glenwood GmbH	PA2256/003/001	Tablet	- C02AC - C02AC01	- Clonidine hydrochloride		- Oral use
Catasart Plus 16mg/12.5mg tablets	Rowex Ltd	PA0711/164/001 Interchangeable List Code: IC0029-036-002	Tablet		- Candesartan cilexetil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Catephen 10 % ointment	Kora Corporation Limited trading as Kora Healthcare	PA1748/003/001	Ointment	- D06BB - D06BB12	- Green tea dry extract	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical
Catiolanze	Santen OY	EU/1/23/1763/001-004	Eye drops, emulsion in single-dose container	- S01EE01	- Latanoprost	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Caverject 10 micrograms Powder and Solvent for Solution for Injection	Pfizer Healthcare Ireland	PA0822/115/002	Powder and solvent for solution for injection	- G04BE - G04BE01	- Alprostadil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intracavernous use
Caverject 20 micrograms Powder and Solvent for Solution for Injection	Pfizer Healthcare Ireland	PA0822/115/003	Powder and solvent for solution for injection	- G04BE - G04BE01	- Alprostadil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intracavernous use
Cayston	Gilead Sciences Ireland UC	EU/1/09/543/001	Powder and solvent for nebuliser solution	- J01DF01	- Aztreonam (as lysine salt)		- Inhalation use
Ceclova 75 mg/20 mg modified-release hard capsules	Aenova IP GmbH	PA22984/001/001	Modified-release capsule, hard	- M01AB - M01AB55	- Diclofenac sodium - Omeprazole	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Cefixime 200 mg film-coated tablets	Orchid Europe Limited	PA1335/002/001	Film-coated tablet	- J01D	- Cefixime	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Cefixime Nectar Lifesciences 100 mg/5 ml Powder for Oral Suspension	NECLIFE PT UNIPESSOAL LDA	PA22914/001/001	Powder for oral suspension	- J01DA08	- Cefixime	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cefotaxime 1 g powder for solution for injection/infusion	Noridem Enterprises Limited	PA1122/019/002	Powder for solution for injection/infusion	- J01DD - J01DD01	- Cefotaxime	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Cefotaxime 1g Powder for solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/223/002	Powder for solution for injection/infusion	- J01DD - J01DD01	- Cefotaxime sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Cefotaxime 2 g powder for solution for injection/infusion	Noridem Enterprises Limited	PA1122/019/003	Powder for solution for injection/infusion	- J01DD - J01DD01	- Cefotaxime	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Cefotaxime 500 mg powder for solution for injection/infusion	Noridem Enterprises Limited	PA1122/019/001	Powder for solution for injection/infusion	- J01DD - J01DD01	- Cefotaxime	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Cefotaxime 500mg Powder for solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/223/001	Powder for solution for injection/infusion	- J01DD - J01DD01	- Cefotaxime sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Cefotaxime Netpharmalab 1g Powder for solution for injection or infusion	Netpharmalab Consulting Services S. L.	PA22665/001/001	Powder for solution for injection/infusion	- J01DD - J01DD01	- Cefotaxime	Generic application (Article 10(1) of Directive No 2001/83/EC)	
Ceftal 250mg coated tablets	Rowex Ltd	PA0711/101/002	Coated tablet	- J01DC - J01DC02	- Cefuroxime	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ceftal 500 mg Coated Tablets	Rowex Ltd	PA0711/101/003	Coated tablet	- J01DC - J01DC02	- Cefuroxime	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ceftazidime 1 g powder for solution for injection/infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/012/002	Powder for solution for injection/infusion	- J01DD - J01DD02	- Ceftazidime	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Ceftazidime 1g Powder for solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/224/001	Powder for solution for injection/infusion	- J01DD - J01DD02	- Ceftazidime		- Intravenous use
Ceftazidime 2 g powder for solution for injection/infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/012/003	Powder for solution for injection/infusion	- J01DD - J01DD02	- Ceftazidime	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Ceftazidime 2g Powder for solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/224/002	Powder for solution for injection/infusion	- J01DD - J01DD02	- Ceftazidime		- Intravenous use
Ceftazidime 500 mg powder for solution for injection	Hikma Farmacêutica (Portugal) S.A.	PA1217/012/001	Powder for solution for injection	- J01DD - J01DD02	- Ceftazidime	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Ceftriaxone 1 g powder for solution for injection/infusion	AS Kalceks	PA2165/017/001	Powder for solution for injection/infusion	- J01DD - J01DD04	- Ceftriaxone sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Ceftriaxone 1g Powder for solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/225/001	Powder for solution for injection/infusion	- J01DD - J01DD04	- Ceftriaxone		- Intramuscular use - Intravenous use
Ceftriaxone 1g powder for solution for injection/infusion	JED Pharma Limited	PA23183/006/001	Solution for injection/infusion	- J01DD04	- Ceftriaxone sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous bolus use - Intravenous drip use - Intravenous use
Ceftriaxone 2 g powder for solution for injection/infusion	AS Kalceks	PA2165/017/002	Powder for solution for injection/infusion	- J01DD - J01DD04	- Ceftriaxone sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ceftriaxone 2g Powder for Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/225/002	Powder for solution for injection/infusion	- J01DD - J01DD04	- Ceftriaxone sodium		- Intramuscular use - Intravenous use
Cefuroxime 1.5 g Powder for Injection/Infusion	Flynn Pharma Limited	PA1226/009/002	Powder for solution for injection/infusion	- J01DC - J01DC02	- Cefuroxime Sodium		- Intravenous use
Cefuroxime 1.5 g powder for solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/006/002	Powder for solution for injection/infusion	- J01DC - J01DC02	- Cefuroxime Sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Cefuroxime 1500 mg Powder for solution for injection or infusion	Stravencon Ltd	PA1947/002/003	Powder for solution for injection/infusion	- J01DC - J01DC02	- Cefuroxime Sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Cefuroxime 250 mg Powder for solution for injection	Stravencon Ltd	PA1947/002/001	Powder for solution for injection	- J01DC - J01DC02	- Cefuroxime Sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Cefuroxime 750 mg Powder for Injection/Infusion	Flynn Pharma Limited	PA1226/009/001	Powder for solution for injection/infusion	- J01DC - J01DC02	- Cefuroxime Sodium		- Intramuscular use - Intravenous use
Cefuroxime 750 mg Powder for solution for injection	Stravencon Ltd	PA1947/002/002	Powder for solution for injection	- J01DC - J01DC02	- Cefuroxime Sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Cefuroxime 750 mg powder for solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/006/001	Powder for solution for injection/infusion	- J01DC - J01DC02	- Cefuroxime Sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Cefuroxime Milpharm 250mg Film-coated tablets	Aurobindo Pharma (Malta) Limited	PA1445/022/001	Film-coated tablet	- J01DA	- Cefuroxime axetil (amorphous)	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cefuroxime Milpharm 500mg Film-coated tablets	Aurobindo Pharma (Malta) Limited	PA1445/022/002	Film-coated tablet	- J01DA	- Cefuroxime axetil (amorphous)	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Celdoxome pegylated liposomal	Yes Pharmaceutical Development Services GmbH	EU/1/22/1666/001-004	Concentrate for solution for infusion	- L01DB01	- DOXORUBICIN HYDROCHLORIDE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Celebrex 100 mg hard capsules	Upjohn EESV	PA23055/006/001	Capsule, hard	- M01AH - M01AH01	- Celecoxib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Celebrex 200 mg hard capsules	Upjohn EESV	PA23055/006/002	Capsule, hard	- M01AH - M01AH01	- Celecoxib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Celebrex 200 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/118/002	Capsule, hard	- M01AH - M01AH01	- Celecoxib	ZZZ PPA	- Oral use
Celecoxib 100mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/228/001	Capsule, hard	- M01AH - M01AH01	- Celecoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Celecoxib 200mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/228/002	Capsule, hard	- M01AH - M01AH01	- Celecoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Celecoxib Krka 100mg capsules, hard	KRKA, d.d., Novo mesto	PA1347/033/001	Capsule, hard	- M01AH - M01AH01	- Celecoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Celecoxib Krka 200mg capsules, hard	KRKA, d.d., Novo mesto	PA1347/033/002	Capsule, hard	- M01AH - M01AH01	- Celecoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
CellCept	Roche Registration GmbH	EU/1/96/005/001	Capsule, hard	- L04AA - L04AA06	- Mycophenolate mofetil		
CellCept	Roche Registration GmbH	EU/1/96/005/002	Film-coated tablet	- L04AA - L04AA06	- Mycophenolate mofetil		
CellCept	Roche Registration GmbH	EU/1/96/005/003	Capsule, hard	- L04AA - L04AA06	- Mycophenolate mofetil		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
CellCept	Roche Registration GmbH	EU/1/96/005/004	Film-coated tablet	- L04AA - L04AA06	- Mycophenolate mofetil		
CellCept	Roche Registration GmbH	EU/1/96/005/005	Powder for concentrate for solution for infusion	- L04AA - L04AA06	- Mycophenolate mofetil		- Intravenous use
CellCept	Roche Registration GmbH	EU/1/96/005/006	Powder for oral suspension	- L04AA - L04AA06	- Mycophenolate mofetil		- Oral use
Celluvisc 0.5 %w/v eye drops solution, unit dose	AbbVie Limited	PA1824/016/002	Eye drops, solution	- S01XA - S01XA20	- Carmellose sodium		- Ocular use
Celluvisc 1% w/v Eye drops, solution, unit dose	AbbVie Limited	PA1824/016/001	Eye drops, solution	- S01XA - S01XA20	- Carmellose sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Celluvisc 1% w/v Eye drops, solution, unit dose	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/016/001	Eye drops, solution	- S01XA - S01XA20	- Carmellose sodium		
Celluvisc 1.0 % w/v eye drops, solution, unit dose	PCO Manufacturing Ltd.	PPA0465/259/001	Eye drops, solution	- S01XA20	- Carmellose sodium	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Ocular use
Celluvisc 1.0% w/v Eye drops, solution, unit dose	IMED Healthcare Ltd.	PPA1463/147/001	Eye drops, solution	- S01XA - S01XA20	- Carmellose sodium		- Ocular use
Celsentri	ViiV Healthcare BV	EU/1/07/418/011	Film-coated tablet	- J05AX - J05AX09	- Maraviroc	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Celsentri	ViiV Healthcare BV	EU/1/07/418/012	Film-coated tablet	- J05AX - J05AX09	- Maraviroc	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Celsentri	ViiV Healthcare BV	EU/1/07/418/1-5	Film-coated tablet	- J05AX - J05AX09	- Maraviroc	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Celsentri	ViiV Healthcare BV	EU/1/07/418/6-10	Film-coated tablet	- J05AX - J05AX09	- Maraviroc	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Celsentri	ViiV Healthcare BV	EU/01/07/418/013	Oral solution	- J05AX - J05AX09	- Maraviroc	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Celsior solution for organ preservation	Institut Georges Lopez - IGL	PA1996/001/001	Solution for organ preservation	- V07AB	- Glutathione - Mannitol - Lactobionic acid - Glutamic acid - Sodium hydroxide - Calcium chloride 2 h2o - Potassium chloride - Magnesium chloride 6 h2o - Histidine	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Extracorporeal use
Celsunax	Pinax Pharma GmbH	EU/1/21/1560/001-002	Solution for injection	- V09AB03	- Ioflupane (123I)	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Centrax 10mg Tablets	Pfizer Healthcare Ireland	PA0822/010/001	Tablet	- N05BA - N05BA11	- Prazepam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Centyl K 2.5 mg/573 mg modified-release tablets	KARO PHARMA AB	PA22650/002/002	Modified-release tablet	- C03AB - C03AB01	- Bendroflumethiazide - Potassium chloride		- Oral use
Ceplene 0.5 mg/0.5 ml solution for injection	Laboratoires DELBERT	EU/1/08/477/1	Solution for injection	- L03AX - L03AX14	- Histamine dihydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Ceprotin	Baxter Vaccine AG	EU/1/01/190/001	Powder and solvent for solution for injection	- B01AD - B01AD12	- Protein c		- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ceprotin	Baxter Vaccine AG	EU/1/01/190/002	Powder and solvent for solution for injection	- B01AX - B01AX12	- Protein c		- Intravenous use
Cerazette 75 microgram film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/016/001	Film-coated tablet	- G03AC - G03AC09	- Desogestrel	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cerdelga	Genzyme Europe B.V.	EU/1/14/974/001-002	Capsule, hard	- A16AX - A16AX10	- Eliglustat (as tartrate)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cerezyme	Genzyme Europe B.V.	EU/1/97/053/001	Powder for concentrate for solution for infusion	- A16AB - A16AB02	- Imiglucerase		- Intravenous use
Cerezyme	Genzyme Europe B.V.	EU/1/97/053/002	Powder for concentrate for solution for infusion	- A16AB - A16AB02	- Imiglucerase		- Intravenous use
Cerezyme	Genzyme Europe B.V.	EU/1/97/053/003	Powder for concentrate for solution for infusion	- A16AB - A16AB02	- Imiglucerase	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Cerezyme	Genzyme Europe B.V.	EU/1/97/053/004	Powder for concentrate for solution for infusion	- A16AB - A16AB02	- Imiglucerase	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Cerezyme	Genzyme Europe B.V.	EU/1/97/053/005	Powder for concentrate for solution for infusion	- A16AB - A16AB02	- Imiglucerase	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Cernevit, Powder for Solution for Injection or Infusion	Baxter Holding B.V.	PA2299/019/001	Powder for solution for injection/infusion	- A11BA	- Retinol palmitate - Cholecalciferol - Dl-a-tocopherol - Ascorbic acid - Cocarboxylase tetrahydrate - Riboflavin sodium phosphate - Pyridoxine hydrochloride - Cyanocobalamin - Folic acid - Dexpanthenol - D-biotin - Nicotinamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Certican 0.1mg Dispersible Tablets	Novartis Ireland Limited	PA0896/005/005	Dispersible tablet	- L04AA - L04AA18	- Everolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Certican 0.25mg Dispersible Tablets	Novartis Ireland Limited	PA0896/005/006	Dispersible tablet	- L04AA - L04AA18	- Everolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Certican 0.25mg Tablets	Novartis Ireland Limited	PA0896/005/001	Tablet	- L04AA - L04AA18	- Everolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Certican 0.5mg Tablets	Novartis Ireland Limited	PA0896/005/002	Tablet	- L04AA - L04AA18	- Everolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Certican 0.75mg Tablets	Novartis Ireland Limited	PA0896/005/003	Tablet	- L04AA - L04AA18	- Everolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Certican 1 mg Tablets	Novartis Ireland Limited	PA0896/005/004	Tablet	- L04AA - L04AA18	- Everolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cerubidin 20 mg Powder for Concentrate for Solution for Infusion	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/096/001	Powder for concentrate for solution for infusion	- L01DB - L01DB02	- DAUNORUBICIN HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Cervarix	GlaxoSmithKline Biologicals S.A.	EU/1/07/419/1-12	Suspension for injection	- J07BM - J07BM02	- Hpv 16 l1 protein - Hpv 18 l1 protein		- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Cetirelief Allergy 10mg Film-coated Tablets	Phoenix Labs	PA1113/014/001	Film-coated tablet	- R06AE - R06AE07	- Cetirizine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cetirizine dihydrochloride Pinewood 10 mg film-coated Tablets	Pinewood Laboratories Ltd	PA0281/252/001 Interchangeable List Code: IC0088-002-003	Film-coated tablet		- Cetirizine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cetrine 10 mg Film-coated Tablets	Rowex Ltd	PA0711/075/001 Interchangeable List Code: IC0088-002-003	Film-coated tablet		- Cetirizine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cetrine Allergy 1 mg/ml oral solution	Rowex Ltd	PA0711/075/003	Oral solution	- R06AE - R06AE07	- Cetirizine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cetrine Allergy 10mg Film-coated Tablets	Rowex Ltd	PA0711/075/002	Film-coated tablet	- R06AE - R06AE07	- Cetirizine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cetriz 10mg Film-coated Tablets	Teva B.V.	PA1986/114/001	Film-coated tablet	- R06AE - R06AE07	- Cetirizine hydrochloride		- Oral use
Cetrotide	Merck Europe B.V.	EU/1/99/100/001	Powder and solvent for solution for injection	- H01CC - H01CC02	- Cetrorelix acetate		- Subcutaneous use
Cetrotide	Merck Europe B.V.	EU/1/99/100/002	Powder and solvent for solution for injection	- H01CC - H01CC02	- Cetrorelix acetate		- Subcutaneous use
Cetrotide	Merck Europe B.V.	EU/1/99/100/003	Powder and solvent for solution for injection	- H01CC - H01CC02	- Cetrorelix acetate		- Subcutaneous use
Cevenfacta	Laboratoire francais du Fractionnement et des Biotechnolgies	EU/1/22/1664/001	Powder and solvent for solution for injection	- B02BD08	- Eptacog beta (activated)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Cevenfacta	Laboratoire francais du Fractionnement et des Biotechnolgies	EU/1/22/1664/002	Powder and solvent for solution for injection	- B02BD08	- Eptacog beta (activated)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Cevenfacta	Laboratoire francais du Fractionnement et des Biotechnolgies	EU/1/22/1664/003	Powder and solvent for solution for injection	- B02BD08	- Eptacog beta (activated)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ceziboe 0.25 mg solution for injection in pre-filled syringe	Sun Pharmaceutical Industries Europe B.V.	PA2050/005/001	Solution for injection in pre-filled syringe	- H01CC02	- Cetrorelix	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Champix	Pfizer Europe MA EEIG	EU/1/06/360/01	Film-coated tablet	- N07BA - N07BA03	- Varenicline tartrate		
Champix	Pfizer Europe MA EEIG	EU/1/06/360/02	Film-coated tablet	- N07BA - N07BA03	- Varenicline tartrate		
Chenodeoxycholic acid	Leadiant Gmbh	EU/1/16/1110/001	Capsule, hard	- A05AA - A05AA01	- Chenodeoxycholic acid	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Chirocaine 1.25 mg/ml solution for infusion	AbbVie Limited	PA1824/003/005	Solution for infusion	- N01BB - N01BB10	- Levobupivacaine hydrochloride		- Epidural use
Chirocaine 2.5 mg/ml solution for injection/concentrate for solution for infusion	AbbVie Limited	PA1824/003/001	Solution for injection/infusion	- N01BB - N01BB10	- Levobupivacaine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Chirocaine 5 mg/ml solution for injection/concentrate for solution for infusion	AbbVie Limited	PA1824/003/002	Solution for injection/infusion	- N01BB - N01BB10	- Levobupivacaine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Chirocaine 7.5 mg/ml solution for injection/concentrate for solution for infusion	AbbVie Limited	PA1824/003/003	Solution for injection/infusion	- N01BB - N01BB10	- Levobupivacaine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
ChloraPrep 2% w/v / 70% v/v impregnated cutaneous swab	Becton Dickinson France	PA2287/001/003	Impregnated cutaneous swab	- D08AC52	- Chlorhexidine digluconate - Isopropyl alcohol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
ChloraPrep 2% w/v/ 70% v/v cutaneous solution	Becton Dickinson France	PA2287/001/002	Cutaneous solution	- D08AC - D08AC52	- Chlorhexidine gluconate - Isopropyl alcohol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
ChloraPrep with Tint 2% w/v / 70% v/v cutaneous solution	Becton Dickinson France	PA2287/001/001	Cutaneous solution	- D08AC - D08AC52	- Chlorhexidine gluconate - Isopropyl alcohol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Chlorhexidine acetate 0.015% w/v and Cetrimide 0.15% w/v Irrigation solution	Baxter Holding B.V.	PA2299/005/001	Irrigation solution	- D08AC - D08AC52	- Chlorhexidine acetate - Cetrimide		- Topical
Chlorhexidine Acetate BP 0.05% w/v Irrigation solution	Baxter Holding B.V.	PA2299/004/001	Irrigation solution	- B05CA - B05CA02	- Chlorhexidine acetate		- Topical
Chlorhexidine Gluconate Antiseptic Mouthwash Original Flavour 0.2% w/v Oromucosal Solution	Ecolab Deutschland GmbH	PA1843/003/001	Oromucosal solution	- A01AB - A01AB03	- Chlorhexidine gluconate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Chlorhexidine Gluconate Antiseptic Mouthwash Peppermint Flavour 0.2% w/v Oromucosal Solution	Ecolab Deutschland GmbH	PA1843/003/002	Oromucosal solution	- A01AB - A01AB03	- Chlorhexidine gluconate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use
Chloromycetin 0.5% w/v Redidrops eye drops, solution	Amdipharm Limited	PA1142/021/001	Eye drops, solution	- S01AA - S01AA01	- Chloramphenicol		- Ocular use
Chlorphenamine 10 mg/ml Solution for Injection	Evolan Pharma AB	PA2262/003/001	Solution for injection	- R06AB - R06AB04	- Chlorphenamine maleate		- Intramuscular use - Intravenous use - Subcutaneous use
Chlorpromazine Elixir BP 25 mg/5 ml Oral Solution	Pinewood Laboratories Ltd	PA0281/124/001	Oral solution	- N05AA - N05AA01	- CHLORPROMAZINE HYDROCHLORIDE		- Oral use
CHOLEDIAM Kit for radiopharmaceutical preparation of technetium [99mTc] mebrofenin injection	MEDiAM	PA1229/001/001	Powder for solution for injection	- V09DA04	- Mebrofenin		- Intravenous use
CHOLESTAGEL 625 mg FILM-COATED tablets	CHEPLAPHARM Arzneimittel GmbH	EU/1/03/268/1-3	Tablet	- C10AC - C10AC04			- Oral use
Cholib	Viatris Healthcare Limited	EU/1/13/866/001-002	Film-coated tablet	- C10BA - C10BA04	- Micronized fenofibrate - Simvastatin with 0.2% butylated hydroxyanisole (bha), (E320)	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Cholib	Viatris Healthcare Limited	EU/1/13/866/003-004	Film-coated tablet	- C10BA - C10BA04	- Micronized fenofibrate - Simvastatin with 0.2% butylated hydroxyanisole (bha), (E320)	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Cholurso 250 mg film-coated tablets	Laboratoires Mayoly Spindler	PA1913/002/001	Film-coated tablet	- A05AA - A05AA02	- Ursodeoxycholic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Cholurso 500 mg film-coated tablets	Laboratoires Mayoly Spindler	PA1913/002/002	Film-coated tablet	- A05AA - A05AA02	- Ursodeoxycholic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Chondromel 400 mg Capsules	IBSA Farmaceutici Italia S.r.l	PA1104/003/001	Capsule, hard	- M01	- Chondroitin sulfate		- Oral use
Cialis	Eli Lilly Nederland B.V.	EU/1/02/237/006	Film-coated tablet	- G04BE - G04BE08	- Tadalafil		- Oral use
CIALIS	Eli Lilly Nederland B.V.	EU/1/02/237/1-5	Film-coated tablet	- G04BE - G04BE08	- Tadalafil		- Oral use
Cialis	Eli Lilly Nederland B.V.	EU/1/02/237/7-8	Film-coated tablet	- G04BE - G04BE08	- Tadalafil		- Oral use
Cialis for men 10 mg film-coated tablets	A. Nattermann & Cie. GmbH	PA25208/001/001	Film-coated tablet	- G04BE08	- Tadalafil	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Ciambra	Menarini International Operations Luxembourg S.A.	EU/1/15/1055/001	Powder for concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed disodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
CIAMBRA	Menarini International Operations Luxembourg S.A.	EU/1/15/1055/002	Powder for concentrate for solution for infusion	- L01BA04	- PEMETREXED DISODIUM	Article 10(1) - Generic Application	- Intra-venous
Cibinqo	Pfizer Europe MA EEIG	EU/1/21/1593/001-005	Film-coated tablet	- D11AH - D11AH08	- Abrocitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cibinqo	Pfizer Europe MA EEIG	EU/1/21/1593/006-010	Film-coated tablet	- D11AH - D11AH08	- Abrocitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cibinqo	Pfizer Europe MA EEIG	EU/1/21/1593/011-015	Film-coated tablet	- D11AH - D11AH08	- Abrocitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cifloxager 250 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/069/001	Film-coated tablet	- J01MA - J01MA02	- Ciprofloxacin		- Oral use
Cifloxager 500 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/069/002	Film-coated tablet	- J01MA - J01MA02	- Ciprofloxacin		- Oral use
Cifoban 136 mmol/l solution for infusion	Fresenius Medical Care Deutschland GmbH	PA1350/008/001	Solution for injection	- B05ZB	- Trisodium citrate dihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Cifox 250 mg Film-coated tablets	Rowex Ltd	PA0711/122/001	Film-coated tablet	- J01MA - J01MA02	- Ciprofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cifox 500 mg Film-coated tablets	Rowex Ltd	PA0711/122/002	Film-coated tablet	- J01MA - J01MA02	- Ciprofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cifox 750 mg Film-coated tablets	Rowex Ltd	PA0711/122/003	Film-coated tablet	- J01MA - J01MA02	- Ciprofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cilique 250/35 micrograms tablets	Gedeon Richter Plc	PA1330/029/001	Tablet	- G03AA - G03AA11	- Norgestimate - Ethinylestradiol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ciloxan 3 mg/ml ear drops, solution	Novartis Ireland Limited	PA0896/006/001	Ear drops, solution	- S02AA - S02AA15	- Ciprofloxacin hydrochloride		- Auricular use
Cimeldine 400 mg Film-coated tablets	Clonmel Healthcare Ltd	PA0126/077/002	Film-coated tablet	- A02BA - A02BA01	- Cimetidine		- Oral use
Cimzia	UCB Pharma S.A.	EU/1/09/544/1-2	Solution for injection in pre-filled syringe	- L04AB - L04AB05	- Certolizumab pegol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Cinacalcet Accordpharma 30 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/20/1429/001-004 Interchangeable List Code: IC0134-033-003	Film-coated tablet		- Cinacalcet hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Cinacalcet Accordpharma 60 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/20/1429/005-008 Interchangeable List Code: IC0134-127-003	Film-coated tablet		- Cinacalcet hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cinacalcet Accordpharma 90 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/20/1429/009-012 Interchangeable List Code: IC0134-166-003	Film-coated tablet		- Cinacalcet hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cinacalcet Clonmel 30 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/306/001 Interchangeable List Code: IC0134-033-003	Film-coated tablet		- Cinacalcet hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cinacalcet Clonmel 60 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/306/002 Interchangeable List Code: IC0134-127-003	Film-coated tablet		- Cinacalcet hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cinacalcet Clonmel 90 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/306/003 Interchangeable List Code: IC0134-166-003	Film-coated tablet		- Cinacalcet hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cinacalcet Mylan 30 mg film-coated tablets	Mylan Pharmaceuticals Limited	EU/1/15/1054/001-004 Interchangeable List Code: IC0134-033-003	Film-coated tablet		- Cinacalcet hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cinacalcet Mylan 60 mg film-coated tablets	Mylan Pharmaceuticals Limited	EU/1/15/1054/005-007 Interchangeable List Code: IC0134-127-003	Film-coated tablet		- Cinacalcet hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cinacalcet Mylan 90 mg film-coated tablets	Mylan Pharmaceuticals Limited	EU/1/15/1054/008-010 Interchangeable List Code: IC0134-166-003	Film-coated tablet		- Cinacalcet hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cinacalcet Teva 30 mg film-coated tablets	Teva B.V.	PA1986/007/001 Interchangeable List Code: IC0134-033-003	Film-coated tablet		- Cinacalcet hydrochloride - TALC PH.EUR.	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cinacalcet Teva 60 mg film-coated tablets	Teva B.V.	PA1986/007/002 Interchangeable List Code: IC0134-127-003	Film-coated tablet		- Cinacalcet hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cinacalcet Teva 90 mg film-coated tablets	Teva B.V.	PA1986/007/003 Interchangeable List Code: IC0134-166-003	Film-coated tablet		- Cinacalcet hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cinqaero	Teva B.V.	EU/1/16/1125/001	Concentrate for solution for infusion		- Reslizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Cinryze	Takeda Manufacturing Austria AG	EU/1/11/688/001	Powder and solvent for solution for injection	- B06AC01	- C1 inhibitor	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ciplox 250 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/100/001	Film-coated tablet	- J01MA - J01MA02	- Ciprofloxacin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ciplox 500 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/100/002	Film-coated tablet	- J01MA - J01MA02	- Ciprofloxacin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ciplox 750 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/100/003	Film-coated tablet	- J01MA - J01MA02	- Ciprofloxacin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ciprager 10 mg Film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/047/001 Interchangeable List Code: IC0073-002-003	Film-coated tablet		- Citalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ciprager 20 mg Film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/047/002 Interchangeable List Code: IC0073-003-003	Film-coated tablet		- Citalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ciprager 40 mg Film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/047/003 Interchangeable List Code: IC0073-004-003	Film-coated tablet		- Citalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cipramil 10 mg film-coated tablets	Lundbeck (Ireland) Limited	PA0776/001/001 Interchangeable List Code: IC0073-002-003	Film-coated tablet		- Citalopram		- Oral use
Cipramil 20 mg film-coated tablets	Lundbeck (Ireland) Limited	PA0776/001/002 Interchangeable List Code: IC0073-003-003	Film-coated tablet		- Citalopram		- Oral use
Cipramil 40 mg/ml Oral drops, solution	Lundbeck (Ireland) Limited	PA0776/001/004	Oral drops, solution	- N06AB - N06AB04	- Citalopram		- Oral use
Ciprofloxacin 2 mg/ml Solution for infusion	Noridem Enterprises Limited	PA1122/005/001	Solution for infusion	- J01MA - J01MA02	- Ciprofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Ciprofloxacin Krka 250 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/035/001	Film-coated tablet	- J01MA - J01MA02	- Ciprofloxacin hydrochloride		- Oral use
Ciprofloxacin Krka 500 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/035/002	Film-coated tablet	- J01MA - J01MA02	- Ciprofloxacin hydrochloride		- Oral use
Ciprofloxacin Krka 750 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/035/003	Film-coated tablet	- J01MA - J01MA02	- Ciprofloxacin hydrochloride		- Oral use
Ciprofloxacin Teva 250 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/031/002	Film-coated tablet	- J01MA - J01MA02	- Ciprofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ciprofloxacin Teva 500 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/031/003	Film-coated tablet	- J01MA - J01MA02	- Ciprofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ciprotan 10mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/131/001 Interchangeable List Code: IC0073-002-003	Film-coated tablet		- Citalopram		- Oral use
Ciprotan 20mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/131/002 Interchangeable List Code: IC0073-003-003	Film-coated tablet		- Citalopram		- Oral use
Circadin	RAD Neurim Pharmaceuticals EEC SARL	EU/1/07/392/001	Prolonged-release tablet	- N05CH - N05CH01	- Melatonin		
Cisatracurium 2 mg/ml solution for injection/infusion	Noridem Enterprises Limited	PA1122/017/001	Solution for injection/infusion	- M03AC - M03AC11	- Cisatracurium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Cisatracurium 2 mg/ml solution for injection/infusion	AS Kalceks	PA2165/008/001	Solution for injection/infusion	- M03AC11	- Cisatracurium Besilate - Cisatracurium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Cisplatin 1 mg/ml Concentrate for Solution for Infusion	Pfizer Healthcare Ireland	PA0822/199/001	Concentrate for solution for infusion	- L01XA - L01XA01	- Cisplatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Cisplatin 1mg/ml Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/081/001	Concentrate for solution for infusion	- L01XA - L01XA01	- Cisplatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Citalopram Bluefish 10 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/018/001 Interchangeable List Code: IC0073-002-003	Film-coated tablet		- Citalopram hydrobromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Citalopram Bluefish 20 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/018/002 Interchangeable List Code: IC0073-003-003	Film-coated tablet		- Citalopram hydrobromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Citalopram Bluefish 40 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/018/003 Interchangeable List Code: IC0073-004-003	Film-coated tablet		- Citalopram hydrobromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Citalopram Teva 10 mg film-coated tablets	Teva Pharma B.V.	PA0749/019/001 Interchangeable List Code: IC0073-002-003	Film-coated tablet		- Citalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Citalopram Teva 20 mg film-coated tablets	Teva Pharma B.V.	PA0749/019/002 Interchangeable List Code: IC0073-003-003	Film-coated tablet		- Citalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Citalopram Teva 40mg film-coated tablets	Teva Pharma B.V.	PA0749/019/003 Interchangeable List Code: IC0073-004-003	Film-coated tablet		- Citalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Citanest with Octapressin Dental, Prilocaine Hydrochloride 3 % w/v, Felypressin 0.54 micrograms/ml Solution for Injection	DENTSPLY DeTrey GmbH	PA1045/001/001	Solution for injection	- N01BB - N01BB54	- Felypressin - Prilocaine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Citidaron 1.5 mg tablets	Aflofarm Farmacja Polska Sp. z o.o.	PA22714/001/001	Tablet	- N07BA	- Cytisine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
CitraFleet oral solution	Casen-Recordati S.L.	PA2028/002/002	Oral solution	- A06AB58	- Sodium picosulfate - Magnesium oxide, light - Citric acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
CitraFleet, Powder for oral solution in sachet	Casen-Recordati S.L.	PA2028/002/001	Powder for oral solution in sachet	- A06AB - A06AB58	- Sodium picosulfate - Light magnesium oxide - Citric acid anhydrous	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Citrol 10 mg Film-Coated Tablets	Rowex Ltd	PA0711/064/001 Interchangeable List Code: IC0073-002-003	Film-coated tablet		- Citalopram hydrobromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
CITROL 20 mg Film-Coated Tablets	Rowex Ltd	PA0711/064/002 Interchangeable List Code: IC0073-003-003	Film-coated tablet		- Citalopram hydrobromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Citrol 30 mg Film-Coated Tablets	Rowex Ltd	PA0711/064/003	Film-coated tablet	- N06AB - N06AB04	- Citalopram hydrobromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Claforan Powder for Solution for Injection 1g	Amdipharm Limited	PA1142/041/002	Powder for solution for injection	- J01DD - J01DD01	- Cefotaxime sodium		- Intramuscular use - Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Claforan Powder for Solution for Injection 500mg	Amdipharm Limited	PA1142/041/001	Powder for solution for injection	- J01DD - J01DD01	- Cefotaxime sodium		- Intramuscular use - Intravenous use
Clareeze Allergy 10 mg Tablets	Phoenix Labs	PA1113/015/001	Tablet	- R06AX - R06AX13	- Loratadine		- Oral use
Clariscan 279.32 mg/ml solution for injection	GE Healthcare AS	PA0735/011/001	Solution for injection	- V08CA - V08CA02	- Gadoteric acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Clariscan 279.32 mg/ml solution for injection in pre-filled syringe	GE Healthcare AS	PA0735/011/002	Solution for injection in pre-filled syringe	- V08CA - V08CA02	- Gadoteric acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Clarithromycin 250 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/002/001 Interchangeable List Code: IC0072-130-003	Film-coated tablet		- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clarithromycin 250 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/197/001 Interchangeable List Code: IC0072-130-003	Film-coated tablet		- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clarithromycin 500 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/197/002 Interchangeable List Code: IC0072-117-003	Film-coated tablet		- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clarithromycin 500 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/002/002 Interchangeable List Code: IC0072-117-003	Film-coated tablet		- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clarithromycin 500 mg Powder for concentrate for solution for infusion	Noridem Enterprises Limited	PA1122/025/001	Powder for concentrate for solution for infusion	- J01FA09	- Clarithromycin lactobionate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Clarithromycin 500 mg Powder for Concentrate for Solution for Infusion	Amdipharm Limited	PA1142/022/001	Powder for concentrate for solution for infusion	- J01FA - J01FA09	- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Clarithromycin 500 mg powder for concentrate for solution for infusion	hameln pharma gmbh	PA2237/003/001	Powder for concentrate for solution for infusion	- J01FA09	- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Clarithromycin Krka 250 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/068/001 Interchangeable List Code: IC0072-130-003	Film-coated tablet		- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clarithromycin Krka 500 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/068/002 Interchangeable List Code: IC0072-117-003	Film-coated tablet		- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clarithromycin Teva 250 mg film-coated tablets	Teva Pharma B.V.	PA0749/148/001 Interchangeable List Code: IC0072-130-003	Film-coated tablet		- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clarithromycin Teva 500 mg film-coated tablets	Teva Pharma B.V.	PA0749/148/002 Interchangeable List Code: IC0072-117-003	Film-coated tablet		- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clarityn 10 mg Tablets	Bayer Limited	PA1410/075/001	Tablet	- R06AX - R06AX13	- Loratadine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Clarityn 10 mg Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/060/001	Tablet	- R06AX - R06AX13	- Loratadine		- Oral use
Clarityn 1mg/1ml Syrup	Bayer Limited	PA1410/075/002	Syrup	- R06AX - R06AX13	- Loratadine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Clavamel Forte 500mg/125mg film-coated tablet	Clonmel Healthcare Ltd	PA0126/243/001 Interchangeable List Code: IC0037-073-003	Film-coated tablet		- Amoxicillin - Clavulanic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cleenema Ready-to-Use 21.4g / 9.4g Enema	Casen-Recordati S.L.	PA2028/001/001	Rectal solution	- A06AG - A06AG01	- Sodium dihydrogen phosphate dihydrate - Disodium phosphate dodecahydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Rectal use
Clenil Modulite 100 micrograms per metered dose Pressurised Inhalation Solution	Chiesi Farmaceutici S.p.A.	PA0584/006/002	Pressurised inhalation, solution	- R03BA - R03BA01	- Beclometasone dipropionate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Inhalation use
Clenil Modulite 200 micrograms per metered dose Pressurised Inhalation Solution	Chiesi Farmaceutici S.p.A.	PA0584/006/003	Pressurised inhalation, solution	- R03BA - R03BA01	- Beclometasone dipropionate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Inhalation use
Clenil Modulite 250 micrograms per metered dose Pressurised Inhalation Solution	Chiesi Farmaceutici S.p.A.	PA0584/006/004	Pressurised inhalation, solution	- R03BA - R03BA01	- Beclometasone dipropionate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Inhalation use
Clenil Modulite 50 micrograms per metered dose Pressurised Inhalation Solution	Chiesi Farmaceutici S.p.A.	PA0584/006/001	Pressurised inhalation, solution	- R03BA - R03BA01	- Beclometasone dipropionate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Inhalation use
Clexane 10,000 IU (100 mg)/1 ml Solution for Injection in pre-filled syringes	PCO Manufacturing Ltd.	PPA0465/477/001	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium		- Intravenous use - Subcutaneous use
Clexane 10,000 IU (100mg)/1ml Solution for Injection in pre-filled syringes	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/097/001	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Clexane 2,000 IU (20mg) /0.2 mL Solution for Injection in pre-filled syringes	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/097/004	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Clexane 2,000 IU (20mg) /0.2 ml Solution for Injection in pre-filled syringes	PCO Manufacturing Ltd.	PPA0465/477/006	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium		- Intravenous use
Clexane 4,000 IU (40 mg) /0.4 ml Solution for Injection in pre-filled syringes	PCO Manufacturing Ltd.	PPA0465/477/002	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium		- Subcutaneous use
Clexane 4,000 IU (40mg) /0.4 mL Solution for Injection in pre-filled syringes	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/097/005	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Clexane 6,000 IU (60 mg) /0.6 ml Solution for Injection in pre-filled syringes	PCO Manufacturing Ltd.	PPA0465/477/003	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium		- Subcutaneous use
Clexane 6,000 IU (60mg) /0.6 mL Solution for Injection in pre-filled syringes	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/097/006	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Clexane 8,000 IU (80 mg) /0.8 ml Solution for Injection in pre-filled syringes	PCO Manufacturing Ltd.	PPA0465/477/004	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium		- Subcutaneous use
Clexane 8,000 IU (80mg) /0.8 mL Solution for Injection in pre-filled syringes	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/097/007	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Clexane Forte 12,000 IU (120 mg) / 0.8 ml Solution for Injection in pre-filled syringes	PCO Manufacturing Ltd.	PPA0465/477/005	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium		- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Clexane Forte 12,000 IU (120mg) / 0.8 mL Solution for Injection in pre-filled syringes	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/097/008	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Clexane Forte 15,000 IU (150mg)/1ml Solution for Injection in pre-filled syringes	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/097/002	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium		- Subcutaneous use
Climara 50 micrograms/24 hours Transdermal Patch	Bayer Limited	PA1410/015/001	Transdermal patch	- G03CA - G03CA03	- Estradiol	Full application (Article 8(3) of Directive No 2001/83/EC)	
Climara Forte 100 micrograms/24 hours Transdermal Patch	Bayer Limited	PA1410/015/002	Transdermal patch	- G03CA - G03CA03	- Estradiol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Clindamycin + Benzoyl Peroxide 10 mg/g + 50 mg/g gel	Morningside Healthcare (Malta) Limited	PA23142/015/001	Gel	- D10AF51	- CLINDAMYCIN PHOSPHATE - Benzoyl Peroxide, Hydrous	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Clindamycin 150 mg Capsule	Chanelle Medical Unlimited Company	PA0688/044/001	Capsule, hard	- D10AF - D10AF01 - G01AA - G01AA10 - J01F	- Clindamycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clindamycin 150 mg Capsules, hard	Renata Pharmaceuticals (Ireland) Limited	PA22865/004/002	Capsule, hard	- J01FF01	- Clindamycin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clindamycin 150 mg/ml solution for injection	Fresenius Kabi Deutschland GmbH	PA2059/007/001	Solution for injection	- J01FF - J01FF01	- CLINDAMYCIN PHOSPHATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Clindamycin 150 mg/ml Solution for injection/infusion	Noridem Enterprises Limited	PA1122/033/001	Solution for injection/infusion	- J01FF01	- CLINDAMYCIN PHOSPHATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Clindamycin 300 mg Capsules	EG (Eurogenerics)	PA25213/001/001	Capsule, hard	- D10AF - D10AF01 - G01AA - G01AA10 - J01F	- Clindamycin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clindamycin 300 mg Capsules, hard	Renata Pharmaceuticals (Ireland) Limited	PA22865/004/003	Capsule, hard	- J01FF01	- Clindamycin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clindamycin 75 mg Capsules, hard	Renata Pharmaceuticals (Ireland) Limited	PA22865/004/001	Capsule, hard	- J01FF01	- Clindamycin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
CLINIMIX N14G30E, solution for infusion	Baxter Holding B.V.	PA2299/020/001	Solution for infusion	- B05BA - B05BA01	- L-leucine - L-phenylalanine - L-methionine - L-lysine - L-isoleucine - L-valine - L-histidine - L-threonine - L-tryptophan - L-alanine - L-arginine - Glycine - L-proline - L-serine - L-tyrosine - Sodium acetate trihydrate - Dibasic potassium phosphate - Sodium chloride - Magnesium chloride hexahydrate - Glucose - Calcium chloride dihydrate		- Intravenous use
Clobazam Essential Pharmaceuticals 1 mg/ml oral suspension	Essential Pharmaceuticals Limited	PA22662/004/001	Oral suspension	- N05BA09	- Clobazam	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Clobazam Thame 10mg/5ml Oral Suspension	Syri Pharma Limited t/a Thame Laboratories	PA22697/006/002	Oral suspension	- N05BA - N05BA09	- Clobazam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clobazam Thame 5mg/5ml Oral Suspension	Syri Pharma Limited t/a Thame Laboratories	PA22697/006/001	Oral suspension	- N05BA - N05BA09	- Clobazam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clodel 75 mg film-coated tablets	Rowex Ltd	PA0711/166/001 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- Clopidogrel hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Clomid 50 mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/020/001	Tablet	- G03GB - G03GB02	- Clomiphene citrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Clonactil 100 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/026/002	Film-coated tablet	- N05AA - N05AA01	- CHLORPROMAZINE HYDROCHLORIDE		- Oral use
Clonactil 25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/026/003	Film-coated tablet	- N05AA - N05AA01	- CHLORPROMAZINE HYDROCHLORIDE		- Oral use
Clonactil 50 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/026/001	Film-coated tablet	- N05AA - N05AA01	- CHLORPROMAZINE HYDROCHLORIDE		- Oral use
Clonazepam Rosemont 0.5 mg/5 ml oral solution	Taw Pharma (Ireland) Limited	PA23081/009/001	Oral solution	- N03AE - N03AE01	- Clonazepam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clonfolic 0.4 mg Tablets	Clonmel Healthcare Ltd	PA0126/095/001	Tablet	- B03BB - B03BB01	- Folic acid		- Oral use
Clonocid 250 mg film-coated Tablets	Clonmel Healthcare Ltd	PA0126/136/001 Interchangeable List Code: IC0072-130-003	Film-coated tablet		- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clonocid 500 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/136/002 Interchangeable List Code: IC0072-117-003	Film-coated tablet		- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Clopidogrel Zentiva	Zentiva k.s.	EU/1/08/465/1-14 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- Clopidogrel	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Clopidogrel 75mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/198/001 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- Clopidogrel hydrogensulfate		- Oral use
Clopidogrel BGR	Laboratoires BIOGARAN	EU/1/09/558/1-12 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- Clopidogrel	Not Currently Available	- Oral use
Clopidogrel Bluefish 75 mg Film-coated Tablets	Bluefish Pharmaceuticals AB	PA1436/026/001 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- Clopidogrel besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clopidogrel Clonmel 75mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/279/001 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- Clopidogrel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clopidogrel Krka	KRKA, d.d., Novo mesto	EU/1/09/556/1-9 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- Clopidogrel hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
CLOPIDOGREL KRKA D.D.	Krka, d.d., Novo mesto	EU/1/09/562/001-9 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- CLOPIDOGREL HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clopidogrel MSN 75 mg film-coated tablets	MSN Labs Europe Limited	PA23250/005/001	Film-coated tablet	- B01AC04	- Clopidogrel Hydrogen Sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clopidogrel ratiopharm	Teva B.V.	EU/1/14/975/001-017 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- Clopidogrel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
CLOPIDOGREL TAD	TAD Pharma GmbH	EU/1/09/555/1-9 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- CLOPIDOGREL HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clopidogrel Taw Pharma	Taw Pharma (Ireland) Ltd	EU/1/09/559/001-016 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- Clopidogrel hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
CLOPIDOGREL TEVA	Teva B.V.	EU/1/09/540/1-16 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- CLOPIDOGREL HYDROGEN SULPHATE	Article 10(1) - Generic Application	- Oral use
Clopidogrel Viatris	Viatris Limited	EU/1/09/568/001-020 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- Clopidogrel besylate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clopidogrel Zentiva	Zentiva k.s.	EU/1/08/465/15-17 Interchangeable List Code: IC0005-029-003	Film-coated tablet		- Clopidogrel		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Clopidogrel/Acetylsalicylic acid Mylan	Mylan Pharmaceuticals Limited	EU/1/19/1395/001-005 Interchangeable List Code: IC0043-030-003	Film-coated tablet		- Clopidogrel hydrogen sulphate - Acetylsalicylic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clopidogrel/Acetylsalicylic acid Mylan	Mylan Pharmaceuticals Limited	EU/1/19/1395/006-010 Interchangeable List Code: IC0043-031-003	Film-coated tablet		- Clopidogrel hydrogen sulphate - Acetylsalicylic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clopidogrel/Acetylsalicylic acid Zentiva	sanofi-aventis groupe	EU/1/10/623/1-7 Interchangeable List Code: IC0043-030-003	Film-coated tablet		- Acetylsalicylic acid - Clopidogrel hydrogen sulphate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Clopidogrel/Acetylsalicylic acid Zentiva	sanofi-aventis groupe	EU/1/10/623/8-14 Interchangeable List Code: IC0043-031-003	Film-coated tablet		- Acetylsalicylic acid - Clopidogrel hydrogen sulphate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Clopixol 10mg Film-coated Tablets	Lundbeck (Ireland) Limited	PA0776/002/003	Film-coated tablet	- N05AF - N05AF05	- Zuclopenthixol hydrochloride		- Oral use
Clopixol 200 mg/ml Solution for Injection	Lundbeck (Ireland) Limited	PA0776/002/001	Solution for injection	- N05AF - N05AF05	- ZUCLOPENTHIXOL DECANOATE		- Subcutaneous use
Clopixol Conc. 500 mg/ml Solution for Injection	Lundbeck (Ireland) Limited	PA0776/002/002	Solution for injection	- N05AF - N05AF05	- ZUCLOPENTHIXOL DECANOATE		- Submucosal use
Clorom 250 mg Film-Coated Tablets	Rowex Ltd	PA0711/061/001 Interchangeable List Code: IC0072-130-003	Film-coated tablet		- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clorom 500 mg film-coated tablets	Rowex Ltd	PA0711/061/002 Interchangeable List Code: IC0072-117-003	Film-coated tablet		- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clorom XL 500 mg Prolonged-Release Tablets	Morningside Healthcare (Malta) Limited	PA23142/006/001 Interchangeable List Code: IC0072-117-050	Prolonged-release tablet		- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Clozaril 100 mg tablets	Mylan IRE Healthcare Limited	PA2010/020/002	Tablet	- N05AH - N05AH02	- Clozapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Clozaril 25 mg Tablets	Mylan IRE Healthcare Limited	PA2010/020/001	Tablet	- N05AH - N05AH02	- Clozapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Coagadex	BPL Bioproducts Laboratory GmbH	EU/1/16/1087/001	Powder and solvent for solution for injection	- B02BD - B02BD13	- Human coagulation factor x	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Coagadex	BPL Bioproducts Laboratory GmbH	EU/1/16/1087/002	Powder and solvent for solution for injection	- B02BD - B02BD13	- Human coagulation factor x	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Co-amoxiclav 1000 mg/200 mg powder for solution for injection/infusion	Instituto Biochimico Italiano G. Lorenzini S.p.A.	PA2220/002/002	Powder for solution for injection/infusion	- J01CR - J01CR02	- Amoxicillin - Clavulanic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Co-amoxiclav 1000mg/200mg Powder for Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/226/002	Powder for solution for injection/infusion	- J01CR - J01CR02	- Amoxicillin sodium - potassium clavulanate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Co-amoxiclav 1000mg/200mg powder for solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/026/001	Powder for solution for injection/infusion	- J01CR - J01CR02	- Amoxicillin - Clavulanic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Co-amoxiclav 2000 mg/200 mg powder for solution for infusion	Instituto Biochimico Italiano G. Lorenzini S.p.A.	PA2220/002/003	Powder for solution for infusion	- J01CR - J01CR02	- Amoxicillin - Clavulanic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Co-amoxiclav 250mg/125mg Film-coated tablets	Brown & Burk IR Limited	PA23148/004/001 Interchangeable List Code: IC0037-074-003	Film-coated tablet		- Amoxicillin - Clavulanic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Co-amoxiclav 500 mg/100 mg powder for solution for injection/infusion	Instituto Biochimico Italiano G. Lorenzini S.p.A.	PA2220/002/001	Powder for solution for injection/infusion	- J01CR - J01CR02	- Amoxicillin - Clavulanic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Co-amoxiclav 500mg/100mg Powder for Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/226/001	Powder for solution for injection/infusion	- J01CR - J01CR02	- Amoxicillin sodium - potassium clavulanate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Co-amoxiclav 500mg/125mg Film-coated tablets	Brown & Burk IR Limited	PA23148/004/002 Interchangeable List Code: IC0037-073-003	Film-coated tablet		- Amoxicillin - Clavulanic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Co-amoxiclav 875mg/125mg Film-coated Tablets	Brown & Burk IR Limited	PA23148/004/003 Interchangeable List Code: IC0037-072-003	Film-coated tablet		- Amoxicillin - Clavulanic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Co-amoxiclav Bluefish 500 mg/125 mg film- coated tablets	Bluefish Pharmaceuticals AB	PA1436/002/002 Interchangeable List Code: IC0037-073-003	Film-coated tablet		- Amoxicillin - Clavulanic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Co-amoxiclav Bluefish 875 mg/125 mg film- coated tablets	Bluefish Pharmaceuticals AB	PA1436/002/003 Interchangeable List Code: IC0037-072-003	Film-coated tablet		- Amoxicillin - Clavulanic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Co-amoxiclav Sugar Free 200 mg/28.5 mg/5 ml Powder for Oral Suspension	Brown & Burk IR Limited	PA23148/005/001	Powder for oral suspension	- J01CR - J01CR02	- Amoxicillin - Clavulanic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Co-Amoxiclav Sugar Free 400 mg/57 mg/5 ml Powder for Oral Suspension	Brown & Burk IR Limited	PA23148/005/002 Interchangeable List Code: IC0037-076-034	Powder for oral suspension		- Amoxicillin - Clavulanic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Co-Amoxiclav TEVA 1000 mg/200 mg Powder for Solution for Injection/Infusion	Teva Pharma B.V.	PA0749/011/002	Powder for solution for injection/infusion	- J01CR - J01CR02	- Amoxicillin - Clavulanic acid		- Intravenous use
Co-Amoxiclav TEVA 500 mg/100 mg Powder for Solution for Injection/Infusion	Teva Pharma B.V.	PA0749/011/001	Powder for solution for injection/infusion	- J01CR - J01CR02	- Amoxicillin - Clavulanic acid		- Intravenous use
CoAprovel	Sanofi Pharma Bristol-Myers Squibb SNC	EU/1/98/86/023-028	Tablet	- C09DA - C09DA04	- Irbesartan - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
COAPROVEL	Sanofi Pharma Bristol-Myers Squibb SNC	EU/1/98/86/23-28	Tablet	- C09DA04	- IRBESARTAN - HYDROCHLOROTHIAZIDE		- Oral use
CoAprovel	Sanofi Winthrop Industrie	EU/1/98/086/001	Tablet	- C09DA - C09DA04	- Irbesartan - Hydrochlorothiazide		- Oral use
CoAprovel	Sanofi Winthrop Industrie	EU/1/98/086/001-003	Tablet	- C09DA - C09DA04	- Irbesartan - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
CoAprovel	Sanofi Winthrop Industrie	EU/1/98/086/004	Tablet	- C09DA - C09DA04	- Irbesartan - Hydrochlorothiazide		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
CoAprovel	Sanofi Winthrop Industrie	EU/1/98/086/004-006	Tablet	- C09DA - C09DA04	- Irbesartan - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
CoAprovel	Sanofi Winthrop Industrie	EU/1/98/086/007	Tablet	- C09DA - C09DA04	- Irbesartan - Hydrochlorothiazide		- Oral use
Co-codamol 15 mg/500 mg film-coated tablets	Azure Pharmaceuticals Ltd.	PA22871/020/001	Film-coated tablet	- N02AJ06	- Paracetamol - Codeine phosphate hemihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Cocois Ointment, coal tar 12.0% sulphur for external use 4.0%, salicylic acid 2.0%	RPH Pharmaceuticals AB	PA1638/005/001	Ointment	- D11AC - D11AC08	- Coal tar solution - Sulphur for external use - Salicylic acid		- Topical use
Codant 30 mg Tablets	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/029/001	Tablet	- R05DA - R05DA04	- Codeine phosphate hemihydrate		- Oral use
Codinex Codeine Phosphate 15mg/5ml Oral Solution	Pinewood Laboratories Ltd	PA0281/005/001	Oral solution	- R05DA - R05DA04	- Codeine phosphate hemihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Co-Diovan 160 mg/12.5 mg film-coated tablets	Novartis Ireland Limited	PA0896/007/002 Interchangeable List Code: IC0040-077-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Co-Diovan 160 mg/12.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/226/002 Interchangeable List Code: IC0040-077-003	Film-coated tablet		- Hydrochlorothiazide - Valsartan		- Oral use
Co-Diovan 160 mg/12.5 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/043/002 Interchangeable List Code: IC0040-077-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	ZZZ PPA	- Oral use
Co-Diovan 160 mg/25 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/043/003 Interchangeable List Code: IC0040-078-003	Film-coated tablet		- Hydrochlorothiazide - Valsartan	ZZZ PPA	- Oral use
Co-Diovan 160 mg/25 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/226/003 Interchangeable List Code: IC0040-078-003	Film-coated tablet		- Hydrochlorothiazide - Valsartan		- Oral use
Co-Diovan 160 mg/25 mg film-coated tablets	Novartis Ireland Limited	PA0896/007/003 Interchangeable List Code: IC0040-078-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Co-Diovan 160 mg/25 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/046/001 Interchangeable List Code: IC0040-078-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide		- Oral use
Co-Diovan 320 mg/12.5 mg film-coated tablets	Novartis Ireland Limited	PA0896/007/004 Interchangeable List Code: IC0040-079-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Co-Diovan 320 mg/12.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/226/005 Interchangeable List Code: IC0040-079-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide		- Oral use
Co-Diovan 320 mg/25 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/226/004 Interchangeable List Code: IC0040-080-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	ZZZ PPA	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Co-Diovan 320 mg/25 mg film-coated tablets	Novartis Ireland Limited	PA0896/007/005 Interchangeable List Code: IC0040-080-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Co-Diovan 80 mg/12.5 mg film-coated tablets	Novartis Ireland Limited	PA0896/007/001 Interchangeable List Code: IC0040-081-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Co-Diovan 80 mg/12.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/226/001 Interchangeable List Code: IC0040-081-003	Film-coated tablet		- Hydrochlorothiazide - Valsartan		- Oral use
Co-Diovan 80 mg/12.5 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/043/001 Interchangeable List Code: IC0040-081-003	Film-coated tablet		- Hydrochlorothiazide - Valsartan	ZZZ PPA	- Oral use
Codipar 15 mg/ 500 mg Capsules	Amdipharm Limited	PA1142/023/002	Capsule, hard	- N02AJ - N02AJ06	- Paracetamol - Codeine phosphate hemihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Colchicine 500 microgram Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/002/001	Tablet	- M04AC - M04AC01	- Colchicine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Colchicine Tiofarma 1000 microgram tablets	Tiofarma B.V.	PA2200/001/002	Tablet	- M04AC - M04AC01	- COLCHICINE PH. EUR.	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Colchicine Tiofarma 500 microgram tablets	Tiofarma B.V.	PA2200/001/001	Tablet	- M04AC - M04AC01	- COLCHICINE PH. EUR.	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Coldenza 6C Tablets	A. Nelson & Company Limited	HOA1149/005/001	Tablet		- Gelsemium sempervirens (ghp)		- Oral use
Colecalciferol 30000 IU film-coated tablets	Consilient Health Limited	PA1876/008/004	Film-coated tablet	- A11CC - A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Colecalciferol 1000 IU film-coated tablets	Consilient Health Limited	PA1876/008/002	Film-coated tablet	- A11CC - A11CC05	- Cholecalciferol - Cholecalciferol concentrate (powder form)	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Colecalciferol 3000 IU/ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/007/001	Oral solution	- A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Colecalciferol 7000 IU film-coated tablets	Consilient Health Limited	PA1876/008/003	Film-coated tablet	- A11CC - A11CC05	- Cholecalciferol - Cholecalciferol concentrate (powder form)	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Colecalciferol 800 IU capsules, soft	Strides Pharma (Cyprus) Limited	PA22639/002/001	Capsule, soft	- A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Colecalciferol 800 IU film-coated tablets	Consilient Health Limited	PA1876/008/001	Film-coated tablet	- A11CC - A11CC05	- Cholecalciferol - Cholecalciferol concentrate (powder form)	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Colecalciferol Aristo 20,000 IU soft capsules	Aristo Pharma GmbH	PA1983/002/001	Capsule, soft	- A11CC - A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Colecalciferol EQL Pharma 2000 IU tablet	EQL Pharma AB	PA22981/001/002	Tablet	- A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Colecalciferol EQL Pharma 800 IU tablet	EQL Pharma AB	PA22981/001/001	Tablet	- A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Colica Colic Granules	A. Nelson & Company Limited	HOA1149/001/001	Granules		- CITRULLUS COLOCYNTHIS 30C HAP/PH.EUR - Dioscorea villosa	National Rules Authorisation (Article 16.2 Directive 2001/83/EC.)	
Colistimethate sodium 1 million IU Powder for nebuliser solution	Noridem Enterprises Limited	PA1122/030/001	Powder for nebuliser solution	- J01XB01	- Colistimethate sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Colistimethate sodium 1 million IU Powder for solution for injection/infusion	Noridem Enterprises Limited	PA1122/031/001	Powder for solution for injection/infusion	- J01XB01	- Colistimethate sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intrathecal use - Intravenous use
Colistimethate sodium 2 million IU Powder for nebuliser solution	Noridem Enterprises Limited	PA1122/030/002	Powder for nebuliser solution	- J01XB01	- Colistimethate sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Colistimethate sodium 2 million IU Powder for solution for injection/infusion	Noridem Enterprises Limited	PA1122/031/002	Powder for solution for injection/infusion	- J01XB01	- Colistimethate sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intrathecal use - Intravenous use
Colobreathe	Teva B.V.	EU/1/11/747/001	Inhalation powder, hard capsule	- J01XB - J01XB01	- Colistimethate sodium (r inn)	ZZZ --Unknown--	- Inhalation use
Colofac 135 mg Tablets	Mylan IRE Healthcare Limited	PA2010/007/001	Coated tablet	- A03AA - A03AA04	- Mebeverine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
COLOMYCIN 1 million International Units (IU) Powder for solution for injection, infusion or inhalation	Teva B.V.	PA1986/046/001	Powder for solution for injection/infusion	- J01XB - J01XB01	- Colistimethate sodium	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
COLOMYCIN 2 million International Units (IU) Powder for solution for injection, infusion or inhalation	Teva B.V.	PA1986/046/002	Powder for solution for injection/infusion	- J01XB - J01XB01	- Colistimethate sodium	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Coloprep 1500 mg Tablets	Laboratoires Mayoly Spindler	PA1993/003/001	Tablet	- A06AD - A06AD17	- Sodium phosphate monobasic - Sodium phosphate dibasic, anhydrous	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Colpermin Gastro-resistant Capsules Peppermint oil 0.2ml	Johnson & Johnson (Ireland) Limited	PA0330/034/001	Gastro-resistant capsule, hard	- A03AX	- Peppermint oil		- Oral use
Columvi	Roche Registration GmbH	EU/1/23/1742/001	Concentrate for solution for infusion	- L01 - L01FX28	- Glofitamab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Columvi	Roche Registration GmbH	EU/1/23/1742/002	Concentrate for solution for infusion	- L01 - L01FX28	- Glofitamab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Combigan 2 mg/ml + 5 mg/ml eye drops, solution	AbbVie Limited	PA1824/019/001	Eye drops, solution	- S01ED - S01ED51	- Brimonidine tartrate - Timolol Maleate		- Ocular use
Combiprasal 0.5 mg/2.5 mg per 2.5 ml nebuliser solution	Pharma Stulln GmbH	PA1815/001/001 Interchangeable List Code: IC0081-136-052	Nebuliser solution		- Ipratropium bromide - SALBUTAMOL SULFATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Combivir	ViiV Healthcare BV	EU/1/98/058/001	Film-coated tablet	- J05AR - J05AR01	- Zidovudine - Lamivudine		

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Combivir	ViiV Healthcare BV	EU/1/98/058/002	Film-coated tablet	- J05AR - J05AR01	- Zidovudine - Lamivudine		
Combodart 0.5 mg/ 0.4 mg hard capsules	GlaxoSmithKline (Ireland) Limited	PA1077/118/001 Interchangeable List Code: IC0036-065-001	Capsule, hard		- Dutasteride - Tamsulosin hydrochloride		- Oral use
Combodart 0.5 mg/ 0.4 mg hard capsules	IMED Healthcare Ltd.	PPA1463/068/001 Interchangeable List Code: IC0036-065-001	Capsule, hard		- Dutasteride - Tamsulosin hydrochloride	ZZZ PPA	- Oral use
Combodart 0.5 mg/ 0.4 mg hard capsules	Merit Pharmaceuticals Limited	PPA23080/025/001 Interchangeable List Code: IC0036-065-001	Capsule, hard		- Dutasteride - Tamsulosin hydrochloride		- Oral use
Combodart 0.5 mg/0.4 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/334/001 Interchangeable List Code: IC0036-065-001	Capsule, hard		- Dutasteride - Tamsulosin hydrochloride		- Oral use
Combogesic 10 mg/ml Paracetamol + 3 mg/ml Ibuprofen solution for infusion	JED Pharma Ltd	PA23183/002/001	Solution for infusion	- N02BE51	- Paracetamol - Ibuprofen sodium dihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Cometriq	Ipsen Pharma	EU/1/13/890/001	Capsule, hard	- L01XE - L01XE26	- Cabozantinib (s)-malate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cometriq	Ipsen Pharma	EU/1/13/890/002-003	Capsule, hard	- L01XE - L01XE26	- Cabozantinib (s)-malate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Comirnaty	BioNTech Manufacturing GmbH	EU/1/20/1528/010	Concentrate for dispersion for injection	- J07BN01	- Tozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty	BioNTech Manufacturing GmbH	EU/1/20/1528/001	Concentrate for dispersion for injection	- J07BN01	- Tozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty	BioNTech Manufacturing GmbH	EU/1/20/1528/002-003	Concentrate for dispersion for injection	- J07BN01	- Tozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty	BioNTech Manufacturing GmbH	EU/1/20/1528/004-005	Concentrate for dispersion for injection	- J07BN01	- Tozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1528/018	Dispersion for injection	- J07BN01	- Tozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1528/019	Dispersion for injection	- J07BN01	- Tozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1528/020	Dispersion for injection	- J07BN01	- Tozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1528/021	Concentrate for dispersion for injection	- J07BN01	- Tozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1528/022	Dispersion for injection	- J07BN01	- Tozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1528/023	Dispersion for injection	- J07BN01	- Tozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1528/024	Concentrate for dispersion for injection	- J07BN01	- Tozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1258/021	Concentrate for dispersion for injection	- J07BN01	- Tozinameran	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty Original/Omicron BA.1	BioNTech Manufacturing GmbH	EU/1/20/1528/006-007	Concentrate for dispersion for injection	- J07BN01	- Tozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty Original/Omicron BA.4-5	BioNTech Manufacturing GmbH	EU/1/20/1528/008-009	Dispersion for injection	- J07BN01	- Tozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty Original/Omicron BA.4-5	BioNTech Manufacturing GmbH	EU/1/20/1528/011	Concentrate for dispersion for injection	- J07BN01	- Tozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty Original/Omicron BA.4-5	BioNTech Manufacturing GmbH	EU/1/20/1528/012	Concentrate for dispersion for injection	- J07BN01	- Tozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty Original/Omicron BA.4-5	BioNTech Manufacturing GmbH	EU/1/20/1528/015-016	Concentrate for dispersion for injection	- J07BN01	- Tozinameran - Famtozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty Original/Omicron BA.4-5	BioNTech Manufacturing GmbH	EU/1/20/1528/017	Dispersion for injection	- J07BN01	- Tozinameran - Famtozinameran	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Comirnaty Original/Omicron BA.4-5	BioNTech Manufacturing GmbH	EU/1/20/1258/008-009	Dispersion for injection	- J07BX - J07BX03	- Tozinameran - COVID-19 mRNA vaccine (nucleoside-modified)	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Competact	Takeda Pharma A/S	EU/1/06/354/001-009	Tablet	- A10BD05	- METFORMIN HYDROCHLORIDE - Pioglitazone	Not Currently Available	- Oral use
Competact 15 mg/850 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	EU/1/06/354/001-012	Film-coated tablet	- A10BD05	- Pioglitazone - Metformin Hydrochloride		- Oral use
Compound Sodium Lactate Intravenous Infusion BP, Ecobag (Hartmann's Solution	B. Braun Medical Limited	PA0179/004/008	Solution for infusion	- B05BB - B05BB01	- Sodium chloride - Potassium chloride - Sodium lactate solution - Calcium chloride dihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Compound Sodium Lactate Intravenous Infusion BP, Solution for Infusion (Hartmann's Solution	B. Braun Medical Limited	PA0179/004/003	Solution for infusion	- B05BB - B05BB01	- Sodium chloride - Potassium chloride - Sodium lactate solution - Calcium chloride dihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Compound Sodium Lactate Solution for Infusion BP	Baxter Holding B.V.	PA2299/012/001	Solution for infusion	- B05BB - B05BB01	- Sodium chloride - Potassium chloride - Calcium chloride dihydrate - Sodium lactate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Comtan	Orion Corporation	EU/1/98/081/001	Tablet	- N04BX - N04BX02	- ENTACAPONE		- Oral use
Comtan	Orion Corporation	EU/1/98/081/002	Tablet	- N04BX	- ENTACAPONE		
Comtan	Orion Corporation	EU/1/98/081/003	Tablet	- N04BX	- ENTACAPONE		
Comtan	Orion Corporation	EU/1/98/081/004	Tablet	- N04BX	- ENTACAPONE		
Comtess	Orion Corporation	EU/1/98/082/001	Tablet	- N04BX - N04BX02	- ENTACAPONE		
Comtess	Orion Corporation	EU/1/98/082/002	Tablet	- N04BX - N04BX02	- ENTACAPONE		
Comtess	Orion Corporation	EU/1/98/082/003	Tablet	- N04BX - N04BX02	- ENTACAPONE		
Comtess	Orion Corporation	EU/1/98/082/004	Tablet	- N04BX - N04BX02	- ENTACAPONE		

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
CONBRIZA	Pfizer Europe MA EEIG	EU/1/09/511/1-4	Film-coated tablet	- G03XC - G03XC02	- Bazedoxifene	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Concerta XL 18 mg prolonged-release tablets	Janssen Sciences Ireland UC	PA22612/002/001	Prolonged-release tablet	- N06BA - N06BA04	- Methylphenidate hydrochloride - Methylphenidate hydrochloride - Methylphenidate hydrochloride		- Oral use
Concerta XL 27 mg prolonged-release tablets	Janssen Sciences Ireland UC	PA22612/002/004	Prolonged-release tablet	- N06BA - N06BA04	- Methylphenidate hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Concerta XL 36 mg prolonged-release tablets	Janssen Sciences Ireland UC	PA22612/002/002	Prolonged-release tablet	- N06BA - N06BA04	- Methylphenidate hydrochloride - Methylphenidate hydrochloride - Methylphenidate hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Condyline 5 mg/ml Cutaneous Solution	Takeda Products Ireland Ltd	PA2229/006/001	Cutaneous solution	- D06BB - D06BB04	- Podophyllotoxin		- Topical
Constella	AbbVie Deutschland GmbH & Co. KG	EU/1/12/801/001-004	Capsule, hard	- A06AX - A06AX04	- Linaclotide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Controloc Control	Takeda GmbH	EU/1/09/515/001	Gastro-resistant tablet	- A02BC - A02BC02	- Pantoprazole sodium sesquihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Controloc Control	Takeda GmbH	EU/1/09/515/001-004	Gastro-resistant tablet	- A02BC - A02BC02	- Pantoprazole sodium sesquihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Copalia	Novartis Europharm Limited	EU/1/06/372/001-008 Interchangeable List Code: IC0042-087-003	Film-coated tablet		- Amlodipine besilate - Valsartan	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Copalia	Novartis Europharm Limited	EU/1/06/372/009-016 Interchangeable List Code: IC0042-086-003	Film-coated tablet		- Amlodipine besilate - Valsartan	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Copalia	Novartis Europharm Limited	EU/1/06/372/017-024 Interchangeable List Code: IC0042-084-003	Film-coated tablet		- Amlodipine besilate - Valsartan	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Copalia HCT	Novartis Europharm Limited	EU/1/09/575/1-12	Film-coated tablet	- C09DX - C09DX01	- Amlodipine besylate - Hydrochlorothiazide - Valsartan		- Oral use
Copalia HCT	Novartis Europharm Limited	EU/1/09/575/13-24	Film-coated tablet	- C09DX - C09DX01	- Hydrochlorothiazide - Valsartan - Amlodipine besylate		- Oral use
Copalia HCT	Novartis Europharm Limited	EU/1/09/575/25-36	Film-coated tablet	- C09DX - C09DX01	- Amlodipine besylate - Hydrochlorothiazide - Valsartan		- Oral use
Copalia HCT	Novartis Europharm Limited	EU/1/09/575/37-48	Film-coated tablet	- C09DX - C09DX01	- Hydrochlorothiazide - Valsartan - Amlodipine besylate		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Copalia HCT	Novartis Europharm Limited	EU/1/09/575/49-60	Film-coated tablet	- C09DX - C09DX01	- Valsartan - Hydrochlorothiazide - Amlodipine besylate		- Oral use
Copaxone 20 mg/ml solution for injection in pre-filled syringe	TEVA GmbH	PA22579/001/001	Solution for injection in pre-filled syringe	- L03AX - L03AX13	- Glatiramer acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Copaxone 40 mg/ml solution for injection in pre-filled syringe	PCO Manufacturing Ltd.	PPA0465/432/002	Solution for injection in pre-filled syringe	- L03AX - L03AX13	- Glatiramer acetate		- Subcutaneous use
Copaxone 40mg/ml solution for injection in pre-filled syringe	TEVA GmbH	PA22579/001/002	Solution for injection in pre-filled syringe	- L03AX - L03AX13	- Glatiramer acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Copiktra	Secura Bio Limited	EU/1/21/1542/001	Capsule, hard	- L01 - L01EM04	- Duvelisib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Copiktra	Secura Bio Limited	EU/1/21/1542/002	Capsule, hard	- L01EM04	- Duvelisib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cordarone X 100mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/142/001	Tablet	- C01BD - C01BD01	- Amiodarone hydrochloride		- Oral use
Cordarone X 200 mg Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/020/002	Tablet	- C01BD - C01BD01	- Amiodarone hydrochloride		- Oral use
Cordarone X 200mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/142/002	Tablet	- C01BD - C01BD01	- Amiodarone hydrochloride		- Oral use
Cordarone X Intravenous, 150mg/3ml, Concentrate for solution for infusion or slow injection	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/142/003	Concentrate for solution for infusion	- C01BD - C01BD01	- Amiodarone hydrochloride		- Intravenous use
Corlentor	Les Laboratoires Servier	EU/1/05/317/1-7	Film-coated tablet	- C01EB - C01EB17	- Ivabradine		- Oral use
Corlentor	Les Laboratoires Servier	EU/1/05/317/8-14	Film-coated tablet	- C01EB - C01EB17	- Ivabradine		- Oral use
Corsodyl 0.2 % w/v Aniseed Mouthwash	Haleon Ireland Limited	PA0678/002/004	Mouthwash	- A01AB - A01AB03	- Chlorhexidine gluconate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oromucosal use
Corsodyl 1% w/w Dental Gel	Haleon Ireland Limited	PA0678/002/001	Dental gel	- A01AB - A01AB03	- Chlorhexidine digluconate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Dental use
Corsodyl Freshmint 0.2% w/v Mouthwash	Haleon Ireland Limited	PA0678/002/005	Mouthwash	- A01AB - A01AB03	- Chlorhexidine digluconate (as chlorhexidine digluconate solution (20% w/v) ph.eur.	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oromucosal use
Cortiment 9 mg prolonged release tablets	Ferring Ireland Ltd	PA1009/026/001	Prolonged-release tablet	- A07EA - A07EA06	- Budesonide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Cortopin 1% w/w Cream	Pinewood Laboratories Ltd	PA0281/071/002	Cream	- D07AA - D07AA02	- Hydrocortisone	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical
Cosartal Plus 100 mg/12.5 mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/190/003 Interchangeable List Code: IC0031-026-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide		- Oral use
Cosartal Plus 100 mg/25 mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/190/002 Interchangeable List Code: IC0031-027-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Cosartal Plus 50 mg/12.5 mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/190/001 Interchangeable List Code: IC0031-025-003	Film-coated tablet		- Hydrochlorothiazide - Losartan potassium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cosentyx	Novartis Europharm Limited	EU/1/14/980/001	Powder for solution for injection	- L04AC - L04AC10	- Secukinumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Cosentyx	Novartis Europharm Limited	EU/1/14/980/002-003	Solution for injection in pre-filled syringe	- L04AC - L04AC10	- Secukinumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Cosentyx	Novartis Europharm Limited	EU/1/14/980/004-005	Solution for injection in pre-filled pen	- L04AC - L04AC10	- Secukinumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Cosentyx	Novartis Europharm Limited	EU/1/14/980/008-009	Solution for injection in pre-filled syringe	- L04AC10	- Secukinumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Cosentyx	Novartis Europharm Limited	EU/1/14/980/012-013	Solution for injection in pre-filled syringe	- QL04AC10	- Secukinumab	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Cosentyx	Novartis Europharm Limited	EU/1/14/980/10-011	Solution for injection in pre-filled pen	- L04AC10	- Secukinumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Cosimprel 10mg/10mg Film-Coated Tablets	Les Laboratoires Servier	PA0568/029/004	Film-coated tablet	- C09BX - C09BX02	- BISOPROLOL FUMARATE - Perindopril arginine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Cosimprel 10mg/5mg Film-Coated Tablets	Les Laboratoires Servier	PA0568/029/003	Film-coated tablet	- C09BX - C09BX02	- BISOPROLOL FUMARATE - Perindopril arginine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Cosimprel 5mg/10mg Film-Coated Tablets	Les Laboratoires Servier	PA0568/029/002	Film-coated tablet	- C09BX - C09BX02	- BISOPROLOL FUMARATE - Perindopril arginine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Cosimprel 5mg/5mg Film-Coated Tablets	Les Laboratoires Servier	PA0568/029/001	Film-coated tablet	- C09BX - C09BX02	- BISOPROLOL FUMARATE - Perindopril arginine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
CosmoFer 50 mg/ml solution for infusion and injection	Originalis B.V.	PPA2306/021/001	Solution for injection/infusion	- B03AC	- IRON (III)	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Intramuscular use - Intravenous use
CosmoFer 50mg/ml solution for infusion and injection	Pharmacosmos A/S	PA0982/001/001	Solution for injection/infusion	- B03AC	- Iron (III) hydroxide dextran complex		- Not Currently Available
COSOPT 20 mg/ml + 5 mg/ml eye drops, solution	IMED Healthcare Ltd.	PPA1463/060/001	Eye drops, solution	- S01ED51	- Timolol - Dorzolamide		- Ocular use
COSOPT 20 mg/ml + 5 mg/ml eye drops, solution	PCO Manufacturing Ltd.	PPA0465/296/001	Eye drops, solution	- S01ED - S01ED51	- Dorzolamide - Timolol	ZZZ PPA	- Ocular use
COSOPT 20mg/ml + 5mg/ml eye drops, solution	Santen OY	PA0879/005/001	Eye drops, solution	- S01ED - S01ED51	- Dorzolamide - Timolol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Not Currently Available
COSOPT Preservative-Free 20 mg/ml + 5 mg/ml, eye drops, solution in single-dose container	Santen OY	PA0879/005/002	Eye drops, solution in single-dose container	- S01ED - S01ED51	- Dorzolamide - Timolol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Cotellic	Roche Registration GmbH	EU/1/15/1048/001	Film-coated tablet	- L01EE02	- Cobimetinib hemifumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Co-Tipol 500 mg/30 mg hard capsules	Clonmel Healthcare Ltd	PA0126/332/001	Capsule, hard	- N02AJ - N02AJ06	- Paracetamol - Codeine phosphate hemihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Co-Tipol 500 mg/30 mg suppositories	Clonmel Healthcare Ltd	PA0126/332/002	Suppository	- N02AJ - N02AJ06	- Paracetamol - Codeine phosphate hemihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Co-Tipol Max 1000 mg/60 mg suppositories	Clonmel Healthcare Ltd	PA0126/332/003	Suppository	- N02AJ - N02AJ06	- Paracetamol - Codeine phosphate hemihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Rectal use
Co-Vatan 160 mg/12.5 mg Film-coated Tablets	Rowex Ltd	PA0711/182/002 Interchangeable List Code: IC0040-077-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Co-Vatan 160 mg/25 mg Film-coated Tablets	Rowex Ltd	PA0711/182/003 Interchangeable List Code: IC0040-078-003	Film-coated tablet		- Valsartan - Hydrocholothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Co-Vatan 80 mg/12.5 mg Film-coated Tablets	Rowex Ltd	PA0711/182/001 Interchangeable List Code: IC0040-081-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Coverdine 10 mg/2.5 mg/10 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/022/003	Film-coated tablet	- C09BX - C09BX01	- Indapamide - Amlodipine - Perindopril arginine		- Oral use
Coverdine 10 mg/2.5 mg/5 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/022/002	Film-coated tablet	- C09BX - C09BX01	- Amlodipine - Indapamide - Perindopril arginine		- Oral use
Coverdine 10mg/2.5mg/10mg film-coated tablets	Originalis B.V.	PPA2306/028/001	Film-coated tablet	- C09BX - C09BX01	- Perindopril arginine - Indapamide - Amlodipine		- Oral use
Coverdine 10mg/2.5mg/10mg film-coated tablets	Les Laboratoires Servier	PA0568/024/005	Film-coated tablet	- C09BX - C09BX01	- Perindopril arginine - Indapamide - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Coverdine 10mg/2.5mg/5mg film-coated tablets	Les Laboratoires Servier	PA0568/024/004	Film-coated tablet	- C09BX - C09BX01	- Perindopril arginine - Indapamide - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Coverdine 5 mg/1.25 mg/5 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/022/001	Film-coated tablet	- C09BX - C09BX01	- Amlodipine - Perindopril arginine - Indapamide		- Oral use
Coverdine 5mg/1.25mg/10mg film-coated tablets	Les Laboratoires Servier	PA0568/024/003	Film-coated tablet	- C09BX - C09BX01	- Perindopril arginine - Indapamide - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Coverdine 5mg/1.25mg/5mg film-coated tablets	Les Laboratoires Servier	PA0568/024/002	Film-coated tablet	- C09BX - C09BX01	- Perindopril arginine - Indapamide - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Coversyl Arginine 10 mg film coated tablets	Les Laboratoires Servier	PA0568/002/006 Interchangeable List Code: IC0002-002-015	Film-coated tablet		- Perindopril arginine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Coversyl Arginine 2.5 mg film-coated tablets	Les Laboratoires Servier	PA0568/002/004	Film-coated tablet	- C09AA - C09AA04	- Perindopril arginine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Coversyl Arginine 5 mg film-coated tablets	Les Laboratoires Servier	PA0568/002/005 Interchangeable List Code: IC0002-001-015	Film-coated tablet		- Perindopril arginine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
COVERSYL ARGININE PLUS	B & S Healthcare	PPA1328/122/001	Film-coated tablet	- C09BA04	- PERINDOPRIL ARGININE - INDAPAMIDE	PPA	- Oral use
Coversyl Arginine Plus 10mg/2.5mg film-coated tablets	Les Laboratoires Servier	PA0568/022/002	Film-coated tablet	- C09BA - C09BA04	- Perindopril arginine - Indapamide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Coversyl Arginine Plus 2.5mg/0.625mg film-coated tablets	Les Laboratoires Servier	PA0568/008/003 Interchangeable List Code: IC0039-019-003	Film-coated tablet		- Perindopril arginine - Indapamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Coversyl Arginine Plus 5mg/1.25mg film-coated tablets	Les Laboratoires Servier	PA0568/016/002 Interchangeable List Code: IC0039-020-003	Film-coated tablet		- Perindopril arginine - Indapamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cozaar 100 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/029/002 Interchangeable List Code: IC0003-024-003	Film-coated tablet		- Losartan potassium	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Cozaar 100 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/106/002 Interchangeable List Code: IC0003-024-003	Film-coated tablet		- Losartan potassium	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Cozaar 100 mg Film-coated Tablets	Organon Pharma (Ireland) Limited	PA23198/002/003 Interchangeable List Code: IC0003-024-003	Film-coated tablet		- Losartan potassium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cozaar 12.5mg Film-coated Tablets	Organon Pharma (Ireland) Limited	PA23198/002/001	Film-coated tablet	- C09CA - C09CA01	- Losartan potassium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cozaar 50 mg Film-coated Tablets	Organon Pharma (Ireland) Limited	PA23198/002/002 Interchangeable List Code: IC0003-023-003	Film-coated tablet		- Losartan potassium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cozaar 50 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/106/001 Interchangeable List Code: IC0003-023-003	Film-coated tablet		- Losartan potassium		- Oral use
Cozaar 50 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/029/001 Interchangeable List Code: IC0003-023-003	Film-coated tablet		- Losartan potassium	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Cozaar Comp 100 mg/12.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/109/004 Interchangeable List Code: IC0031-026-003	Film-coated tablet		- Hydrochlorothiazide - Losartan potassium		- Oral use
Cozaar Comp 100 mg/12.5 mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/001/001 Interchangeable List Code: IC0031-026-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cozaar Comp 100 mg/25 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/109/002 Interchangeable List Code: IC0031-027-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide		- Oral use
Cozaar Comp 100mg/25mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/001/003 Interchangeable List Code: IC0031-027-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Cozaar Comp 50 mg/12.5 mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/001/002 Interchangeable List Code: IC0031-025-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cozaar Comp 50 mg/12.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/109/001 Interchangeable List Code: IC0031-025-003	Film-coated tablet		- Hydrochlorothiazide - Losartan potassium		- Oral use
Cozatan 100 mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/167/002 Interchangeable List Code: IC0003-024-003	Film-coated tablet		- Losartan potassium		- Oral use
Cozatan 50 mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/167/001 Interchangeable List Code: IC0003-023-003	Film-coated tablet		- Losartan potassium		- Oral use
Cozatan Comp 100 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/184/002 Interchangeable List Code: IC0031-027-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cozatan Comp 50 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/184/001 Interchangeable List Code: IC0031-025-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Crampex TabletsCholecalciferol 0.02 mgCalcium Gluconate 200 mgNicotinic Acid 20 mg	Clonmel Healthcare Ltd	PA0126/318/001	Tablet	- A12AX	- Cholecalciferol - Calcium gluconate - Nicotinic acid		- Oral use
Creon 10000 Gastro-resistant Capsules	PCO Manufacturing Ltd.	PPA0465/125/001	Gastro-resistant capsule, hard	- A09AA - A09AA02	- Pancreatin	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Creon 10000 Gastro-Resistant Capsules	IMED Healthcare Ltd.	PPA1463/145/001	Gastro-resistant capsule, hard	- A09AA - A09AA02	- Pancreas powder	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Creon 10000 Gastro-resistant Capsules	Merit Pharmaceuticals Limited	PPA23080/019/001	Gastro-resistant capsule, hard	- A09AA02	- Lipase - Amylase - Protease	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Creon 10000 Gastro-resistant Capsules	Viatris Healthcare Limited	PA23355/006/001	Gastro-resistant capsule, hard	- A09AA - A09AA02	- Pancreas powder	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Creon 20000 Gastro-resistant Capsules, hard	Viatris Healthcare Limited	PA23355/006/004	Gastro-resistant capsule, hard	- A09AA02	- Pancreas Powder Ph. Eur.	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Creon 25000 Gastro-resistant Capsules	Viatris Healthcare Limited	PA23355/006/002	Gastro-resistant capsule, hard	- A09AA - A09AA02	- Pancreas powder	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Creon 25000 Gastro-resistant capsules	IMED Healthcare Ltd.	PPA1463/033/002	Gastro-resistant capsule, hard	- A09AA - A09AA02	- Pancreatin		- Not Currently Available - Oral use
Creon 25000 Gastro-resistant Capsules	PCO Manufacturing Ltd.	PPA0465/125/002	Gastro-resistant capsule, hard	- A09AA - A09AA02	- Pancreatin	ZZZ PPA	- Oral use
Creon 35000 Gastro-resistant Capsules, hard	Viatris Healthcare Limited	PA23355/006/005	Gastro-resistant capsule, hard	- A09AA02	- Pancreas Powder Ph. Eur.	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Creon for Children 5000 Gastro-resistant Granules	Viatris Healthcare Limited	PA23355/006/003	Gastro-resistant granules	- A09AA - A09AA02	- Pancreas powder	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cresemba	Basilea Pharmaceutica Deutschland GmbH	EU/1/15/1036/001	Powder for concentrate for solution for infusion	- J02AC - J02AC05	- Isavuconazonium sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Cresemba	Basilea Pharmaceutica Deutschland GmbH	EU/1/15/1036/002	Powder for concentrate for solution for infusion	- J02AC - J02AC05	- Isavuconazonium sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Crestor 10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/441/002 Interchangeable List Code: IC0006-002-003	Film-coated tablet		- Rosuvastatin	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Crestor 10 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/119/002 Interchangeable List Code: IC0006-002-003	Film-coated tablet		- Rosuvastatin		- Oral use
Crestor 10 mg film-coated tablets	Grunenthal Pharma Ltd	PA2242/016/002 Interchangeable List Code: IC0006-002-003	Film-coated tablet		- Rosuvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Crestor 20 mg film-coated tablets	Grunenthal Pharma Ltd	PA2242/016/003 Interchangeable List Code: IC0006-003-003	Film-coated tablet		- Rosuvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Crestor 20 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/119/003 Interchangeable List Code: IC0006-003-003	Film-coated tablet		- Rosuvastatin		- Oral use
Crestor 20 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/441/003 Interchangeable List Code: IC0006-003-003	Film-coated tablet		- Rosuvastatin	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Crestor 40 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/441/004 Interchangeable List Code: IC0006-004-003	Film-coated tablet		- Rosuvastatin	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Crestor 40 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/119/004 Interchangeable List Code: IC0006-004-003	Film-coated tablet		- Rosuvastatin		- Oral use
Crestor 40 mg film-coated tablets	Grunenthal Pharma Ltd	PA2242/016/004 Interchangeable List Code: IC0006-004-003	Film-coated tablet		- Rosuvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Crestor 5 mg film-coated tablets	Grunenthal Pharma Ltd	PA2242/016/001 Interchangeable List Code: IC0006-001-003	Film-coated tablet		- Rosuvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Crestor 5 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/119/001 Interchangeable List Code: IC0006-001-003	Film-coated tablet		- Rosuvastatin		- Oral use
Crestor 5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/441/001 Interchangeable List Code: IC0006-001-003	Film-coated tablet		- Rosuvastatin	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Crinone 8% w/w progesterone vaginal gel	PCO Manufacturing Ltd.	PPA0465/301/001	Vaginal gel	- G03DA04	- Progesterone		- Vaginal use
Crinone 8% w/w progesterone vaginal gel	IMED Healthcare Ltd.	PPA1463/112/001	Vaginal gel	- G03DA - G03DA04	- Progesterone		- Not Currently Available - Vaginal use
Crinone 8% w/w progesterone vaginal gel	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/031/001	Vaginal gel	- G03DA - G03DA04	- Progesterone		- Vaginal use
Crinone 8% w/w progesterone vaginal gel	Merck Serono (Ireland) Limited	PA2286/001/001	Vaginal gel	- G03DA - G03DA04	- Progesterone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Crystapen 600mg Powder for Solution for Injection or Infusion	Clonmel Healthcare Ltd	PA0126/313/001	Powder for solution for injection/infusion	- J01CE - J01CE01	- Benzylpenicillin Sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
CRYSVITA	Kyowa Kirin Holdings B.V.	EU/1/17/1262/001	Solution for injection	- M05BX - M05BX05	- Recombinant human igg1 monoclonal antibody to fibroblast growth factor 23	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
CRYSVITA	Kyowa Kirin Holdings B.V.	EU/1/17/1262/002	Solution for injection	- M05BX - M05BX05	- Recombinant human igg1 monoclonal antibody to fibroblast growth factor 23	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
CRYSVITA	Kyowa Kirin Holdings B.V.	EU/1/17/1262/003	Solution for injection	- M05BX - M05BX05	- Recombinant human igg1 monoclonal antibody to fibroblast growth factor 23	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Cubicin	Merck Sharp & Dohme BV	EU/1/05/328/001	Powder for solution for injection/infusion	- J01XX - J01XX09	- Daptomycin		
Cubicin	Merck Sharp & Dohme BV	EU/1/05/328/002	Powder for solution for injection/infusion	- J01XX - J01XX09	- Daptomycin		
Cufence	Univar B.V	EU/1/19/1365/001	Capsule, hard	- A16A - A16AX12	- TRIENTINE DIHYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cufence	Univar B.V	EU/1/19/1365/002	Capsule, hard	- A16AX12	- Trientine tetrahydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cuprior 150 mg film-coated tablets	gmp-orphan SA	EU/1/17/1199/001	Film-coated tablet	- A16AX - A16AX12	- Trientine tetrahydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Cuprymina	A.C.O.M. - ADVANCED CENTER ONCOLOGY MACERATA -S.R.L.	EU/1/12/784/001	Radiopharmaceutical precursor, solution	- V	- Copper (64 cu) chloride		
Curanail 5% w/v medicated nail lacquer	Galderma International	PA22743/004/001	Medicated nail lacquer	- D01AE - D01AE16	- Amorolfine	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Cutaneous use
CUROSURF 120 mg/vial Endotracheopulmonary instillation, suspension	Chiesi Farmaceutici S.p.A.	PA0584/005/001	Endotracheopulmonary instillation, suspension	- R07AA - R07AA02	- Porcine lung surfactant	Full application (Article 8(3) of Directive No 2001/83/EC)	- Endotracheopulmonary use
CUROSURF 240 mg/vial Endotracheopulmonary instillation, suspension	Chiesi Farmaceutici S.p.A.	PA0584/005/002	Endotracheopulmonary instillation, suspension	- R07AA - R07AA02	- Porcine lung surfactant	Full application (Article 8(3) of Directive No 2001/83/EC)	- Endotracheopulmonary use
CUTAQUIG, 165 mg/ml, solution for injection	Octapharma (IP) SPRL	PA2219/001/001	Solution for injection	- J06BA - J06BA01	- Human normal immunoglobulin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Cuvitru 200 mg/ml solution for subcutaneous injection	Baxalta Innovations GmbH	PA2004/008/001	Solution for injection	- J06BA01	- Human normal immunoglobulin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Cyanokit	SERB S.A.,	EU/1/07/420/001	Powder for solution for infusion	- V03AB - V03AB33	- Hydroxocobalamin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Cyanokit	Merck Sante s.a.s.	EU/1/07/420/002	Powder for solution for infusion	- V03AB - V03AB33	- Hydroxocobalamin		- Intravenous use
Cyclimorph 10 solution for injection	Amdipharm Limited	PA1142/003/001	Solution for injection	- N02AA - N02AA51	- CYCLIZINE TARTRATE - Morphine tartrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
Cyclimorph 15 Solution for Injection	Amdipharm Limited	PA1142/003/002	Solution for injection	- N02AA - N02AA51	- Cyclizine - Morphine Tartrate BPC 1959	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
Cyclolux 279.32 mg/ml solution for injection	Sanochemia Pharmazeutika GmbH	PA23317/001/001	Solution for injection	- V08CA02	- Gadoteric acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Cyklokapron 100 mg/mL solution for injection/infusion	Pfizer Healthcare Ireland	PA0822/117/001	Solution for injection/infusion	- B02AA - B02AA02	- Tranexamic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Cyklokapron 500 mg Film-coated Tablets	Mylan IRE Healthcare Limited	PA2010/055/001	Film-coated tablet	- B02AA - B02AA02	- TRANEXAMIC ACID PH. EUR.	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cymbalta 30 mg hard gastro-resistant capsules	Eli Lilly Nederland B.V.	EU/1/04/296/1-4 Interchangeable List Code: IC0091-033-006	Gastro-resistant capsule, hard		- Duloxetine hydrochloride	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cymbalta 60 mg hard gastro-resistant capsules	Eli Lilly Nederland B.V.	EU/1/04/296/002-005 Interchangeable List Code: IC0091-127-006	Gastro-resistant capsule, hard		- Duloxetine	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Cymevene 500 mg powder for concentrate for solution for infusion	CHEPLAPHARM Arzneimittel GmbH	PA2239/003/001	Powder for concentrate for solution for infusion	- J05AB - J05AB06	- Ganciclovir		- Intravenous use
Cymex Cream	Teva B.V.	PA1986/112/001	Cream	- D08AJ - D08AJ04	- Cetrimide - Chlorocresol - Dimeticone - Urea	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Topical use
Cyramza	Eli Lilly Nederland B.V.	EU/1/14/957/001-003	Concentrate for solution for infusion	- L01XC	- Ramucirumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Cystadane	Recordati Rare Diseases	EU/1/06/379/001	Oral powder	- A16AA - A16AA06	- Betaine anhydrous	Full application (Article 8(3) of Directive No 2001/83/EC)	
Cystadrops	Recordati Rare Diseases	EU/1/15/1049/001	Eye drops, solution	- S01XA - S01XA21	- Mercaptamine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Cystagon	Recordati Rare Diseases	EU/1/97/039/001	Capsule, hard	- A16AA - A16AA04	- Mercaptamine bitartrate		
Cystagon	Recordati Rare Diseases	EU/1/97/039/002	Capsule, hard	- A16AA - A16AA04	- Mercaptamine bitartrate		
Cystagon	Recordati Rare Diseases	EU/1/97/039/003	Capsule, hard	- A16AA - A16AA04	- Mercaptamine bitartrate		
Cystagon	Recordati Rare Diseases	EU/1/97/039/004	Capsule, hard	- A16AA - A16AA04	- Mercaptamine bitartrate		
Cystopurin 3g Granules for oral solution	Bayer Limited	PA1410/042/001	Granules for oral solution	- A12BA - A12BA02	- Potassium citrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Cytarabine 100 mg/ml Solution for Injection	Pfizer Healthcare Ireland	PA0822/200/002	Solution for injection	- L01BC - L01BC01	- Cytarabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Cytarabine 100 mg/ml Solution for Injection or Infusion	Fresenius Kabi Deutschland GmbH	PA2059/034/001	Solution for injection/infusion	- L01BC - L01BC01	- Cytarabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Cytarabine 100 mg/ml solution for injection or infusion	Accord Healthcare Ireland Ltd.	PA2315/082/001	Solution for injection/infusion	- L01BC - L01BC01	- Cytarabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Cytarabine 20 mg/ml Solution for Injection or Infusion	Pfizer Healthcare Ireland	PA0822/200/001	Solution for injection/infusion	- L01BC - L01BC01	- Cytarabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Cytarabine 20 mg/ml Solution for Injection/Infusion	Accord Healthcare Ireland Ltd.	PA2315/082/002	Solution for injection/infusion	- L01BC - L01BC01	- Cytarabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Cytisinicline APC Pharmlog 1.5 mg film-coated tablets	APC Pharmlog Sp. z o.o.	PA2153/002/001	Film-coated tablet	- N07BA04	- Cytisinicline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Cytotec 200 microgram Tablets	Pfizer Healthcare Ireland	PA0822/118/001	Tablet	- A02BB - A02BB01	- Misoprostol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Dabigatran Etexilate Accord	Accord Healthcare S.L.U.	EU/1/22/1665/001-006	Capsule, hard	- B01AE07	- Dabigatran etexilate mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dabigatran Etexilate Accord	Accord Healthcare S.L.U.	EU/1/22/1665/007-016	Capsule, hard	- B01AE07	- Dabigatran etexilate mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dabigatran Etexilate Accord	Accord Healthcare S.L.U.	EU/1/22/1665/017-027	Capsule, hard	- B01AE07	- Dabigatran etexilate mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dabigatran etexilate Clonmel 110 mg hard capsules	Clonmel Healthcare Ltd	PA0126/340/002	Capsule, hard	- B01AE07	- Dabigatran etexilate mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dabigatran etexilate Clonmel 150 mg hard capsules	Clonmel Healthcare Ltd	PA0126/340/003	Capsule, hard	- B01AE07	- Dabigatran etexilate mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dabigatran etexilate Clonmel 75 mg hard capsules	Clonmel Healthcare Ltd	PA0126/340/001	Capsule, hard	- B01AE07	- Dabigatran etexilate mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dabigatran Etexilate Krka 110 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/110/002	Capsule, hard	- B01AE07	- Dabigatran etexilate mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dabigatran Etexilate Krka 150 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/110/003	Capsule, hard	- B01AE07	- Dabigatran etexilate mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dabigatran Etexilate Krka 75 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/110/001	Capsule, hard	- B01AE07	- Dabigatran etexilate mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dacarbazine Lipomed 1000 mg powder for solution for infusion	Lipomed GmbH	PA1760/001/003	Powder for solution for infusion	- L01AX - L01AX04	- Dacarbazine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Dacarbazine Lipomed 200 mg powder for solution for injection or infusion	Lipomed GmbH	PA1760/001/001	Powder for solution for injection/infusion	- L01AX - L01AX04	- Dacarbazine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Dacarbazine Lipomed 500 mg powder for solution for infusion	Lipomed GmbH	PA1760/001/002	Powder for solution for infusion	- L01AX - L01AX04	- Dacarbazine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Dacarbazine medac 1000 mg, powder for solution for infusion	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/003/004	Powder for solution for infusion	- L01AX - L01AX04	- Dacarbazine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Dacarbazine medac 200 mg, powder for solution for injection/infusion	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/003/002	Powder for solution for injection/infusion	- L01AX - L01AX04	- Dacarbazine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Dacarbazine medac 500 mg, powder for solution for infusion	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/003/003	Powder for solution for infusion	- L01AX - L01AX04	- Dacarbazine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Dacepton 10 mg/ml solution for injection in cartridge	EVER Valinject GmbH	PA1774/001/003	Solution for injection in cartridge	- N04BC - N04BC07	- Apomorphine hydrochloride hemihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Dacepton 5 mg/ml solution for infusion	EVER Valinject GmbH	PA1774/001/002	Solution for infusion	- N04BC - N04BC07	- Apomorphine hydrochloride hemihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Dacogen	Janssen-Cilag International NV	EU/1/12/792/001	Powder for concentrate for solution for infusion	- L01BC - L01BC08	- Decitabine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Dafiro	Novartis Europharm Limited	EU/1/06/371/001-008 Interchangeable List Code: IC0042-087-003	Film-coated tablet		- Amlodipine besilate - Valsartan	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Dafiro	Novartis Europharm Limited	EU/1/06/371/009-016 Interchangeable List Code: IC0042-086-003	Film-coated tablet		- Amlodipine besilate - Valsartan	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Dafiro	Novartis Europharm Limited	EU/1/06/371/017-024 Interchangeable List Code: IC0042-084-003	Film-coated tablet		- Valsartan - Amlodipine besilate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Dafiro HCT	Novartis Europharm Limited	EU/1/09/574/1-12	Film-coated tablet	- C09DX - C09DX01	- Amlodipine besylate - Hydrochlorothiazide - Valsartan	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Dafiro HCT	Novartis Europharm Limited	EU/1/09/574/13-24	Film-coated tablet	- C09DX - C09DX01	- Hydrochlorothiazide - Valsartan - Amlodipine besylate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Dafiro HCT	Novartis Europharm Limited	EU/1/09/574/25-36	Film-coated tablet	- C09DX - C09DX01	- Amlodipine besylate - Hydrochlorothiazide - Valsartan	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Dafiro HCT	Novartis Europharm Limited	EU/1/09/574/37-48	Film-coated tablet	- C09DX - C09DX01	- Hydrochlorothiazide - Valsartan - Amlodipine besylate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Dafiro HCT	Novartis Europharm Limited	EU/1/09/574/49-60	Film-coated tablet	- C09DX - C09DX01	- Valsartan - Hydrochlorothiazide - Amlodipine besylate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Daktarin 2% w/w Cream	JNTL Consumer Health I (Ireland) Limited	PA23490/028/001	Cream	- D01AC - D01AC02	- Miconazole nitrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Cutaneous use
Daktarin 2% w/w Cutaneous Powder	Johnson & Johnson (Ireland) Limited	PA0330/048/002	Cutaneous powder	- D01AC - D01AC02	- Miconazole nitrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Cutaneous use
Daktarin 20 mg/g Oral Gel	Johnson & Johnson (Ireland) Limited	PA0330/048/003	Oral gel	- A01AB - A01AB09	- Miconazole	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Dalacin 100 mg Vaginal Ovule	Pfizer Healthcare Ireland	PA0822/119/001	Pessary	- G01AA - G01AA10	- CLINDAMYCIN PHOSPHATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Dalacin 2 % Vaginal Cream	PCO Manufacturing Ltd.	PPA0465/416/001	Vaginal cream	- J01FF - J01FF01	- Clindamycin		- Vaginal use
Dalacin 2% Vaginal Cream	Pfizer Healthcare Ireland	PA0822/119/002	Vaginal cream	- G01AA - G01AA10	- CLINDAMYCIN PHOSPHATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Dalacin C 150 mg Hard Capsules	Pfizer Healthcare Ireland	PA0822/120/001	Capsule, hard	- J01FF - J01FF01	- Clindamycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Dalacin C 150 mg Hard Capsules	PCO Manufacturing Ltd.	PPA0465/205/001	Capsule, hard	- D10AF - D10AF01	- Clindamycin		- Oral use
Dalacin C 150 mg Hard Capsules	Merit Pharmaceuticals Limited	PPA23080/008/001	Capsule, hard	- J01FF01	- Clindamycin	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Dalacin C 150 mg hard capsules	IMED Healthcare Ltd.	PPA1463/150/001	Capsule, hard	- J01FF - J01FF01	- Clindamycin		- Oral use
Dalacin C Phosphate 150 mg/ml Concentrate for Solution for injection/infusion, 2ml	Pfizer Healthcare Ireland	PA0822/120/002	Concentrate for solution for injection/infusion	- J01FF - J01FF01	- Clindamycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Dalacin C Phosphate 150 mg/ml Concentrate for Solution for injection/infusion, 4ml	Pfizer Healthcare Ireland	PA0822/120/003	Concentrate for solution for injection/infusion	- J01FF - J01FF01	- Clindamycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Dalacin T Topical Lotion 10 mg/ml Cutaneous Emulsion	Pfizer Healthcare Ireland	PA0822/121/001	Cutaneous emulsion	- D10AF - D10AF01	- Clindamycin		- Topical use
Dalmane 15 mg Hard Capsules	Mylan IRE Healthcare Limited	PA2010/039/001	Capsule, hard	- N05CD - N05CD01	- FLURAZEPAM HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Dalmane 30 mg Hard Capsules	Mylan IRE Healthcare Limited	PA2010/039/002	Capsule, hard	- N05CD - N05CD01	- FLURAZEPAM HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Dancex SR 10 mg Prolonged-Release Tablets	Rowex Ltd	PA0711/143/002 Interchangeable List Code: IC0066-002-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dancex SR 20 mg Prolonged-Release Tablets	Rowex Ltd	PA0711/143/003 Interchangeable List Code: IC0066-003-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Dancex SR 40 mg Prolonged-Release Tablets	Rowex Ltd	PA0711/143/004 Interchangeable List Code: IC0066-004-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dancex SR 5 mg Prolonged-Release Tablets	Rowex Ltd	PA0711/143/001 Interchangeable List Code: IC0066-001-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dancex SR 80 mg Prolonged-Release Tablets	Rowex Ltd	PA0711/143/006 Interchangeable List Code: IC0066-005-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dancex SR Plus 10 mg/5 mg Prolonged-release tablets	Rowex Ltd	PA0711/250/002 Interchangeable List Code: IC0102-016-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE - NALOXONE HYDROCHLORIDE		- Oral use
Dancex SR Plus 20 mg/10 mg Prolonged-release tablets	Rowex Ltd	PA0711/250/003 Interchangeable List Code: IC0102-061-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE - NALOXONE HYDROCHLORIDE		- Oral use
Dancex SR Plus 40 mg/20 mg Prolonged-release tablets	Rowex Ltd	PA0711/250/004 Interchangeable List Code: IC0102-160-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE - NALOXONE HYDROCHLORIDE		- Oral use
Dancex SR Plus 5 mg/2.5 mg Prolonged-release tablets	Rowex Ltd	PA0711/250/001 Interchangeable List Code: IC0102-159-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE - NALOXONE HYDROCHLORIDE		- Oral use
Dantrium 100 mg Capsules	Norgine B.V.	PA1336/004/002	Capsule, hard	- M03CA - M03CA01	- DANTROLENE SODIUM		- Oral use
Dantrium 25 mg Capsules	Norgine B.V.	PA1336/004/001	Capsule, hard	- M03CA - M03CA01	- DANTROLENE SODIUM		- Oral use
Dantrium Intravenous 20 mg powder for solution for injection	Norgine B.V.	PA1336/004/003	Powder for solution for injection	- M03CA - M03CA01	- Dantrolene sodium		- Intravenous use
Dapagliflozin Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/111/002	Film-coated tablet	- A10BK01	- Dapagliflozin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dapagliflozin Krka 5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/111/001	Film-coated tablet	- A10BK01	- Dapagliflozin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dapagliflozin Viatris	Viatris Limited	EU/1/23/1721/001-012	Film-coated tablet	- A10BK01	- Dapagliflozin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dapagliflozin Viatris	Viatris Limited	EU/1/23/1721/013-024	Film-coated tablet	- A10BK01	- Dapagliflozin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Daptomycin 350 mg powder for solution for injection/infusion	hameln pharma gmbh	PA2237/005/001	Powder for solution for injection/infusion	- J01XX09	- Daptomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Daptomycin 350 mg powder for solution for injection/infusion	Reddy Holding GmbH	PA23092/004/001	Powder for solution for injection/infusion	- J01XX09	- Daptomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Daptomycin 500 mg powder for solution for injection/infusion	Reddy Holding GmbH	PA23092/004/002	Powder for solution for injection/infusion	- J01XX09	- Daptomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Daptomycin 500 mg powder for solution for injection/infusion	hameln pharma gmbh	PA2237/005/002	Powder for solution for injection/infusion	- J01XX09	- Daptomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Daptomycin Accord Healthcare 350 mg powder for solution for injection/infusion	Accord Healthcare Ireland Ltd.	PA2315/258/001	Powder for solution for injection/infusion	- J01XX09	- Daptomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Daptomycin Accord Healthcare 500 mg powder for solution for injection/infusion	Accord Healthcare Ireland Ltd.	PA2315/258/002	Powder for solution for injection/infusion	- J01XX09	- Daptomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Daptomycin Accordpharma 350 mg powder for solution for injection/infusion	Accord Healthcare Ireland Ltd.	PA2315/237/001	Powder for solution for injection/infusion	- J01XX - J01XX09	- Daptomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Daptomycin Accordpharma 500 mg powder for solution for injection/infusion	Accord Healthcare Ireland Ltd.	PA2315/237/002	Powder for solution for injection/infusion	- J01XX - J01XX09	- Daptomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Daptomycin Hospira	Pfizer Europe MA EEIG	EU/1/17/1175/001-002	Powder for solution for injection/infusion	- J01XX - J01XX09	- Daptomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Daptomycin Hospira	Pfizer Europe MA EEIG	EU/1/17/1175/003-004	Powder for solution for injection/infusion	- J01XX - J01XX09	- Daptomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Daptomycin Noridem 350 mg Powder for solution for injection/infusion	Noridem Enterprises Limited	PA1122/021/001	Powder for solution for injection/infusion	- J01XX - J01XX09	- Daptomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Daptomycin Noridem 500 mg Powder for solution for injection/infusion	Noridem Enterprises Limited	PA1122/021/002	Powder for solution for injection/infusion	- J01XX - J01XX09	- Daptomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Daptomycin Xellia 350 mg powder for solution for injection/infusion	Xellia Pharmaceuticals ApS	PA1982/003/001	Powder for solution for injection/infusion	- J01XX - J01XX09	- Daptomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Daptomycin Xellia 500 mg powder for solution for injection/infusion	Xellia Pharmaceuticals ApS	PA1982/003/002	Powder for solution for injection/infusion	- J01XX - J01XX09	- Daptomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Darunavir Clonmel 600 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/299/002	Film-coated tablet	- J05AE - J05AE10	- Darunavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Darunavir Clonmel 800 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/299/003	Film-coated tablet	- J05AE - J05AE10	- Darunavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Darunavir Krka	KRKA, d.d., Novo mesto	EU/1/17/1249/001-004	Film-coated tablet	- J05AE - J05AE10	- Darunavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Darunavir Krka	KRKA, d.d., Novo mesto	EU/1/17/1249/005-008	Film-coated tablet	- J05AE - J05AE10	- Darunavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Darunavir Krka	KRKA, d.d., Novo mesto	EU/1/17/1249/009-010	Film-coated tablet	- J05AE - J05AE10	- Darunavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
DARUNAVIR KRKA D.D.	Krka d.d., Novo mesto	EU/1/17/1248/001-004	Film-coated tablet	- J05AE10	- DARUNAVIR	Article 10(1) - Generic Application	- Oral use
DARUNAVIR KRKA D.D.	Krka d.d., Novo mesto	EU/1/17/1248/005-008	Film-coated tablet	- J05AE10	- DARUNAVIR	Article 10(1) - Generic Application	- Oral use
DARUNAVIR KRKA D.D.	Krka d.d., Novo mesto	EU/1/17/1248/009-010	Film-coated tablet	- J05AE10	- DARUNAVIR	Article 10(1) - Generic Application	- Oral use
Darunavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1140/001-005	Film-coated tablet	- J05AE - J05AE10	- Darunavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Darunavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1140/006-011	Film-coated tablet	- J05AE - J05AE10	- Darunavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Darunavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1140/012-021	Film-coated tablet	- J05AE - J05AE10	- Darunavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Darunavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1140/022-029	Film-coated tablet	- J05AE - J05AE10	- Darunavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Darunavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1140/030-038	Film-coated tablet	- J05AE - J05AE10	- Darunavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Darunavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1140/039-045	Film-coated tablet	- J05AE - J05AE10	- Darunavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Darunavir Rowex 800 mg Film-coated tablets	Rowex Ltd	PA0711/269/004	Film-coated tablet	- J05AE - J05AE10	- Darunavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Darzalex	Janssen-Cilag International NV	EU/1/16/1101/001-002	Concentrate for solution for infusion	- L01XC24	- Daratumumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Darzalex	Janssen-Cilag International NV	EU/1/16/1101/004	Solution for injection	- L01XC	- Daratumumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Dasatinib Clonmel 100 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/310/004	Film-coated tablet	- L01EA02	- Dasatinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dasatinib Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/310/001	Film-coated tablet	- L01EA02	- Dasatinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dasatinib Clonmel 50 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/310/002	Film-coated tablet	- L01EA02	- Dasatinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dasatinib Clonmel 70 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/310/003	Film-coated tablet	- L01EA02	- Dasatinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dasatinib Krka 100 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/093/005	Film-coated tablet	- L01XE06	- Dasatinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dasatinib Krka 140 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/093/006	Film-coated tablet	- L01XE06	- Dasatinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dasatinib Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/093/001	Film-coated tablet	- L01XE06	- Dasatinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dasatinib Krka 50 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/093/002	Film-coated tablet	- L01XE06	- Dasatinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dasatinib Krka 70 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/093/003	Film-coated tablet	- L01XE06	- Dasatinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dasatinib Krka 80 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/093/004	Film-coated tablet	- L01XE06	- Dasatinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Dasatinib Teva 100 mg Film-coated Tablets	Teva B.V.	PA1986/066/004	Film-coated tablet	- L01XE06	- Dasatinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dasatinib Teva 20 mg Film-coated Tablets	Teva B.V.	PA1986/066/001	Film-coated tablet	- L01XE06	- Dasatinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dasatinib Teva 50 mg Film-coated Tablets	Teva B.V.	PA1986/066/002	Film-coated tablet	- L01XE06	- Dasatinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dasatinib Teva 70 mg Film-coated Tablets	Teva B.V.	PA1986/066/003	Film-coated tablet	- L01XE06	- Dasatinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dasselta	KRKA, d.d., Novo mesto	EU/1/11/739/001-008	Film-coated tablet	- R06AX - R06AX27	- Desloratidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
DaTSCAN	GE Healthcare B.V.	EU/1/00/135/001	Solution for injection	- V09AB - V09AB03	- Ioflupane		- Intravenous use
Daurismo	Pfizer Europe MA EEIG	EU/1/20/1451/003-004	Film-coated tablet	- L01XX63	- Glasdegib Maleate	Full application (Article 8(3) of Directive No 2001/83/EC)	
Daurismo	Pfizer Europe MA EEIG	EU/1/20/1451/001-002	Film-coated tablet	- L01XX63	- Glasdegib Maleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Daxas	AstraZeneca AB	EU/1/10/636/001-007	Film-coated tablet	- R03DX - R03DX07	- Roflumilast		- Oral use
Daxas	AstraZeneca AB	EU/1/10/636/008	Tablet	- R03DX - R03DX07	- Roflumilast	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
DDAVP/Desmopressin 4 micrograms/ml Solution for Injection	Ferring Ireland Ltd	PA1009/001/002	Solution for injection	- H01BA - H01BA02	- DESMOPRESSIN ACETATE		- Intramuscular use - Intravenous use - Subcutaneous use
Decapeptyl 3-month, 11.25 mg Powder and solvent for suspension for injection	IMED Healthcare Ltd.	PPA1463/126/001	Powder and solvent for suspension for injection	- L02AE04	- Triptorelin	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Intramuscular use
Decapeptyl 3-month, 11.25 mg Powder and solvent for suspension for injection	Originalis B.V.	PPA2306/022/001	Powder and solvent for suspension for injection	- L02AE04	- Triptorelin	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Intramuscular use - Subcutaneous use
Decapeptyl 3-month, 11.25 mg powder and solvent for suspension for injection	PCO Manufacturing Ltd.	PPA0465/261/001	Powder and solvent for suspension for injection	- L02AE04	- Triptorelin	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Intramuscular use - Subcutaneous use
Decapeptyl 3-month, 11.25 mgPowder and solvent for suspension for injection	Ipsen Pharmaceuticals Limited	PA0869/003/002	Powder and solvent for suspension for injection	- L02AE - L02AE04	- Triptorelin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Decapeptyl 6-month 22.5 mg Powder and solvent for prolonged-release suspension for injection	Ipsen Pharmaceuticals Limited	PA0869/003/003	Powder and solvent for prolonged-release suspension for injection	- L02AE - L02AE04	- Triptorelin pamoate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Decapeptyl 6-month 22.5 mg Powder and solvent for prolonged-release suspension for injection	PCO Manufacturing Ltd.	PPA0465/261/002	Powder and solvent for prolonged-release suspension for injection	- L02AE04	- Triptorelin	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Decapeptyl 6-month 22.5 mg Powder and solvent for prolonged-release suspension for injection	IMED Healthcare Ltd.	PPA1463/126/002	Powder and solvent for prolonged-release suspension for injection	- L02AE04	- Triptorelin	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Intramuscular use
Decapeptyl SR, 3 mg powder and solvent for suspension for injection	Ipsen Pharmaceuticals Limited	PA0869/003/001	Powder and solvent for suspension for injection	- L02AE - L02AE04	- Triptorelin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Dectova	GlaxoSmithKline Trading Services Limited	EU/1/18/1349/001	Solution for infusion	- J05AH - J05AH01	- Zanamivir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Deferasirox Accord 180 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/19/1412/005-008 Interchangeable List Code: IC0133-135-003	Film-coated tablet		- Deferasirox	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Deferasirox Accord 360 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/19/1412/009-012 Interchangeable List Code: IC0133-180-003	Film-coated tablet		- Deferasirox	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Deferasirox Accord 90 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/19/1412/001-004 Interchangeable List Code: IC0133-166-003	Film-coated tablet		- Deferasirox	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Deferasirox Mylan 180 mg film-coated tablets	Mylan Pharmaceuticals Limited	EU/1/19/1386/006-010 Interchangeable List Code: IC0133-135-003	Film-coated tablet		- Deferasirox	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Deferasirox Mylan 360 mg film-coated tablets	Mylan Pharmaceuticals Limited	EU/1/19/1386/011-016 Interchangeable List Code: IC0133-180-003	Film-coated tablet		- Deferasirox	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Deferasirox Mylan 90 mg film-coated tablets	Mylan Pharmaceuticals Limited	EU/1/19/1386/001-005 Interchangeable List Code: IC0133-166-003	Film-coated tablet		- Deferasirox	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Deferasirox Pharmathen 180 mg film-coated tablets	Pharmathen S.A.	PA1368/021/002 Interchangeable List Code: IC0133-135-003	Film-coated tablet		- Deferasirox	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Deferasirox Pharmathen 360 mg film-coated tablets	Pharmathen S.A.	PA1368/021/003 Interchangeable List Code: IC0133-180-003	Film-coated tablet		- Deferasirox	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Deferasirox Pharmathen 90 mg film-coated tablets	Pharmathen S.A.	PA1368/021/001 Interchangeable List Code: IC0133-166-003	Film-coated tablet		- Deferasirox	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Deferiprone Lipomed	Lipomed GmbH	EU/1/18/1310/001	Film-coated tablet	- V03AC02	- Deferiprone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Defitelio	Gentium S.p.A.	EU/01/13/878/001	Concentrate for solution for infusion	- B01AX - B01AX01	- Defibrotide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Degarelix Accord	Accord Healthcare S.L.U.	EU/1/23/1753/001-002	Powder and solvent for solution for injection	- L02BX02	- Degarelix Acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Degarelix Accord	Accord Healthcare S.L.U.	EU/1/23/1753/003	Powder and solvent for solution for injection	- L02BX02	- Degarelix Acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Delstrigo	Merck Sharp & Dohme BV,	EU/1/18/1333/001-002	Film-coated tablet	- J05AR24	- Doravirine - Lamivudine - Tenofovir disoproxil fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
DELTACORTRIL ENTERIC 2.5 mg gastro-resistant tablets	Phoenix Labs	PA1113/003/002	Gastro-resistant tablet	- H02AB - H02AB06	- Prednisolone	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
DELTACORTRIL ENTERIC 5 mg gastro-resistant tablets	Phoenix Labs	PA1113/003/001	Gastro-resistant tablet	- H02AB - H02AB06	- Prednisolone		- Oral use
Deltyba	Otsuka Novel Products GmbH	EU/1/13/875/001-003	Film-coated tablet	- J04AK - J04AK06	- Delamanid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Deltyba	Otsuka Novel Products GmbH	EU/1/13/875/005	Dispersible tablet	- J04AK06	- Delamanid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda	Takeda GmbH	EU/1/22/1699/001	Powder and solvent for solution for injection	- J07BX04	- Dengue virus serotype 1# (live, attenuated) - Dengue virus, serotype 2, live, attenuated - Dengue virus serotype 3# (live, attenuated) - Dengue virus serotype 4# (live, attenuated)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda	Takeda GmbH	EU/1/22/1699/002	Powder and solvent for solution for injection	- J07BX04	- Dengue virus serotype 1# (live, attenuated) - Dengue virus, serotype 2, live, attenuated - Dengue virus serotype 3# (live, attenuated) - Dengue virus serotype 4# (live, attenuated)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda	Takeda GmbH	EU/1/22/1699/003	Powder and solvent for solution for injection	- J07BX04	- Dengue virus serotype 1# (live, attenuated) - Dengue virus, serotype 2, live, attenuated - Dengue virus serotype 3# (live, attenuated) - Dengue virus serotype 4# (live, attenuated)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda	Takeda GmbH	EU/1/22/1699/004	Powder and solvent for solution for injection	- J07BX04	- Dengue virus serotype 1# (live, attenuated) - Dengue virus, serotype 2, live, attenuated - Dengue virus serotype 3# (live, attenuated) - Dengue virus serotype 4# (live, attenuated)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Dengvaxia	Sanofi Pasteur	EU/1/18/1338/001-0005	Powder and solvent for suspension for injection	- J07BX	- Live, attenuated, chimeric dengue virus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Dentinox Cradle Cap Treatment Shampoo, Sodium lauryl ether sulpho-succinate 6% w/w, Sodium lauryl ether sulphate 2.7% w/w	Phoenix Labs	PA1113/020/001	Shampoo	- D11AX	- Sodium laurylether sulfate - Sodium lauryl ether sulfo succinate	Competence of personnel (Article 23 of Directive No 2010/63/EU)	- Topical
Dentinox Infant Colic Drops 21 mg/2.5 ml Oral Suspension	Phoenix Labs	PA1113/021/001	Oral suspension	- A03AX - A03AX13	- Dimeticone, activated		- Oral use
Denzapine 100 mg Tablets	Clonmel Healthcare Ltd	PA0126/235/002	Tablet	- N05AH - N05AH02	- Clozapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Not Currently Available - Oral use
Denzapine 200 mg Tablets	Clonmel Healthcare Ltd	PA0126/235/004	Tablet	- N05AH - N05AH02	- Clozapine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Denzapine 25 mg Tablets	Clonmel Healthcare Ltd	PA0126/235/001	Tablet	- N05AH - N05AH02	- Clozapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Not Currently Available - Oral use
Denzapine 50 mg Tablets	Clonmel Healthcare Ltd	PA0126/235/003	Tablet	- N05AH - N05AH02	- Clozapine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Denzapine 50 mg/ml Oral Suspension	Clonmel Healthcare Ltd	PA0126/235/005	Oral suspension	- N05AH - N05AH02	- Clozapine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Depixol 20mg/ml Solution for Injection	Lundbeck (Ireland) Limited	PA0776/003/001	Solution for injection	- N05AF - N05AF01	- FLUPENTIXOL DECANOATE		- Subcutaneous use
Depixol Conc. 100mg/ml Solution for Injection	Lundbeck (Ireland) Limited	PA0776/003/002	Solution for injection	- N05AF - N05AF01	- FLUPENTIXOL DECANOATE		- Subcutaneous use
Depo-Medrone 40 mg/ml Suspension for Injection 1 ml vial	Pfizer Healthcare Ireland	PA0822/122/001	Suspension for injection	- H02AB - H02AB04	- Methylprednisolone acetate		- Not Currently Available
Depo-Medrone 40 mg/ml Suspension for Injection 2 ml vial	Pfizer Healthcare Ireland	PA0822/122/002	Suspension for injection	- H02AB - H02AB04	- Methylprednisolone acetate		- Not Currently Available
Depo-Medrone 40 mg/ml Suspension for Injection 3 ml vial	Pfizer Healthcare Ireland	PA0822/122/003	Suspension for injection	- H02AB - H02AB04	- Methylprednisolone acetate		- Not Currently Available
Depo-Medrone 40mg/ml with Lidocaine 10mg/ml Suspension for Injection, 2ml vial	Pfizer Healthcare Ireland	PA0822/123/002	Suspension for injection	- H02AB - H02AB04	- Methylprednisolone acetate - Lidocaine hydrochloride		- Not Currently Available
Depo-Provera 150 mg/ml Suspension for Injection	Pfizer Healthcare Ireland	PA0822/124/001	Suspension for injection	- G03AC - G03AC06	- Medroxyprogesterone acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Depreger 100 mg film-coated tablet	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/067/002 Interchangeable List Code: IC0064-024-003	Film-coated tablet		- Sertraline		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Depreger 50 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/067/001 Interchangeable List Code: IC0064-023-003	Film-coated tablet		- Sertraline		- Oral use
Derbac M Liquid 0.5% w/w cutaneous emulsion	LanesHealth (Ireland) Limited	PA22702/001/001	Cutaneous emulsion	- P03AX - P03AX03	- Malathion	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical use
DERMATRANS 10 mg/24 h transdermal patch	Rottapharm Ltd	PA0868/006/002	Transdermal patch	- C01DA - C01DA02	- Glyceryl trinitrate		- Transdermal use
DERMATRANS 15 mg/24 h transdermal patch	Rottapharm Ltd	PA0868/006/003	Transdermal patch	- C01DA - C01DA02	- Glyceryl trinitrate		- Transdermal use
DERMATRANS 5 mg/24 h transdermal patch	Rottapharm Ltd	PA0868/006/001	Transdermal patch	- C01DA - C01DA02	- Glyceryl trinitrate		- Transdermal use
Dermovate 0.05 % w/w Ointment	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/005/001	Ointment	- D07AD - D07AD01	- Clobetasol propionate		- Topical use
Dermovate 0.05% w/w Cream	GlaxoSmithKline (Ireland) Limited	PA1077/005/001	Cream	- D07AD - D07AD01	- Clobetasol propionate		- Topical use
Dermovate 0.05% w/w Ointment	GlaxoSmithKline (Ireland) Limited	PA1077/005/002	Ointment	- D07AD - D07AD01	- Clobetasol propionate		- Topical use
Dermovate Scalp Application 0.05% w/v Cutaneous Solution	GlaxoSmithKline (Ireland) Limited	PA1077/005/003	Cutaneous solution	- D07AD - D07AD01	- Clobetasol propionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Dermovate Scalp Application 0.05% w/v cutaneous solution	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/005/002	Cutaneous solution	- D07AD01	- Clobetasol propionate		- Topical use
Descovy	Gilead Sciences Ireland UC	EU/1/16/1099/001-002	Film-coated tablet	- J05AR - J05AR17	- Emtricitabine - Tenofovir alafenamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Descovy	Gilead Sciences Ireland UC	EU/1/16/1099/003-004	Film-coated tablet	- J05AR - J05AR17	- Emtricitabine - Tenofovir alafenamide	Full application (Article 8(3) of Directive No 2001/83/EC)	
Desenex Ointment Zinc Undecylenate 20% w/w Undecylenic Acid 5% w/w	Clonmel Healthcare Ltd	PA0126/154/001	Ointment	- D01AE - D01AE04	- Zinc undecylenate - Undecylenic acid		- Topical use
Desenex Powder Zinc undecylenate 20% w/w Undecylenic Acid 2.0% w/w	Clonmel Healthcare Ltd	PA0126/154/002	Cutaneous powder	- D01AE - D01AE04	- Zinc undecylenate - Undecylenic acid		- Topical use
Desferal 500mg Vials Powder for Solution for Injection or Powder for Concentrate for Solution for Infusion	Novartis Ireland Limited	PA0896/008/001	Powder for solution for injection/infusion	- V03AC - V03AC01	- Deferoxamine mesilate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Deslor 0.5 mg/ml Oral Solution	Rowex Ltd	PA0711/202/002	Oral solution	- R06AX - R06AX27	- Desloratidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Deslor 5 mg Film-Coated Tablets	Rowex Ltd	PA0711/202/001	Film-coated tablet	- R06AX - R06AX27	- Desloratidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Desloratadine	Actavis Group hf	EU/1/11/745/001-009	Film-coated tablet	- R06AX - R06AX27	- Desloratidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
DESLORATADINE	Ratiopharm GmbH	EU/1/11/746/001-012	Film Coated Tablet	- R06AX27	- DESLORATIDINE	Article 10(1) - Generic Application	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Desloratadine 5mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/016/001	Film-coated tablet	- R06AX - R06AX27	- Desloratidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Desloratadine Glenmark 5 mg Tablets	Glenmark Arzneimittel GmbH	PA22645/004/001	Tablet	- R06AX - R06AX27	- Desloratidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Desloratadine ratiopharm	Ratiopharm GmbH	EU/1/11/746/001-011	Film-coated tablet	- R06AX27	- DESLORATADINE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Desloratadine Teva	Teva B.V.	EU/1/11/732/001-013	Film-coated tablet	- R06AX - R06AX27	- Desloratidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Desmospray, Desmopressin Nasal Spray	Ferring Ireland Ltd	PA1009/005/001	Nasal spray, solution	- H01BA - H01BA02	- DESMOPRESSIN ACETATE		- Nasal use
Desmotabs Melt 120 micrograms oral lyophilisate	Ferring Ireland Ltd	PA1009/007/003	Oral lyophilisate	- H01BA - H01BA02	- DESMOPRESSIN ACETATE		- Oral use
Desmotabs Melt 120 micrograms oral lyophilisate	IMED Healthcare Ltd.	PPA1463/174/001	Oral lyophilisate	- H01BA - H01BA02	- DESMOPRESSIN ACETATE	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Sublingual use
Desmotabs Melt 120 micrograms oral lyophilisate	PCO Manufacturing Ltd.	PPA0465/260/001	Oral lyophilisate	- H01BA - H01BA02	- Desmopressin		- Sublingual use
Desmotabs Melt 240 micrograms oral lyophilisate	Ferring Ireland Ltd	PA1009/007/004	Oral lyophilisate	- H01BA - H01BA02	- DESMOPRESSIN ACETATE		- Oral use
Desmotabs Melt 60 micrograms oral lyophilisate	Ferring Ireland Ltd	PA1009/007/002	Oral lyophilisate	- H01BA - H01BA02	- DESMOPRESSIN ACETATE		- Oral use
Desogestrel Rowex 75 microgram Film-coated Tablets	Rowex Ltd	PA0711/243/001	Film-coated tablet	- G03AC - G03AC09	- Desogestrel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Desunin 10 000 IU soft capsules	Viatris Limited	PA23266/005/001	Capsule, soft	- A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Desunin 1000 IU Tablets	Viatris Healthcare Limited	PA23355/009/002	Tablet	- A11C	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Desunin 2000 IU Tablets	Viatris Healthcare Limited	PA23355/009/003	Tablet	- A11C	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Desunin 25,000 IU soft capsules	Viatris Limited	PA23266/005/002	Capsule, soft	- A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Desunin 4000 IU Tablets	Viatris Healthcare Limited	PA23355/009/004	Tablet	- A11C	- Colecalciferol concentrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Desunin 800 IU Tablets	Viatris Healthcare Limited	PA23355/009/001	Tablet	- A11CC - A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Detrunorm 15 mg Film-coated Tablets	Apogepha Arzneimittel GmbH	PA0803/004/001	Film-coated tablet	- G04BD - G04BD06	- Propiverine hydrochloride		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Detrunorm XL 30 mg Modified-Release Capsules	Consilient Health Limited	PA1876/009/001	Modified-release capsule, hard	- G04BD - G04BD06	- Propiverine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Detrunorm XL 45 mg Modified-Release Capsules	Consilient Health Limited	PA1876/009/002	Modified-release capsule, hard	- G04BD - G04BD06	- Propiverine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Detrusitol 1 mg film-coated tablets	Upjohn EESV	PA23055/014/001 Interchangeable List Code: IC0025-039-003	Film-coated tablet		- Tolterodine tartrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Detrusitol 2 mg film-coated tablets	Upjohn EESV	PA23055/014/002 Interchangeable List Code: IC0025-006-003	Film-coated tablet		- Tolterodine tartrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Detrusitol SR 2 mg, prolonged-release capsules, hard	Upjohn EESV	PA23055/007/001 Interchangeable List Code: IC0025-006-032	Prolonged-release capsule, hard		- Tolterodine tartrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Detrusitol SR 4 mg, prolonged-release capsules, hard	Upjohn EESV	PA23055/007/002 Interchangeable List Code: IC0025-008-032	Prolonged-release capsule, hard		- Tolterodine tartrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Dettol Antiseptic Disinfectant 4.8% w/v, concentrate for cutaneous solution	Reckitt Benckiser Ireland Ltd	PA0979/004/002	Concentrate for cutaneous solution	- D08AE - D08AE05	- Chloroxylenol		- Topical use
Dexafree 1 mg/ml eye drops, solution in single dose container	IMED Healthcare Ltd.	PPA1463/193/001	Eye drops, solution	- S01BA - S01BA01	- DEXAMETHASONE PHOSPHATE		- Ocular use
Dexafree 1mg/ml eye drops, solution in single dose container	Laboratoires Thea	PA1107/005/001	Eye drops, solution in single-dose container	- S01BA - S01BA01	- DEXAMETHASONE PHOSPHATE	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Ocular use
Dexamethasone 10mg/5ml Oral Solution	Taw Pharma (Ireland) Limited	PA23081/007/001	Oral solution	- H02AB - H02AB02	- Dexamethasone sodium phosphate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dexamethasone 2mg Tablets	Aspen Pharma Trading Limited	PA1691/014/001	Tablet	- H02AB - H02AB02	- Dexamethasone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Not Currently Available
Dexamethasone Activase 0.5 mg Tablets	Activase Pharmaceuticals Limited	PA1567/002/001	Tablet	- H02AB02	- Dexamethasone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Dexamethasone Activase 2 mg Tablets	Activase Pharmaceuticals Limited	PA1567/002/002	Tablet	- H02AB02	- Dexamethasone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Dexamethasone Phosphate 1mg/ml (as sodium phosphate) Eye Drops Solution in a single dose container	Wockhardt UK Limited	PA1339/052/001	Eye drops, solution in single-dose container	- S01BA - S01BA01	- DEXAMETHASONE PHOSPHATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Dexamethasone Phosphate 4 mg/ml Solution for Injection	Pfizer Healthcare Ireland	PA0822/201/001	Solution for injection	- H02AB - H02AB02	- Dexamethasone sodium phosphate		- Intravenous use
Dexamethasone Phosphate 4 mg/ml solution for injection	hameln pharma gmbh	PA2237/004/001	Solution for injection	- H02AB02	- Dexamethasone sodium phosphate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intraarticular use - Intrabursal use - Intralesional use - Intramuscular use - Intravenous use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Dexamethasone phosphate 4 mg/ml solution for injection	Fresenius Kabi Deutschland GmbH	PA2059/077/001	Solution for injection	- H02AB02	- Dexamethasone sodium phosphate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Infiltration - Intraarticular use - Intrabursal use - Intramuscular use - Intravenous use
Dexamethasone phosphate 4 mg/ml solution for injection/infusion	AS Kalceks	PA2165/014/001	Solution for injection/infusion	- H02AB02	- Dexamethasone sodium phosphate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Infiltration - Intraarticular use - Intramuscular use - Intravenous use - Subconjunctival use
Dexamethasone phosphate 4mg/ml Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/237/002	Solution for injection/infusion	- H02AB - H02AB02	- Dexamethasone sodium phosphate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Dexamethasone Phosphate Krka 4 mg/ml solution for injection/infusion	KRKA, d.d., Novo mesto	PA1347/091/001	Solution for injection/infusion	- H02AB - H02AB02	- Dexamethasone sodium phosphate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Dexamethasone phosphate Noridem 4 mg/mL Solution for injection	Noridem Enterprises Limited	PA1122/020/001	Solution for injection	- H02AB02	- Dexamethasone sodium phosphate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intraarticular use - Intralesional use - Intramuscular use - Intravenous use - Subcutaneous use
Dexamethasone phosphate Teva 4 mg/ml solution for injection	Teva B.V.	PA1986/105/001	Solution for injection	- H02AB02	- Dexamethasone sodium phosphate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Infiltration - Intraarticular use - Intramuscular use - Intravenous use - Subconjunctival use
Dexdor	Orion Corporation	EU/1/11/718/001-006	Concentrate for solution for infusion	- N05CM - N05CM18	- Dexmedetomidine hydrochloride		- Intravenous use
Dexeta 1.37 mg/ml eye drops, solution in single dose container	SIFI S.p.A.	PA23335/001/001	Eye drops, solution in single-dose container	- S01BA01	- DEXAMETHASONE PHOSPHATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Deximune 100 mg Soft Capsules	Dexcel Pharma GmbH	PA2261/001/003	Capsule, soft	- L04AD - L04AD01	- Ciclosporin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Deximune 25 mg Soft Capsules	Dexcel Pharma GmbH	PA2261/001/001	Capsule, soft	- L04AD - L04AD01	- Ciclosporin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Deximune 50 mg soft capsules	Dexcel Pharma GmbH	PA2261/001/002	Capsule, soft	- L04AD - L04AD01	- Ciclosporin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Dexliq 4 mg/ml Oral Solution	Laboratoires CTRS	PA2137/001/001	Oral solution	- H02AB - H02AB02	- Dexamethasone sodium phosphate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion	AS Kalceks	PA2165/010/001	Concentrate for solution for infusion	- N05CM18	- Dexmedetomidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion	Baxter Holding B.V.	PA2299/050/001	Concentrate for solution for infusion	- N05CM18	- Dexmedetomidine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Dexmedetomidine Accord	Accord Healthcare S.L.U.	EU/1/19/1418/001-010	Concentrate for solution for infusion	- N05CM18	- Dexmedetomidine hydrochloride - Dexmedetomidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Dexmedetomidine B. Braun 100 micrograms/ml concentrate for solution for infusion	B. Braun Melsungen AG	PA0736/042/001	Concentrate for solution for infusion	- N05CM18	- Dexmedetomidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Dexmedetomidine EVER Pharma 100 micrograms/ml concentrate for solution for infusion	EVER Valinject GmbH	PA1774/002/001	Concentrate for solution for infusion	- N05CM - N05CM18	- Dexmedetomidine hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Dexmedetomidine Kabi 100 micrograms/mL concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/076/001	Concentrate for solution for infusion	- N05CM18	- Dexmedetomidine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Dexsol 2 mg/ 5 ml Oral Solution	Taw Pharma (Ireland) Limited	PA23081/006/001	Oral solution	- H02AB - H02AB02	- Dexamethasone sodium phosphate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Diabact UBT 50 mg tablets	Laboratoires Mayoly Spindler	PA1993/004/001	Tablet	- V04CX	- 13c-urea		- Oral use
Diabrezide 80 mg tablets	L. Molteni & C. dei F.lli Alitti	PA0925/001/001	Tablet	- A10BB - A10BB09	- Gliclazide		- Oral use
Diaclide MR 30 mg modified-release tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/030/002 Interchangeable List Code: IC0086-033-050	Modified-release tablet		- Gliclazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Diaclide MR 60 mg modified-release tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/030/003 Interchangeable List Code: IC0086-127-050	Modified-release tablet		- Gliclazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Diacomit	Biocodex	EU/1/06/367/001-3	Capsule, hard	- N03AX - N03AX17	- Stiripentol		
Diacomit	Biocodex	EU/1/06/367/013	Capsule, hard	- N03AX17	- Stiripentol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Diacomit	Biocodex	EU/1/06/367/10-12	Powder for oral suspension in sachet	- N03AX - N03AX17	- Stiripentol		
Diacomit	Biocodex	EU/1/06/367/4-6	Capsule, hard	- N03AX - N03AX17	- Stiripentol		
Diacomit	Biocodex	EU/1/06/367/7-9	Powder for oral suspension in sachet	- N03AX - N03AX17	- Stiripentol		- Oral use
Diacronal MR 30 mg modified-release tablets	KRKA, d.d., Novo mesto	PA1347/024/002 Interchangeable List Code: IC0086-033-050	Modified-release tablet		- Gliclazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Diacronal MR 60 mg modified-release tablets	KRKA, d.d., Novo mesto	PA1347/024/001 Interchangeable List Code: IC0086-127-050	Modified-release tablet		- Gliclazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Diafer 50 mg/ml solution for injection	Pharmacosmos A/S	PA0982/004/001	Solution for injection	- B03AC	- IRON (III)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Diaglyc 30 mg modified-release tablets	Teva Pharma B.V.	PA0749/076/001 Interchangeable List Code: IC0086-033-050	Modified-release tablet		- Gliclazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Diamicron MR 30 mg modified-release tablets	Les Laboratoires Servier	PA0568/013/001 Interchangeable List Code: IC0086-033-050	Modified-release tablet		- Gliclazide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
DIAMICRON MR 60 mg modified-release tablets	Les Laboratoires Servier	PA0568/013/002 Interchangeable List Code: IC0086-127-050	Modified-release tablet		- Gliclazide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Diamox 250 mg Tablets	Amdipharm Limited	PA1142/020/003	Tablet	- S01EC - S01EC01	- Acetazolamide		- Oral use
Diamox SR 250mg Modified Release Hard Capsules	Amdipharm Limited	PA1142/020/001	Modified-release capsule, hard	- S01EC - S01EC01	- Acetazolamide		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Dianeal PD4 Glucose 1.36 % w/v (13.6 mg/ml), Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/015/001	Solution for peritoneal dialysis	- B05DB	- Sodium chloride - Sodium lactate - Calcium chloride dihydrate ph. eur. - Magnesium chloride hexahydrate - Glucose anhydrous - Glucose monohydrate		- Intraperitoneal use
Dianeal PD4 Glucose 2.27 % w/v (22.7 mg/ml), Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/015/002	Solution for peritoneal dialysis	- B05DB	- Sodium chloride - Sodium lactate - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Glucose anhydrous - Glucose monohydrate		- Intraperitoneal use
Dianeal PD4 Glucose 3.86 % w/v (38.6 mg/ml), Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/015/003	Solution for peritoneal dialysis	- B05DB	- Glucose anhydrous - Glucose monohydrate - Sodium chloride - Sodium lactate - Calcium chloride dihydrate - Magnesium chloride hexahydrate		- Intraperitoneal use
Dianette 2 mg/35 microgram coated tablets	IMED Healthcare Ltd.	PPA1463/164/001	Coated tablet	- G03HB - G03HB01	- Cyproterone acetate - Ethinylestradiol		- Oral use
Dianette 2 mg/35 microgram coated tablets	PCO Manufacturing Ltd.	PPA0465/050/001	Coated tablet	- G03HB - G03HB01	- Cyproterone acetate - Ethinylestradiol		- Oral use
Dianette 2 mg/35 microgram coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/033/001	Coated tablet	- G03HB01	- Cyproterone acetate - Ethinylestradiol		- Oral use
Dianette 2mg/35 microgram coated tablets	Bayer Limited	PA1410/003/001	Coated tablet	- G03HB - G03HB01	- Cyproterone acetate - Ethinylestradiol ph.eur.	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Diazemuls Emulsion for Injection 5 mg/ml	Accord Healthcare Ireland Ltd.	PA2315/098/001	Emulsion for injection	- N05BA - N05BA01	- Diazepam		- Intravenous use
Diazepam 10mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/199/002	Tablet	- N05BA - N05BA01	- Diazepam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Diazepam 5mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/199/001	Tablet	- N05BA - N05BA01	- Diazepam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Diclac 1% w/w Gel	Rowex Ltd	PA0711/009/002 Interchangeable List Code: IC0056-115-043	Gel		- Diclofenac sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Cutaneous use
Diclac 100mg Suppositories	Rowex Ltd	PA0711/009/009 Interchangeable List Code: IC0056-024-046	Suppository		- Diclofenac sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Rectal use
Diclac 25 mg/ml Solution for Injection 3 ml Ampoule	Rowex Ltd	PA0711/009/010	Solution for injection	- M01AB - M01AB05	- Diclofenac sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Diclac 50 mg Gastro-resistant Tablets	Rowex Ltd	PA0711/009/008 Interchangeable List Code: IC0056-023-016	Gastro-resistant tablet		- Diclofenac sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Diclac 75 mg Prolonged-release Tablet	Rowex Ltd	PA0711/009/003 Interchangeable List Code: IC0056-028-024	Prolonged-release tablet		- Diclofenac sodium		- Oral use
Diclac Relief 1% w/w Gel	Rowex Ltd	PA0711/009/005	Gel	- M02AA - M02AA15	- Diclofenac sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Topical
Diclac Retard 100 mg Prolonged-release Tablets	Rowex Ltd	PA0711/009/006 Interchangeable List Code: IC0056-024-024	Prolonged-release tablet		- Diclofenac sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Diclo 75mg prolonged release tablets	Pinewood Laboratories Ltd	PA0281/106/001 Interchangeable List Code: IC0056-028-024	Prolonged-release tablet		- Diclofenac sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Diclofenac 140 mg medicated plaster	IBSA Farmaceutici Italia S.r.l	PA1104/005/001	Medicated plaster	- M02AA15	- Diclofenac epolamine	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Cutaneous use
Diclofenac Liderlens 40 mg/ml cutaneous spray solution	Nutra Essential Otc S.L.	PA23205/001/001	Cutaneous spray, solution	- M02AA15	- Diclofenac sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Diclomel Max Strength 2% w/w gel	Clonmel Healthcare Ltd	PA0126/372/001	Gel	- M02AA15	- Diclofenac sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Dicycloverine hydrochloride 10mg/5ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/008/001	Oral solution	- A03AA - A03AA07	- Dicycloverine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dienogest Stragen 2 mg film-coated tablets	G&G Pharmaceutical (Netherlands) B.V.	PA23029/001/001	Film-coated tablet	- G03DB - G03DB08	- Dienogest	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Difene 1% w/w Gel	Glenwood GmbH	PA2256/001/005 Interchangeable List Code: IC0056-115-043	Gel		- Diclofenac sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Cutaneous use
Difene 100 mg Dual Release Capsules	Glenwood GmbH	PA2256/001/004	Modified-release capsule, hard	- M01AB - M01AB05	- Diclofenac sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Difene 100mg Suppositories	Glenwood GmbH	PA2256/001/006 Interchangeable List Code: IC0056-024-046	Suppository		- Diclofenac sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Rectal use
Difene 25mg Capsules	Glenwood GmbH	PA2256/001/001	Gastro-resistant capsule, hard	- M01AB - M01AB05	- Diclofenac sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Difene 50mg Capsules	Glenwood GmbH	PA2256/001/002 Interchangeable List Code: IC0056-023-016	Gastro-resistant capsule, hard		- Diclofenac sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Difene 75 mg Dual Release Capsules	Glenwood GmbH	PA2256/001/003	Modified-release capsule, hard	- M01AB - M01AB05	- Diclofenac sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Difene Spray Gel 4% w/w Cutaneous Spray, Solution	Glenwood GmbH	PA2256/001/007	Cutaneous spray, solution	- M02AA - M02AA15	- Diclofenac sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Differin 0.1% w/w Cream	Galderma International	PA22743/005/001	Cream	- D10AD - D10AD03	- Adapalene	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use - Topical
Differin 0.1% w/w Cream	PCO Manufacturing Ltd.	PPA0465/437/002	Cream	- D10AD - D10AD03	- Adapalene		- Cutaneous use - Topical

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Differin 0.1% w/w cream	IMED Healthcare Ltd.	PPA1463/120/001	Cream	- D10AD - D10AD03	- Adapalene		- Cutaneous use
Differin 0.1% w/w gel	IMED Healthcare Ltd.	PPA1463/120/002	Gel	- D10AD - D10AD03	- Adapalene		- Cutaneous use
Differin 0.1% w/w gel	PCO Manufacturing Ltd.	PPA0465/437/001	Gel	- D10AD - D10AD03	- Adapalene		- Cutaneous use
Differin 0.1% w/w Gel	Galderma International	PA22743/005/002	Gel	- D10AD - D10AD03	- Adapalene	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Difflam Oral Rinse 0.15% w/v, gargle	Mylan IRE Healthcare Limited	PA2010/030/002	Gargle	- A01AD - A01AD02	- BENZYDAMINE HYDROCHLORIDE		- Oral use
Difflam Spray, 0.15% w/v, Oromucosal Spray	Mylan IRE Healthcare Limited	PA2010/030/003	Oromucosal spray	- A01AD - A01AD02	- BENZYDAMINE HYDROCHLORIDE		- Not Currently Available
Dificlir	Tillotts Pharma GmbH	EU/1/11/733/001-004	Film-coated tablet	- A07AA - A07AA12	- Fidaxomicin		- Oral use
Dificlir	Tillotts Pharma GmbH	EU/1/11/733/005	Granules for oral suspension	- A07AA12	- Fidaxomicin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Diflucan 10 mg/ml powder for oral suspension	Pfizer Healthcare Ireland	PA0822/211/006	Powder for oral suspension	- J02AC - J02AC01	- Fluconazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Diflucan 150 mg hard capsules	Pfizer Healthcare Ireland	PA0822/211/002	Capsule, hard	- J02AC - J02AC01	- Fluconazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Diflucan 2 mg/ml solution for infusion	Pfizer Healthcare Ireland	PA0822/211/004	Solution for infusion	- J02AC - J02AC01	- Fluconazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Oral use
Diflucan 2 mg/ml solution for infusion	Pfizer Healthcare Ireland	PA0822/211/005	Solution for infusion	- J02AC - J02AC01	- Fluconazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Oral use
Diflucan 200 mg hard capsules	Pfizer Healthcare Ireland	PA0822/211/003	Capsule, hard	- J02AC - J02AC01	- Fluconazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Oral use
Diflucan 40 mg/ml powder for oral suspension	Pfizer Healthcare Ireland	PA0822/211/007	Powder for oral suspension	- J02AC - J02AC01	- Fluconazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Diflucan 50 mg hard capsules	Pfizer Healthcare Ireland	PA0822/211/001	Capsule, hard	- J02AC - J02AC01	- Fluconazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Digestisan oral drops	A.Vogel Ireland Limited	TR2309/007/001	Oral drops, solution			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Dilacort 2.5 mg gastro-resistant tablets	Crescent Pharma International Limited	PA22699/001/001	Gastro-resistant tablet	- H02AB - H02AB06	- Prednisolone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dilacort 5 mg gastro-resistant tablets	Crescent Pharma International Limited	PA22699/001/002	Gastro-resistant tablet	- H02AB - H02AB06	- Prednisolone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dimethyl fumarate Accord	Accord Healthcare S.L.U.	EU/1/22/1711/001	Gastro-resistant capsule, hard	- L04AX07	- Dimethyl Fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dimethyl fumarate Accord	Accord Healthcare S.L.U.	EU/1/22/1711/002-003	Gastro-resistant capsule, hard	- L04AX07	- Dimethyl Fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Dimethyl Fumarate Mylan	Mylan IRE Healthcare Limited	EU/1/22/1634/001-0004	Gastro-resistant capsule, hard	- L04AX07	- Dimethyl Fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dimethyl Fumarate Mylan	Mylan IRE Healthcare Limited	EU/1/22/1634/005-010	Gastro-resistant capsule, hard	- L04AX07	- Dimethyl Fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dimethyl Fumarate Polpharma	Zaklady Farmaceutyczne POLPHARMA S.A.	EU/1/22/1635/001-002	Gastro-resistant capsule, hard	- L04AX07	- Dimethyl Fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dimethyl Fumarate Polpharma	Zaklady Farmaceutyczne POLPHARMA S.A.	EU/1/22/1635/003-004	Gastro-resistant capsule, hard	- L04AX07	- Dimethyl Fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dimethyl fumarate Teva	TEVA GmbH	EU/1/22/1702/001-003	Gastro-resistant capsule, hard	- L04AX07	- Dimethyl Fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dimethyl fumarate Teva	TEVA GmbH	EU/1/22/1702/004-008	Gastro-resistant capsule, hard	- L04AX07	- Dimethyl Fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dimethyl Fumurate Neuraxpharm	Laboratorios Lesvi, S.L.	EU/1/22/1637/001-002	Gastro-resistant capsule, hard	- L04AX07	- Dimethyl Fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dimethyl Fumurate Neuraxpharm	Laboratorios Lesvi, S.L.	EU/1/22/1637/003-005	Gastro-resistant capsule, hard	- L04AX07	- Dimethyl Fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dioralyte Blackcurrant Powder for Oral Solution	Phoenix Labs	PA1113/025/001	Powder for oral solution	- A07CA	- Sodium chloride - Potassium chloride - Glucose - Disodium hydrogen citrate		- Oral use
Dioralyte Citrus Powder for Oral Solution	Phoenix Labs	PA1113/025/002	Powder for oral solution	- A07CA	- Glucose - Sodium chloride - Disodium hydrogen citrate - Potassium chloride		- Oral use
Dioralyte Natural, Powder for oral solution	Phoenix Labs	PA1113/026/001	Powder for oral solution	- A07CA	- Glucose - Sodium chloride - Potassium chloride - Disodium hydrogen citrate		- Oral use
Dioralyte Rebalance Blackcurrant Powder for Oral Solution	Phoenix Labs	PA1113/028/001	Powder for oral solution	- A07CA	- Sodium chloride - Potassium chloride - Glucose - Disodium hydrogen citrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Dioralyte Rebalance Citrus Powder for Oral Solution	Phoenix Labs	PA1113/028/002	Powder for oral solution	- A07CA	- Sodium chloride - Potassium chloride - Glucose - Disodium hydrogen citrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Dioralyte Rebalance Natural Powder for Oral Solution	Phoenix Labs	PA1113/028/003	Powder for oral solution	- A07CA	- Sodium chloride - Potassium chloride - Glucose - Disodium hydrogen citrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Diovan 160 mg film-coated tablets	Novartis Ireland Limited	PA0896/009/002 Interchangeable List Code: IC0038-082-003	Film-coated tablet		- Valsartan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Diovan 160 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/461/001 Interchangeable List Code: IC0038-082-003	Film-coated tablet		- Valsartan		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Diovan 320 mg film-coated tablets	Novartis Ireland Limited	PA0896/009/004 Interchangeable List Code: IC0038-083-003	Film-coated tablet		- Valsartan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Diovan 3mg/ml oral solution	Novartis Ireland Limited	PA0896/009/005	Oral solution	- C09CA - C09CA03	- Valsartan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Diovan 40 mg film-coated tablets	Novartis Ireland Limited	PA0896/009/003 Interchangeable List Code: IC0038-004-003	Film-coated tablet		- Valsartan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Diovan 80 mg film-coated tablets	Novartis Ireland Limited	PA0896/009/001 Interchangeable List Code: IC0038-005-003	Film-coated tablet		- Valsartan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Diovan 80 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/461/002 Interchangeable List Code: IC0038-005-003	Film-coated tablet		- Valsartan		- Oral use
Dipentum 250mg hard Capsules	Atnahs Pharma Netherlands B.V.	PA22657/001/001	Capsule, hard	- A07EC - A07EC03	- Olsalazine sodium		- Oral use
Dipentum 500mg Tablets	Atnahs Pharma Netherlands B.V.	PA22657/001/002	Tablet	- A07EC - A07EC03	- Olsalazine sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Dipeptiven, concentrate for solution for infusion	Fresenius AG	PA0697/002/001	Concentrate for solution for infusion	- B05XB - B05XB02	- L-alanyl-l glutamine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Diprivan 1% w/v Emulsion for Injection or Infusion, Pre-filled Syringe	Aspen Pharma Trading Limited	PA1691/022/001	Emulsion for injection/infusion	- N01AX - N01AX10	- Propofol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Diprobase Cream	Phoenix Labs	PA1113/030/001	Cream	- D02AC		Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
DiproSalic 0.05% w/w + 2% w/w Scalp Application	PCO Manufacturing Ltd.	PPA0465/487/001	Cutaneous solution	- D07XC - D07XC01	- BETAMETHASONE DIPROPIONATE - Salicylic acid		- Cutaneous use
DiproSalic 0.05% w/w + 2% w/w scalp application	IMED Healthcare Ltd.	PPA1463/206/001	Cutaneous solution	- D07XC - D07XC01	- Betamethasone dipropionate - Salicylic acid		- Cutaneous use
DiproSalic 0.05% w/w + 2% w/w scalp application	Organon Pharma (Ireland) Limited	PA23198/009/001	Cutaneous solution	- D07XC - D07XC01	- Betamethasone dipropionate - Salicylic acid		- Cutaneous use
Dipyridamole 200mg/5ml Oral Suspension	Syri Pharma Limited t/a Thame Laboratories	PA22697/009/001	Oral suspension	- B01AC - B01AC07	- Dipyridamole	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Disprin Direct 300 mg Orodispersible Tablets	Reckitt Benckiser Ireland Ltd	PA0979/007/001	Orodispersible tablet	- N02BA - N02BA01	- Aspirin		- Oral use
Disprin Extra Strength 500 mg Effervescent tablets	Reckitt Benckiser Ireland Ltd	PA0979/006/002	Effervescent tablet	- N02BA - N02BA01	- Acetylsalicylic acid		- Oral use
Disprin Original 300 mg Dispersible Tablets	Reckitt Benckiser Ireland Ltd	PA0979/006/001	Dispersible tablet	- N02BA - N02BA01	- Acetylsalicylic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Distaclor 125mg/5ml Granules for Oral Suspension	Flynn Pharma Limited	PA1226/001/002	Granules for oral suspension	- J01DC - J01DC04	- Cefaclor		- Oral use
Distaclor 250mg/5ml Granules for Oral Suspension	Flynn Pharma Limited	PA1226/001/003	Granules for oral suspension	- J01DC - J01DC04	- Cefaclor		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Distaclor LA 375 mg Prolonged Release Tablets	Flynn Pharma Limited	PA1226/001/004	Prolonged-release tablet	- J01DC - J01DC04	- Cefaclor monohydrate		- Oral use
Distaclor LA Forte 500 mg prolonged release tablets	Flynn Pharma Limited	PA1226/001/005	Prolonged-release tablet	- J01DC - J01DC04	- Cefaclor monohydrate		- Oral use
diTeBooster, suspension for injection in pre-filled single-dose syringes.Diphtheria and tetanus vaccine (adsorbed, reduced antigen content).	AJ Vaccines A/S	PA2160/001/001	Suspension for injection in pre-filled syringe	- J07AM - J07AM51	- Diphtheria toxoid - Tetanus toxoid		- Intramuscular use
Divigel 0.1% w/w Gel, 1 mg/dose	Merit Pharmaceuticals Limited	PPA23080/026/001	Gel	- G03CA - G03CA03	- Estradiol		- Transdermal use
Divigel 0.1% w/w Gel, 1 mg/dose	Orion Corporation	PA1327/002/001	Gel	- G03CA - G03CA03	- Estradiol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Transdermal use
Dnord 255 microgram soft capsules	Nordic Pharma Limited	PA23343/001/001	Capsule, soft	- A11CC06	- Calcifediol monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Dobutamine 12.5mg/ml Concentrate for Solution for Infusion	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/137/001	Concentrate for solution for infusion	- C01CA07	- DOBUTAMINE HYDROCHLORIDE		- Intravenous use
Docetaxel 20mg/ml concentrate for solution for infusion	Seacross Pharma (Europe) Limited	PA22766/001/001	Concentrate for solution for infusion	- L01CD - L01CD02	- Docetaxel anhydrous	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Docetaxel Accord	Accord Healthcare S.L.U.	EU/1/12/769/001	Concentrate for solution for infusion	- L01CD - L01CD02	- Docetaxel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Docetaxel Accord	Accord Healthcare S.L.U.	EU/1/12/769/003	Concentrate for solution for infusion	- L01CD - L01CD02	- Docetaxel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Docetaxel Accord 80 mg/4 ml concentrate for solution for infusion	Accord Healthcare S.L.U.	EU/1/12/769/002	Concentrate for solution for infusion	- L01CD - L01CD02	- Docetaxel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Docetaxel Kabi	Fresenius Kabi Deutschland GmbH	EU/1/12/770/001	Concentrate for solution for infusion	- L01CD - L01CD02	- Docetaxel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
DOCETAXEL KABI	Fresenius Kabi Deutschland GmbH	EU/1/12/770/002	Concentrate for solution for infusion	- L01CD02	- DOCETAXEL	Article 10(1) - Generic Application	- Intra-venous
DOCETAXEL KABI	Fresenius Kabi Deutschland GmbH	EU/1/12/770/003	Concentrate for solution for infusion	- L01CD02	- DOCETAXEL	Article 10(1) - Generic Application	- Intra-venous
DOCETAXEL KABI	Fresenius Kabi Deutschland GmbH	EU/1/12/770/004	Concentrate for solution for infusion	- L01CD02	- DOCETAXEL	Article 10(1) - Generic Application	- Intra-venous
Docetaxel Mylan	Mylan S.A.S.	EU/1/11/748/001-006	Concentrate for solution for infusion	- L01CD - L01CD02	- Anhydrous docetaxel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Docetaxel Pfizer 10 mg/mL concentrate for solution for infusion	Pfizer Healthcare Ireland	PA0822/146/001	Concentrate for solution for infusion	- L01CD - L01CD02	- Docetaxel	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Dolenio 1500mg Film-coated tablets	Blue Bio Pharmaceuticals Ltd	PA1516/001/001	Film-coated tablet	- M01AX - M01AX05	- Glucosamine sulfate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Dolmatil 200mg Tablets	Neuraxpharm Ireland Limited	PA23229/010/001	Tablet	- N05AL - N05AL01	- Sulpiride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Dolocopin 40mg/g Cream	Ferndale Laboratories Limited	PA22869/001/001	Cream	- N01BB02	- Lidocaine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Cutaneous use
Domerid 10mg tablets	Rowex Ltd	PA0711/046/001 Interchangeable List Code: IC0085-002-014	Tablet		- Domperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Domerid Relief 10mg tablets	Rowex Ltd	PA0711/046/002	Tablet	- A03FA - A03FA03	- Domperidone		- Oral use
Dona 1500 mg powder for oral solution	PCO Manufacturing Ltd.	PPA0465/401/001	Powder for oral solution	- M01AX - M01AX05	- Glucosamine sulfate sodium chloride		- Oral use
Dona 1500 mg Powder for oral solution	Mylan IRE Healthcare Limited	PA2010/022/002	Powder for oral solution	- M01AX - M01AX05	- Glucosamine sulfate - Sodium chloride - Glucosamine sulfate sodium chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Dona 1500 mg Powder for oral solution	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/035/001	Powder for oral solution	- M01AX - M01AX05	- Glucosamine sulfate		- Oral use
Dona 500mg Capsules	Mylan IRE Healthcare Limited	PA2010/022/001	Capsule, hard	- M01AX - M01AX05	- Glucosamine sulfate sodium chloride - GLUCOSAMINE SULPHATE	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Donepezil 10mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/033/002 Interchangeable List Code: IC0062-002-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Donepezil 5mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/033/001 Interchangeable List Code: IC0062-001-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Donepezil Hydrochloride 10mg Film-coated Tablets	Brillpharma (Ireland) Limited	PA22749/004/002 Interchangeable List Code: IC0062-002-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Donepezil Hydrochloride 5mg Film-coated Tablets	Brillpharma (Ireland) Limited	PA22749/004/001 Interchangeable List Code: IC0062-001-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Donepezil Hydrochloride Bluefish 10mg Film-coated Tablet	Bluefish Pharmaceuticals AB	PA1436/015/002 Interchangeable List Code: IC0062-002-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Donepezil Hydrochloride Bluefish 5mg Film-coated Tablet	Bluefish Pharmaceuticals AB	PA1436/015/001 Interchangeable List Code: IC0062-001-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Donepezil Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/014/004 Interchangeable List Code: IC0062-002-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Donepezil Krka 5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/014/003 Interchangeable List Code: IC0062-001-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Donepezil Teva 10 mg film-coated tablets	Teva Pharma B.V.	PA0749/194/002 Interchangeable List Code: IC0062-002-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Donepezil Teva 5 mg film-coated tablets	Teva Pharma B.V.	PA0749/194/001 Interchangeable List Code: IC0062-001-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Donesyn 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/183/002 Interchangeable List Code: IC0062-002-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Donesyn 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/183/001 Interchangeable List Code: IC0062-001-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Donopa, 50 %/50 % v/v, medicinal gas, compressed	SOL S.p.A.	PA1848/003/001	Medicinal gas, compressed	- N01AX - N01AX63	- Oxygen - Nitrous oxide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
Dopamine Hydrochloride 40 mg/ml Sterile Concentrate	Pfizer Healthcare Ireland	PA0822/202/001	Concentrate for solution for infusion	- C01CA - C01CA04	- DOPAMINE HYDROCHLORIDE		- Not Currently Available
Doptelet	Swedish Orphan Biovitrum AB(publ)	EU/1/19/1373/001-002	Film-coated tablet	- B02BX - B02BX08	- Avatrombopag maleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Dormeasan Sleep Valerian-Hops oral drops	A.Vogel Ireland Limited	TR2309/005/001	Oral drops, solution			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Dorzolamide + Timolol PharmaSwiss 20 mg/ml + 5 mg/ml, eye drops solution	Bausch + Lomb Ireland Limited	PA23259/003/001	Eye drops, solution	- S01ED - S01ED51	- Dorzolamide hydrochloride - Timolol Maleate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Dorzolamide PharmaSwiss 20 mg/ml eye drops solution	Bausch + Lomb Ireland Limited	PA23259/002/001	Eye drops, solution	- S01EC - S01EC03	- Dorzolamide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Dostinex 500 microgram Tablets	PCO Manufacturing Ltd.	PPA0465/338/001	Tablet	- G02CB - G02CB03	- Cabergoline		- Oral use
Dostinex 500 microgram tablets	IMED Healthcare Ltd.	PPA1463/162/001	Tablet	- G02CB - G02CB03	- Cabergoline		- Oral use
Dostinex 500 microgram tablets	Pfizer Healthcare Ireland	PA0822/126/001	Tablet	- G02CB - G02CB03	- Cabergoline	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Dosulepin Hydrochloride 25 mg Hard Capsules	Azure Pharmaceuticals Ltd	PA22871/013/001	Capsule, hard	- N06AA16	- Dosulepin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dosulepin Hydrochloride Azure 75 mg Coated Tablets	Azure Pharmaceuticals Ltd	PA22871/025/001	Coated tablet	- N06AA16	- Dosulepin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dotagraf 279.32 mg/ml solution for injection	Bayer Limited	PA1410/082/001	Solution for injection	- V08CA - V08CA02	- Gadolinium oxide - DOTA ACID - Meglumine - Gadoteric acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Dotagraf 279.32 mg/ml solution for injection	Bayer Limited	PA1410/082/002	Solution for injection	- V08CA - V08CA02	- Gadolinium oxide - DOTA ACID - Meglumine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Dotarem 279.32 mg/ml solution for injection	Guerbet	PA0686/003/002	Solution for injection	- V08CA - V08CA02	- Gadoteric acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Dotarem 279.32 mg/ml solution for injection in pre-filled syringe	Guerbet	PA0686/003/005	Solution for injection in pre-filled syringe	- V08CA - V08CA02	- Gadoteric acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
DOVATO	ViiV Healthcare BV	EU/1/19/1370/001-002	Film-coated tablet	- J05AR25	- Dolutegravir sodium - Lamivudine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Dovobet 50 microgram/g + 0.5 mg/g gel	LEO Pharma A/S	PA1025/001/002	Gel	- D05AX - D05AX52	- Calcipotriol - Betamethasone	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Cutaneous use
Dovobet 50 microgram/g + 0.5 mg/g gel	PCO Manufacturing Ltd.	PPA0465/213/002	Gel	- D05AX - D05AX52	- Calcipotriol - Betamethasone		- Cutaneous use
Dovobet 50 microgram/g + 0.5 mg/g Ointment	B & S Healthcare	PPA1328/066/001	Ointment	- D05AX52	- Calcipotriol - Betametasone dipropionate	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Topical use
Dovobet® 50 microgram/g + 0.5 mg/g ointment	LEO Pharma A/S	PA1025/001/001	Ointment	- D05AX - D05AX52	- Calcipotriol - Betamethasone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Dovonex 50 microgram/g Ointment	Leo Laboratories Limited	PA0046/061/001	Ointment	- D05AX - D05AX02	- Calcipotriol, anhydrous	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical
Dovonex 50 micrograms/g Cream	Leo Laboratories Limited	PA0046/061/002	Cream	- D05AX - D05AX02	- Calcipotriol hydrate		- Topical
Doxacar 4 mg Prolonged release Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/076/001 Interchangeable List Code: IC0021-008-024	Prolonged-release tablet		- Doxazosin mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Doxane XL 4 mg prolonged-release tablets	Rowex Ltd	PA0711/103/001 Interchangeable List Code: IC0021-008-024	Prolonged-release tablet		- Doxazosin mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Doxapram Hydrochloride 20mg/ml Solution for Injection	MercuryPharm Ltd	PA0857/003/002	Solution for injection	- R07AB - R07AB01	- Doxapram hydrochloride		- Intravenous use
Doxapram Hydrochloride 2mg/ml Solution for Infusion	MercuryPharm Ltd	PA0857/003/001	Solution for infusion	- R07AB - R07AB01	- Doxapram hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Doxatan 1mg tablets	Clonmel Healthcare Ltd	PA0126/202/001 Interchangeable List Code: IC0021-039-002	Tablet		- Doxazosin mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Doxatan 2mg tablets	Clonmel Healthcare Ltd	PA0126/202/002 Interchangeable List Code: IC0021-006-002	Tablet		- Doxazosin mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Doxatan 4mg tablets	Clonmel Healthcare Ltd	PA0126/202/003	Tablet	- C02CA - C02CA04	- Doxazosin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Doxatan XL 4 mg Prolonged-release Tablets	Clonmel Healthcare Ltd	PA0126/202/004 Interchangeable List Code: IC0021-008-024	Prolonged-release tablet		- Doxazosin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Doxorubicin 2 mg/ml Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/083/001	Concentrate for solution for infusion	- L01DB - L01DB01	- DOXORUBICIN HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Intravesical use
Doxorubicin 2mg/ml Concentrate for Solution for Infusion	Seacross Pharma (Europe) Limited	PA22766/004/001	Concentrate for solution for infusion	- L01DB - L01DB01	- DOXORUBICIN HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Intravesical use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Doxorubicin Rivopharm 2 mg/ml concentrate for solution for infusion	Rivopharm Limited	PA2318/002/001	Concentrate for solution for infusion	- L01DB - L01DB01	- DOXORUBICIN HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Intravesical use
Doxorubicin Teva 2 mg/ml Concentrate for Solution for Infusion	Teva Pharma B.V.	PA0749/083/001	Concentrate for solution for infusion	- L01DB - L01DB01	- DOXORUBICIN HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Doxpirexel 20 mg/ 20 mg modified-release tablets	Exeltis healthcare S.L.	PA22998/004/001	Modified-release tablet	- R06AA59	- Pyridoxine hydrochloride - Doxylamine hydrogen succinate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Doxycycline Bluefish 100 mg Capsules	Bluefish Pharmaceuticals AB	PA1436/030/001	Capsule, hard	- J01AA - J01AA02	- Doxycycline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Doxycycline Pinewood 100 mg Capsules	Pinewood Laboratories Ltd	PA0281/161/001	Capsule, hard	- J01AA - J01AA02	- Doxycycline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Doxycycline Teva 100mg Hard Capsules	Teva B.V.	PA1986/081/001	Capsule, hard	- J01AA - J01AA02	- Doxycycline hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	
Doxylamine/Pyridoxine Exeltis 10 mg/10 mg gastro-resistant tablets	Exeltis healthcare S.L.	PA22998/001/001	Gastro-resistant tablet	- R06AA59	- Doxylamine - Pyridoxine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Doxylamine/Pyridoxine Exeltis Healthcare 20mg/ 20mg modified-release tablets	Exeltis healthcare S.L.	PA22998/005/001	Modified-release tablet	- R06AA59	- Doxylamine hydrogen succinate - Pyridoxine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Dozept 10 mg film-coated-tablets	Rowex Ltd	PA0711/141/002 Interchangeable List Code: IC0062-002-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dozept 5 mg film-coated tablets	Rowex Ltd	PA0711/141/001 Interchangeable List Code: IC0062-001-015	Film-coated tablet		- Donepezil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dozol Oral Solution Paracetamol 120 mg/5 ml Diphenhydramine Hydrochloride 12.5 mg/5 ml	Phoenix Healthcare Ltd	PA1721/005/001	Oral solution	- N02BE - N02BE51	- Diphenhydramine hydrochloride - Paracetamol		- Oral use
Drapolene Cream Benzalkonium chloride 0.01% w/w Cetrimide 0.2% w/w	Ravira Limited	PA2034/001/001	Cream	- D08AJ - D08AJ01 - D08AJ04	- Benzalkonium chloride solution - Cetrimide		- Topical
Dretine 0.03 mg/3 mg Film-coated Tablets	Theramex Ireland Limited	PA22668/007/001	Film-coated tablet	- G03AA - G03AA12	- Ethinylestradiol - Drospirenone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dretinelle 0.02 mg/3 mg Film-coated Tablets	Theramex Ireland Limited	PA22668/006/001	Film-coated tablet	- G03FA - G03FA17	- Ethinylestradiol - Drospirenone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Droperidol 0.5 mg/ml solution for injection	Sintetica GmbH	PA22835/005/001	Solution for injection	- N05AD08	- Droperidol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Dropizol 10 mg/ml Oral Drops Solution	Atnahs Pharma Nordics A/S	PA2245/001/001	Oral drops, solution	- A07DA - A07DA02	- OPIUM TINCTURE	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Drovelis	Chemical Works Of Gedeon Richter PLC	EU/1/21/1547/001-004	Film-coated tablet	- G03AA - G03AA18	- Drospirenone - Estetrol - Estetrol monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Drynol 10 mg orodispersible tablet	Menarini International Operations Luxembourg S.A.	PA0865/018/002	Orodispersible tablet	- R06AX - R06AX29	- Bilastine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Drynol 2.5 mg/ml oral solution	Menarini International Operations Luxembourg S.A.	PA0865/018/003	Oral solution	- R06AX - R06AX29	- Bilastine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Drynol 20 mg orodispersible tablets	Menarini International Operations Luxembourg S.A.	PA0865/018/004	Orodispersible tablet	- R06AX29	- Bilastine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Drynol 20 mg Tablets	Menarini International Operations Luxembourg S.A.	PA0865/018/001	Tablet	- R06AX - R06AX29	- Bilastine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Drynol 20mg Tablets	PCO Manufacturing Ltd.	PPA0465/424/001	Tablet	- R06AX - R06AX29	- Bilastine		- Oral use
Drynol 6 mg/mL eye drops, solution	Menarini International Operations Luxembourg S.A.	PA0865/018/005	Eye drops, solution	- S01GX13	- Bilastine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Duac Once Daily 10mg/g + 50mg/g Ge	GlaxoSmithKline (Ireland) Limited	PA1077/120/001	Gel	- D10AF - D10AF51	- CLINDAMYCIN PHOSPHATE - Benzoyl peroxide hydrous		- Topical
Duaklir Genuair	Covis Pharma Europe B.V.	EU/1/14/964/001-002	Inhalation powder	- R03AL - R03AL05	- Micronized aclidinium bromide - Micronized formoterol fumarate dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Duavive	Pfizer Europe MA EEIG	EU/1/14/960/001	Modified-release tablet	- G03CX	- Conjugated estrogens (ce) - Bazedoxifene acetate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Ducressa 1 mg/ml + 5 mg/ml, eye drops, solution	Santen OY	PA0879/009/001	Eye drops, solution	- S01CA01	- Levofloxacin - Dexamethasone	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Ocular use
DUKORAL	Crucell Sweden AB	EU/1/03/263/1-3	Suspension and effervescent granules for oral suspension	- J07AE - J07AE01	- Cholera vaccine		- Oral use
Dulcolax 10mg Suppositories	Opella Healthcare France SAS T/A Sanofi	PA23180/018/002	Suppository	- A06AB - A06AB02	- Bisacodyl	Full application (Article 8(3) of Directive No 2001/83/EC)	- Rectal use
Dulcolax 5mg Gastro-resistant Tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/018/003	Gastro-resistant tablet	- A06AB - A06AB02	- Bisacodyl	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Dulcolax Pico Liquid 5 mg/5 ml oral solution	Opella Healthcare France SAS T/A Sanofi	PA23180/017/001	Oral solution	- A06AB - A06AB08	- Sodium picosulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Duloxetine	IC Company	IC0091	Not assigned			Not Currently Available	
Duloxetine Accord 30 mg hard gastro-resistant capsules	Accord Healthcare Ireland Ltd.	PA2315/268/001 Interchangeable List Code: IC0091-033-006	Gastro-resistant capsule, hard		- Duloxetine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Duloxetine Accord 60 mg hard gastro-resistant capsules	Accord Healthcare Ireland Ltd.	PA2315/268/002 Interchangeable List Code: IC0091-127-006	Gastro-resistant capsule, hard		- Duloxetine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Duloxetine Clonmel 30 mg gastro resistant capsules, hard	Clonmel Healthcare Ltd	PA0126/269/002 Interchangeable List Code: IC0091-033-006	Gastro-resistant capsule, hard		- Duloxetine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Duloxetine Clonmel 60 mg gastro-resistant capsules, hard	Clonmel Healthcare Ltd	PA0126/269/004 Interchangeable List Code: IC0091-127-006	Gastro-resistant capsule, hard		- Duloxetine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Duloxetine Krka 30 mg hard gastro-resistant capsules	KRKA, d.d., Novo mesto	PA1347/051/002 Interchangeable List Code: IC0091-033-006	Gastro-resistant capsule, hard		- Duloxetine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Duloxetine Krka 60 mg hard gastro-resistant capsules	KRKA, d.d., Novo mesto	PA1347/051/004 Interchangeable List Code: IC0091-127-006	Gastro-resistant capsule, hard		- Duloxetine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Duloxetine Lilly 30 mg hard gastro-resistant capsules	Eli Lilly Nederland B.V.	EU/1/14/972/001-003 Interchangeable List Code: IC0091-033-006	Gastro-resistant capsule, hard		- Duloxetine hydrochloride	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Duloxetine Lilly 60 mg hard gastro-resistant capsules	Eli Lilly Nederland B.V.	EU/1/14/972/005-009 Interchangeable List Code: IC0091-127-006	Gastro-resistant capsule, hard		- Duloxetine hydrochloride	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Duloxetine Mylan 30 mg hard gastro-resistant capsules	Mylan Pharmaceuticals Limited	EU/1/15/1010/01-010 Interchangeable List Code: IC0091-033-006	Gastro-resistant capsule, hard		- Duloxetine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Duloxetine Mylan 60 mg hard gastro-resistant capsules	Mylan Pharmaceuticals Limited	EU/1/15/1010/011-020 Interchangeable List Code: IC0091-127-006	Gastro-resistant capsule, hard		- Duloxetine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Duloxetine Pinewood 30 mg hard gastro-resistant capsules	Pinewood Laboratories Ltd	PA0281/270/001 Interchangeable List Code: IC0091-033-006	Gastro-resistant capsule, hard		- Duloxetine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Duloxetine Pinewood 60 mg hard gastro-resistant capsules	Pinewood Laboratories Ltd	PA0281/270/002 Interchangeable List Code: IC0091-127-006	Gastro-resistant capsule, hard		- Duloxetine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Duloxetine Zentiva 30 mg hard gastro-resistant capsules	Zentiva k.s.	EU/1/15/1028/001-003 Interchangeable List Code: IC0091-033-006	Gastro-resistant capsule, hard		- Duloxetine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Duloxetine Zentiva 60 mg hard gastro-resistant capsules	Zentiva k.s.	EU/1/15/1028/004-007 Interchangeable List Code: IC0091-127-006	Gastro-resistant capsule, hard		- Duloxetine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Duodopa 20 mg/ml + 5 mg/ml intestinal gel	AbbVie Limited	PA1824/002/001	Intestinal gel	- N04BA - N04BA02	- Levodopa - Carbidopa	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Topical
DuoPlavin	Sanofi-Aventis Groupe	EU/1/10/619/002-007	Film-coated tablet	- B01AC - B01AC30	- Acetylsalicylic acid - Clopidogrel hydrogen sulphate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
DuoPlavin	Sanofi Winthrop Industrie	EU/1/10/619/008-014 Interchangeable List Code: IC0043-031-003	Film-coated tablet		- Acetylsalicylic acid - Clopidogrel hydrogensulfate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
DuoPlavin	Sanofi Winthrop Industrie	EU/1/10/619/01-07 Interchangeable List Code: IC0043-030-003	Film-coated tablet		- Acetylsalicylic acid - Clopidogrel hydrogensulfate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
DuoResp Spiromax	Teva Pharma B.V.	EU/1/14/920 /001-003	Inhalation powder	- R03AK07	- Budesonide - Formoterol fumatrate dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
DuoResp Spiromax	Teva Pharma B.V.	EU/1/14/920 /004-006	Inhalation powder	- R03AK07	- Budesonide - Formoterol fumatrate dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
DuoResp Spiromax Teva	Teva Pharma B.V.	EU/1/14/921/001-003	Inhalation powder	- R03AK07	- Budesonide - Formoterol fumarate dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
DuoResp Spiromax Teva	Teva Pharma B.V.	EU/1/14/921/004-006	Inhalation powder	- R03AK07	- Budesonide - Formoterol fumarate dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Duotrav (Extravan)	Novartis Europharm Limited	EU/1/06/338/001-003	Eye drops, solution	- S01ED - S01ED51	- Travopost - Timolol - Timolol Maleate		
Duphalac 3.335 g/5 ml Oral Solution	Mylan IRE Healthcare Limited	PA2010/009/001 Interchangeable List Code: IC0099-151-019	Oral solution		- Lactulose	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Duphaston 10 mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/010/001	Film-coated tablet	- G03DB - G03DB01	- Dydrogesterone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Dupixent	Sanofi Winthrop Industrie	EU/1/17/1229/001-008	Solution for injection in pre-filled syringe	- L04A	- Dupilumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Dupixent	Sanofi Winthrop Industrie	EU/1/17/1229/009-0016	Solution for injection	- D11AH05	- Dupilumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Dupixent	Sanofi Winthrop Industrie	EU/1/17/1229/021-022	Solution for injection	- D11AH05	- Dupilumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Dupixent	Sanofi Winthrop Industrie	EU/1/17/1229/023-025	Solution for injection	- D11AH05	- Dupilumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Dupixent	Sanofi Winthrop Industrie	EU/1/17/1229/026-028	Solution for injection	- D11AH05	- Dupilumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Duraphat 5000 ppm Fluoride Toothpaste	Colgate-Palmolive A/S	PA22581/001/001	Toothpaste	- A01AA - A01AA01	- Sodium fluoride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Not Currently Available
Durogesic DTrans 100 micrograms/hour transdermal patch	Janssen Sciences Ireland UC	PA22612/004/004	Transdermal patch	- N02AB - N02AB03	- Fentanyl	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Durogesic DTrans 100 micrograms/hour Transdermal Patch	PCO Manufacturing Ltd.	PPA0465/314/004	Transdermal patch	- N02AB03	- Fentanyl		- Transdermal use
Durogesic DTrans 12 micrograms/hour Transdermal Patch	PCO Manufacturing Ltd.	PPA0465/314/005	Transdermal patch	- N02AB03	- Fentanyl		- Transdermal use
Durogesic DTrans 12 micrograms/hour Transdermal Patch	Janssen Sciences Ireland UC	PA22612/004/005	Transdermal patch	- N02AB - N02AB03	- Fentanyl	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Durogesic DTrans 25 micrograms/hour transdermal patch	Janssen Sciences Ireland UC	PA22612/004/001	Transdermal patch	- N02AB - N02AB03	- Fentanyl	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Durogesic DTrans 25 micrograms/hour Transdermal Patch	PCO Manufacturing Ltd.	PPA0465/314/001	Transdermal patch	- N02AB03	- Fentanyl		- Transdermal use
Durogesic DTrans 50 micrograms/hour Transdermal Patch	PCO Manufacturing Ltd.	PPA0465/314/002	Transdermal patch	- N02AB03	- Fentanyl		- Transdermal use
Durogesic DTrans 50 micrograms/hour Transdermal Patch	Janssen Sciences Ireland UC	PA22612/004/002	Transdermal patch	- N02AB - N02AB03	- Fentanyl	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Durogesic DTrans 75 micrograms/hour Transdermal Patch	Janssen Sciences Ireland UC	PA22612/004/003	Transdermal patch	- N02AB - N02AB03	- Fentanyl	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Durogesic DTrans 75 micrograms/hour Transdermal Patch	PCO Manufacturing Ltd.	PPA0465/314/003	Transdermal patch	- N02AB03	- Fentanyl		- Transdermal use
Dutasteride Krka 0.5 mg capsules, soft	KRKA, d.d., Novo mesto	PA1347/069/001 Interchangeable List Code: IC0140-040-001	Capsule, soft		- Dutasteride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dutasteride Rowa 0.5 mg soft capsules	Rowa Pharmaceuticals Limited	PA0074/076/002 Interchangeable List Code: IC0140-040-001	Capsule, soft		- Dutasteride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dutasteride Teva 0.5 mg soft capsules	Teva Pharma B.V.	PA0749/167/001 Interchangeable List Code: IC0140-040-001	Capsule, soft		- Dutasteride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dutasteride/Tamsulosin hydrochloride 0.5 mg /0.4 mg hard capsules	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/230/001 Interchangeable List Code: IC0036-065-001	Capsule, hard		- Dutasteride - Tamsulosin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/222/001 Interchangeable List Code: IC0036-065-001	Capsule, hard		- Dutasteride - Tamsulosin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dutasteride/Tamsulosin hydrochloride Pinewood 0.5 mg/0.4 mg hard capsules	Pinewood Laboratories Ltd	PA0281/216/001 Interchangeable List Code: IC0036-065-001	Capsule, hard		- Dutasteride - Tamsulosin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dutasteride/Tamsulosin Rowa 0.5 mg/0.4 mg hard capsules.	Rowa Pharmaceuticals Limited	PA0074/076/001 Interchangeable List Code: IC0036-065-001	Capsule, hard		- Tamsulosin hydrochloride - Dutasteride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Dymista 137 micrograms / 50 micrograms per actuation, Nasal Spray Suspension	Viatris Healthcare Limited	PA23355/010/001	Nasal spray, suspension	- R01AD - R01AD58	- Azelastine hydrochloride - Fluticasone propionate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Nasal use
Dymista 137 micrograms / 50 micrograms per actuation, Nasal Spray Suspension	Merit Pharmaceuticals Limited	PPA23080/018/001	Nasal spray, suspension	- R01AD - R01AD58	- Fluticasone propionate - Azelastine hydrochloride		- Nasal use
Dymista 137 micrograms / 50 micrograms per actuation, Nasal Spray Suspension	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/024/001	Nasal spray, suspension	- R01AD - R01AD58	- Fluticasone propionate - Azelastine hydrochloride		- Nasal use
Dymista 137 micrograms/50 micrograms per actuation nasal spray, suspension	IMED Healthcare Ltd.	PPA1463/151/001	Nasal spray, suspension	- R01AD - R01AD58	- Azelastine hydrochloride - Fluticasone propionate		- Nasal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Dymista 137 micrograms/50 micrograms per actuation nasal spray, suspension	PCO Manufacturing Ltd.	PPA0465/422/001	Nasal spray, suspension	- R01AD - R01AD58	- Azelastine hydrochloride - Fluticasone propionate		- Nasal use
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/001	Powder for solution for injection	- M01AH - M01AH04	- Parecoxib Sodium		- Intravenous use
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/002	Powder and solvent for solution for injection	- M01AH04	- Parecoxib Sodium		- Intravenous use
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/003	Powder and solvent for solution for injection	- M01AH04	- Parecoxib Sodium		- Intravenous use
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/004	Powder and solvent for solution for injection	- M01AH04	- Parecoxib Sodium		- Intravenous use
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/005	Powder for solution for injection	- M01AH - M01AH04	- Parecoxib Sodium		- Intravenous use
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/006	Powder and solvent for solution for injection	- M01AH - M01AH04	- Parecoxib Sodium		- Intravenous use
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/007	Powder and solvent for solution for injection	- M01AH - M01AH04	- Parecoxib Sodium		- Intravenous use
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/008	Powder and solvent for solution for injection	- M01AH - M01AH04	- Parecoxib Sodium		- Intravenous use
Dysport 500 units Powder for solution for injection	Ipsen Pharma	PA1613/002/001	Powder for solution for injection	- J06AA - J06AA04	- Clostridium botulinum toxin type a haemagglutinin complex		- Not Currently Available
Dzuveo	Laboratoire AGUETTANT	EU/1/18/1284/001-002	Sublingual tablet	- N01AH - N01AH03	- SUFENTANIL CITRATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Sublingual use
E45 Cream White Soft Paraffin 14.5% w/w Light Liquid Paraffin 12.6% w/w Anhydrous Lanolin 1.0% w/w	KARO PHARMA AB	PA22650/007/001	Cream	- D02AX	- White soft paraffin - Light liquid paraffin - Lanolin anhydrous		- Topical use
Easofen 200mg Film-Coated Tablets	Clonmel Healthcare Ltd	PA0126/060/001	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Easofen for Children Six Plus Strawberry 200mg/5ml Oral Suspension	Clonmel Healthcare Ltd	PA0126/060/004	Oral suspension	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Easofen for Children Strawberry 100mg/5ml Oral Suspension	Clonmel Healthcare Ltd	PA0126/060/003	Oral suspension	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Easofen Max Strength 400 mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/060/002	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Easofen Rapid Relief Max Strength 400 mg soft capsules	Clonmel Healthcare Ltd	PA0126/343/001	Capsule, soft	- M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Easolief Duo 500mg/150mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/294/001	Film-coated tablet	- N02BE - N02BE51	- Paracetamol - Ibuprofen	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Ebglyss	Almirall, S.A.	EU/1/23/1765/001-006	Solution for injection in pre-filled syringe	- D11AH10	- Lebrikizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Ebglyss	Almirall, S.A.	EU/1/23/1765/007-012	Solution for injection in pre-filled pen	- D11AH10	- Lebrikizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ebilfumin	Actavis Group PTC ehf	EU/1/14/915/001-002	Capsule, hard	- J05AH - J05AH02	- Oseltamivir phosphate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
EBILFUMIN	Actavis Group PTC ehf	EU/1/14/915/003-004	Capsule, hard	- J05AH02	- OSELTAMIVIR PHOSPHATE	Article 10(1) - Generic Application	- Oral use
EBILFUMIN	Actavis Group PTC ehf	EU/1/14/915/005-006	Capsule, hard	- J05AH02	- OSELTAMIVIR PHOSPHATE	Article 10(1) - Generic Application	- Oral use
EBIXA	H. Lundbeck A/S	EU/1/02/219/001-003 Interchangeable List Code: IC0022-002-003	Film-coated tablet		- Memantine		- Oral use
Ebixa	H. Lundbeck A/S	EU/1/02/219/005-006 Interchangeable List Code: IC0022-107-019	Oral solution		- MEMANTINE HYDROCHLORIDE		- Oral use
Ebixa	H. Lundbeck A/S	EU/1/02/219/022 Interchangeable List Code: IC0022-106-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ebixa	H. Lundbeck A/S	EU/1/02/219/023-035 Interchangeable List Code: IC0022-003-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ebvallo	Pierre Fabre Medicament	EU/1/22/1700/001	Dispersion for injection		- Tabelecleucel	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ebymect	AstraZeneca AB	EU/1/15/1051/001-006 Interchangeable List Code: IC0090-143-003	Film-coated tablet		- Metformin Hydrochloride - Dapagliflozin propanediol monohydrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Ebymect	AstraZeneca AB	EU/1/15/1051/007-012 Interchangeable List Code: IC0090-142-003	Film-coated tablet		- Metformin Hydrochloride - Dapagliflozin propanediol monohydrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Ecalta	Pfizer Europe MA EEIG	EU/1/07/416/001	Powder and solvent for concentrate for solution for infusion	- J02AX - J02AX06	- Anidulafungin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ecalta	Pfizer Europe MA EEIG	EU/1/07/416/002	Powder for concentrate for solution for infusion	- J02AX - J02AX06	- Anidulafungin		- Intravenous use
Ecansya	KRKA, d.d., Novo mesto	EU/1/12/763/001-006 Interchangeable List Code: IC0079-062-003	Film-coated tablet		- Capecitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ecansya	KRKA, d.d., Novo mesto	EU/1/12/763/007-012 Interchangeable List Code: IC0079-029-003	Film-coated tablet		- Capecitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ecansya	KRKA, d.d., Novo mesto	EU/1/12/763/013-018 Interchangeable List Code: IC0079-117-003	Film-coated tablet		- Capecitabine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Echinace Tablets	Sona Nutrition Ltd	TR1725/001/001	Film-coated tablet	- R07AX	- ECHINACEA PURPUREA POWDER EXTRACT 6-7:1 (EQUIVALENT TO 762 MG - 889 MG OF ECHINACEA PURPUREA ROOT)	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Echinaforce Cold & Flu tablets	A. Vogel Ireland Ltd,	TR2309/009/004	Tablet		- Extract (as dry extract) from fresh echinacea purpurea (l.) moench herb - Extract (as dry extract) from fresh echinacea purpurea (l.) moench root	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Echinaforce Cold and Flu chewable tablets	A.Vogel Ireland Limited	TR2309/009/003	Chewable tablet			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Echinaforce Cold and Flu Oral Drops	A.Vogel Ireland Limited	TR2309/009/002	Oral drops, solution	- L03A	- Tincture from fresh echinacea purpurea (l.) moench herb (1:12-13) extraction solvent: ethanol 57.3%m/m - Tincture from fresh echinacea purpurea (l.) moench root (1:11-12). extraction solvent: ethanol 57.3%m/m	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Echinaforce Forte Cold and Flu tablets	A. Vogel Ireland Ltd,	TR2309/009/001	Tablet		- Extract (as dry extract) from fresh echinacea purpurea (l.) moench herb - Extract (as dry extract) from fresh echinacea purpurea (l.) moench root	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Echinaforce Hot Drink Cold and Flu Echinacea concentrate for oral solution	A.Vogel Ireland Limited	TR2309/009/005	Concentrate for oral solution		- Tincture from fresh echinacea purpurea (l.) moench root (1:11). extraction solvent: 65 %v/v - Tincture from fresh echinacea purpurea (l.) moench herb (1:12). extraction solvent: ethanol 65% v/v	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Echinaforce Sore Throat Spray	A.Vogel Ireland Limited	TR2309/013/001	Oromucosal spray, solution	- R02A	- Tincture from fresh echinacea purpurea (l) moench herb (1:12-13) extraction solvent:ethanol 65 v/v	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Eczibet 20 mg/g + 1 mg/g cream	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/196/001	Cream	- D07CC - D07CC01	- Betamethasone - Fusidic acid	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Edarbi	Takeda Pharma A/S	EU/1/11/734/001-004	Tablet	- C09CA - C09CA09	- Azilsartan medoxomil	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Edarbi	Takeda Pharma A/S	EU/1/11/734/005-008	Tablet	- C09CA	- Azilsartan medoxomil	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Edarbi	Takeda Pharma A/S	EU/1/11/734/009-011	Tablet	- C09CA	- Azilsartan medoxomil	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Edicis 2mg kit for radiopharmaceutical preparation	CIS bio International	PA0677/021/001	Kit for radiopharmaceutical preparation	- V09CA	- N'n'-ethylene-(l,l) - dicysteine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Edistride	AstraZeneca AB	EU/1/15/1052/001-005	Film-coated tablet	- A10BX - A10BX09	- Dapagliflozin propanediol monohydrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Edistride	AstraZeneca AB	EU/1/15/1052/006-010	Film-coated tablet	- A10BX - A10BX09	- Dapagliflozin propanediol monohydrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Edluar 10 mg sublingual tablets	Mylan IRE Healthcare Limited	PA2010/050/002	Sublingual tablet	- N05CF - N05CF02	- Zolpidem tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Sublingual use
Edluar 5 mg sublingual tablets	Mylan IRE Healthcare Limited	PA2010/050/001	Sublingual tablet	- N05CF - N05CF02	- Zolpidem tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Sublingual use
Edronax 4 mg tablets	Pfizer Healthcare Ireland	PA0822/127/001	Tablet	- N06AX - N06AX18	- Reboxetine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
EDURANT	Janssen-Cilag International NV	EU/1/11/736/001	Film-coated tablet	- J05AG - J05AG05	- Rilpivirine (as hydrochloride)		- Oral use
Efavirenz Teva	Teva B.V.	EU/1/11/742/001-010	Film-coated tablet	- J05AG - J05AG03	- Efavirenz	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Efavirenz/Emtricitabine/Tenofovir Disoproxil Clonmel 600 mg/200 mg/245 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/301/001	Film-coated tablet	- J05AR - J05AR06	- Efavirenz - Emtricitabine - Tenofovir disoproxil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Efavirenz/Emtricitabine/Tenofovir disoproxil Krka	KRKA, d.d., Novo mesto	EU/1/17/1263/001-002	Film-coated tablet	- J05AR - J05AR06	- Tenofovir disoproxil succinate - Efavirenz - Emtricitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Efavirenz/Emtricitabine/Tenofovir disoproxil Mylan	Mylan Pharmaceuticals Limited	EU/1/17/1222/001-002	Film-coated tablet	- J05AR - J05AR06	- Efavirenz - Tenofovir disoproxil maleate - Emtricitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Efavirenz/Emtricitabine/Tenofovir disoproxil Teva 600 mg/200 mg/245 mg Film-coated Tablets	Teva B.V.	PA1986/033/001	Film-coated tablet	- J05AR - J05AR06	- Efavirenz - Emtricitabine - Tenofovir disoproxil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Efavirenz/Emtricitabine/Tenofovir disoproxil Zentiva	Zentiva k.s.	EU/1/17/1210/001	Film-coated tablet	- J05AR - J05AR06	- Tenofovir disoproxil phosphate - Efavirenz - Emtricitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Efexor XL 150 mg prolonged-release capsules, hard	Viatris Healthcare Limited	PA23355/002/003 Interchangeable List Code: IC0026-062-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Efexor XL 37.5 mg prolonged-release capsules, hard	Viatris Healthcare Limited	PA23355/002/001 Interchangeable List Code: IC0026-063-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Efexor XL 75 mg prolonged-release capsules, hard	Viatris Healthcare Limited	PA23355/002/002 Interchangeable List Code: IC0026-028-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Efexor XL 75 mg prolonged-release capsules, hard	PCO Manufacturing Ltd.	PPA0465/085/003 Interchangeable List Code: IC0026-028-030	Prolonged-release capsule, hard		- Venlafaxine	ZZZ PPA	- Oral use
Efexor XL 75 mg prolonged-release capsules, hard	IMED Healthcare Ltd.	PPA1463/209/001 Interchangeable List Code: IC0026-028-030	Prolonged-release capsule, hard		- Venlafaxine	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Effentora	Teva B.V.	EU/1/08/441/1-2	Buccal tablet	- N02AB - N02AB03	- FENTANYL CITRATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Effentora	Teva B.V.	EU/1/08/441/3-4	Buccal tablet	- N02AB - N02AB03	- FENTANYL CITRATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Effentora	Teva B.V.	EU/1/08/441/5-6	Buccal tablet	- N02AB - N02AB03	- FENTANYL CITRATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Effentora	Teva B.V.	EU/1/08/441/7-8	Buccal tablet	- N02AB - N02AB03	- FENTANYL CITRATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Effentora	Teva B.V.	EU/1/08/441/9-10	Buccal tablet	- N02AB - N02AB03	- FENTANYL CITRATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Efficib	Merck Sharp & Dohme BV,	EU/1/08/457/1-7 Interchangeable List Code: IC0070-121-003	Film-coated tablet		- Sitagliptin phosphate - Metformin Hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Efficib	Merck Sharp & Dohme BV	EU/1/08/457/8-14 Interchangeable List Code: IC0070-122-003	Film-coated tablet		- Sitagliptin phosphate - Metformin Hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Efient	Substipharm	EU/1/08/503/1-7	Film-coated tablet	- B01AC - B01AC22	- Prasugrel hydrochloride		- Oral use
Efient	Substipharm	EU/1/08/503/8-14	Film-coated tablet	- B01AC - B01AC22	- Prasugrel hydrochloride		- Oral use
Efluelda Tetra, suspension for injection in pre-filled syringe	Sanofi Pasteur	PA2131/015/001	Suspension for injection in pre-filled syringe	- J07BB02	- B/PHUKET/3073/2013 -LIKE STRAIN (B/PHUKET/3073/2013, WILD TYPE) - A/Darwin/9/2021 (H3N2) - like strain (A/Darwin/9/2021, IVR-228) - B/Austria/1359417/2021 - like strain (B/Michigan/01/2021, wild type) - A/Victoria/4897/2022 (H1N1)pdm09-like strain (A/Victoria/4897/2022, IVR-238	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Efmody	Diurnal Europe B.V.	EU/1/21/1549/001	Modified-release capsule, hard	- H02AB09	- Hydrocortisone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Efmody	Diurnal Europe B.V.	EU/1/21/1549/002	Modified-release capsule, hard	- H02AB09	- Hydrocortisone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Efmody	Diurnal Europe B.V.	EU/1/21/1549/003	Modified-release capsule, hard	- H02AB09	- Hydrocortisone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
EFRACEA 40 mg modified-release hard capsules	Galderma International	PA22743/006/001	Modified-release capsule, hard	- J01AA02	- Doxycycline	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Efudix 5 % w/w Cream	Mylan IRE Healthcare Limited	PA2010/049/001	Cream	- L01BC - L01BC02	- Fluorouracil		- Topical
Egostar 22400 IU film-coated tablets	Jaba Recordati S.A.	PA23312/001/001	Film-coated tablet	- A11CC05	- Cholecalciferol concentrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Eklira Genuair	Covis Pharma Europe B.V.	EU/1/12/778/001-003	Inhalation powder	- R03BB - R03BB05	- Micronized aclidinium bromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Eladynos	Theramex Ireland Limited	EU/1/22/1706/001	Solution for injection in pre-filled syringe	- H05AA - H05AA04	- Abaloparatide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Elantan 20 mg Tablets	Merus Labs Luxco II S.à.R.L.	PA2118/002/003	Tablet	- C01DA - C01DA14	- Isosorbid-5-mononitrat		- Oral use
Elantan LA 25mg Prolonged Release Capsules	Merus Labs Luxco II S.à.R.L.	PA2118/002/005	Prolonged-release capsule, hard	- C01DA - C01DA14	- ISOSORBIDE MONONITRATE		- Oral use
Elantan LA 50 mg Prolonged Release Capsules, hard	Merus Labs Luxco II S.à.R.L.	PA2118/002/004	Prolonged-release capsule, hard	- C01DA - C01DA14	- ISOSORBIDE MONONITRATE		- Oral use
Elaprase	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/06/365/1-3	Concentrate for solution for infusion	- A16AB09	- Idursulfase		- Intravenous use
Eldepryl 5 mg Tablet	Orion Corporation	PA1327/003/001	Tablet	- N04BD - N04BD01	- Selegiline hydrochloride		- Oral use
Elebrato Ellipta	GlaxoSmithKline Trading Services Limited	EU/1/17/1237/001-003	Inhalation powder, pre-dispensed	- R03AL08	- Fluticasone furoate - Umeclidinium bromide - Vilanterol trifenatate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Eletriptan 20mg Film-coated tablet	Chanelle Medical Unlimited Company	PA0688/048/001	Film-coated tablet	- N02CC - N02CC06	- ELETRIPTAN	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Eletriptan 40mg Film-coated tablet	Chanelle Medical Unlimited Company	PA0688/048/002	Film-coated tablet	- N02CC - N02CC06	- ELETRIPTAN	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Elfabrio	Chiesi Farmaceutici S.p.A.	EU/1/23/1724/001-003	Concentrate for solution for infusion	- A16AB - A16AB20	- Pegunigalsidase Alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
ELIGARD 22.5 mg powder and solvent for solution for injection	Recordati Industria Chimica e Farmaceutica SpA	PA0812/005/002	Powder and solvent for solution for injection	- L02AE - L02AE02	- Leuprorelin acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
ELIGARD 45 mg powder and solvent for solution for injection	Recordati Industria Chimica e Farmaceutica SpA	PA0812/005/003	Powder and solvent for solution for injection	- L02AE - L02AE02	- Leuprorelin acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
ELIGARD 7.5 mg powder and solvent for solution for injection	Recordati Industria Chimica e Farmaceutica SpA	PA0812/005/001	Powder and solvent for solution for injection	- L02AE - L02AE02	- Leuprorelin acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Eliquis 2.5 mg film-coated tablets	Bristol-Myers Squibb Pharma EEIG	EU/1/11/691/001-005, 013 Interchangeable List Code: IC0124-018-003	Film-coated tablet		- Apixaban	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Eliquis 5 mg film-coated tablets	Bristol-Myers Squibb Pharma EEIG	EU/1/11/691/006-012 Interchangeable List Code: IC0124-001-003	Film-coated tablet		- Apixaban	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ellaone	Laboratoire HRA Pharma	EU/1/09/522/001	Tablet	- G03AD - G03AD02	- ULIPRISTAL (INN)		- Oral use
ELLAONE	Laboratoire HRA Pharma	EU/1/09/552/003	Film-coated tablet	- G03AD02	- ULIPRISTAL ACETATE	Article 8(3) - Full new Application	- Oral use
Ellura hard capsules	Laboratoire Pharmaceutique Pharmatoka SAS	TR22953/001/001	Capsule, hard	- G04BX	- Cranberry fruit juice refined dry extract	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Elmiron (previously called Pentosan)	bene-Arzneimittel GmbH	EU/1/17/1189/001-002	Capsule, hard	- G04BX - G04BX15	- Pentosan polysulfate sodium	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Elocon 0.1% w/w Cream	Organon Pharma (Ireland) Limited	PA23198/010/001	Cream	- D07AC13	- Mometasone furoate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Elocon 0.1% w/w Cream	PCO Manufacturing Ltd.	PPA0465/268/001	Cream	- D07AC - D07AC13	- Mometasone furoate		- Topical use
Elocon 0.1% w/w Ointment	PCO Manufacturing Ltd.	PPA0465/268/003	Ointment	- D07AC - D07AC13	- Mometasone furoate		- Topical use
Elocon 0.1% w/w Ointment	Organon Pharma (Ireland) Limited	PA23198/010/002	Ointment	- D07AC - D07AC13	- Mometasone furoate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Elocon 0.1% w/w Scalp Lotion, Cutaneous Solution	Organon Pharma (Ireland) Limited	PA23198/010/003	Cutaneous solution	- D07AC - D07AC13	- Mometasone furoate		- Topical use
ELOCTA	Swedish Orphan Biovitrum AB	EU/1/15/1046/001	Powder and solvent for solution for injection	- B02BD - B02BD02	- Efmoroctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
ELOCTA	Swedish Orphan Biovitrum AB	EU/1/15/1046/002	Powder and solvent for solution for injection	- B02BD - B02BD02	- Efmoroctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
ELOCTA	Swedish Orphan Biovitrum AB	EU/1/15/1046/003	Powder and solvent for solution for injection	- B02BD - B02BD02	- Efmoroctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
ELOCTA	Swedish Orphan Biovitrum AB	EU/1/15/1046/004	Powder and solvent for solution for injection	- B02BD - B02BD02	- Efmoroctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
ELOCTA	Swedish Orphan Biovitrum AB	EU/1/15/1046/005	Powder and solvent for solution for injection	- B02BD - B02BD02	- Efmoroctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
ELOCTA	Swedish Orphan Biovitrum AB	EU/1/15/1046/006	Powder and solvent for solution for injection	- B02BD - B02BD02	- Efmoroctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
ELOCTA	Swedish Orphan Biovitrum AB	EU/1/15/1046/007	Powder and solvent for solution for injection	- B02BD - B02BD02	- Efmoroctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Elocta	Swedish Orphan Biovitrum AB(publ)	EU/1/15/1046/008	Powder and solvent for solution for injection	- B02BD02	- Efmoroctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Elocta	Swedish Orphan Biovitrum AB(publ)	EU/1/15/1046/009	Powder and solvent for solution for injection	- B02BD02	- Efmoroctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Elocta	Swedish Orphan Biovitrum AB(publ)	EU/1/15/1046/010	Powder and solvent for solution for injection	- B02BD02	- Efmoroctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Elonva	N.V. Organon	EU/1/09/609/001	Solution for injection	- G03GA - G03GA09	- Corifollitropin alfa		- Subcutaneous use
Elonva	N.V. Organon	EU/1/09/609/002	Solution for injection	- G03GA - G03GA09	- Corifollitropin alfa		- Subcutaneous use
ELREXFIO	Pfizer Europe MA EEIG	EU/1/23/1770/001-002	Solution for injection	- L01	- Elranatamab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Eltroxin 100 microgram Tablets	Amdipharm Limited	PA1142/028/002	Tablet	- H03AA - H03AA01	- Levothyroxine sodium	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Eltroxin 25 microgram Tablets	Amdipharm Limited	PA1142/029/001	Tablet	- H03AA - H03AA01	- Levothyroxine sodium		- Oral use
Eltroxin 50 microgram Tablets	Amdipharm Limited	PA1142/028/001	Tablet	- H03AA - H03AA01	- Levothyroxine sodium	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Elucirem	Guerbet	EU/1/23/1772/001-010	Solution for injection	- V08CA12	- Gadopiclenol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Elvina 0.03mg/3mg film-coated tablets	Gedeon Richter Plc	PA1330/007/001	Film-coated tablet	- G03AA - G03AA12	- Drospirenone - Ethinylestradiol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Elvinette 0.02mg/3mg film-coated tablets	Gedeon Richter Plc	PA1330/008/001	Film-coated tablet	- G03AA - G03AA12	- Drospirenone - Ethinylestradiol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Elymbus 0.1 mg/g eye gel in single-dose container	Laboratoires Thea	PA1107/019/001	Eye gel in single-dose container	- S01EE03	- Bimatoprost	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Elzonris	TMC Pharma (EU) Limited	EU/1/20/1504/001	Concentrate for solution for infusion	- L01X - L01XX67	- Tagraxofusp	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Emadine	Immedica Pharma AB	EU/1/98/095/001	Eye drops, solution	- S01GX - S01GX06	- Emedastine difumarate		- Ocular use
Emadine	Immedica Pharma AB	EU/1/98/095/002	Eye drops, solution	- S01GX	- Emedastine difumarate		- Ocular use
Emadine	Immedica Pharma AB	EU/1/98/095/003	Eye drops, solution	- S01GX	- Emedastine difumarate		- Ocular use
Emadine	Immedica Pharma AB	EU/1/98/095/004	Eye drops, solution	- S01GX	- Emedastine difumarate		- Ocular use
Emazole 20 mg gastro-resistant tablets	Rowex Ltd	PA0711/158/001 Interchangeable List Code: IC0004-003-016	Gastro-resistant tablet		- Esomeprazole magnesium dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Emazole 40 mg gastro-resistant tablets	Rowex Ltd	PA0711/158/002 Interchangeable List Code: IC0004-004-016	Gastro-resistant tablet		- Esomeprazole magnesium dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Emazole Control 20 mg gastro-resistant tablets	IQ Pharmatek Ltd	PA22777/001/001	Gastro-resistant tablet	- A02BC - A02BC02	- Esomeprazole magnesium dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Embesin 40 I.U./2 ml concentrate for solution for infusion	Orpha-Devel Handels und Vertriebs GmbH	PA1353/005/001	Concentrate for solution for infusion	- H01BA - H01BA01	- Argipressin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Emend	Merck Sharp & Dohme BV,	EU/1/03/262/009-010	Capsule, hard	- A04AD - A04AD12	- Aprepitant	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Emend	Merck Sharp & Dohme BV,	EU/1/03/262/011	Powder for oral suspension	- A04AD - A04AD12	- Aprepitant	Full application (Article 8(3) of Directive No 2001/83/EC)	
EMEND	Merck Sharp and Dohme Limited	EU/1/03/262/1-6	Capsule, hard	- A04AD - A04AD12	- Aprepitant		- Oral use
Emend	Merck Sharp & Dohme BV,	EU/1/03/262/7-8	Capsule, hard	- A04AD - A04AD12	- Aprepitant		
Emerade 150 micrograms solution for injection in pre-filled pen	PharmaSwiss Ceska republika s.r.o.	PA1696/009/001	Solution for injection in pre-filled pen	- C01CA - C01CA24	- Adrenaline		- Intramuscular use
Emerade 300 micrograms solution for injection in pre-filled pen	PharmaSwiss Ceska republika s.r.o.	PA1696/009/002	Solution for injection in pre-filled pen	- C01CA - C01CA24	- Adrenaline		- Intramuscular use
Emerade 500 micrograms solution for injection in pre-filled pen	PharmaSwiss Ceska republika s.r.o.	PA1696/009/003	Solution for injection in pre-filled pen	- C01CA - C01CA24	- Adrenaline		- Intramuscular use
Emgality	Eli Lilly Nederland B.V.	EU/1/18/1330/001-004	Solution for injection	- N02CX08	- GALCANEZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Emizof 4 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/083/003 Interchangeable List Code: IC0114-008-061	Film-coated tablet		- Ondansetron		- Oral use
Emizof 8 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/083/002 Interchangeable List Code: IC0114-009-061	Film-coated tablet		- Ondansetron		- Oral use
EMLA 5% w/w Cream	Aspen Pharma Trading Limited	PA1691/023/001	Cream	- N01BB - N01BB20	- Lidocaine - Prilocaine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical
Empliciti	Bristol-Myers Squibb Pharma EEIG	EU/1/16/1088/001	Powder for concentrate for solution for infusion	- L01XC	- Elotuzumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Empliciti	Bristol-Myers Squibb Pharma EEIG	EU/1/16/1088/002	Powder for concentrate for solution for infusion	- L01XC	- Elotuzumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
EMSELEX	zr pharma& GmbH	EU/1/04/294/1-12	Prolonged-release tablet	- G04BD - G04BD10	- Darifenacin hydrobromide		- Oral use
Emtricitabine/Tenofovir disoproxil Accordpharma 200 mg/245 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/200/002 Interchangeable List Code: IC0107-165-003	Film-coated tablet		- Emtricitabine - Tenofovir disoproxil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Emtricitabine/Tenofovir disoproxil Clonmel 200 mg/245 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/289/001 Interchangeable List Code: IC0107-165-003	Film-coated tablet		- Emtricitabine - Tenofovir disoproxil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Emtricitabine/Tenofovir disoproxil Krka 200 mg/245 mg film-coated tablets	KRKA, d.d., Novo mesto	EU/1/16/1151/001-004 Interchangeable List Code: IC0107-165-003	Film-coated tablet		- Emtricitabine - Tenofovir disoproxil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Emtricitabine/Tenofovir disoproxil Krka d.d 200 mg/245 mg film-coated tablets	KRKA, d.d., Novo mesto	EU/1/17/1182/001-004 Interchangeable List Code: IC0107-165-003	Film-coated tablet		- Tenofovir disoproxil - Emtricitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film-coated tablets	Mylan Pharmaceuticals Limited	EU/1/16/1133/001-006 Interchangeable List Code: IC0107-165-003	Film-coated tablet		- Emtricitabine - Tenofovir disoproxil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Emtricitabine/Tenofovir disoproxil Teva 200 mg/245 mg film-coated tablets	Teva B.V.	PA1986/016/001 Interchangeable List Code: IC0107-165-003	Film-coated tablet		- Emtricitabine - Tenofovir disoproxil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Emtricitabine/Tenofovir disoproxil Tillomed 200 mg/245 mg film-coated tablets	Tillomed Pharma GmbH	PA22720/008/001 Interchangeable List Code: IC0107-165-003	Film-coated tablet		- Emtricitabine - Tenofovir disoproxil fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Emtricitabine/Tenofovir disoproxil Zentiva 200 mg/245 mg film-coated tablets	Zentiva k.s.	EU/1/16/1148/001-002 Interchangeable List Code: IC0107-165-003	Film-coated tablet		- Tenofovir disoproxil - Emtricitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Emtriva	Gilead Sciences Ireland UC	EU/1/03/261/1-3	Capsule, hard	- J05AF - J05AF09	- Emtricitabine		- Oral use
Emulsiderm Emollient Bath Additive / Cutaneous Emulsion liquid paraffin 25% w/w, isopropyl myristate 25% w/w, benzalkonium chloride 0.5% w/w	Dermal Laboratories (Ireland) Limited	PA23128/005/001	Cutaneous emulsion	- D02AX	- Isopropyl myristate - Liquid paraffin - Benzalkonium chloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Emulsifying Ointment	Ovelle Limited	PA0206/019/001	Ointment	- D02AX	- Liquid paraffin - White soft paraffin - Emulsifying wax		- Topical
Enalapril maleate Accord 10mg tablets	Accord Healthcare Ireland Ltd.	PA2315/241/002	Tablet	- C09AA02	- Enalapril maleate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Enalapril maleate Accord 20mg tablets	Accord Healthcare Ireland Ltd.	PA2315/241/003	Tablet	- C09AA02	- Enalapril maleate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Enalapril maleate Accord 5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/241/001	Tablet	- C09AA02	- Enalapril maleate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Enalapril/Lercanidipine Krka 10mg/10mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/029/001	Film-coated tablet	- C09BB - C09BB02	- Enalapril maleate - Lercanidipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Enalapril/Lercanidipine Krka 20mg/10mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/029/002	Film-coated tablet	- C09BB - C09BB02	- Enalapril maleate - Lercanidipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
ENAP 10mg Tablets	Rowex Ltd	PA0711/028/002	Tablet	- C09AA - C09AA02	- Enalapril maleate		- Oral use
ENAP 20mg Tablets	Rowex Ltd	PA0711/028/003	Tablet	- C09AA - C09AA02	- Enalapril maleate		- Oral use
ENAP 5mg Tablets	Rowex Ltd	PA0711/028/001	Tablet	- C09AA - C09AA02	- Enalapril maleate		- Oral use
ENBREL	Pfizer Europe MA EEIG	EU/1/99/126/001-003	Powder for solution for injection	- L04AB - L04AB01	- Etanercept		- Subcutaneous use
Enbrel	Pfizer Europe MA EEIG	EU/1/99/126/002	Powder for solution for injection	- L04AB - L04AB01	- Etanercept		
Enbrel	Pfizer Europe MA EEIG	EU/1/99/126/013-015	Solution for injection in pre-filled syringe	- L04AB - L04AB01	- Etanercept		
Enbrel	Pfizer Europe MA EEIG	EU/1/99/126/016-021	Solution for injection in pre-filled syringe	- L04AB - L04AB01	- Etanercept		
Enbrel	Pfizer Europe MA EEIG	EU/1/99/126/022	Powder and solvent for solution for injection	- L04AB - L04AB01	- Etanercept		- Subcutaneous use
Enbrel	Pfizer Europe MA EEIG	EU/1/99/126/023-025	Solution for injection in pre-filled pen	- L04AB - L04AB01	- Etanercept		
EndolucinBeta	ITM Medical Isotopes GmbH	EU/1/16/1105/001-002	Radiopharmaceutical precursor, solution	- V10X	- Lutetium (177lu) chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravitreal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Endoxana Coated Tablets 50 mg	Baxter Holding B.V.	PA2299/027/003	Coated tablet	- L01AA - L01AA01	- Cyclophosphamide monohydrate		- Oral use
Endoxana Injection 1000 mg Powder for Solution for Injection	Baxter Holding B.V.	PA2299/027/002	Powder for solution for injection	- L01AA - L01AA01	- Cyclophosphamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Endoxana Injection 500 mg Powder for Solution for Injection	Baxter Holding B.V.	PA2299/027/001	Powder for solution for injection	- L01AA - L01AA01	- Cyclophosphamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Enerzair Breezhaler 114 micrograms/46 micrograms/136 micrograms inhalation powder, hard capsules	Novartis Europharm Limited	EU/1/20/1438/001-005	Inhalation powder, hard capsule	- R03AL12	- Indacaterol acetate - Glycopyrronium bromide - Mometasone furoate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Engerix B 10 micrograms/0.5 ml Suspension for injection in pre-filled syringe Hepatitis B (rDNA) vaccine (adsorbed) (HBV)	GlaxoSmithKline (Ireland) Limited	PA1077/023/001	Suspension for injection in pre-filled syringe	- J07BC - J07BC01	- Hepatitis b surface antigen, recominant	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Engerix B 20 micrograms/1 ml Suspension for injection in pre-filled syringe Hepatitis B (rDNA) vaccine (adsorbed) (HBV)	GlaxoSmithKline (Ireland) Limited	PA1077/023/002	Suspension for injection in pre-filled syringe	- J07BC - J07BC01	- Hepatitis b surface antigen, recominant	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Enhertu	Daiichi Sankyo Europe GmbH	EU/1/20/1508/001	Powder for concentrate for solution for infusion	- L01XC41	- Trastuzumab Deruxtecan	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Enjaymo	Genzyme Europe B.V.	EU/1/22/1687/001-002	Solution for infusion	- L04 - L04AA55	- Sutimlimab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Enoxaparin sodium Ledraxen 10,000 IU (100 mg)/1 mL, solution for injection in pre-filled syringe	Venipharm	PA23258/001/001	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Enoxaparin sodium Ledraxen 2,000 IU (20 mg)/0.2 mL, solution for injection in pre-filled syringe	Venipharm	PA23258/001/005	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Enoxaparin sodium Ledraxen 4,000 IU (40 mg)/0.4 mL, solution for injection in pre-filled syringe	Venipharm	PA23258/001/004	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Enoxaparin sodium Ledraxen 6,000 IU (60 mg)/0.6 mL, solution for injection in pre-filled syringe	Venipharm	PA23258/001/003	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Enoxaparin sodium Ledraxen 8,000 IU (80 mg)/0.8 mL, solution for injection in pre-filled syringe	Venipharm	PA23258/001/002	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Enrylaze	Jazz Pharmaceuticals Ireland Limited	EU/1/23/1747/001	Solution for injection/infusion	- L01XX02	- Crisantaspase	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Enspryng	Roche Registration GmbH	EU/1/21/1559/001	Solution for injection in pre-filled syringe	- L04AA - L04AC19	- Satralizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Enstilar 50 micrograms/g + 0.5 mg/g cutaneous foam	LEO Pharma A/S	PA1025/005/001	Cutaneous foam	- D05AX - D05AX52	- Calcipotriol - Betamethasone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Entacapone	Orion Corporation	EU/1/11/708/001-004	Film-coated tablet	- N04BX - N04BX02	- Entacapone	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
ENTACAPONE TEVA	Teva B.V.	EU/1/10/665/001-004	Film-coated tablet	- N04BX02	- ENTACAPONE	Article 10(1) - Generic Application	- Oral use
Entecavir Accord	Accord Healthcare S.L.U.	EU/1/17/1211/001-003	Film-coated tablet	- J05AF - J05AF10	- Entecavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Entecavir Accord	Accord Healthcare S.L.U.	EU/1/17/1211/004-006	Film-coated tablet	- J05AF - J05AF10	- Entecavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Entecavir Mylan	Mylan Pharmaceuticals Limited	EU/1/17/1227/001-005	Film-coated tablet	- J05AF - J05AF10	- Entecavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Entecavir Mylan	Mylan Pharmaceuticals Limited	EU/1/17/1227/006-010	Film-coated tablet	- J05AF - J05AF10	- Entecavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Entecavir Rowex 0.5 mg Film-coated tablets	Rowex Ltd	PA0711/274/001	Film-coated tablet	- J05AF - J05AF10	- ENTECAVIR MONOHYDRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Entocort CR 3 mg Gastro-resistant Capsule, Hard	PCO Manufacturing Ltd.	PPA0465/467/001	Gastro-resistant capsule, hard	- A07EA - A07EA06	- Budesonide		- Oral use
Entocort CR 3 mg Gastro-resistant Capsule, Hard	IMED Healthcare Ltd.	PPA1463/178/001	Gastro-resistant capsule, hard	- A07EA06	- Budesonide		- Oral use
Entocort® CR 3 mg Gastro-resistant Capsule, Hard	Tillotts Pharma GmbH	PA2018/003/001	Gastro-resistant capsule, hard	- A07EA - A07EA06	- Budesonide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Entonox	BOC Gases Ireland Ltd	PA0208/005/001	Medicinal gas, compressed	- N01AX - N01AX13	- Oxygen - Nitrous oxide		- Inhalation use
Entresto	Novartis Europharm Limited	EU/1/15/1058/001	Film-coated tablet	- C09DX - C09DX04	- Sacubitril valsartan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Entresto	Novartis Europharm Limited	EU/1/15/1058/002-004	Film-coated tablet	- C09DX - C09DX04	- Sacubitril valsartan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Entresto	Novartis Europharm Limited	EU/1/15/1058/005-007	Film-coated tablet	- C09DX - C09DX04	- Sacubitril valsartan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Entresto	Novartis Europharm Limited	EU/1/15/1058/023	Granules	- C09DX - C09DX04 - QC09DX04	- Sacubitril - Valsartan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ENTYVIO	Takeda Pharma A/S	EU/1/14/923/001	Powder for concentrate for solution for infusion	- L04AA33	- Vedolizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Entyvio	Takeda Pharma A/S	EU/1/14/923/002-004	Solution for injection in pre-filled syringe	- L04AA33	- Vedolizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Entyvio	Takeda Pharma A/S	EU/1/14/923/005-007	Solution for injection in pre-filled pen	- L04AA33	- Vedolizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	
Enurev Breezhaler	Novartis Europharm Limited	EU/1/12/789/001-006	Inhalation powder, hard capsule	- R03AB06	- Glycopyrronium bromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Envarsus	Chiesi Farmaceutici S.p.A.	EU/1/14/35/001-003	Prolonged-release tablet	- L04AD - L04AD02	- Tacrolimus monohydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Envarsus	Chiesi Farmaceutici S.p.A.	EU/1/14/35/004-006	Prolonged-release tablet	- L04AD - L04AD02	- Tacrolimus monohydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Envarsus	Chiesi Farmaceutici S.p.A.	EU/1/14/35/007-009	Prolonged-release tablet	- L04AD - L04AD02	- Tacrolimus monohydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
ENYGLID	Krka d.d., Novo mesto	EU/1/09/580/13-18	Tablet	- A10BX02	- REPAGLINIDE	Article 10(1) - Generic Application	- Oral use
ENYGLID	Krka d.d., Novo mesto	EU/1/09/580/1-6	Tablet	- A10BX02	- REPAGLINIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
ENYGLID	Krka d.d., Novo mesto	EU/1/09/580/7-12	Tablet	- A10BX02	- REPAGLINIDE	Article 10(1) - Generic Application	- Oral use
Enzalutamide Rowex 40 mg film-coated tablets	Rowex Ltd	PA0711/332/001	Film-coated tablet	- L02BB04	- Enzalutamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Enzalutamide Rowex 80 mg film-coated tablets	Rowex Ltd	PA0711/332/002	Film-coated tablet	- L02BB04	- Enzalutamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Epaclob 1 mg/ml Oral Suspension	Ethypharm	PA0549/026/001	Oral suspension	- N05BA - N05BA09	- Clobazam	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Epaclob 2 mg/ml Oral Suspension	Ethypharm	PA0549/026/002	Oral suspension	- N05BA - N05BA09	- Clobazam	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Epanutin 100 mg Hard Capsules	PCO Manufacturing Ltd.	PPA0465/244/001	Capsule, hard	- N03AB - N03AB02	- PHENYTOIN SODIUM		- Oral use
Epanutin 100 mg Hard Capsules	Upjohn EESV	PA23055/003/003	Capsule, hard	- N03AB - N03AB02	- PHENYTOIN SODIUM	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epanutin 25 mg Hard Capsules	Upjohn EESV	PA23055/003/001	Capsule, hard	- N03AB - N03AB02	- PHENYTOIN SODIUM	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epanutin 30 mg/5ml Oral Suspension	Upjohn EESV	PA23055/003/007	Oral suspension	- N03AB - N03AB02	- Phenytoin		- Oral use
Epanutin 300 mg Hard Capsules	Upjohn EESV	PA23055/003/004	Capsule, hard	- N03AB - N03AB02	- PHENYTOIN SODIUM	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epanutin 50 mg Hard Capsules	Upjohn EESV	PA23055/003/002	Capsule, hard	- N03AB - N03AB02	- PHENYTOIN SODIUM	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epanutin Infatabs 50mg Chewable Tablets	Upjohn EESV	PA23055/003/005	Chewable tablet	- N03AB - N03AB02	- Phenytoin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epanutin Ready Mixed Parenteral 250mg/5ml Solution for Injection or Infusion	Upjohn EESV	PA23055/003/006	Solution for injection/infusion	- N03AB - N03AB02	- PHENYTOIN SODIUM	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Epclusa	Gilead Sciences Ireland UC	EU/1/16/1116/001	Film-coated tablet	- J05A	- Sofosbuvir - Velpatasvir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epclusa	Gilead Sciences Ireland UC	EU/1/16/1116/002	Film-coated tablet	- J05A - J05AP55	- Sofosbuvir	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epclusa	Gilead Sciences Ireland UC	EU/1/16/1116/003	Coated granules	- J05AP55	- Sofosbuvir - Velpatasvir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Epclusa	Gilead Sciences Ireland UC	EU/1/16/1116/004	Coated granules	- J05AP55	- Sofosbuvir - Velpatasvir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ephedrine Hydrochloride 3 mg/ml solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/011/001	Solution for injection in pre-filled syringe	- C01CA26	- Ephedrine hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Ephedrine Hydrochloride 30mg in 1ml Solution for Injection	Ethypharm	PA0549/027/001	Solution for injection	- C01CA26	- Ephedrine hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Epiduo 0.1%/2.5% gel	Galderma International	PA22743/007/001	Gel	- D10AD53	- Adapalene - Benzoyl Peroxide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Cutaneous use
Epiduo 0.3 %/2.5 % gel	Galderma International	PA22743/007/002	Gel	- D10AD53	- Adapalene - Benzoyl Peroxide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Cutaneous use
Epidyolex	Jazz Pharmaceuticals Ireland Limited	EU/1/19/1389/001	Oral solution	- N03AX	- CANNABIDIOL	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epilim 100 mg Crushable Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/001	Tablet	- N03AG - N03AG01	- Sodium valproate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epilim Chrono 200mg Prolonged Release Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/010	Prolonged-release tablet	- N03AG - N03AG01	- Sodium valproate - Valproic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epilim Chrono 300mg Prolonged Release Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/011	Prolonged-release tablet	- N03AG - N03AG01	- Sodium valproate - Valproic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epilim Chrono 500mg Prolonged Release Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/012	Prolonged-release tablet	- N03AG - N03AG01	- Sodium valproate - Valproic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epilim Chronosphere 100mg prolonged-release granules	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/005	Prolonged-release granules	- N03AG - N03AG01	- Sodium valproate - Valproic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epilim Chronosphere 250mg prolonged-release granules	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/006	Prolonged-release granules	- N03AG - N03AG01	- Sodium valproate - Valproic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epilim Chronosphere 500mg prolonged-release granules	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/007	Prolonged-release granules	- N03AG - N03AG01	- Sodium valproate - Valproic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epilim Enteric 200 mg gastro-resistant coated tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/002	Gastro-resistant tablet	- N03AG - N03AG01	- Sodium valproate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epilim Enteric 500mg Gastro-resistant Coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/003	Gastro-resistant tablet	- N03AG - N03AG01	- Sodium valproate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epilim Intravenous 400mg powder and solvent for solution for injection or infusion	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/013	Powder and solvent for solution for injection/infusion	- N03AG - N03AG01	- Sodium valproate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Epilim Liquid 200 mg/5ml Oral Solution	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/014	Oral solution	- N03AG - N03AG01	- Sodium valproate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Epilim Syrup 200mg/5ml Oral Solution	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/015	Oral solution	- N03AG - N03AG01	- Sodium valproate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
EPINITRIL 10 mg/24 h transdermal patch	Rottapharm Ltd	PA0868/003/002	Transdermal patch	- C01DA - C01DA02	- Glyceryl trinitrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Transdermal use
EPINITRIL 15 mg/24 h transdermal patch	Rottapharm Ltd	PA0868/003/003	Transdermal patch	- C01DA - C01DA02	- Glyceryl trinitrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Transdermal use
EPINITRIL 5 mg/24 h transdermal patch	Rottapharm Ltd	PA0868/003/001	Transdermal patch	- C01DA - C01DA02	- Glyceryl trinitrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Transdermal use
EpiPen 300 micrograms solution for injection in pre-filled pen	Viatris Healthcare Limited	PA23355/011/002	Solution for injection in pre-filled pen	- C01CA - C01CA24	- Adrenaline	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intramuscular use
EpiPen Junior 150 micrograms solution for injection in pre-filled pen	Viatris Healthcare Limited	PA23355/011/001	Solution for injection in pre-filled pen	- C01CA - C01CA24	- Adrenaline	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intramuscular use
Epirubicin 2 mg/ml Solution for Injection	Seacross Pharma (Europe) Limited	PA22766/003/001	Solution for injection	- L01DB - L01DB03	- Epirubicin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Epirubicin Hydrochloride 2 mg/ml solution for injection or infusion	Accord Healthcare Ireland Ltd.	PA2315/034/001	Solution for injection/infusion	- L01DB - L01DB03	- Epirubicin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Intravesical use
Epistatus 10 mg oromucosal solution	SERB S.A.,	PA20595/002/001	Oromucosal solution	- N05CD08	- Midazolam	Hybrid application (Article 13(3) of Directive No 2001/82/EC)	- Oromucosal use
Epistatus 2.5 mg oromucosal solution	SERB S.A.,	PA20595/002/002	Oromucosal solution	- N05CD08	- Midazolam	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oromucosal use
Epistatus 5 mg oromucosal solution	SERB S.A.,	PA20595/002/003	Oromucosal solution	- N05CD08	- Midazolam	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oromucosal use
Epistatus 7.5 mg oromucosal solution	SERB S.A.,	PA20595/002/004	Oromucosal solution	- N05CD08	- Midazolam	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oromucosal use
Epivir	ViiV Healthcare BV	EU/1/96/015/001	Coated tablet	- J05AF - J05AF05	- Lamivudine		- Oral use
Epivir	ViiV Healthcare BV	EU/1/96/015/002	Oral solution	- J05A	- Lamivudine		- Oral use
Epivir	ViiV Healthcare BV	EU/1/96/015/003	Film-coated tablet	- J05AF - J05AF05	- Lamivudine		- Oral use
Eplerenone 25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/085/001 Interchangeable List Code: IC0115-022-003	Film-coated tablet		- Eplerenone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Eplerenone 50 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/085/002 Interchangeable List Code: IC0115-023-003	Film-coated tablet		- Eplerenone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Eplerenone Bluefish 25 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/022/001 Interchangeable List Code: IC0115-022-003	Film-coated tablet		- Eplerenone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Eplerenone Bluefish 50 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/022/002 Interchangeable List Code: IC0115-023-003	Film-coated tablet		- Eplerenone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Eplerenone Krka 25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/078/001 Interchangeable List Code: IC0115-022-003	Film-coated tablet		- Eplerenone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Eplerenone Krka 50 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/078/002 Interchangeable List Code: IC0115-023-003	Film-coated tablet		- Eplerenone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Eplerenone Mylan 25 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/168/001 Interchangeable List Code: IC0115-022-003	Film-coated tablet		- Eplerenone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Eplerenone Rowex 25 mg film-coated tablets	Rowex Ltd	PA0711/235/001 Interchangeable List Code: IC0115-022-003	Film-coated tablet		- Eplerenone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Eplerenone Rowex 50 mg film-coated tablets	Rowex Ltd	PA0711/235/002 Interchangeable List Code: IC0115-023-003	Film-coated tablet		- Eplerenone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/11-12	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/1-2	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/13-14	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/15-16	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/21-22	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Epoetin alfa	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/23-24	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Epoetin alfa	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/25-26	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Epoetin alfa	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/3-4	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/5-6	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/7-8	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/9-10	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Recombinant human erythropoietin alfa		- Intravenous use - Subcutaneous use
Eporatio	Ratiopharm GmbH	EU/1/09/573/11-16	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use
Eporatio	Ratiopharm GmbH	EU/1/09/573/1-2	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use
Eporatio	Ratiopharm GmbH	EU/1/09/573/17-22	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use
Eporatio	Ratiopharm GmbH	EU/1/09/573/23-28	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Eporatio	Ratiopharm GmbH	EU/1/09/573/3-4	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use
Eporatio	Ratiopharm GmbH	EU/1/09/573/5-6	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use
Eporatio	Ratiopharm GmbH	EU/1/09/573/7-8	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use
Eporatio	Ratiopharm GmbH	EU/1/09/573/9-10	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Xm01 drug substance epoetin theta		- Intravenous use - Subcutaneous use
Eptifibatide Accord 0.75 mg/ml solution for infusion	Accord Healthcare S.L.U.	EU/1/15/1065/001	Solution for infusion	- B01AC - B01AC16	- Eptifibatide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Eptifibatide Accord 2 mg/ml solution for injection	Accord Healthcare S.L.U.	EU/1/15/1065/002	Solution for injection	- B01AC - B01AC16	- Eptifibatide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Epysqli	Samsung Bioepis NL B.V.	EU/1/23/1735/001	Concentrate for solution for infusion	- L04AA25	- Eculizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Equasym XL 10 mg modified-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/001/001	Modified-release capsule, hard	- N06BA04	- Methylphenidate hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Equasym XL 20 mg modified-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/001/002	Modified-release capsule, hard	- N06BA - N06BA04	- Methylphenidate hydrochloride		
Equasym XL 30 mg modified-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/001/003	Modified-release capsule, hard	- N06BA04	- Methylphenidate hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Equasym XL 40 mg modified-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/001/004	Modified-release capsule, hard	- N06BA - N06BA04	- Methylphenidate hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Equasym XL 50 mg modified-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/001/005	Modified-release capsule, hard	- N06BA - N06BA04	- Methylphenidate hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Equasym XL 60 mg modified-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/001/006	Modified-release capsule, hard	- N06BA - N06BA04	- Methylphenidate hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Erbitux	Merck Europe B.V.	EU/1/04/281/001	Solution for infusion	- L01XC - L01XC06	- Cetuximab		- Intravenous use
Erbitux	Merck Europe B.V.	EU/1/04/281/2-5	Solution for infusion	- L01XC - L01XC06	- Cetuximab, chimeric antibody		- Intravenous use
Erdotin 300 mg capsules	Galen Pharma Ireland Limited	PA22680/004/001	Capsule, hard	- R05CB - R05CB15	- Erdosteine		- Oral use
Erelzi (Formely known: Etanercept Sandoz)	Sandoz GmbH	EU/1/17/1195/001-004	Solution for injection in pre-filled syringe	- L04AB - L04AB01	- Etanercept	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Erelzi (Formely known: Etanercept Sandoz)	Sandoz GmbH	EU/1/17/1195/005-012	Solution for injection	- L04AB - L04AB01	- Etanercept	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Eribulin Advanz Pharma 0.44 mg/ml solution for injection	Advanz Pharma Limited	PA23450/001/001	Solution for injection	- L01XX41	- Eribulin mesylate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Erivedge	Roche Registration GmbH	EU/1/13/848/001	Capsule, hard	- L01XX43	- Vismodegib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Erleada	Janssen-Cilag International NV	EU/1/18/1342/001-003	Film-coated tablet	- L02BB05	- APALUTAMIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Erleada	Janssen-Cilag International NV	EU/1/18/1342/004-006	Film-coated tablet	- L02BB05	- APALUTAMIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ertapenem SUN	Sun Pharmaceutical Industries Europe B.V.	EU/1/22/1656/001-002	Powder for concentrate for solution for infusion	- J01DH03	- Ertapenem sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
ERtracER Solution for Injection	Curium Pharma Ireland Limited	PA1125/002/001	Solution for injection	- V09IX - V09IX04	- Fludeoxyglucose [18F]	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Ervebo	Merck Sharp & Dohme BV,	EU/1/19/1392/001	Solution for injection	- J07BX - J07BX02	- Recombinant Vesicular Stomatitis Virus - Zaire Ebolavirus Vaccine (Live Attenuated)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Erwinase 10 000 U powder for solution for injection/infusion	Porton Biopharma Limited	PA23208/001/001	Powder for solution for injection/infusion	- L01XX02	- Crisantaspase	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Erythrocin 250 mg Tablets	Amdipharm Limited	PA1142/008/002	Film-coated tablet	- J01FA - J01FA01	- Erythromycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Erythrocin 500 mg Tablets	Amdipharm Limited	PA1142/008/003	Film-coated tablet	- J01FA - J01FA01	- Erythromycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Erythrocin IV Lactobionate 1 g Powder for Concentrate for Solution for Infusion	Amdipharm Limited	PA1142/008/001	Powder for concentrate for solution for infusion	- J01FA - J01FA01	- Erythromycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Erythroped Adult 500mg Film-coated Tablets	Amdipharm Limited	PA1142/006/004	Film-coated tablet	- J01FA - J01FA01	- Erythromycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Erythroped PI SF 125mg/5ml granules for oral suspension	Amdipharm Limited	PA1142/006/002	Granules for oral suspension	- J01FA - J01FA01	- Erythromycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Erythroped SF 250mg/5ml granules for oral suspension	Amdipharm Limited	PA1142/006/001	Granules for oral suspension	- J01FA - J01FA01	- Erythromycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Esbriet	Roche Registration GmbH	EU/1/11/667/005-008	Film-coated tablet	- L04AX - L04AX05	- Pirfenidone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Esbriet 267 mg film-coated tablets	Roche Registration GmbH	EU/1/11/667/007-008 Interchangeable List Code: IC0127-173-009	Film-coated tablet		- Pirfenidone	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Esbriet 267 mg hard capsules	Roche Registration GmbH	EU/1/11/667/001-003 Interchangeable List Code: IC0127-173-009	Capsule, hard		- Pirfenidone	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Esbriet 534 mg film-coated tablets	Roche Registration GmbH	EU/1/11/667/009-010 Interchangeable List Code: IC0127-174-003	Film-coated tablet		- Pirfenidone	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Esbriet 801 mg film-coated tablets	Roche Registration GmbH	EU/1/11/667/011 Interchangeable List Code: IC0127-175-003	Film-coated tablet		- Pirfenidone	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Esciprex 10 mg film-coated tablets	Rowex Ltd	PA0711/194/002 Interchangeable List Code: IC0071-002-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Esciprex 15 mg film-coated tablets	Rowex Ltd	PA0711/194/003 Interchangeable List Code: IC0071-032-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Esciprex 20 mg film-coated tablets	Rowex Ltd	PA0711/194/004 Interchangeable List Code: IC0071-003-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Esciprex 5 mg film-coated tablets	Rowex Ltd	PA0711/194/001 Interchangeable List Code: IC0071-001-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram 10 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/008/002 Interchangeable List Code: IC0071-002-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/086/002 Interchangeable List Code: IC0071-002-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram 15 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/008/003 Interchangeable List Code: IC0071-032-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram 20 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/008/004 Interchangeable List Code: IC0071-003-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram 20 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/086/003 Interchangeable List Code: IC0071-003-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram 20mg/ml Oral drops, solution	Chanelle Medical Unlimited Company	PA0688/041/001	Oral drops, solution	- N06AB - N06AB10	- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/086/001 Interchangeable List Code: IC0071-001-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram 5 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/008/001 Interchangeable List Code: IC0071-001-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Bluefish 10 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/023/002 Interchangeable List Code: IC0071-002-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Bluefish 15 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/023/003 Interchangeable List Code: IC0071-032-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Escitalopram Bluefish 20 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/023/004 Interchangeable List Code: IC0071-003-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Bluefish 5 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/023/001 Interchangeable List Code: IC0071-001-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Glenmark 10 mg film-coated tablets	Glenmark Arzneimittel GmbH	PA22645/005/002 Interchangeable List Code: IC0071-002-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Glenmark 15 mg film-coated tablets	Glenmark Arzneimittel GmbH	PA22645/005/003 Interchangeable List Code: IC0071-032-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Glenmark 20 mg film-coated tablets	Glenmark Arzneimittel GmbH	PA22645/005/004 Interchangeable List Code: IC0071-003-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Glenmark 5 mg film-coated tablets	Glenmark Arzneimittel GmbH	PA22645/005/001 Interchangeable List Code: IC0071-001-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Grindeks 10 mg film-coated tablets	AS Grindeks	PA22992/007/002 Interchangeable List Code: IC0071-002-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Grindeks 20 mg film-coated tablets	AS Grindeks	PA22992/007/003 Interchangeable List Code: IC0071-003-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Grindeks 5 mg film-coated tablets	AS Grindeks	PA22992/007/001 Interchangeable List Code: IC0071-001-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/046/002 Interchangeable List Code: IC0071-002-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Krka 15 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/046/003 Interchangeable List Code: IC0071-032-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/046/004 Interchangeable List Code: IC0071-003-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Krka 5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/046/001 Interchangeable List Code: IC0071-001-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Pinewood 10 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/262/002 Interchangeable List Code: IC0071-002-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Pinewood 15 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/262/003 Interchangeable List Code: IC0071-032-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Escitalopram Pinewood 20 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/262/004 Interchangeable List Code: IC0071-003-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Pinewood 5 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/262/001 Interchangeable List Code: IC0071-001-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Teva 10 mg film-coated tablets	Teva Pharma B.V.	PA0749/111/002 Interchangeable List Code: IC0071-002-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Teva 15 mg film-coated tablets	Teva Pharma B.V.	PA0749/111/003 Interchangeable List Code: IC0071-032-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Teva 20 mg film-coated tablets	Teva Pharma B.V.	PA0749/111/004 Interchangeable List Code: IC0071-003-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalopram Teva 5 mg film-coated tablets	Teva Pharma B.V.	PA0749/111/001 Interchangeable List Code: IC0071-001-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalpro 10 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/108/002 Interchangeable List Code: IC0071-002-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalpro 15 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/108/003 Interchangeable List Code: IC0071-032-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalpro 20 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/108/004 Interchangeable List Code: IC0071-003-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Escitalpro 5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/108/001 Interchangeable List Code: IC0071-001-003	Film-coated tablet		- Escitalopram oxalate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Esketamine Sintetica 25 mg/ml solution for injection/infusion	Sintetica GmbH	PA22835/002/002	Solution for injection/infusion	- N01AX14	- ESKETAMINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Esketamine Sintetica 5 mg/ml solution for injection/infusion	Sintetica GmbH	PA22835/002/001	Solution for injection/infusion	- N01AX14	- ESKETAMINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Esmeron 10 mg/ml solution for injection/infusion	Merck Sharp & Dohme Ireland (Human Health) Limited	PA1286/058/001	Solution for injection/infusion	- M03AC - M03AC09	- Rocuronium bromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Esmya	Gedeon Richter Plc	EU/1/12/750/001	Tablet	- G03XB - G03XB02	- Ulipristal acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Esomeprazole 20 mg gastro-resistant tablets	Brillpharma (Ireland) Limited	PA22749/023/001 Interchangeable List Code: IC0004-003-016	Gastro-resistant tablet		- Esomeprazole	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Esomeprazole 20 mg gastro-resistant tablets	Brillpharma (Ireland) Limited	PA22749/007/001 Interchangeable List Code: IC0004-003-016	Gastro-resistant tablet		- Esomeprazole magnesium dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Esomeprazole 20 mg gastro-resistant tablets	Accord Healthcare Ireland Ltd.	PA2315/127/003 Interchangeable List Code: IC0004-003-016	Gastro-resistant tablet		- Esomeprazole magnesium dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Esomeprazole 20 mg hard gastro-resistant capsules	Chefaro Ireland DAC	PA1186/027/001	Gastro-resistant capsule, hard	- A02BC05	- Esomeprazole	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Esomeprazole 40 mg gastro-resistant tablets	Accord Healthcare Ireland Ltd.	PA2315/127/004 Interchangeable List Code: IC0004-004-016	Gastro-resistant tablet		- Esomeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Esomeprazole 40 mg gastro-resistant tablets	Brillpharma (Ireland) Limited	PA22749/007/002 Interchangeable List Code: IC0004-004-016	Gastro-resistant tablet		- Esomeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Esomeprazole 40 mg Powder for Solution for Injection/Infusion	Accord Healthcare Ireland Ltd.	PA2315/160/001	Powder for solution for injection/infusion	- A02BC - A02BC05	- Esomeprazole sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Esomeprazole 40 mg powder for solution injection/infusion	Accord Healthcare Ireland Ltd.	PA2315/132/005	Powder for solution for injection/infusion	- A02BC - A02BC05	- Esomeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Esomeprazole Aristo 20 mg gastro-resistant capsules, hard	Aristo Pharma GmbH	PA1983/001/001 Interchangeable List Code: IC0004-003-016	Gastro-resistant capsule, hard		- Esomeprazole magnesium dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Esomeprazole Aristo 40 mg gastro-resistant capsules, hard	Aristo Pharma GmbH	PA1983/001/002 Interchangeable List Code: IC0004-004-016	Gastro-resistant capsule, hard		- Esomeprazole magnesium dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Esomeprazole Clonmel 20 mg gastro-resistant capsules, hard	Clonmel Healthcare Ltd	PA0126/208/001 Interchangeable List Code: IC0004-003-016	Gastro-resistant capsule, hard		- Esomeprazole	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Esomeprazole Clonmel 40 mg gastro-resistant capsules, hard	Clonmel Healthcare Ltd	PA0126/208/002 Interchangeable List Code: IC0004-004-016	Gastro-resistant capsule, hard		- Esomeprazole	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Esomeprazole Krka 20 mg hard gastro-resistant capsules	KRKA, d.d., Novo mesto	PA1347/017/001 Interchangeable List Code: IC0004-003-016	Gastro-resistant capsule, hard		- Esomeprazole	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Esomeprazole Krka 40 mg hard gastro-resistant capsules	KRKA, d.d., Novo mesto	PA1347/017/002 Interchangeable List Code: IC0004-004-016	Gastro-resistant capsule, hard		- Esomeprazole	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Esomeprazole Ticerin 40 mg powder for solution for injection or infusion	Laboratórios Azevedos - Indústria Farmacêutica S.A	PA1852/002/001	Powder for solution for injection/infusion	- A02BC - A02BC05	- Esomeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Esomeprazole Tillomed 40 mg powder for solution for injection/infusion	Laboratorios Tillomed Spain, S.L.U.	PA2321/002/001	Powder for solution for injection/infusion	- A02BC05	- Esomeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Esperoct	Novo Nordisk A/S	EU/1/19/1374/001	Powder and solvent for solution for injection	- B02BD - B02BD02	- TUROCTOCOG ALFA PEGOL	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Esperoct	Novo Nordisk A/S	EU/1/19/1374/002	Powder and solvent for solution for injection	- B02BD - B02BD02	- TUROCTOCOG ALFA PEGOL	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Esperoct	Novo Nordisk A/S	EU/1/19/1374/003	Powder and solvent for solution for injection	- B02BD - B02BD02	- TUROCTOCOG ALFA PEGOL	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Esperoct	Novo Nordisk A/S	EU/1/19/1374/004	Powder and solvent for solution for injection	- B02BD - B02BD02	- TUROCTOCOG ALFA PEGOL	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Esperoct	Novo Nordisk A/S	EU/1/19/1374/005	Powder and solvent for solution for injection	- B02BD - B02BD02	- TUROCTOCOG ALFA PEGOL	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Espestesin 40 mg/ml + 5 microgram/ml solution for injection	Pierrel S.p.A.	PA25244/001/002	Solution for injection	- N01BB - N01BB58	- Articaine hydrochloride - Epinephrine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Dental use
Espestesin Forte 40 mg/ml + 10 microgram/ml solution for injection	Pierrel S.p.A.	PA25244/001/001	Solution for injection	- N01BB - N01BB58	- Articaine hydrochloride - Epinephrine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Dental use
Espranor 2 mg Oral Lyophilisate	Ethypharm	PA0549/024/001	Oral lyophilisate	- N07BC - N07BC01	- Buprenorphine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oromucosal use
Espranor 8 mg Oral Lyophilisate	Ethypharm	PA0549/024/002	Oral lyophilisate	- N07BC - N07BC01	- Buprenorphine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oromucosal use
Estradiol SUN 10 micrograms vaginal tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/006/001	Vaginal tablet	- G03CA03	- Estradiol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Vaginal use
Estradot 100 micrograms/24 hours, transdermal patch	Novartis Ireland Limited	PA0896/010/004	Transdermal patch	- G03CA - G03CA03	- Estradiol hemihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Estradot 25 micrograms/24 hours, transdermal patch	Novartis Ireland Limited	PA0896/010/005	Transdermal patch	- G03CA - G03CA03	- Estradiol hemihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Estradot 37.5 micrograms/24 hours, transdermal patch	Novartis Ireland Limited	PA0896/010/001	Transdermal patch	- G03CA - G03CA03	- Estradiol hemihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Estradot 50 micrograms/24 hours, transdermal patch	Novartis Ireland Limited	PA0896/010/002	Transdermal patch	- G03CA - G03CA03	- Estradiol hemihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Estradot 75 micrograms/24 hours, transdermal patch	Novartis Ireland Limited	PA0896/010/003	Transdermal patch	- G03CA - G03CA03	- Estradiol hemihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Estrofem 2 mg film-coated tablets	Novo Nordisk A/S	PA0218/050/001	Film-coated tablet	- G03CA - G03CA03	- Estradiol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Etalopro 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/212/002 Interchangeable List Code: IC0071-002-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etalopro 15 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/212/003 Interchangeable List Code: IC0071-032-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etalopro 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/212/004 Interchangeable List Code: IC0071-003-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Etalopro 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/212/001 Interchangeable List Code: IC0071-001-003	Film-coated tablet		- Escitalopram	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ethambutol Hydrochloride 100mg film-coated tablets	Morningside Healthcare (Malta) Limited	PA23142/004/001	Film-coated tablet	- J04AK - J04AK02	- Ethambutol hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ethambutol Hydrochloride 400mg film-coated tablets	Morningside Healthcare (Malta) Limited	PA23142/004/002	Film-coated tablet	- J04AK - J04AK02	- Ethambutol hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.02 mg/ 3 mg Film-coated Tablets	Laboratorios Leon Farma, S.A.	PA1474/008/001	Film-coated tablet	- G03AA - G03AA12	- Drospirenone - Ethinylestradiol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/ 3 mg Film-coated Tablets	Laboratorios Leon Farma, S.A.	PA1474/008/002	Film-coated tablet	- G03AA - G03AA12	- Drospirenone - Ethinylestradiol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ethinylestradiol / Drospirenone Leon Farma 0.02mg/3 mg Film-coated Tablets	Laboratorios Leon Farma, S.A.	PA1474/004/001	Film-coated tablet	- G03AA - G03AA12	- Drospirenone - Ethinylestradiol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ethinylestradiol / Drospirenone Leon Farma 0.03mg/3 mg Film-coated Tablets	Laboratorios Leon Farma, S.A.	PA1474/004/002	Film-coated tablet	- G03AA - G03AA12	- Drospirenone - Ethinylestradiol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ethylex 50 mg film-coated tablets	Aop Orphan Pharmaceuticals GmbH	PA0934/002/001	Film-coated tablet	- N07BB - N07BB04	- Naltrexone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoflam 5% w/w Gel	Phoenix Labs	PA1113/002/001	Gel	- M02AA - M02AA06	- Etofenamate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Etonogestrel/Ethinyl estradiol 0.120 mg/0.015 mg per 24 hours vaginal delivery system	Laboratorios Leon Farma, S.A.	PA1474/014/001	Vaginal delivery system	- G02BB - G02BB01	- Etonogestrel - Ethinylestradiol ph.eur.	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Vaginal use
Etoposide 20 mg/ml concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/036/001	Concentrate for solution for infusion	- L01CB - L01CB01	- Etoposide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Etoposide 20mg/ml Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/201/001	Concentrate for solution for infusion	- L01CB - L01CB01	- Etoposide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Etoposide-Teva 20 mg/ml Concentrate for Solution for Infusion	Teva Pharma B.V.	PA0749/002/001	Concentrate for solution for infusion	- L01CB - L01CB01	- Etoposide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Etoricoxib 120 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/018/004 Interchangeable List Code: IC0108-167-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 120 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/018/004 Interchangeable List Code: IC0108-167-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 120 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/210/004 Interchangeable List Code: IC0108-167-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Etoricoxib 120 mg film-coated tablets	Chanelle Medical Unlimited Company	PA0688/032/004 Interchangeable List Code: IC0108-167-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 120 mg film-coated tablets	Rowex Ltd	PA0711/232/004 Interchangeable List Code: IC0108-167-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 30 mg film-coated tablets	Rowex Ltd	PA0711/232/001 Interchangeable List Code: IC0108-033-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 30 mg film-coated tablets	Chanelle Medical Unlimited Company	PA0688/032/001 Interchangeable List Code: IC0108-033-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 30 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/210/001 Interchangeable List Code: IC0108-033-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 30 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/018/001 Interchangeable List Code: IC0108-033-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 30 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/018/001 Interchangeable List Code: IC0108-033-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 60 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/018/002 Interchangeable List Code: IC0108-127-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 60 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/018/002 Interchangeable List Code: IC0108-127-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 60 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/210/002 Interchangeable List Code: IC0108-127-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 60 mg film-coated tablets	Chanelle Medical Unlimited Company	PA0688/032/002 Interchangeable List Code: IC0108-127-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 60 mg film-coated tablets	Rowex Ltd	PA0711/232/002 Interchangeable List Code: IC0108-127-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 90 mg film-coated tablets	Rowex Ltd	PA0711/232/003 Interchangeable List Code: IC0108-166-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 90 mg film-coated tablets	Chanelle Medical Unlimited Company	PA0688/032/003 Interchangeable List Code: IC0108-166-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 90 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/210/003 Interchangeable List Code: IC0108-166-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Etoricoxib 90 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/018/003 Interchangeable List Code: IC0108-166-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib 90 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/018/003 Interchangeable List Code: IC0108-166-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib Krka 120 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/064/004 Interchangeable List Code: IC0108-167-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib Krka 30 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/064/001 Interchangeable List Code: IC0108-033-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib Krka 60 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/064/002 Interchangeable List Code: IC0108-127-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib Krka 90 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/064/003 Interchangeable List Code: IC0108-166-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib Teva 120 mg film-coated tablets	Teva B.V.	PA1986/002/004 Interchangeable List Code: IC0108-167-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib Teva 30 mg film-coated tablets	Teva B.V.	PA1986/002/001 Interchangeable List Code: IC0108-033-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib Teva 60 mg film-coated tablets	Teva B.V.	PA1986/002/002 Interchangeable List Code: IC0108-127-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etoricoxib Teva 90 mg film-coated tablets	Teva B.V.	PA1986/002/003 Interchangeable List Code: IC0108-166-003	Film-coated tablet		- Etoricoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Etrivex 500 micrograms/g shampoo	Galderma International	PA22743/008/001	Shampoo	- D07AD - D07AD01	- Clobetasol propionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Eucardic 12.5 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/001/002	Tablet	- C07AG - C07AG02	- Carvedilol		- Oral use
Eucardic 25 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/001/003	Tablet	- C07AG - C07AG02	- Carvedilol		- Oral use
Eucardic 6.25 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/001/001	Tablet	- C07AG - C07AG02	- Carvedilol		- Oral use
Eucreas	Novartis Europharm Limited	EU/1/07/425/13-15	Film-coated tablet	- A10BD08	- Vildagliptin - Metformin hci	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Eucreas	Novartis Europharm Limited	EU/1/07/425/1-6	Film-coated tablet	- A10BD08	- Metformin hci - Vildagliptin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Eucreas	Novartis Europharm Limited	EU/1/07/425/16-18	Film-coated tablet	- A10BD08	- Vildagliptin - Metformin hci		
Eucreas	Novartis Europharm Limited	EU/1/07/425/7-12	Film-coated tablet	- A10BD08	- Metformin hci - Vildagliptin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Eumovate Cream 0.05% w/w	GlaxoSmithKline (Ireland) Limited	PA1077/006/001	Cream	- D07AB - D07AB01	- CLOBETASONE BUTYRATE		- Topical
Euphrasia	A. Nelson & Company Limited	HOR1149/011/001	Pillules		- Euphrasia officinalis		- Oral use
Eurartesim	Alfasigma S.p.A	EU/1/11/716/001-004	Film-coated tablet	- P01BF - P01BF05	- Piperaquine phosphate - Dihydroartemisinin	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Eurartesim	Sigma-Tau Industrie Farmaceutiche Riunite SpA	EU/1/11/716/005	Film-coated tablet	- P01BA - P01BE - P01BE05	- Dihydroartemisinin - Piperaquine phosphate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Eurax 10% w/w Cream	Clonmel Healthcare Ltd	PA0126/325/001	Cream	- D04AX	- Crotamiton		- Cutaneous use
Evenity	UCB Pharma S.A.	EU/1/19/1411/001-002	Solution for injection in pre-filled pen	- M05BX - M05BX06	- ROMOSOZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Evenity	UCB Pharma S.A.	EU/1/19/1411/003-004	Solution for injection in pre-filled syringe	- M05BX - M05BX06	- ROMOSOZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Everolimus TAD 10 mg tablets	TAD Pharma GmbH	PA0876/009/003	Tablet	- L01XE - L01XE10	- Everolimus	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Everolimus TAD 2.5 mg tablets	TAD Pharma GmbH	PA0876/009/001	Tablet	- L01XE - L01XE10	- Everolimus	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Everolimus TAD 5 mg tablets	TAD Pharma GmbH	PA0876/009/002	Tablet	- L01XE - L01XE10	- Everolimus	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Evicel	Omrix Biopharmaceuticals S.A.	EU/1/08/473/1-3	Solution for sealant	- B02BB - B02BB01	- Human fibrinogen - Human thrombin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Epilesional use
Eviplera	Gilead Sciences Ireland UC	EU/1/11/737/001-002	Film-coated tablet	- J05AR - J05AR08	- Rilpivirine hydrochloride - Tenofovir disoproxil fumarate (tdf) - Emtricitabine	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Evista	Substipharm	EU/1/98/073/001	Film-coated tablet	- G03X	- Raloxifene		
Evista	Substipharm	EU/1/98/073/002	Film-coated tablet	- G03X	- Raloxifene		
Evista	Substipharm	EU/1/98/073/003	Film-coated tablet	- G03X	- Raloxifene		
Evista	Substipharm	EU/1/98/073/004	Film-coated tablet	- G03X	- Raloxifene		
Evkeeza	Ultragenyx Germany GmbH	EU/1/21/1551/001-002	Concentrate for solution for infusion	- C10AX	- Evinacumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Evoltra	Sanofi B.V.	EU/1/06/334/01	Concentrate for solution for infusion	- L01BB - L01BB06	- Clofarabine		- Intravenous use
Evorel 50 micrograms per 24 hours Transdermal Patch	Theramex Ireland Limited	PA22668/008/001	Transdermal patch	- G03CA - G03CA03	- Estradiol hemihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Evorel Conti 50/170 micrograms per 24 hours Transdermal Patch	Theramex Ireland Limited	PA22668/009/001	Transdermal patch	- G03CA - G03CA53	- Estradiol hemihydrate - Norethisterone acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Evorel Conti 50/170 micrograms per 24 hours transdermal patch	PCO Manufacturing Ltd.	PPA0465/489/001	Transdermal patch	- G03FA01	- Estradiol - Norethisterone acetate		- Transdermal use
Evotaz	Bristol-Myers Squibb Pharma EEIG	EU/1/15/1025/001-002	Film-coated tablet	- J05AR - J05AR15	- Atazanavir - Cobicistat	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
EVRA	Gedeon Richter Plc	EU/1/02/223/001	Transdermal patch	- G03AA	- Norelgestromin - Ethinylestradiol		
Evra	Gedeon Richter Plc	EU/1/02/223/002	Transdermal patch	- G03AA03	- Norelgestromin - Ethinylestradiol		

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Evra	Gedeon Richter Plc	EU/1/02/223/003	Transdermal patch	- G03AA03	- Norelgestromin - Ethinylestradiol		
Evrenzo	Astellas Pharma Europe B.V.	EU/1/21/1574/001	Film-coated tablet	- B03XA - B03XA05	- Roxadustat	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Evrenzo	Astellas Pharma Europe B.V.	EU/1/21/1574/002	Film-coated tablet	- B03XA - B03XA05	- Roxadustat	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Evrenzo	Astellas Pharma Europe B.V.	EU/1/21/1574/003	Film-coated tablet	- B03XA - B03XA05	- Roxadustat	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Evrenzo	Astellas Pharma Europe B.V.	EU/1/21/1574/004	Film-coated tablet	- B03XA - B03XA05	- Roxadustat	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Evrenzo	Astellas Pharma Europe B.V.	EU/1/21/1574/005	Film-coated tablet	- B03XA - B03XA05	- Roxadustat	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Evrysdi	Roche Registration GmbH	EU/1/21/1531/001	Powder for oral solution	- M09AX - M09AX10	- Risdiplam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Gastroenteral use - Oral use
EVUSHELD	AstraZeneca AB	EU/1/22/1651/001	Solution for injection	- J06B - J06BD03	- Tixagevimab - Cilgavimab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
EXALIEF	BIAL - Portela & Cª, S.A.	EU/1/09/520/1-6	Tablet	- N03AF04	- ESLICARBAZEPINE ACETATE		- Oral use
Excedrin 250 mg/ 250 mg/ 65 mg film coated tablets	Haleon Ireland Limited	PA0678/122/001	Film-coated tablet	- N02BE - N02BE51	- Acetylsalicylic acid - Paracetamol - Caffeine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
EXELON	Novartis Europharm Limited	EU/1/98/066/001	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		
Exelon	Novartis Europharm Limited	EU/1/98/066/002	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Exelon	Novartis Europharm Limited	EU/1/98/066/003	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Exelon	Novartis Europharm Limited	EU/1/98/066/004	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Exelon	Novartis Europharm Limited	EU/1/98/066/005	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Exelon	Novartis Europharm Limited	EU/1/98/066/006	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Exelon	Novartis Europharm Limited	EU/1/98/066/007	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Exelon	Novartis Europharm Limited	EU/1/98/066/008	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Exelon	Novartis Europharm Limited	EU/1/98/066/009	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Exelon	Novartis Europharm Limited	EU/1/98/066/010	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Exelon	Novartis Europharm Limited	EU/1/98/066/011	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Exelon	Novartis Europharm Limited	EU/1/98/066/012	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		
Exelon	Novartis Europharm Limited	EU/1/98/066/013	Oral solution	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Exelon	Novartis Europharm Limited	EU/1/98/066/027-030	Transdermal patch	- N06DA - N06DA03	- Rivastigmine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Exelon	Novartis Europharm Limited	EU/1/98/066/19-22	Transdermal patch	- N06DA - N06DA03	- Rivastigmine base	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Exelon	Novartis Europharm Limited	EU/1/98/066/23-26	Transdermal patch	- N06DA - N06DA03	- Rivastigmine base	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Exemestane 25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/087/001 Interchangeable List Code: IC0142-022-040	Film-coated tablet		- Exemestane	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Exemestane Teva 25 mg film-coated tablets	Teva B.V.	PA1986/115/001 Interchangeable List Code: IC0142-022-040	Film-coated tablet		- Exemestane	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Exforge	Novartis Europharm Limited	EU/1/06/370/001-008 Interchangeable List Code: IC0042-087-003	Film-coated tablet		- Amlodipine besilate - Valsartan	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Exforge	Novartis Europharm Limited	EU/1/06/370/009-016 Interchangeable List Code: IC0042-086-003	Film-coated tablet		- Amlodipine besilate - Valsartan	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Exforge	Novartis Europharm Limited	EU/1/06/370/017-024 Interchangeable List Code: IC0042-084-003	Film-coated tablet		- Valsartan - Amlodipine besilate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Exforge HCT	Novartis Europharm Limited	EU/1/09/569/1-12	Film-coated tablet	- C09DX - C09DX01	- Amlodipine besylate - Hydrochlorothiazide - Valsartan	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Exforge HCT	Novartis Europharm Limited	EU/1/09/569/13-24	Film-coated tablet	- C09DX - C09DX01	- Hydrochlorothiazide - Valsartan - Amlodipine besylate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Exforge HCT	Novartis Europharm Limited	EU/1/09/569/25-36	Film-coated tablet	- C09DX - C09DX01	- Amlodipine besylate - Hydrochlorothiazide - Valsartan	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Exforge HCT	Novartis Europharm Limited	EU/1/09/569/37-48	Film-coated tablet	- C09DX - C09DX01	- Hydrochlorothiazide - Valsartan - Amlodipine besylate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Exforge HCT	Novartis Europharm Limited	EU/1/09/569/49-60	Film-coated tablet	- C09DX - C09DX01	- Valsartan - Hydrochlorothiazide - Amlodipine besylate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Exjade	Novartis Europharm Limited	EU/1/06/356/020	Granules	- V03AC - V03AC03	- Deferasirox	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Exjade	Novartis Europharm Limited	EU/1/06/356/021	Granules	- V03AC - V03AC03	- Deferasirox	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Exjade	Novartis Europharm Limited	EU/1/06/356/022	Granules	- V03AC - V03AC03	- Deferasirox	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Exjade 180 mg film-coated tablets	Novartis Europharm Limited	EU/1/06/356/014-016 Interchangeable List Code: IC0133-135-003	Film-coated tablet		- Deferasirox	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Exjade 360 mg film-coated tablets	Novartis Europharm Limited	EU/1/06/356/017-019 Interchangeable List Code: IC0133-180-003	Film-coated tablet		- Deferasirox	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Exjade 90 mg film-coated tablets	Novartis Europharm Limited	EU/1/06/356/011-013 Interchangeable List Code: IC0133-166-003	Film-coated tablet		- Deferasirox	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Exjade Dispersible	Novartis Europharm Limited	EU/1/06/356/001-009	Dispersible tablet	- V03AC - V03AC03	- Deferasirox	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
EXOCIN (Ofloxacin) 0.3% w/v Eye Drops Solution	AbbVie Limited	PA1824/014/001	Eye drops, solution	- S01AE - S01AE01	- Ofloxacin		- Ocular use
Exorex Lotion 5% v/w Cutaneous Emulsion	Teva B.V.	PA1986/078/001	Cutaneous emulsion	- D05AA	- Coal tar solution	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical
EXPAREL liposomal	Pacira Ireland Limite	EU/1/20/1489/001-004	Prolonged-release dispersion for injection	- N01BB01	- Bupivacaine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Infiltration - Perineural use
Expudyne 250mg/5ml oral solution	JED Pharma Limited	PA23183/003/001	Oral solution	- R05CB03	- Carbocisteine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Expudyne Rx 750 mg/5 ml oral solution	JED Pharma Limited	PA23183/005/001	Oral solution	- R05CB03	- Carbocisteine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Exputex 250mg / 5ml Oral Solution	Phoenix Labs	PA1113/010/001	Oral solution	- R05CB - R05CB03	- Carbocisteine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Extavia	Novartis Europharm Limited	EU/1/08/454/1,2,5	Powder and solvent for solution for injection	- L03AB - L03AB08	- Interferon beta-1b	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Subcutaneous use
Exterol 5% w/w Ear Drops, Solution	Dermal Laboratories (Ireland) Limited	PA23128/006/001	Ear drops, solution	- S02AA06	- Urea hydrogen peroxide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Auricular use
EXTRANEAL Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/017/001	Solution for peritoneal dialysis	- B05DA	- Icodextrin - Sodium chloride - Sodium (S) - lactate - Calcium chloride - Magnesium chloride		- Intraperitoneal use
Exviera	AbbVie Deutschland GmbH & Co. KG	EU/1/14/983/001	Film-coated tablet	- J	- Dasabuvir sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Eylea	Bayer AG	EU/1/12/797/001-002	Solution for injection	- S01LA - S01LA05	- Aflibercept	Full application (Article 8(3) of Directive No 2001/83/EC)	
Eylea	Bayer AG	EU/1/12/797/003	Solution for injection	- S01LA05	- Aflibercept	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravitreal use
Eyreida 0.3 mg/ml eye drops, solution	Morningside Healthcare (Malta) Limited	PA23142/014/001	Eye drops, solution	- S01EE03	- Bimatoprost	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Eyzeetan 0.3 mg/ml + 5 mg/ml eye drops, solution	Morningside Healthcare (Malta) Limited	PA23142/013/001	Eye drops, solution	- S01ED51	- Bimatoprost - Timolol Maleate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ezetimibe 10 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/088/001 Interchangeable List Code: IC0104-002-002	Tablet		- Ezetimibe	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe 10 mg tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/198/001 Interchangeable List Code: IC0104-002-002	Tablet		- Ezetimibe	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe Krka 10 mg tablets	KRKA, d.d., Novo mesto	PA1347/066/001 Interchangeable List Code: IC0104-002-002	Tablet		- Ezetimibe	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe Rowa 10 mg tablets	Rowa Pharmaceuticals Limited	PA0074/074/001 Interchangeable List Code: IC0104-002-002	Tablet		- Ezetimibe	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe Teva 10 mg tablets	Teva B.V.	PA1986/012/001 Interchangeable List Code: IC0104-002-002	Tablet		- Ezetimibe	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/ Atorvastatin Zentiva 10 mg/10 mg film-coated tablets	Zentiva k.s.	PA1701/009/001	Film-coated tablet	- C10BA05	- Ezetimibe - Atorvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/ Atorvastatin Zentiva 10 mg/20 mg film-coated tablets	Zentiva k.s.	PA1701/009/002	Film-coated tablet	- C10BA05	- Ezetimibe - Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/ Atorvastatin Zentiva 10 mg/40 mg film-coated tablets	Zentiva k.s.	PA1701/009/003	Film-coated tablet	- C10BA05	- Ezetimibe - Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/ Atorvastatin Zentiva 10 mg/80 mg film-coated tablets	Zentiva k.s.	PA1701/009/004	Film-coated tablet	- C10BA05	- Ezetimibe - Atorvastatin calcium trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/Simvastatin 10 mg/40 mg tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/180/002 Interchangeable List Code: IC0034-059-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/Simvastatin 10mg/20mg Tablet	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/180/001 Interchangeable List Code: IC0034-051-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/Simvastatin 10mg/80mg Tablet	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/180/003 Interchangeable List Code: IC0034-060-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/Simvastatin Accord 10mg/20mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/225/001 Interchangeable List Code: IC0034-051-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/Simvastatin Accord 10mg/40mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/225/002 Interchangeable List Code: IC0034-059-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/Simvastatin Accord 10mg/80mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/225/003 Interchangeable List Code: IC0034-060-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/Simvastatin Clonmel 10 mg/10 mg tablets	Clonmel Healthcare Ltd	PA0126/281/001 Interchangeable List Code: IC0034-017-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ezetimibe/Simvastatin Clonmel 10 mg/20 mg tablets	Clonmel Healthcare Ltd	PA0126/281/002 Interchangeable List Code: IC0034-051-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/Simvastatin Clonmel 10 mg/40 mg tablets	Clonmel Healthcare Ltd	PA0126/281/003 Interchangeable List Code: IC0034-059-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/Simvastatin Clonmel 10 mg/80 mg tablets	Clonmel Healthcare Ltd	PA0126/281/004 Interchangeable List Code: IC0034-060-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/Simvastatin Krka 10 mg/10 mg tablets	KRKA, d.d., Novo mesto	PA1347/067/001 Interchangeable List Code: IC0034-017-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/Simvastatin Krka 10 mg/20 mg tablets	KRKA, d.d., Novo mesto	PA1347/067/002 Interchangeable List Code: IC0034-051-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/Simvastatin Krka 10 mg/40 mg tablets	KRKA, d.d., Novo mesto	PA1347/067/003 Interchangeable List Code: IC0034-059-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/Simvastatin Teva Pharma 10 mg/20 mg tablets	Teva B.V.	PA1986/067/001 Interchangeable List Code: IC0034-051-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/Simvastatin Teva Pharma 10 mg/40 mg tablets	Teva B.V.	PA1986/067/002 Interchangeable List Code: IC0034-059-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetimibe/Simvastatin Teva Pharma 10 mg/80 mg tablets	Teva B.V.	PA1986/067/003 Interchangeable List Code: IC0034-060-002	Tablet		- Ezetimibe - Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ezetrol 10 mg tablets	Organon Pharma (Ireland) Limited	PA23198/023/001 Interchangeable List Code: IC0104-002-002	Tablet		- Ezetimibe	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ezetrol 10 mg tablets	PCO Manufacturing Ltd.	PPA0465/227/001 Interchangeable List Code: IC0104-002-002	Tablet		- Ezetimibe		- Oral use
Ezetrol 10 mg tablets	IMED Healthcare Ltd.	PPA1463/187/001 Interchangeable List Code: IC0104-002-002	Tablet		- Ezetimibe		- Oral use
Fabrazyme	Genzyme Europe B.V.	EU/1/01/188/001-002	Powder for concentrate for solution for infusion	- A16AB - A16AB04	- Protein c agalsidase beta (recombinant human-a-galactoside a)	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Fabrazyme	Genzyme Europe B.V.	EU/1/01/188/001-003	Powder for concentrate for solution for infusion	- A16AB04	- Agalsidase Beta	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Fabrazyme	Genzyme Europe B.V.	EU/1/01/188/003	Powder for concentrate for solution for infusion	- A16AB - A16AB04	- Protein c agalsidase beta (recombinant human-a-galactoside a)	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Fabrazyme	Genzyme Europe B.V.	EU/1/01/188/004-006	Powder for concentrate for solution for infusion	- A16AB - A16AB04	- Protein c agalsidase beta (recombinant human-a-galactoside a)	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Famciclovir 500 mg Film-Coated Tablets	Medinutrix Ltd.	PA2030/001/001	Film-coated tablet	- J05AB - J05AB09	- Famciclovir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Famciclovir Teva 250 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/025/002	Film-coated tablet	- J05AB - J05AB09	- Famciclovir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Famotidine Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/344/001	Film-coated tablet	- A02BA03	- Famotidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Famotidine Clonmel 40 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/344/002	Film-coated tablet	- A02BA03	- Famotidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fampridine Accord	Accord Healthcare S.L.U.	EU/1/20/1477/001-002	Prolonged-release tablet	- N07XX07	- Fampridine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fampridine Rowa 10 mg prolonged-release tablets	Rowa Pharmaceuticals Limited	PA0074/087/001	Prolonged-release tablet	- N07XX07	- Fampridine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fampyra	Biogen Netherlands B.V.	EU/1/11/699/001-002	Prolonged-release tablet	- N07XX - N07XX07	- Fampridine (4-aminopyridine)	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Famvir 125 mg film-coated tablets	Phoenix Labs	PA1113/018/001	Film-coated tablet	- J05AB - J05AB09	- Famciclovir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Famvir 250 mg film-coated tablets	Phoenix Labs	PA1113/018/002	Film-coated tablet	- J05AB - J05AB09	- Famciclovir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Famvir 250 mg Film-Coated Tablets	IMED Healthcare Ltd.	PPA1463/166/001	Film-coated tablet	- J05AB - J05AB09	- Famciclovir		- Oral use
Famvir 250 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/212/001	Film-coated tablet	- J05AB - J05AB09	- Famciclovir		- Oral use
Famvir 500 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/212/002	Film-coated tablet	- J05AB - J05AB09	- Famciclovir		- Oral use
Famvir 500 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/166/002	Film-coated tablet	- J05AB - J05AB09	- Famciclovir		- Oral use
Famvir 500 mg film-coated tablets	Phoenix Labs	PA1113/018/003	Film-coated tablet	- J05AB - J05AB09	- Famciclovir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Fanhdi 1000 IU powder and solvent for solution for injection	Instituto Grifols S.A.	PA0849/001/003	Powder and solvent for solution for injection	- B02BD - B02BD02	- Human coagulation factor viii	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Fanhdi 250 IU powder and solvent for solution for injection	Instituto Grifols S.A.	PA0849/001/001	Powder and solvent for solution for injection	- B02BD - B02BD02	- Human coagulation factor viii	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Fanhdi 500 IU powder and solvent for solution for injection	Instituto Grifols S.A.	PA0849/001/002	Powder and solvent for solution for injection	- B02BD - B02BD02	- Human coagulation factor viii	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Fareston	Orion Corporation	EU/1/96/004/001	Tablet	- L02BA - L02BA02	- Toremifene citrate		
Fareston	Orion Corporation	EU/1/96/004/002	Tablet	- L02BA - L02BA02	- Toremifene		
Farydak	zr pharma& GmbH	EU/1/15/1023/001-003	Capsule, hard	- L01X	- Panobinostat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Farydak	zr pharma& GmbH	EU/1/15/1023/004-006	Capsule, hard	- L01X	- Panobinostat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Farydak	zr pharma& GmbH	EU/1/15/1023/007-009	Capsule, hard	- L01X	- Panobinostat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Fasenra	AstraZeneca AB	EU/1/17/1252/001-002	Solution for injection in pre-filled syringe	- R03DX - R03DX10	- Benralizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Faslodex 250 mg Solution for injection	AstraZeneca AB	EU/1/03/269/001-002 Interchangeable List Code: IC0129-130-063	Solution for injection in pre-filled syringe		- Fulvestrant		
Fastum 2.5% w/w Gel	A. Menarini Industrie Farmaceutische Riunite S.r.l.	PA0512/001/001	Gel	- M02AA - M02AA10	- Ketoprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Fastum 2.5% w/w Gel	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/025/001	Gel	- M02AA - M02AA10	- Ketoprofen		- Topical use
Fasturtec	Sanofi Winthrop Industrie	EU/1/00/170/001-002	Powder and solvent for concentrate for solution for infusion	- V03AF - V03AF07	- Rasburicase	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Faverin 100 mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/031/002	Film-coated tablet	- N06AB - N06AB08	- Fluvoxamine maleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Faverin 50 mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/031/001	Film-coated tablet	- N06AB - N06AB08	- Fluvoxamine maleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Febuxostat Accord 120mg Film Coated Tablet	Accord Healthcare Ireland Ltd.	PA2315/023/002	Film-coated tablet	- M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Febuxostat Accord 80mg Film Coated Tablet	Accord Healthcare Ireland Ltd.	PA2315/023/001	Film-coated tablet	- M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Febuxostat Clonmel 120 mg Film-coated tablets	Clonmel Healthcare Ltd	PA0126/295/002	Film-coated tablet	- M04AA - M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Febuxostat Clonmel 80 mg Film-coated tablets	Clonmel Healthcare Ltd	PA0126/295/001	Film-coated tablet	- M04AA - M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Febuxostat Krka	KRKA, d.d., Novo mesto	EU/1/18/1347/001-004	Film-coated tablet	- M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Febuxostat Krka	KRKA, d.d., Novo mesto	EU/1/18/1347/005-008	Film-coated tablet	- M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Febuxostat Mylan	Mylan Pharmaceuticals Limited	EU/1/17/1194/001-008	Film-coated tablet	- M04AA - M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Febuxostat Mylan	Mylan Pharmaceuticals Limited	EU/1/17/1194/009-016	Film-coated tablet	- M04AA - M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Febuxostat Pinewood 120 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/160/002	Film-coated tablet	- M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Febuxostat Pinewood 80 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/160/001	Film-coated tablet	- M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Febuxostat Rowa 120 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/085/002	Film-coated tablet	- M04AA - M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Febuxostat Rowa 80 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/085/001	Film-coated tablet	- M04AA - M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Febuxostat Rowex 120 mg Film-coated Tablets	Rowex Ltd	PA0711/273/002	Film-coated tablet	- M04AA - M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Febuxostat Rowex 80 mg Film-coated Tablets	Rowex Ltd	PA0711/273/001	Film-coated tablet	- M04AA - M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Febuxostat Tillomed 120 mg film-coated tablets	Laboratorios Tillomed Spain, S.L.U.	PA2321/004/002	Film-coated tablet	- M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Febuxostat Tillomed 80 mg film-coated tablets	Laboratorios Tillomed Spain, S.L.U.	PA2321/004/001	Film-coated tablet	- M04AA03	- Febuxostat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fefol Spansule 150 mg/0.5 mg Modified Release Capsules	Intapharm Labs Ltd	PA23101/001/001	Modified-release capsule, hard	- B03AD - B03AD03	- Dried ferrous sulphate - Folic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
FEIBA 50 U/ml powder and solvent for solution for infusion	Baxalta Innovations GmbH	PA2004/001/002	Powder and solvent for solution for infusion	- B02BD - B02BD03	- Feiba	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Feldene 5mg/g Gel	Pfizer Healthcare Ireland	PA0822/194/003	Gel	- M02AA - M02AA07	- Piroxicam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical
Femara 2.5 mg film-coated tablets	Novartis Ireland Limited	PA0896/012/001 Interchangeable List Code: IC0117-018-003	Film-coated tablet		- Letrozole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Femara 2.5 mg film-coated tablets	Originalis B.V.	PPA2306/001/001 Interchangeable List Code: IC0117-018-003	Film-coated tablet		- Letrozole		- Oral use
Fematab 1mg film-coated tablet	Mylan IRE Healthcare Limited	PA2010/011/001	Film-coated tablet	- G03CA - G03CA03	- Estradiol hemihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Fematab 2mg Film-coated tablet	Mylan IRE Healthcare Limited	PA2010/011/002	Film-coated tablet	- G03CA - G03CA03	- Estradiol hemihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Femoston 1/10mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/012/001	Film-coated tablet	- G03FB - G03FB08	- Estradiol hemihydrate - Dydrogesterone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Femoston 2/10mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/012/002	Film-coated tablet	- G03FB - G03FB08	- Estradiol hemihydrate - Dydrogesterone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Femoston-conti 0.5 mg/2.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/464/002	Film-coated tablet	- G03FA - G03FA14	- Estradiol - Dydrogesterone		- Oral use
Femoston-conti 0.5mg/2.5mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/012/003	Film-coated tablet	- G03FA - G03FA14	- Estradiol - Dydrogesterone	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Femoston-conti 1 mg/5 mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/012/004	Film-coated tablet	- G03FA - G03FA14	- Estradiol - Dydrogesterone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Femoston-conti 1 mg/5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/464/001	Film-coated tablet	- G03FA - G03FA14	- Dydrogesterone - Estradiol		- Oral use
Femoston-conti 1 mg/5 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/189/001	Film-coated tablet	- G03FA - G03FA14	- Estradiol - Dydrogesterone		- Oral use
FENDRIX	GlaxoSmithKline Biologicals S.A.	EU/1/04/0299/001-003	Suspension for injection	- J07BC - J07BC01	- Hepatitis b vaccine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Fenopine 100mg/5ml Oral Suspension	Pinewood Laboratories Ltd	PA0281/088/004	Oral suspension	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fenopine 200 mg/5 ml Oral Suspension	Pinewood Laboratories Ltd	PA0281/088/005	Oral suspension	- M01AE01	- Ibuprofen ph. eur.	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Fenopine for Children Six Plus Strawberry 200mg/5ml Oral Suspension	Pinewood Laboratories Ltd	PA0281/088/006	Oral suspension	- M01AE01	- Ibuprofen	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Fentadur 100 micrograms/hour Transdermal Patch	Lavipharm S.A.	PA1676/002/004	Transdermal patch	- N02AB - N02AB03	- Fentanyl	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Transdermal use
Fentadur 12 micrograms/hour transdermal patch	Lavipharm S.A.	PA1676/002/005	Transdermal patch	- N02AB - N02AB03	- Fentanyl	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Transdermal use
Fentadur 25 micrograms/hour Transdermal Patch	Lavipharm S.A.	PA1676/002/001	Transdermal patch	- N02AB - N02AB03	- Fentanyl	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Transdermal use
Fentadur 50 micrograms/hour Transdermal Patch	Lavipharm S.A.	PA1676/002/002	Transdermal patch	- N02AB - N02AB03	- Fentanyl	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Transdermal use
Fentadur 75 micrograms/hour Transdermal Patch	Lavipharm S.A.	PA1676/002/003	Transdermal patch	- N02AB - N02AB03	- Fentanyl	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Transdermal use
Fental Matrix 100 micrograms/hour transdermal patch	Rowex Ltd	PA0711/146/004	Transdermal patch	- N02AB - N02AB03	- Fentanyl	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Transdermal use
Fental Matrix 25 micrograms/hour transdermal patch	Rowex Ltd	PA0711/146/001	Transdermal patch	- N02AB - N02AB03	- Fentanyl	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Transdermal use
Fental Matrix 50 micrograms/hour transdermal patch	Rowex Ltd	PA0711/146/002	Transdermal patch	- N02AB - N02AB03	- Fentanyl	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Transdermal use
Fental Matrix 75 micrograms/hour transdermal patch	Rowex Ltd	PA0711/146/003	Transdermal patch	- N02AB - N02AB03	- Fentanyl	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Transdermal use
Fentanyl 100 micrograms in 2 ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/122/001	Solution for injection	- N01AH - N01AH01	- FENTANYL CITRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Fentanyl 50 micrograms/ml solution for injection	AS Kalceks	PA2165/011/001	Solution for injection	- N01AH01	- Fentanyl	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Fentanyl 500 micrograms in 10 ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/122/002	Solution for injection	- N01AH - N01AH01	- FENTANYL CITRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Feraccru	Norgine B.V.	EU/1/15/1075/001	Capsule, hard	- B03AB - B03AB10	- Ferric maltol		- Oral use
Ferinject 50 mg iron/mL dispersion for injection/infusion	Vifor France	PA0949/004/001	Dispersion for injection/infusion	- B03AC	- IRON CARBOXYMALTOSE		- Intravenous use
Ferric carboxymaltose 50 mg iron/ml solution for injection/infusion	Rowex Ltd	PA0711/315/001	Solution for injection/infusion	- B03AC	- Ferric carboxymaltose	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
FERRIPROX	Chiesi Farmaceutici S.p.A.	EU/1/99/108/001	Film-coated tablet	- V03AC - V03AC02	- Deferiprone		- Oral use
Ferriprox	Chiesi Farmaceutici S.p.A.	EU/1/99/108/002-003	Oral solution	- V03AC - V03AC02	- Deferiprone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ferriprox	Chiesi Farmaceutici S.p.A.	EU/1/99/108/004-006	Film-coated tablet	- V03AC - V03AC02	- Deferiprone		- Oral use
Ferrograd 325mg Prolonged release Tablets	Teofarma S.R.L.	PA1235/001/001	Prolonged-release tablet	- B03AA - B03AA07	- Ferrous sulphate		- Oral use
Ferrograd C 325mg/500mg Prolonged release Tablets	Teofarma S.R.L.	PA1235/002/001	Prolonged-release tablet	- B03AA - B03AA07	- Ferrous sulfate - Sodium ascorbate		- Oral use
Ferrograd Folic 325mg/0.35mg Prolonged release Tablets	Teofarma S.R.L.	PA1235/003/001	Prolonged-release tablet	- B03AD - B03AD03	- Ferrous sulfate - Folic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Fesoterodine Accord 4 mg prolonged-release tablets	Accord Healthcare Ireland Ltd.	PA2315/243/002 Interchangeable List Code: IC0139-008-024	Prolonged-release tablet		- Fesoterodine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fesoterodine Accord 8 mg prolonged-release tablets	Accord Healthcare Ireland Ltd.	PA2315/243/001 Interchangeable List Code: IC0139-009-024	Prolonged-release tablet		- Fesoterodine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fesoterodine Aristo 4 mg prolonged-release tablets	Aristo Pharma GmbH	PA1983/007/001 Interchangeable List Code: IC0139-008-024	Prolonged-release tablet		- Fesoterodine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fesoterodine Aristo 8 mg prolonged-release tablets	Aristo Pharma GmbH	PA1983/007/002 Interchangeable List Code: IC0139-009-024	Prolonged-release tablet		- Fesoterodine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fesoterodine Clonmel 4 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/335/001 Interchangeable List Code: IC0139-008-024	Prolonged-release tablet		- Fesoterodine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fesoterodine Clonmel 8 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/335/002 Interchangeable List Code: IC0139-009-024	Prolonged-release tablet		- Fesoterodine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fesoterodine Doc 4 mg prolonged-release tablets	DOC Generici S.r.l.	PA2244/002/001 Interchangeable List Code: IC0139-008-024	Prolonged-release tablet		- Fesoterodine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fesoterodine Doc 8 mg prolonged-release tablets	DOC Generici S.r.l.	PA2244/002/002 Interchangeable List Code: IC0139-009-024	Prolonged-release tablet		- Fesoterodine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fesoterodine Pinewood 4 mg prolonged-release tablets	Pinewood Laboratories Ltd	PA0281/215/001 Interchangeable List Code: IC0139-008-024	Prolonged-release tablet		- Fesoterodine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Fesoterodine Pinewood 8 mg prolonged-release tablets	Pinewood Laboratories Ltd	PA0281/215/002 Interchangeable List Code: IC0139-009-024	Prolonged-release tablet		- Fesoterodine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fesoterodine Rowa 4 mg prolonged-release tablets	Rowa Pharmaceuticals Limited	PA0074/091/001 Interchangeable List Code: IC0139-008-024	Prolonged-release tablet		- Fesoterodine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fesoterodine Rowa 8 mg prolonged-release tablets	Rowa Pharmaceuticals Limited	PA0074/091/002 Interchangeable List Code: IC0139-009-024	Prolonged-release tablet		- Fesoterodine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fetcroja	Shionogi B.V.	EU/1/20/1434/001	Powder for concentrate for solution for infusion	- J01DI04	- Cefiderocol Sulfate Tosilate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Fexeric	Akebia Europe Limited	EU/1/15/1039/001	Film-coated tablet	- V03AE	- Ferric citrate coordination complex	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Fexo Allergy Relief 120 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/096/001	Film-coated tablet	- R06AX26	- Fexofenadine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fexofast 120 mg Film-coated Tablets	Cipla Europe NV	PA1963/014/001	Film-coated tablet	- R06AX - R06AX26	- Fexofenadine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Fexofast 180 mg Film-coated Tablets	Cipla Europe NV	PA1963/014/002	Film-coated tablet	- R06AX - R06AX26	- Fexofenadine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Fexofenadine Hydrochloride 120 mg Film-coated tablets	Azure Pharmaceuticals Ltd	PA22871/004/002	Film-coated tablet	- R06AX26	- Fexofenadine hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Fexofenadine hydrochloride 120 mg Film-coated tablets	Chanelle Medical Unlimited Company	PA0688/017/001	Film-coated tablet	- R06AX - R06AX26	- Fexofenadine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fexofenadine hydrochloride 180 mg Film-coated Tablets	Chanelle Medical Unlimited Company	PA0688/017/002	Film-coated tablet	- R06AX - R06AX26	- Fexofenadine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fexofenadine Hydrochloride 180 mg Film-coated tablets	Azure Pharmaceuticals Ltd	PA22871/004/003	Film-coated tablet	- R06AX26	- Fexofenadine hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Fiasp	Novo Nordisk A/S	EU/1/16/1160/001-011	Solution for injection	- A10AB - A10AB05	- Insulin aspart	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Fiasp	Novo Nordisk A/S	EU/1/16/1160/001-013	Solution for injection	- A10AB - A10AB05	- Insulin aspart	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Fibrovein 0.2% Solution for Injection	STD Pharmaceutical (Ireland) Limited	PA22778/002/001	Solution for injection	- C05BB04	- Sodium tetradecyl sulfate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Fibrovein 0.5% Solution for Injection	STD Pharmaceutical (Ireland) Limited	PA22778/002/002	Solution for injection	- C05BB04	- Sodium tetradecyl sulfate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Fibrovein 1% Solution for Injection	STD Pharmaceutical (Ireland) Limited	PA22778/002/003	Solution for injection	- C05BB04	- Sodium tetradecyl sulfate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Fibrovein 3% Solution for Injection	STD Pharmaceutical (Ireland) Limited	PA22778/002/004	Solution for injection	- C05BB04	- Sodium tetradecyl sulfate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
FIBRYGA, 1 g, powder and solvent for solution for injection/infusion	Octapharma (IP) SPRL	PA2219/011/001	Powder and solvent for solution for injection/infusion	- B02BB01	- Human fibrinogen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Filgrastim HEXAL	Hexal AG	EU/1/08/496/1-4	Solution for injection in pre-filled syringe	- L03AA - L03AA02	- Ep2006 (recombinant human granulocyte-colony stimulating factor)	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Filgrastim Hexal	Hexal AG	EU/1/08/496/5-8	Solution for injection in pre-filled syringe	- L03AA - L03AA02	- Ep2006 (recombinant human granulocyte-colony stimulating factor)	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Filsuvez	Amryt Pharmaceuticals DAC,	EU/1/22/1652/001-002	Gel	- D03AX - D03AX13	- BETULAE CORTEX DRY EXTRACT (5-10 : 1); EXTRACTION SOLVENT: N-HEPTANE 95% (W/W)	Full application (Article 8(3) of Directive No 2001/83/EC)	
Finasteride 1mg film-coated tablets	Careforsons Ireland Limited	PA22753/002/001	Film-coated tablet	- D11AX10	- Finasteride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Finasteride 5 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/089/001	Film-coated tablet	- G04CB - G04CB01	- Finasteride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fingolimod 0.5 mg hard capsules	Rowa Pharmaceuticals Limited	PA0074/086/001	Capsule, hard	- L04AA27	- Fingolimod	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fingolimod Accord	Accord Healthcare S.L.U.	EU/1/20/1450/001-006	Capsule, hard	- L04AA27	- FINGOLIMOD HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fingolimod Bluefish 0.5 mg hard capsules	Bluefish Pharmaceuticals AB	PA1436/035/001	Capsule, hard	- L04AA27	- FINGOLIMOD HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fingolimod Clonmel 0.5 mg hard capsules	Clonmel Healthcare Ltd	PA0126/319/001	Capsule, hard	- L04AA27	- Fingolimod	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fingolimod Krka 0.5 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/101/001	Capsule, hard	- L04AA27	- FINGOLIMOD HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fingolimod MSN 0.5 mg hard capsules	MSN Labs Europe Limited	PA23250/007/001	Capsule, hard	- L04AA27	- Fingolimod	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fingolimod Mylan	Mylan IRE Healthcare Limited	EU/1/21/1573/001-024	Capsule, hard	- L04AA27	- FINGOLIMOD HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fingolimod Pharmathen 0.5 mg hard capsules	Pharmathen S.A.	PA1368/019/001	Capsule, hard	- L04AA27	- Fingolimod	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fingolimod Teva 0.5 mg hard capsules	Norton Waterford	PA0436/047/001	Capsule, hard	- L04AA27	- Fingolimod	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fingolimod Tillomed 0.5 mg hard capsules	Tillomed Pharma GmbH	PA23169/001/001	Capsule, hard	- L04AA27	- Fingolimod	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Finlee	Novartis Europharm Limited	EU/1/23/1767/001-002	Dispersible tablet	- L01EC02	- Dabrafenib Mesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Finomel Emulsion for Infusion	Baxter Holding B.V.	PA2299/044/002	Emulsion for infusion	- B05BA - B05BA01	- Alanine - Arginine - Glycine - Histidine - Isoleucine - Leucine - Lysine hydrochloride - Methionine - Phenylalanine - Proline - Serine - Threonine - Tryptophan - Tyrosine - Valine - Sodium acetate trihydrate - Potassium chloride - Calcium chloride dihydrate - Magnesium sulphate heptahydrate - Sodium Glycerophosphate Hydrate - Zinc sulphate heptahydrate - Glucose monohydrate - Soya Bean Oil, Refined Ph.Eur - Olive oil, refined - Medium chain triglycerides saturated - Fish oil, rich in omega-3 acids	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Finomel Peri Emulsion for Infusion	Baxter Holding B.V.	PA2299/044/001	Emulsion for infusion	- B05BA - B05BA01	- Alanine - Arginine - Glycine - Histidine - Isoleucine - Leucine - Lysine hydrochloride - Methionine - Phenylalanine - Proline - Serine - Threonine - Tryptophan - Tyrosine - Valine - Sodium acetate trihydrate - Potassium chloride - Calcium chloride dihydrate - Magnesium sulphate heptahydrate - Sodium Glycerophosphate Hydrate - Zinc sulphate heptahydrate - Glucose monohydrate - Soya Bean Oil, Refined Ph.Eur - Olive oil, refined - Medium chain triglycerides saturated - Fish oil, rich in omega-3 acids	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Finovare 20 mg/g Cream	Citrine Healthcare Limited	PA23214/001/001	Cream	- D06AX01	- Fusidic acid	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Fintepla	UCB Pharma S.A.	EU/1/20/1491/001-004	Oral solution	- N03AX - N03AX26	- Fenfluramine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Fintrid 5 mg film-coated tablets	Aurobindo Pharma (Malta) Limited	PA1445/019/001	Film-coated tablet	- G04CB - G04CB01	- Finasteride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Firazyr	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/08/461/001-002	Solution for injection in pre-filled syringe	- B06AC - B06AC02	- Icatibant	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Firdapse	SERB S.A.,	EU/1/09/601/001	Tablet	- N07XX05	- 3,4-diaminopyridine phosphate		- Oral use
Firmagon	Ferring Pharmaceuticals A/S	EU/1/08/504/001	Powder and solvent for solution for injection	- L02BX - L02BX02	- Degarelix (as acetate)		- Subcutaneous use
Firmagon	Ferring Pharmaceuticals A/S	EU/1/08/504/002	Powder and solvent for solution for injection	- L02BX - L02BX02	- Degarelix (as acetate)		- Subcutaneous use
Fixapost 50 micrograms/ml + 5 mg/ml eye drops, solution in single-dose container	Laboratoires Thea	PA1107/014/001	Eye drops, solution in single-dose container	- S01ED - S01ED51	- Timolol - Latanoprost	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Flagyl 400mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/100/008	Film-coated tablet	- P01AB01	- Metronidazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Flagyl-S 200mg/5ml Oral Suspension	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/100/001	Oral suspension	- P01AB01	- Metronidazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Flebogamma	Instituto Grifols S.A.	EU/1/07/404/1-5	Solution for infusion	- J06BA - J06BA02	- Human normal immunoglobulin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Flebogamma DIF	Instituto Grifols S.A.	EU/1/07/404/006-008	Solution for infusion	- J06BA - J06BA02	- Human normal immunoglobulin		- Intravenous use
Flecainide 100mg Tablets	Teva B.V.	PA1986/050/002	Tablet	- C01BC - C01BC04	- Flecainide acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Flecainide 50mg Tablets	Teva B.V.	PA1986/050/001	Tablet	- C01BC - C01BC04	- Flecainide acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Flector Tissugel 140 mg medicated plaster	IBSA Farmaceutici Italia S.r.l	PA1104/004/001	Medicated plaster	- M02AA - M02AA15	- Diclofenac epolamine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Cutaneous use
Flexbumin 200 g/l solution for infusion	Baxalta Innovations GmbH	PA2004/002/001	Solution for infusion	- B05AA - B05AA01	- Human plasma protein	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Flixabi	Samsung Bioepis NL B.V.	EU/1/16/1106/001	Powder for concentrate for solution for infusion	- L04AB - L04AB02	- Infliximab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Flixonase Allergy Relief 50 micrograms per dose Nasal Spray	Haleon Ireland Limited	PA0678/095/001	Nasal spray, suspension	- R01AD - R01AD08	- Fluticasone propionate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intranasal use
Flixotide Diskus 100 micrograms, Inhalation Powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/044/010	Inhalation powder, pre-dispensed	- R03BA - R03BA05	- Fluticasone propionate		- Inhalation use
Flixotide Diskus 250 micrograms, Inhalation Powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/044/011	Inhalation powder, pre-dispensed	- R03BA - R03BA05	- Fluticasone propionate		- Inhalation use
Flixotide Diskus 50 micrograms, Inhalation Powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/044/009	Inhalation powder, pre-dispensed	- R03BA - R03BA05	- Fluticasone propionate		- Inhalation use
Flixotide Diskus 500 micrograms, Inhalation Powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/044/012	Inhalation powder, pre-dispensed	- R03BA - R03BA05	- Fluticasone propionate		- Inhalation use
Flixotide Evohaler	GlaxoSmithKline (Ireland) Limited	PA1077/044/014	Pressurised inhalation, suspension	- R03BA - R03BA05	- Fluticasone propionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Flixotide Evohaler 125 micrograms per metered dose Pressurised Inhalation, Suspension	IMED Healthcare Ltd.	PPA1463/156/001	Pressurised inhalation, suspension	- R03BA - R03BA05	- Fluticasone propionate		- Inhalation use
Flixotide Evohaler 125 micrograms per metered dose pressurised inhalation, suspension	PCO Manufacturing Ltd.	PPA0465/073/001	Pressurised inhalation, suspension	- R03BA - R03BA05	- FLUTICASONE PROPIONATE		- Inhalation use
Flixotide Evohaler 250 micrograms per metered dose pressurised inhalation, suspension	PCO Manufacturing Ltd.	PPA0465/073/002	Pressurised inhalation, suspension	- R03BA - R03BA05	- FLUTICASONE PROPIONATE	ZZZ PPA	- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Flixotide Evohaler 250 micrograms per metered dose Pressurised Inhalation, Suspension	IMED Healthcare Ltd.	PPA1463/156/002	Pressurised inhalation, suspension	- R03BA - R03BA05	- Fluticasone propionate		- Inhalation use
Flixotide Evohaler 250 micrograms per metered dose Pressurised Inhalation, Suspension	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/019/002	Pressurised inhalation, suspension	- R03BA - R03BA05	- FLUTICASONE PROPIONATE		- Inhalation use
Flixotide Evohaler 250 micrograms per metered dose Pressurised Inhalation, Suspension	GlaxoSmithKline (Ireland) Limited	PA1077/044/015	Pressurised inhalation, suspension	- R03BA - R03BA05	- Fluticasone propionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Flixotide Evohaler 50 micrograms per metered dose pressurised inhalation, suspension	PCO Manufacturing Ltd.	PPA0465/073/005	Pressurised inhalation, suspension	- R03BA - R03BA05	- FLUTICASONE PROPIONATE		- Inhalation use
Flixotide Evohaler 50 micrograms per metered dose, Pressurised Inhalation Suspension	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/019/001	Pressurised inhalation, suspension	- R03BA - R03BA05	- Fluticasone propionate		- Inhalation use
Flixotide Evohaler 50 micrograms per metered dose, Pressurised Inhalation Suspension	IMED Healthcare Ltd.	PPA1463/156/003	Pressurised inhalation, suspension	- R03BA05	- Fluticasone propionate	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Inhalation use
Flixotide Evohaler 50 micrograms per metered dose, Pressurised Inhalation Suspension	GlaxoSmithKline (Ireland) Limited	PA1077/044/013	Pressurised inhalation, suspension	- R03BA - R03BA05	- Fluticasone propionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Flolan 0.5 mg powder and solvent for solution for infusion	GlaxoSmithKline (Ireland) Limited	PA1077/058/002	Powder and solvent for solution for infusion	- B01AC - B01AC09	- Epoprostenol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Flolan 1.5 mg powder and solvent for solution for infusion	GlaxoSmithKline (Ireland) Limited	PA1077/058/001	Powder and solvent for solution for infusion	- B01AC - B01AC09	- Epoprostenol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Floxapen 1000 mg powder for solution for injection or infusion	Teva B.V.	PA1986/111/003	Powder for solution for injection/infusion	- J01CF - J01CF05	- Flucloxacillin	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Floxapen 2000 mg powder for solution for injection or infusion	Teva B.V.	PA1986/111/004	Powder for solution for injection/infusion	- J01CF - J01CF05	- Flucloxacillin	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Floxapen 250mg Powder for solution for Injection or Infusion	Teva B.V.	PA1986/111/001	Powder for solution for injection/infusion	- J01CF - J01CF05	- Flucloxacillin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intraarticular use - Intramuscular use - Intrapleural use - Intravenous use
Floxapen 500 mg Powder for Solution for Injection or Infusion	Teva B.V.	PA1986/111/002	Powder for solution for injection/infusion	- J01CF - J01CF05	- Flucloxacillin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intraarticular use - Intramuscular use - Intrapleural use - Intravenous use
Fluad Tetra	Seqirus Netherlands B.V.	EU/1/20/1433/001-004	Suspension for injection in pre-filled syringe	- J07BB02	- A/(H1N1)-LIKE VIRUS ANTIGEN - A/(H3N2)-LIKE VURUS ANTIGEN - B (Victoria Lineage) - Like Virus Antigen - B (Yamagata Lineage)-Like Virus Antigen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Fluarix Tetra suspension for injection in pre-filled syringe Influenza vaccine (split virion, inactivated)	GlaxoSmithKline (Ireland) Limited	PA1077/134/001	Suspension for injection in pre-filled syringe	- J07BB - J07BB02	- A/Victoria/4897/2022 (H1N1)pdm09-like strain (A/Victoria/4897/2022, IVR-238 - A/Darwin/9/2021 (H3N2)-like strain (A/Darwin/6/2021, IVR-227) - B/Austria/1359417/2021 - like strain (B/Austria/1359417/2021, BVR-26) [Victoria lineage] - B/PHUKET/3073/2013 -LIKE STRAIN (B/PHUKET/3073/2013, WILD TYPE)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Flucelvax Tetra	Seqirus Netherlands B.V.	EU/1/18/1326/001	Suspension for injection in pre-filled syringe	- J07BB02	- A/(H3N2)-LIKE VURUS ANTIGEN - A/(H1N1)-LIKE VIRUS ANTIGEN - INFLUENZA B VIRUS INACTIVATED HAEMAGGLUTININ	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Flucillin – Flucloxacillin Capsules 250 mg	Pinewood Laboratories Ltd	PA0281/031/004 Interchangeable List Code: IC0089-130-001	Capsule, hard		- Flucloxacillin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Flucillin – Flucloxacillin capsules 500 mg	Pinewood Laboratories Ltd	PA0281/031/005 Interchangeable List Code: IC0089-117-009	Capsule, hard		- Flucloxacillin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Flucloxacillin 1000 mg Film-coated Tablets	Azure Pharmaceuticals Ltd	PA22871/026/002	Film-coated tablet	- J01CF05	- FLUCLOXACILLIN SODIUM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Flucloxacillin 1000 mg powder for solution for injection or infusion	Esteve Pharmaceuticals GmbH	PA22709/001/002	Powder for solution for injection/infusion	- J01CF - J01CF05	- FLUCLOXACILLIN SODIUM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Flucloxacillin 1000 mg powder for solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/069/002	Powder for solution for injection/infusion	- J01CF05	- FLUCLOXACILLIN SODIUM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intraarticular use - Intramuscular use - Intrapleural use - Intravenous use
Flucloxacillin 1000 mg Powder for solution for injection/infusion	Ibigen Srl	PA1862/003/003	Powder for solution for injection/infusion	- J01CF - J01CF05	- FLUCLOXACILLIN SODIUM	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Flucloxacillin 125 mg/5 ml Powder for Oral Solution, Sugar Free	Brillpharma (Ireland) Limited	PA22749/024/001 Interchangeable List Code: IC0089-129-060	Powder for oral solution		- FLUCLOXACILLIN SODIUM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Flucloxacillin 125mg/5ml Oral Solution	Athlone Pharmaceuticals Limited	PA1418/016/003 Interchangeable List Code: IC0089-129-060	Powder for oral solution		- FLUCLOXACILLIN SODIUM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Flucloxacillin 125mg/5ml Oral Solution BP	Athlone Pharmaceuticals Limited	PA1418/015/001 Interchangeable List Code: IC0089-129-060	Powder for oral solution		- FLUCLOXACILLIN SODIUM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Flucloxacillin 1g Powder for Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/228/003	Powder for solution for injection/infusion	- J01CF - J01CF05	- Flucloxacillin sodium monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Flucloxacillin 2000 mg powder for solution for injection/infusion	Ibigen Srl	PA1862/003/004	Powder for solution for injection/infusion	- J01CF - J01CF05	- FLUCLOXACILLIN SODIUM	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Flucloxacillin 2000 mg powder for solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/069/003	Powder for solution for injection/infusion	- J01CF05	- FLUCLOXACILLIN SODIUM	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intraarticular use - Intramuscular use - Intrapleural use - Intravenous use
Flucloxacillin 250 mg Capsules	Athlone Pharmaceuticals Limited	PA1418/016/001 Interchangeable List Code: IC0089-130-001	Capsule, hard		- Flucloxacillin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Flucloxacillin 250 mg Capsules	Athlone Laboratories Ltd	PA0298/016/001 Interchangeable List Code: IC0089-130-001	Capsule, hard		- Flucloxacillin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Flucloxacillin 250 mg Powder for solution for injection/infusion	Ibigen Srl	PA1862/003/001	Powder for solution for injection/infusion	- J01CF - J01CF05	- FLUCLOXACILLIN SODIUM	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Flucloxacillin 250 mg/5 ml Powder for Oral Solution, Sugar Free	Brillpharma (Ireland) Limited	PA22749/024/002 Interchangeable List Code: IC0089-131-060	Powder for oral solution		- FLUCLOXACILLIN SODIUM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Flucloxacillin 250mg Powder for Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/228/001	Powder for solution for injection/infusion	- J01CF - J01CF05	- Flucloxacillin sodium monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Flucloxacillin 250mg/5ml Oral Solution	Athlone Pharmaceuticals Limited	PA1418/016/004 Interchangeable List Code: IC0089-131-060	Oral solution		- Flucloxacillin	Complete application (stand-alone) - Council Directive 81/851/EEC	- Oral use
Flucloxacillin 500 mg capsules	Athlone Pharmaceuticals Limited	PA1418/016/002 Interchangeable List Code: IC0089-117-009	Capsule, hard		- Flucloxacillin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Flucloxacillin 500 mg capsules	Athlone Laboratories Ltd	PA0298/016/002 Interchangeable List Code: IC0089-117-009	Capsule, hard		- FLUCLOXACILLIN SODIUM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Flucloxacillin 500 mg film-coated tablets	Azure Pharmaceuticals Ltd	PA22871/026/001 Interchangeable List Code: IC0089-117-009	Film-coated tablet		- FLUCLOXACILLIN SODIUM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Flucloxacillin 500 mg powder for solution for injection or infusion	Esteve Pharmaceuticals GmbH	PA22709/001/001	Powder for solution for injection/infusion	- J01CF - J01CF05	- FLUCLOXACILLIN SODIUM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Flucloxacillin 500 mg powder for solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/069/001	Powder for solution for injection/infusion	- J01CF05	- FLUCLOXACILLIN SODIUM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intraarticular use - Intramuscular use - Intrapleural use - Intravenous use
Flucloxacillin 500 mg Powder for solution for injection/infusion	Ibigen Srl	PA1862/003/002	Powder for solution for injection/infusion	- J01CF - J01CF05	- FLUCLOXACILLIN SODIUM	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Flucloxacillin 500mg Powder for Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/228/002	Powder for solution for injection/infusion	- J01CF - J01CF05	- Flucloxacillin sodium monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Flucol 150 mg Hard capsules	Rowex Ltd	PA0711/057/003	Capsule, hard	- J02AC - J02AC01	- Fluconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Flucol 200 mg Hard capsules	Rowex Ltd	PA0711/057/004	Capsule, hard	- J02AC - J02AC01	- Fluconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Flucol 50 mg Hard capsules	Rowex Ltd	PA0711/057/001	Capsule, hard	- J02AC - J02AC01	- Fluconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fluconazole 150 mg hard capsule	Accord Healthcare Ireland Ltd.	PA2315/090/002	Capsule, hard	- J02AC - J02AC01	- Fluconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fluconazole 2 mg / mL Solution for infusion	Noridem Enterprises Limited	PA1122/006/001	Solution for infusion	- J02AC - J02AC01	- Fluconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Fluconazole 2 mg/ml solution for infusion	B. Braun Melsungen AG	PA0736/030/001	Solution for infusion	- J02AC - J02AC01	- Fluconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Fluconazole 2 mg/ml solution for infusion	Baxter Holding B.V.	PA2299/033/001	Solution for infusion	- J02AC - J02AC01	- Fluconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Fluconazole 200 mg hard capsule	Accord Healthcare Ireland Ltd.	PA2315/090/003	Capsule, hard	- J02AC - J02AC01	- Fluconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fluconazole 2mg/ml Solution for Infusion, non-PVC bag	Baxter Holding B.V.	PA2299/033/002	Solution for infusion	- J02AC - J02AC01	- Fluconazole		- Intravenous use
Fluconazole 50 mg hard capsule	Accord Healthcare Ireland Ltd.	PA2315/090/001	Capsule, hard	- J02AC - J02AC01	- Fluconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fludara 10 mg film-coated tablets	Genzyme Europe B.V.	PA0611/004/002	Film-coated tablet	- L01BB - L01BB05	- Fludarabine phosphate		- Oral use
Fludarabine Phosphate 25mg/ml Concentrate for Solution for Injection or Infusion	Accord Healthcare Ireland Ltd.	PA2315/035/001	Concentrate for solution for injection/infusion	- L01BB - L01BB05	- Fludarabine phosphate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Fludrocortisone acetate 0.1 mg tablets	Mylan IRE Healthcare Limited	PA2010/064/001	Tablet	- H02AA - H02AA02	- Fludrocortisone acetate		
Fludrocortisone Acetate Renata 0.1 mg tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/007/001	Tablet	- H02AA02	- Fludrocortisone acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fluenz Tetra	AstraZeneca AB	EU/1/13/887/003-004	Nasal spray, suspension	- J07BB - J07BB03	- Influenza virus, type a, h1n1 - Influenza virus, type a, h3n2 - Influenza virus, type b (yamagata lineage) - Influenza virus, type b (victoria lineage)	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Fluimucil 200 mg granules for oral solution	Zambon S.p.A.	PA1441/001/001	Granules for oral solution	- R05CB - R05CB01	- Acetylcysteine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Flumazenil 0.1 mg/ml solution for injection	Fresenius Kabi Deutschland GmbH	PA2059/037/001	Solution for injection	- V03AB - V03AB25	- Flumazenil	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Fluorescein 100 mg/ml Solution for injection	Pharmargus Limited	PA2273/001/001	Solution for injection	- S01JA01	- Fluorescein sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Fluorouracil 25 mg/ml Solution for Injection or Infusion	Pfizer Healthcare Ireland	PA0822/223/001	Solution for injection/infusion	- L01BC - L01BC02	- Fluorouracil sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Fluorouracil 50 mg/ml solution for injection or infusion	Accord Healthcare Ireland Ltd.	PA2315/091/001	Solution for injection/infusion	- L01BC - L01BC02	- Fluorouracil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Fluoxetine 20 mg/ 5 ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/010/001	Oral solution	- N06AB - N06AB03	- FLUOXETINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fluoxetine 20mg Hard Capsules	Brillpharma (Ireland) Limited	PA22749/002/001 Interchangeable List Code: IC0075-003-001	Capsule, hard		- Fluoxetine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fluoxetine 60 mg Hard Capsules	Brillpharma (Ireland) Limited	PA22749/002/002 Interchangeable List Code: IC0075-127-001	Capsule, hard		- Fluoxetine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fluticasone propionate 50 micrograms/actuation, nasal spray, suspension	Haleon Ireland Limited	PA0678/118/001	Nasal spray, suspension	- R01AD - R01AD08	- Fluticasone propionate (micronised)	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Nasal use
Flutiform 125 microgram/5 microgram per metered dose pressurised inhalation, suspension	IMED Healthcare Ltd.	PPA1463/138/002	Pressurised inhalation, suspension	- R03AK - R03AK11	- FLUTICASONE PROPIONATE - Formoterol fumarate		- Inhalation use
Flutiform 125 microgram/5 microgram per metered dose pressurised inhalation, suspension	Mundipharma Pharmaceuticals Limited	PA1688/013/002	Pressurised inhalation, suspension	- R03AK - R03AK11	- Fluticasone propionate - Formoterol fumarate dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Flutiform 250 microgram/10 microgram per metered dose pressurised inhalation, suspension	Mundipharma Pharmaceuticals Limited	PA1688/013/003	Pressurised inhalation, suspension	- R03AK - R03AK11	- Fluticasone propionate - Formoterol fumarate dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Flutiform 250 microgram/10 microgram per metered dose pressurised inhalation, suspension	IMED Healthcare Ltd.	PPA1463/138/001	Pressurised inhalation, suspension	- R03AK - R03AK11	- FLUTICASONE PROPIONATE - Formoterol fumarate		- Inhalation use
Flutiform 50 microgram/5 microgram per metered dose pressurised inhalation, suspension	Mundipharma Pharmaceuticals Limited	PA1688/013/001	Pressurised inhalation, suspension	- R03AK - R03AK11	- Fluticasone propionate - Formoterol fumarate dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Fluzac 20mg Capsules	Rowex Ltd	PA0711/110/001 Interchangeable List Code: IC0075-003-001	Capsule, hard		- FLUOXETINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
FML Liquifilm 0.1% w/v Sterile Eye Drops Suspension	AbbVie Limited	PA1824/008/001	Eye drops, suspension	- S01BA - S01BA07	- Fluorometholone		- Topical use
Foclivia	Seqirus S.r.l.	EU/1/09/577/1-4	Suspension for injection	- J07BB - J07BB02	- A/vietnam/1194/2004 (h5n1) virus surface inactivated antigen		- Intramuscular use
Folic Acid 400 microgram Tablets	Generic Pharma International (G.P.I) Limited	PA23155/001/001	Tablet	- B03BB - B03BB01	- Folic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Folic Acid 5mg Tablets	Clonmel Healthcare Ltd	PA0126/057/001	Tablet	- B03BB - B03BB01	- Folic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Folinic acid (as calcium folinate) 10 mg/ml solution for injection/infusion	AS Kalceks	PA2165/024/001	Solution for injection/infusion	- V03AF03	- Calcium folinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Folinic acid (as calcium folinate) 10mg/ml solution for injection or infusion	Fresenius Kabi Deutschland GmbH	PA2059/001/001	Solution for injection/infusion	- V03AF - V03AF03	- Folinic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Folinic Acid (as Calcium Folinate) 15mg Tablets	Pfizer Healthcare Ireland	PA0822/198/001	Tablet	- V03AF - V03AF03	- Folinic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fomepizole SERB 5 mg/mL, concentrate for solution for infusion.	SERB S.A.,	PA20595/001/001	Concentrate for solution for infusion	- V03AB - V03AB34	- Fomepizole sulphate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Fomicyt 40mg/ml Powder for solution for infusion	InfectoPharm Arzneimittel und Consilium GmbH	PA1972/001/001	Powder for solution for infusion	- J01XX - J01XX01	- FOSFOMYCIN SODIUM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Fondaparinux Sodium Aspen 1.5 mg/0.3 ml solution for injection, pre-filled syringe	Aspen Pharma Trading Limited	PA1691/034/001	Solution for injection	- B01AX05	- Fondaparinux sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Fondaparinux sodium Aspen 10 mg/0.8 ml solution for injection, pre-filled syringe.	Aspen Pharma Trading Limited	PA1691/034/005	Solution for injection	- B01AX05	- Fondaparinux sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Fondaparinux sodium Aspen 2.5 mg/0.5 ml solution for injection, pre-filled syringe.	Aspen Pharma Trading Limited	PA1691/034/002	Solution for injection	- B01AX05	- Fondaparinux sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Fondaparinux sodium Aspen 5 mg/0.4 ml solution for injection, pre-filled syringe.	Aspen Pharma Trading Limited	PA1691/034/003	Solution for injection	- B01AX05	- Fondaparinux sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Fondaparinux sodium Aspen 7.5 mg/0.6 ml solution for injection, pre-filled syringe.	Aspen Pharma Trading Limited	PA1691/034/004	Solution for injection	- B01AX05	- Fondaparinux sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Formoterol 12 micrograms inhalation powder, hard capsule	Laboratorios LICONSA, S.A.	PA1239/001/001	Inhalation powder, hard capsule	- R03AC - R03AC13	- Formoterol fumarate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
Forsteo	Eli Lilly Nederland B.V.	EU/1/03/247/01-2	Solution for injection	- H05AA - H05AA02	- Teriparatide	New active substance (Article 8(3) of Directive No 2001/83/EC)	
Fortacin	Recordati Ireland Limited	EU/1/13/381/001	Cutaneous spray, solution	- N01BB - N01BB20	- Lidocaine - Prilocaine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Cutaneous use
Fortum 1 g powder for solution for injection or infusion	Sandoz Pharmaceuticals d.d.	PA23311/001/002	Powder for solution for injection/infusion	- J01DD - J01DD02	- Ceftazidime		- Intramuscular use - Subcutaneous use
Fortum 2 g powder for solution for injection or infusion	Sandoz Pharmaceuticals d.d.	PA23311/001/003	Powder for solution for injection/infusion	- J01DD - J01DD02	- Ceftazidime		- Intravenous use
Fortum 500 mg powder for solution for injection	Sandoz Pharmaceuticals d.d.	PA23311/001/001	Powder for solution for injection	- J01DD - J01DD02	- Ceftazidime		- Intramuscular use
Forxiga	AstraZeneca AB	EU/1/12/795/001-005	Film-coated tablet	- A10BK - A10BK01	- Dapagliflozin propanediol monohydrate equivalent to 5mg dapagliflozin	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Forxiga	AstraZeneca AB	EU/1/12/795/006-010	Film-coated tablet	- A10BK - A10BK01	- Dapagliflozin propanediol monohydrate equivalent to 10mg dapagliflozin	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
FOSAMAX Once Weekly 70 mg tablets	Organon Pharma (Ireland) Limited	PA23198/003/001 Interchangeable List Code: IC0051-101-002	Tablet		- Alendronic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Fosavance 70 mg/2800 IU tablets	N.V. Organon	EU/1/05/310/1-4 Interchangeable List Code: IC0052-102-002	Tablet		- Vitamin d3 - Alendronic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Fosavance 70 mg/5600 IU tablets	N.V. Organon	EU/1/05/310/6-8 Interchangeable List Code: IC0052-103-002	Tablet		- Vitamin d3 - Alendronic acid		- Oral use
Foscan	Biolitec Pharma Limited	EU/1/01/197/001	Solution for injection	- L01XD	- Temoporfin		- Intravenous use
Foscan	Biolitec Pharma Limited	EU/1/01/197/002	Solution for injection	- L01XD	- Temoporfin		- Intravenous use
Foscarnet sodium hexahydrate Tillomed 24 mg/ml solution for infusion	Tillomed Pharma GmbH	PA22720/009/001	Solution for infusion	- J05AD01	- Foscarnet Sodium Hexahydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Fostair 100 microgram/6 microgram per actuation pressurised inhalation solution	Chiesi Farmaceutici S.p.A.	PA0584/008/001	Pressurised inhalation, solution	- R03AK08	- Beclometasone dipropionate - Formoterol fumarate dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Fostair 200 microgram/6 microgram per actuation pressurised inhalation solution	Chiesi Farmaceutici S.p.A.	PA0584/008/003	Pressurised inhalation, solution	- R03AK - R03AK08	- Beclometasone dipropionate - Formoterol fumarate dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Fostair Nexthaler 100 micrograms/6 micrograms per metered dose inhalation powder	Chiesi Farmaceutici S.p.A.	PA0584/008/002	Inhalation powder	- R03AK - R03AK08	- Beclometasone dipropionate - Formoterol fumarate dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Fostair Nexthaler 200 micrograms/12 micrograms per metered dose inhalation powder	Chiesi Farmaceutici S.p.A.	PA0584/008/005	Inhalation powder	- R03AK08	- Beclometasone dipropionate - Formoterol fumarate dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Fostair Nexthaler 200 micrograms/6 micrograms per metered dose inhalation powder	Chiesi Farmaceutici S.p.A.	PA0584/008/004	Inhalation powder	- R03AK - R03AK08	- Beclometasone dipropionate - Formoterol fumarate dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Fostepor Once Weekly 70mg tablets	Viatris Limited	PA23266/018/001 Interchangeable List Code: IC0051-101-002	Tablet		- Alendronic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Fostimon 150 IU, powder and solvent for solution for injection	IBSA Farmaceutici Italia S.r.l	PA1104/002/002	Powder and solvent for solution for injection	- G03GA - G03GA04	- Urofollitropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Fostimon 75 IU, powder and solvent for solution for injection	IBSA Farmaceutici Italia S.r.l	PA1104/002/001	Powder and solvent for solution for injection	- G03GA - G03GA04	- Urofollitropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Fostimon PFS 150 IU Powder and Solvent for Solution for Injection	IBSA Farmaceutici Italia S.r.l	PA1104/002/004	Powder and solvent for solution for injection	- G03GA - G03GA04	- Urofollitropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Fostimon PFS 225 IU Powder and Solvent for Solution for Injection	IBSA Farmaceutici Italia S.r.l	PA1104/002/005	Powder and solvent for solution for injection	- G03GA - G03GA04	- Urofollitropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Fostimon PFS 300 IU Powder and Solvent for Solution for Injection	IBSA Farmaceutici Italia S.r.l	PA1104/002/006	Powder and solvent for solution for injection	- G03GA - G03GA04	- Urofollitropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Fostimon PFS 75 IU Powder and Solvent for Solution for Injection	IBSA Farmaceutici Italia S.r.l	PA1104/002/003	Powder and solvent for solution for injection	- G03GA - G03GA04	- Urofollitropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Fotivda	EUSA Pharma (Netherlands) B.V.	EU/1/17/1215/001	Capsule, hard	- L01XE - L01XE34	- Tivozanib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Fotivda	EUSA Pharma (Netherlands) B.V.	EU/1/17/1215/002	Capsule, hard		- Tivozanib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Foznol 1000 mg Chewable Tablets	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/002/004	Chewable tablet	- V03AE - V03AE03	- Lanthanum carbonate hydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Foznol 1000 mg Chewable Tablets	PCO Manufacturing Ltd.	PPA0465/495/001	Chewable tablet	- V03AE - V03AE03	- Lanthanum	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Foznol 1000 mg Oral Powder	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/002/006	Oral powder	- V03AE - V03AE03	- Lanthanum carbonate hydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Foznol 250 mg Chewable Tablets	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/002/001	Chewable tablet	- V03AE - V03AE03	- Lanthanum carbonate hydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Foznol 500 mg Chewable Tablets	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/002/002	Chewable tablet	- V03AE - V03AE03	- Lanthanum carbonate hydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Foznol 750 mg Chewable Tablets	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/002/003	Chewable tablet	- V03AE - V03AE03	- Lanthanum carbonate hydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Foznol 750 mg Oral Powder	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/002/005	Oral powder	- V03AE - V03AE03	- Lanthanum carbonate hydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Freedo 0.03mg/3mg film-coated tablets	Rowex Ltd	PA0711/218/001	Film-coated tablet	- G03AA - G03AA12	- Drospirenone - Ethinylestradiol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Freedonel 0.02 mg/3 mg film-coated tablets	Rowex Ltd	PA0711/208/001	Film-coated tablet	- G03AA - G03AA12	- Ethinylestradiol - Drospirenone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fresenius Propoven 2 % emulsion for injection or infusion, vial	Fresenius Kabi Deutschland GmbH	PA2059/017/003	Emulsion for injection/infusion	- N01AX - N01AX10	- Propofol	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intravenous use
Frisium 10mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/043/001	Tablet	- N05BA - N05BA09	- Clobazam		- Oral use
Frovatriptan 2.5mg Film-coated Tablets	Chanelle Medical Unlimited Company	PA0688/027/001	Film-coated tablet	- N02CC - N02CC07	- Frovatriptan succinate monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
FROVEX 2.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/009/001	Film-coated tablet	- N02CC - N02CC07	- FROVATRIPTAN	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
FROVEX 2.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/321/001	Film-coated tablet	- N02CC - N02CC07	- Frovatriptan succinate monohydrate		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Frumil 40mg/5mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/101/002	Tablet	- C03EB - C03EB01	- Furosemide - AMILORIDE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Fucibet 20 mg/g + 1 mg/g cream	Leo Laboratories Limited	PA0046/040/001	Cream	- D07CC - D07CC01	- Fusidic acid - Betamethasone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Fucibet Lipid 20 mg/g + 1 mg/g cream	PCO Manufacturing Ltd.	PPA0465/231/002	Cream	- D07CC01	- Betamethasone - Fusidic acid	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Cutaneous use
Fucibet Lipid 20mg/g + 1mg/g cream	IMED Healthcare Ltd.	PPA1463/197/001	Cream	- D07CC - D07CC01	- Fusidic acid - Betamethasone		- Topical use
Fucibet Lipid 20mg/g + 1mg/g cream	Leo Laboratories Limited	PA0046/040/002	Cream	- D07CC - D07CC01	- Fusidic acid - Betamethasone		- Topical use
Fucidin 20 mg/g cream	Leo Laboratories Limited	PA0046/004/012	Cream	- D06AX - D06AX01	- Fusidic acid hemihydrate		- Cutaneous use
Fucidin 20 mg/g Cream	IMED Healthcare Ltd.	PPA1463/083/001	Cream	- D06AX - D06AX01	- Fusidic acid		- Not Currently Available
Fucidin 20 mg/g ointment	Leo Laboratories Limited	PA0046/004/008	Ointment	- D06AX - D06AX01	- Sodium fusidate		- Cutaneous use
Fucidin 250mg Tablets	Leo Laboratories Limited	PA0046/004/014	Tablet	- J01XC - J01XC01	- Sodium fusidate		- Oral use
Fucidin H 20mg/g + 10mg/g Cream	Leo Laboratories Limited	PA0046/005/005	Cream	- D07CA - D07CA01	- Fusidic acid anhydrous - HYDROCORTISONE ACETATE		- Cutaneous use
Fucithalmic 10mg/g Viscous Eye Drops, suspension	Amdipharm Limited	PA1142/016/001	Eye drops, suspension	- S01AA - S01AA13	- Fusidic acid anhydrous		- Ocular use
Fulphila	Biosimilar Collaborations Ireland Limited	EU/1/18/1329/001-002	Solution for injection in pre-filled syringe	- L03AA13	- Pegfilgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Fulvestrant 250 mg Solution for injection in pre-filled syringe	Accord Healthcare Ireland Ltd.	PA2315/046/001 Interchangeable List Code: IC0129-130-063	Solution for injection in pre-filled syringe		- Fulvestrant	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Fulvestrant 250 mg solution for injection in pre-filled syringe	Reddy Holding GmbH	PA23092/001/001 Interchangeable List Code: IC0129-130-063	Solution for injection in pre-filled syringe		- Fulvestrant	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Fulvestrant EVER Pharma 250 mg solution for injection in pre-filled syringe	EVER Valinject GmbH	PA1774/006/001 Interchangeable List Code: IC0129-130-063	Solution for injection in pre-filled syringe		- Fulvestrant	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Fulvestrant Mylan 250 mg solution for injection in pre-filled syringe	Mylan Pharmaceuticals Limited	EU/1/17/1253/001-002 Interchangeable List Code: IC0129-130-063	Solution for injection in pre-filled syringe		- Fulvestrant	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Fulvestrant Rowex 250 mg/5 ml solution for injection in pre-filled syringe	Rowex Ltd	PA0711/245/001 Interchangeable List Code: IC0129-130-063	Solution for injection in pre-filled syringe		- Fulvestrant	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Fulvestrant Teva 250 mg Solution for Injection in Pre-filled Syringe	Teva B.V.	PA1986/011/001 Interchangeable List Code: IC0129-130-063	Solution for injection in pre-filled syringe		- Fulvestrant	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Fungasil 250mg Tablets	Clonmel Healthcare Ltd	PA0126/141/001	Tablet	- D01BA - D01BA02	- Terbinafine		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Fungizone 50 mg Powder for sterile concentrate	CHEPLAPHARM Arzneimittel GmbH	PA2239/004/001	Powder for concentrate for solution for infusion	- J02AA - J02AA01	- Amphotericin		- Intravenous use
Furosemide 10 mg/ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/011/003	Oral solution	- C03CA - C03CA01	- Furosemide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Furosemide 10 mg/ml solution for injection	hameln pharma gmbh	PA2237/002/001	Solution for injection	- C03CA01	- Furosemide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Furosemide 10 mg/ml Solution for Injection	Baxter Holding B.V.	PA2299/036/001	Solution for injection	- C03CA - C03CA01	- Furosemide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Furosemide 10 mg/ml Solution for Injection or Infusion	Accord Healthcare Ireland Ltd.	PA2315/163/001	Solution for injection/infusion	- C03CA - C03CA01	- Furosemide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Furosemide 20 mg Tablets	Clonmel Healthcare Ltd	PA0126/008/001	Tablet	- C03CA - C03CA01	- Furosemide		- Oral use
Furosemide 20 mg/2 ml solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/038/001	Solution for injection	- C03CA - C03CA01	- Furosemide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Furosemide 20mg in 2ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/059/004	Solution for injection	- C03CA - C03CA01	- Furosemide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Furosemide 250mg in 25ml Solution for Injection/Infusion	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/059/006	Solution for injection/infusion	- C03CA - C03CA01	- Furosemide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Furosemide 4 mg/ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/011/001	Oral solution	- C03CA - C03CA01	- Furosemide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Furosemide 40 mg Tablets	Clonmel Healthcare Ltd	PA0126/008/002	Tablet	- C03CA - C03CA01	- Furosemide		- Oral use
Furosemide 50mg in 5ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/059/005	Solution for injection	- C03CA - C03CA01	- Furosemide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Furosemide 8 mg/ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/011/002	Oral solution	- C03CA - C03CA01	- Furosemide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Furosemide Bristol 20 mg Tablets	Brillpharma (Ireland) Limited	PA22749/001/001	Tablet	- C03CA - C03CA01	- Furosemide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Furosemide Bristol 40 mg Tablets	Brillpharma (Ireland) Limited	PA22749/001/002	Tablet	- C03CA - C03CA01	- Furosemide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Furosemide Pinewood 20 mg Tablets	Pinewood Laboratories Ltd	PA0281/263/001	Tablet	- C03CA01	- Furosemide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Furosemide Pinewood 40 mg Tablets	Pinewood Laboratories Ltd	PA0281/263/002	Tablet	- C03CA01	- Furosemide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fuzeon	Roche Registration GmbH	EU/1/03/252/001	Powder and solvent for solution for injection	- J05AX - J05AX07	- Enfuvirtide		
Fybogel Citrus 3.5 g Granules	Reckitt Benckiser Ireland Ltd	PA0979/009/001	Granules	- A06AC - A06AC01	- Ispaghula husks		- Oral use
Fybogel Mebeverine Granules for Oral Suspension Ispaghula Husk 3.5g Mebeverine Hydrochloride 135mg	Reckitt Benckiser Ireland Ltd	PA0979/010/001	Granules for oral suspension	- A06AC - A06AC51	- Mebeverine hydrochloride - Ispaghula husks		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Fybogel Orange 3.5 g granules	Reckitt Benckiser Ireland Ltd	PA0979/009/002	Granules	- A06AC - A06AC01	- Ispaghula husks		- Oral use
Fycompa	Eisai GmbH	EU/1/12/776/001	Film-coated tablet	- N03AX - N03AX22	- Perampanel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fycompa	Eisai GmbH	EU/1/12/776/002-004	Film-coated tablet	- N03AX - N03AX22	- Perampanel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fycompa	Eisai GmbH	EU/1/12/776/005-007	Film-coated tablet	- N03AX - N03AX22	- Perampanel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fycompa	Eisai GmbH	EU/1/12/776/008-010	Film-coated tablet	- N03AX - N03AX22	- Perampanel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fycompa	Eisai GmbH	EU/1/12/776/011-013	Film-coated tablet	- N03AX - N03AX22	- Perampanel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fycompa	Eisai GmbH	EU/1/12/776/014-016	Film-coated tablet	- N03AX - N03AX22	- Perampanel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Fycompa	Eisai GmbH	EU/1/12/776/024	Oral suspension	- N03AX - N03AX22	- Perampanel	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Fydrane 0.2 mg/ml + 3.1 mg/ml + 10 mg/ml, solution for injection	Laboratoires Thea	PA1107/012/001	Solution for injection	- S01FA - S01FA56	- Tropicamide - Phenylephrine hydrochloride - Lidocaine Hydrochloride Monohydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Intraocular use
Gabapentin 100 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/164/003 Interchangeable List Code: IC0109-024-001	Capsule, hard		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gabapentin 300 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/164/004 Interchangeable List Code: IC0109-029-001	Capsule, hard		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gabapentin 400 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/164/005 Interchangeable List Code: IC0109-068-001	Capsule, hard		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gabapentin 600 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/164/001 Interchangeable List Code: IC0109-168-003	Film-coated tablet		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gabapentin 800 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/164/002 Interchangeable List Code: IC0109-169-003	Film-coated tablet		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gabapentin Auro 300 mg hard capsules	Aurobindo Pharma (Malta) Limited	PA1445/026/002 Interchangeable List Code: IC0109-029-001	Capsule, hard		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gabapentin Auro 400 mg hard capsules	Aurobindo Pharma (Malta) Limited	PA1445/026/003 Interchangeable List Code: IC0109-068-001	Capsule, hard		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gabapentin Auro100 mg hard capsules	Aurobindo Pharma (Malta) Limited	PA1445/026/001 Interchangeable List Code: IC0109-024-001	Capsule, hard		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Gabapentin Aurobindo 100 mg capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/025/001 Interchangeable List Code: IC0109-024-001	Capsule, hard		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gabapentin Aurobindo 300 mg capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/025/002 Interchangeable List Code: IC0109-029-001	Capsule, hard		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gabapentin Aurobindo 400 mg capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/025/003 Interchangeable List Code: IC0109-068-001	Capsule, hard		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gabapentin Rosemont 50mg/ml Oral Solution	Taw Pharma (Ireland) Limited	PA23081/010/001	Oral solution	- N03AX - N03AX12	- Gabapentin	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Gabin 100 mg capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/020/001 Interchangeable List Code: IC0109-024-001	Capsule, hard		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gabin 300 mg capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/020/002 Interchangeable List Code: IC0109-029-001	Capsule, hard		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gabin 400 mg capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/020/003 Interchangeable List Code: IC0109-068-001	Capsule, hard		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gabitril 10 mg film-coated tablets	Teva Pharma B.V.	PA0749/199/002	Film-coated tablet	- N03AG - N03AG06	- Tiagabine		- Oral use
Gabitril 15 mg film-coated tablets	Teva Pharma B.V.	PA0749/199/003	Film-coated tablet	- N03AG - N03AG06	- Tiagabine		- Oral use
Gabitril 5 mg, film-coated tablet	Teva Pharma B.V.	PA0749/199/001	Film-coated tablet	- N03AG - N03AG06	- Tiagabine anhydrous		- Oral use
Gadovist 1.0 mmol/ml solution for injection	Bayer Limited	PA1410/018/003	Solution for injection	- V08CA - V08CA09	- Gadobutrol		- Intravenous use
Gadovist 1.0 mmol/ml solution for injection	Bayer Limited	PA1410/018/001	Solution for injection	- V08CA - V08CA09	- Gadobutrol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Gadovist 1.0 mmol/ml solution for injection in prefilled cartridge	Bayer Limited	PA1410/018/004	Solution for injection in cartridge	- V08CA - V08CA09	- Gadobutrol		- Intravenous use
Gadovist 1.0 mmol/ml solution for injection in prefilled syringe	Bayer Limited	PA1410/018/002	Solution for injection in pre-filled syringe	- V08CA - V08CA09	- Gadobutrol		- Intravenous use
Galafold	Amicus Therapeutics Europe Limited	EU/1/15/1082/001	Capsule, hard		- Migalastat hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Galfer 140 mg/5ml Oral Suspension	Clonmel Healthcare Ltd	PA0126/314/002	Oral suspension	- B03AA - B03AA02	- Ferrous fumarate Ph.Eur.		- Oral use
Galfer 305 mg Hard Capsules	Clonmel Healthcare Ltd	PA0126/314/001	Capsule, hard	- B03AA - B03AA02	- Ferrous fumarate		- Oral use
Galfer FA 305 mg / 0.35 mg Hard Capsules	Clonmel Healthcare Ltd	PA0126/317/001	Capsule, hard	- B03AD - B03AD02	- Ferrous fumarate - Folic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
GalliaPharm 0.74 – 1.85 GBq radionuclide generator	Eckert & Ziegler Radiopharma GmbH	PA2192/001/001	Radionuclide generator	- V09X	- GERMANIUM (68GE) CHLORIDE - Gallium (68Ga) Chloride	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Route of administration not applicable

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Gallium (Ga67) Citrate injection	Curium Netherlands B.V.	PA0690/003/001	Solution for injection	- V09HX - V09HX01	- Gallium (67 ga) citrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Galsya SR 16 mg prolonged-release capsules, hard	KRKA, d.d., Novo mesto	PA1347/015/002	Prolonged-release capsule, hard	- N06DA - N06DA04	- Galantamine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Galsya SR 24 mg prolonged-release capsules, hard	KRKA, d.d., Novo mesto	PA1347/015/003	Prolonged-release capsule, hard	- N06DA - N06DA04	- Galantamine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Galsya SR 8 mg prolonged-release capsules, hard	KRKA, d.d., Novo mesto	PA1347/015/001	Prolonged-release capsule, hard	- N06DA - N06DA04	- Galantamine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Galtasa 1000 mg gastro-resistant tablets	Faes Farma S.A.	PA0864/001/003	Gastro-resistant tablet	- A07EC02	- Mesalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Galtasa 500 mg gastro-resistant tablets	Faes Farma S.A.	PA0864/001/001	Gastro-resistant tablet	- A07EC02	- Mesalazine	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Galtasa 500 mg suppositories	Faes Farma S.A.	PA0864/001/002	Suppository	- A07EC02	- Mesalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Rectal use
Galvus	Novartis Europharm Limited	EU/1/07/414/1-10	Tablet	- A10BH - A10BH02	- Vildagliptin		- Oral use
Galvus	Novartis Europharm Limited	EU/1/07/414/11-17	Tablet	- A10BH02	- Vildagliptin		- Oral use
Gamanil 70mg film-coated tablets	Zentiva k.s.	PA1701/004/001	Film-coated tablet	- N06AA - N06AA07	- Lofepramine hydrochloride		- Oral use
Gammagard S/DHuman Normal Immunoglobulin for Intravenous Administration Powder and solvent for solution for infusion	Baxalta Innovations GmbH	PA2004/003/001	Powder and solvent for solution for infusion	- J06BA - J06BA02	- HUMAN PLASMA PROTEIN >90% GAMMA GLOBULIN	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Gammanorm, 165 mg/mL, solution for injection	Octapharma (IP) SPRL	PA2219/006/001	Solution for injection	- J06BA - J06BA02	- Human normal immunoglobulin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Gamunex® 10%, 100 mg/ml, solution for infusion	Grifols Deutschland GmbH	PA1405/001/001	Solution for infusion	- J06BA - J06BA02	- Immunoglobulin human normal	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ganfort	AbbVie Deutschland GmbH & Co. KG	EU/1/06/340/001-002	Eye drops, solution	- S01ED - S01ED51	- Bimatoprost - Timolol		
Ganirelix Gedeon Richter	Chemical Works Of Gedeon Richter PLC	EU/1/22/1658/001-002	Solution for injection in pre-filled syringe	- H01CC01	- Ganirelix Acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Gardasil	Merck Sharp & Dohme BV,	EU/1/06/357/01-21	Suspension for injection	- J07BM01	- Quadrivalent human papillomavirus type 11 recombinant vaccine (in) - Quadrivalent human papillomavirus type 16 recombinant vaccine (in) - Quadrivalent human papillomavirus type 18 recombinant vaccine (in) - Quadrivalent human papillomavirus type 6 recombinant vaccine		- Intramuscular use
Gardasil 9	Merck Sharp & Dohme BV,	EU/1/15/1007/001-003	Suspension for injection	- J07B	- Hpv type 6 l1 protein - Hpv type 11 l1 protein - Hpv 16 l1 protein - Hpv 18 l1 protein - Hpv type 31 l1 protein - Hpv type 33 l1 protein - Hpv type 45 l1 protein - Hpv type 52 l1 protein - Hpv type 58 l1 protein	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Gastrografin, 660mg/ml and 100mg/ml Oral and Rectal Solution	Bayer Limited	PA1410/004/001	Oral/rectal solution	- V08AC - V08AC08	- Sodium amidotrizoate - Amidotrizoate meglumine - AMIDOTRIZOIC ACID - Meglumine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Not Currently Available
Gastromiro 612.4mg/ml oral or rectal solution	Bracco Imaging spa	PA1826/005/001	Oral/rectal solution	- V08AB - V08AB04	- Iopamidol		- Oral use - Rectal use
Gaviscon Advance Chewable Tablets Sodium alginate 500 mg, Potassium hydrogen carbonate 100 mg.	Reckitt Benckiser Ireland Ltd	PA0979/011/008	Chewable tablet	- A02BX - A02BX13	- Potassium bicarbonate - Sodium alginate		- Oral use
Gaviscon Advance Oral Suspension Sodium alginate 500 mg, Potassium hydrogen carbonate 100 mg.	Reckitt Benckiser Ireland Ltd	PA0979/011/001	Oral suspension	- A02BX	- Potassium hydrogen carbonate - Sodium alginate		- Oral use
Gaviscon Advance Peppermint Oral Suspension Sachets Sodium Alginate 500mg, Potassium hydrogen carbonate 100 mg Oral suspension.	Reckitt Benckiser Ireland Ltd	PA0979/011/006	Oral suspension	- A02BX - A02BX13	- Sodium alginate - Potassium hydrogen carbonate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Gaviscon Advance Peppermint Oral Suspension Sodium alginate 500 mg, Potassium hydrogen carbonate 100 mg.	Reckitt Benckiser Ireland Ltd	PA0979/011/007	Oral suspension	- A02BX - A02BX13	- Sodium alginate - Potassium hydrogen carbonate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Gaviscon Extra Chewable TabletsSodium alginate 250mgSodium bicarbonate 106.5mgCalcium carbonate 187.5mg	Reckitt Benckiser Ireland Ltd	PA0979/015/012	Chewable tablet	- A02BX - A02BX13	- Sodium alginate - Sodium bicarbonate - Calcium carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Gaviscon Extra Liquid Sachets Peppermint Flavour Oral SuspensionSodium Alginate 500 mg/10 ml Sodium Bicarbonate 213 mg/10 ml Calcium Carbonate 325 mg/10 ml	Reckitt Benckiser Ireland Ltd	PA0979/015/013	Oral suspension in sachet	- A02BX - A02BX13	- Sodium alginate - Sodium bicarbonate - Calcium carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Gaviscon Extra Mixed Berries Flavour Chewable Tablets Sodium alginate 250 mg Sodium hydrogen carbonate 106.5 mg Calcium carbonate 187.5 mg	Reckitt Benckiser Ireland Ltd	PA0979/082/001	Chewable tablet	- A02BX - A02BX13	- Sodium alginate - Sodium hydrogen carbonate - Calcium carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Gaviscon Extra Oral Suspension Sodium alginate 500 mg Sodium bicarbonate 213 mg Calcium carbonate 325 mg	Reckitt Benckiser Ireland Ltd	PA0979/015/011	Oral suspension	- A02BX - A02BX13	- Sodium alginate - Sodium bicarbonate - Calcium carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Gaviscon Infant, Powder for Oral Suspension	Reckitt Benckiser Ireland Ltd	PA0979/012/001	Powder for oral suspension	- A02BX - A02BX13	- Sodium alginate - Magnesium alginate		- Oral use
Gaviscon Liquid Peppermint Flavour, Oral Suspension Sodium alginate 500 mg Sodium bicarbonate 267 mg Calcium carbonate 160 mg	Reckitt Benckiser Ireland Ltd	PA0979/015/002	Oral suspension	- A02AX	- Sodium alginate - Calcium carbonate - Sodium bicarbonate		- Oral use
Gaviscon Liquid Sachets Oral Suspension Sodium alginate 500mg, Sodium bicarbonate 267mg, Calcium carbonate 160mg	Reckitt Benckiser Ireland Ltd	PA0979/015/010	Oral suspension in sachet	- A02BX - A02BX13	- Sodium alginate - Sodium bicarbonate - Calcium carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Gaviscon Liquid-Aniseed Flavour, Oral Suspension Each 10 ml contains: Sodium alginate 500 mg Sodium bicarbonate 267 mg Calcium carbonate 160 mg	Reckitt Benckiser Ireland Ltd	PA0979/015/003	Oral suspension	- A02AX - A02AX13	- Sodium bicarbonate - Calcium carbonate - Sodium alginate		- Oral use
Gaviscon Oral Suspension 500mg/10ml Sodium Alginate 267mg/10ml Sodium Bicarbonate 160mg/10ml Calcium Carbonate	Reckitt Benckiser Ireland Ltd	PA0979/015/001	Oral suspension	- A02AX - A02AX13	- Sodium bicarbonate - Calcium carbonate - Sodium alginate		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Gaviscon Peppermint Chewable Tablets Sodium alginate 250mg Sodium hydrogen Carbonate 133.5mgCalcium Carbonate 80mg	Reckitt Benckiser Ireland Ltd	PA0979/015/004	Chewable tablet	- A02BX - A02BX13	- Sodium alginate - Sodium hydrogen carbonate - Calcium carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Gaviscon Strawberry Chewable Tablets Sodium alginate 250mg Sodium hydrogen Carbonate 133.5mg Calcium Carbonate 80mg	Reckitt Benckiser Ireland Ltd	PA0979/015/005	Chewable tablet	- A02BX - A02BX13	- Sodium alginate - Sodium hydrogen carbonate - Calcium carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Gavreto	Roche Registration GmbH	EU/1/21/1555/001-003	Capsule, hard	- L01EX23	- Pralsetinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Gazyvaro	Roche Registration GmbH	EU/1/14/937/001	Concentrate for solution for infusion	- L01XC - L01XC15	- Obinutuzumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Gedarel 20/150 microgram film-coated tablets	Gedeon Richter Plc	PA1330/006/001	Film-coated tablet	- G03AA - G03AA09	- Ethinyloestradiol - Desogestrel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gedarel extra 30/150 micrograms Film Coated Tablets	Gedeon Richter Plc	PA1330/005/001	Film-coated tablet	- G03AA - G03AA09	- Ethinylestradiol - Desogestrel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gefitinib Mylan	Mylan Pharmaceuticals Limited	EU/1/18/1321/001-002	Film-coated tablet	- L01XE02	- Gefitinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gelaspan Solution for Infusion	B. Braun Melsungen AG	PA0736/034/001	Solution for infusion	- B05AA - B05AA06	- Succinylated gelatine (= modified fluid gelatine) - Sodium chloride - Sodium acetate trihydrate - Potassium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Gelofusine 40mg/ml Solution for Infusion	B. Braun Melsungen AG	PA0736/011/001	Solution for infusion	- B05AA - B05AA06	- Succinylated gelatine (= modified fluid gelatine) - Sodium chloride - Sodium hydroxide		- Intravenous use
Geloplasma Solution for Infusion (Polyolefine/Freeflex Bag)	Fresenius Kabi Deutschland GmbH	PA2059/008/002	Solution for infusion	- B05AA	- Modified liquid gelatine - Sodium chloride - Magnesium chloride hexahydrate - Potassium chloride - Sodium (s)-lactate solution		- Intravenous use
Geloplasma, Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/008/001	Solution for infusion	- B05AA	- Modified liquid gelatine - Sodium chloride - Magnesium chloride hexahydrate - Potassium chloride - Sodium lactate solution		- Intravenous use
Gelsemium	A. Nelson & Company Limited	HOR1149/012/001	Not assigned		- Gelsemium sempervirens		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Geltears 0.2 % w/w carbomer eye gel	Bausch + Lomb Ireland Limited	PA23259/006/001	Eye gel	- S01XA - S01XA20	- Carbomer	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Gemcitabine 1 g Powder for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/092/002	Powder for solution for infusion	- L01BC - L01BC05	- Gemcitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Gemcitabine 1 g powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/039/002	Powder for solution for infusion	- L01BC - L01BC05	- Gemcitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Gemcitabine 100 mg/ml Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/092/004	Concentrate for solution for infusion	- L01BC - L01BC05	- Gemcitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Gemcitabine 2 g powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/039/003	Powder for solution for infusion	- L01BC - L01BC05	- Gemcitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Gemcitabine 200 mg powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/039/001	Powder for solution for infusion	- L01BC - L01BC05	- Gemcitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Gemcitabine 200 mg Powder for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/092/001	Powder for solution for infusion	- L01BC - L01BC05	- Gemcitabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Gemcitabine 2g Powder for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/092/003	Powder for solution for infusion	- L01BC - L01BC05	- Gemcitabine hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Gemcitabine 38 mg/ml Concentrate for Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/039/005	Concentrate for solution for infusion	- L01BC - L01BC05	- Gemcitabine hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Gemcitabine Teva 40mg/ml Concentrate for Solution for Infusion	Teva B.V.	PA1986/122/001	Concentrate for solution for infusion	- L01BC - L01BC05	- Gemcitabine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Gencebok	Gennisium Pharma	EU/1/20/1465/001	Solution for infusion	- N06BC01	- Caffeine - Caffeine citrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
GENOTROPIN	Pfizer Healthcare Ireland	PA0822/128/001	Powder and solvent for solution for injection	- H01AC - H01AC01	- Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
GENOTROPIN	Pfizer Healthcare Ireland	PA0822/128/002	Powder and solvent for solution for injection	- H01AC - H01AC01	- Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/003	Powder and solvent for solution for injection	- H01AC - H01AC01	- Somatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/004	Powder and solvent for solution for injection	- H01AC - H01AC01	- Somatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/005	Powder and solvent for solution for injection	- H01AC - H01AC01	- Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/006	Powder and solvent for solution for injection	- H01AC - H01AC01	- Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/007	Powder and solvent for solution for injection	- H01AC - H01AC01	- Somatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/008	Powder and solvent for solution for injection	- H01AC - H01AC01	- Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/009	Powder and solvent for solution for injection	- H01AC - H01AC01	- Somatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/010	Powder and solvent for solution for injection	- H01AC - H01AC01	- Somatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/011	Powder and solvent for solution for injection	- H01AC - H01AC01	- Somatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/012	Powder and solvent for solution for injection	- H01AC - H01AC01	- Somatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Gentamicin 10 mg/ml solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/242/001	Solution for injection/infusion	- J01GB - J01GB03	- Gentamicin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Gentamicin 20 mg/mL Solution for injection/infusion	Noridem Enterprises Limited	PA1122/023/001	Solution for injection/infusion	- J01GB03	- Gentamicin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Gentamicin 40 mg/ml solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/242/002	Solution for injection/infusion	- J01GB - J01GB03	- Gentamicin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Gentamicin 40 mg/mL Solution for injection/infusion	Noridem Enterprises Limited	PA1122/023/002	Solution for injection/infusion	- J01GB03	- Gentamicin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Gentamicin 80 mg/mL Solution for injection/infusion	Noridem Enterprises Limited	PA1122/023/003	Solution for injection/infusion	- J01GB03	- Gentamicin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Gentamicin Panpharma 40 mg/ml solution for injection/infusion	Panpharma	PA2272/002/001	Solution for injection/infusion	- J01GB - J01GB03	- Gentamicin sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Genticin 0.3% w/v Eye/Ear Drops, Solution	Amdipharm Limited	PA1142/013/002	Ear/eye drops, solution	- S02AA - S02AA14	- Gentamicin sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Auricular use - Ocular use
Genticin 80mg/2ml Solution for Injection	Amdipharm Limited	PA1142/013/001	Solution for injection	- J01GB - J01GB03	- Gentamicin sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops, Suspension	Amdipharm Limited	PA1142/014/001	Ear drops, suspension	- S02CA - S02CA03	- Gentamicin sulfate - HYDROCORTISONE ACETATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Auricular use
Genvoya	Gilead Sciences Ireland UC	EU/1/15/1061/001-002	Film-coated tablet	- J05AR - J05AR18	- Elvitegravir - Cobicistat - Emtricitabine - Tenofovir alafenamide fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Genvoya	Gilead Sciences Ireland UC	EU/1/15/1061/003-004	Film-coated tablet	- J05AR - J05AR18	- Elvitegravir - Cobicistat - Emtricitabine - Tenofovir alafenamide - Tenofovir alafenamide fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Geodon 20mg capsules, hard	Upjohn EESV	PA23055/015/001	Capsule, hard	- N05AE - N05AE04	- Ziprasidone hydrochloride monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Geodon 40mg capsules, hard	Upjohn EESV	PA23055/015/002	Capsule, hard	- N05AE - N05AE04	- Ziprasidone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Geodon 60mg capsules, hard	Upjohn EESV	PA23055/015/003	Capsule, hard	- N05AE - N05AE04	- Ziprasidone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Geodon 80mg capsules, hard	Upjohn EESV	PA23055/015/004	Capsule, hard	- N05AE - N05AE04	- Ziprasidone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Gerax 1 mg Tablets	Aurobindo Pharma (Malta) Limited	PA1445/024/003 Interchangeable List Code: IC0094-039-002	Tablet		- Alprazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gerax 250 microgram Tablets	Aurobindo Pharma (Malta) Limited	PA1445/024/001 Interchangeable List Code: IC0094-145-002	Tablet		- Alprazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gerax 500 microgram Tablets	Aurobindo Pharma (Malta) Limited	PA1445/024/002 Interchangeable List Code: IC0094-040-002	Tablet		- Alprazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Germentin 125 mg/31.25 mg per 5 ml Powder for Oral Suspension	Viatris Limited	PA23266/015/002 Interchangeable List Code: IC0037-071-034	Powder for oral suspension		- Clavulanic acid - Amoxicillin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Germentin 250 mg/125 mg Film-coated Tablets	Viatris Limited	PA23266/015/003 Interchangeable List Code: IC0037-074-003	Film-coated tablet		- potassium clavulanate - Amoxicillin trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Germentin 500 mg/125 mg film coated tablets	Viatris Limited	PA23266/015/001 Interchangeable List Code: IC0037-073-003	Film-coated tablet		- Amoxicillin trihydrate - potassium clavulanate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Geroquel 100 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/090/002 Interchangeable List Code: IC0019-024-003	Film-coated tablet		- Quetiapine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Geroquel 200 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/090/003 Interchangeable List Code: IC0019-067-003	Film-coated tablet		- Quetiapine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Geroquel 25 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/090/001 Interchangeable List Code: IC0019-022-003	Film-coated tablet		- Quetiapine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gerozac 60 mg Capsules, Hard	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/071/001 Interchangeable List Code: IC0075-127-001	Capsule, hard		- FLUOXETINE HYDROCHLORIDE		- Oral use
Ghemaxan 10,000 IU (100 mg)/1 mL solution for injection in pre-filled syringes	Chemi S.p.A.	PA22937/001/005	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Extracorporeal use - Intravenous use - Subcutaneous use
Ghemaxan 12,000 IU (120 mg)/0.8 mL solution for injection in pre-filled syringes	Chemi S.p.A.	PA22937/001/006	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Extracorporeal use - Intravenous use - Subcutaneous use
Ghemaxan 15,000 IU (150 mg)/1 mL solution for injection in pre-filled syringes	Chemi S.p.A.	PA22937/001/007	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Extracorporeal use - Intravenous use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ghemaxan 2,000 IU (20 mg)/0.2 mL solution for injection in pre-filled syringes	Chemi S.p.A.	PA22937/001/001	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Extracorporeal use - Intravenous use - Subcutaneous use
Ghemaxan 4,000 IU (40 mg)/0.4 mL solution for injection in pre-filled syringes	Chemi S.p.A.	PA22937/001/002	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Extracorporeal use - Intravenous use - Subcutaneous use
Ghemaxan 6,000 IU (60 mg)/0.6 mL solution for injection in pre-filled syringes	Chemi S.p.A.	PA22937/001/003	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Extracorporeal use - Intravenous use - Subcutaneous use
Ghemaxan 8,000 IU (80 mg)/0.8 mL solution for injection in pre-filled syringes	Chemi S.p.A.	PA22937/001/004	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Extracorporeal use - Intravenous use - Subcutaneous use
GHRYVELIN	Atnahs Pharma Netherlands B.V.	EU/1/18/1337/001	Granules for oral solution in sachet	- V04CD06	- MACIMORELIN ACETATE		- Oral use
Giapreza	Paion Deutschland GmbH	EU/1/19/1384/001-002	Concentrate for solution for infusion	- C01CX09		Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
GILENYA	Novartis Europharm Limited	EU/1/11/677/001-004	Capsule, hard	- L04AA - L04AA27	- Fingolimod		- Oral use
Gilenya	Novartis Europharm Limited	EU/1/11/677/007-008	Capsule, hard	- L04AA27	- FINGOLIMOD HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ginkgo-Biloba Pharma Nord film-coated tablets	Pharma Nord ApS	TR1242/001/001	Film-coated tablet		- GINKGO BILOBA EXTRACT	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Giotrif	Boehringer Ingelheim International GmbH	EU/1/13/879/001-003	Film-coated tablet	- L01XE - L01XE13	- Afatinib-dimaleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Giotrif	Boehringer Ingelheim International GmbH	EU/1/13/879/004-006	Film-coated tablet	- L01XE - L01XE13	- Afatinib-dimaleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Giotrif	Boehringer Ingelheim International GmbH	EU/1/13/879/007-009	Film-coated tablet	- L01XE - L01XE13	- Afatinib-dimaleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Giotrif	Boehringer Ingelheim International GmbH	EU/1/13/879/010-012	Film-coated tablet	- L01XE - L01XE13	- Afatinib-dimaleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Givlaari	Alnylam Netherlands B.V.	EU/1/20/1428/001	Solution for injection	- A16AX16	- Givosiran Sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Gliadel 7.7 mg Implant	MGI Pharma GmbH	PA22740/001/001	Implant	- L01AD - L01AD01	- Carmustine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intralesional use
Gliclazide MR 30 mg prolonged-release tablets	Brillpharma (Ireland) Limited	PA22749/006/001 Interchangeable List Code: IC0086-033-050	Prolonged-release tablet		- Gliclazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gliolan	Photonamic GmbH & Co. KG	EU/1/07/413/1-3	Powder for oral solution	- L01XD - L01XD04	- 5-aminolevulinic acid hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Glivec	Novartis Europharm Limited	EU/1/01/198/001	Capsule, hard	- L01XE - L01XE01	- Imatinib mesilate		- Oral use
Glivec	Novartis Europharm Limited	EU/1/01/198/002	Capsule, hard	- L01XE - L01XE01	- Imatinib mesilate		- Oral use
Glivec	Novartis Europharm Limited	EU/1/01/198/003	Capsule, hard	- L01XE - L01XE01	- Imatinib mesilate		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Glivec	Novartis Europharm Limited	EU/1/01/198/004	Capsule, hard	- L01XE - L01XE01	- Imatinib mesilate		- Oral use
Glivec	Novartis Europharm Limited	EU/1/01/198/005	Capsule, hard	- L01XE - L01XE01	- Imatinib mesilate		- Oral use
Glivec	Novartis Europharm Limited	EU/1/01/198/006	Capsule, hard	- L01XE - L01XE01	- Imatinib mesilate		- Oral use
Glivec	Novartis Europharm Limited	EU/1/01/198/007	Film-coated tablet	- L01XE - L01XE01	- Imatinib mesilate		- Oral use
Glivec	Novartis Europharm Limited	EU/1/01/198/008	Film-coated tablet	- L01XE - L01XE01	- Imatinib mesilate		- Oral use
Glivec	Novartis Europharm Limited	EU/1/01/198/009	Film-coated tablet	- L01XE - L01XE01	- Imatinib mesilate		- Oral use
Glivec	Novartis Europharm Limited	EU/1/01/198/010	Film-coated tablet	- L01XE - L01XE01	- Imatinib mesilate		- Oral use
GlucaGen HypoKit 1 mg powder and solvent for solution for injection	Novo Nordisk A/S	PA0218/031/002	Powder and solvent for solution for injection	- H04AA - H04AA01	- GLUCAGON	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
GlucaGen Hypokit 1 mg powder and solvent for solution for injection	PCO Manufacturing Ltd.	PPA0465/331/001	Powder and solvent for solution for injection	- H04AA01	- Glucagon hydr0chloride	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Intramuscular use - Subcutaneous use
Glucophage 1000 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/005/003 Interchangeable List Code: IC0067-119-003	Film-coated tablet		- Metformin Hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Glucophage 500 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/005/001 Interchangeable List Code: IC0067-117-003	Film-coated tablet		- Metformin Hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Glucophage 850 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/005/002 Interchangeable List Code: IC0067-118-003	Film-coated tablet		- Metformin Hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Glucosamine Pharma Nord 400 mg Capsules	Pharma Nord ApS	PA1242/001/001	Capsule, hard	- M01AX - M01AX05	- Glucosamine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Glucose 10 % w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/005	Solution for infusion	- B05BA - B05BA03	- Glucose anhydrous		- Intravenous use
Glucose 10 % w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/006	Solution for infusion	- B05BA - B05BA03	- Glucose anhydrous		- Intravenous use
Glucose 10 % w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/007	Solution for infusion	- B05BA - B05BA03	- Glucose anhydrous		- Intravenous use
Glucose 10 % w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/008	Solution for infusion	- B05BA - B05BA03	- Glucose anhydrous		- Intravenous use
Glucose 10 % w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/010	Solution for infusion	- B05BA - B05BA03	- Glucose anhydrous		- Intravenous use
Glucose 10% w/v Solution for Infusion	Baxter Holding B.V.	PA2299/003/002	Solution for infusion	- B05BA - B05BA03	- Glucose	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Glucose 5 % w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/009	Solution for infusion	- B05BA - B05BA03	- Glucose anhydrous		- Intravenous use
Glucose 5% w/v Intravenous Infusion BP, polyolefin/polyamide bag	Baxter Holding B.V.	PA2299/003/001	Solution for infusion	- B05BA - B05BA03	- Glucose	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Glucose 5% w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/003	Solution for infusion	- B05BA - B05BA03	- Glucose anhydrous		- Intravenous use
Glucose 5% w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/004	Solution for infusion	- B05BA - B05BA03	- Glucose anhydrous		- Intravenous use
Glucose 5% w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/001	Solution for infusion	- B05BA - B05BA03	- Glucose anhydrous		- Intravenous use
Glucose 5% w/v, Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/002	Solution for infusion	- B05BA - B05BA03	- Glucose anhydrous		- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Glucose 50% w/v sterile concentrate, concentrate solution for infusion	B. Braun Medical Limited	PA0179/001/039	Concentrate for solution for infusion	- B05BA - B05BA03	- Anhydrous glucose	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Glucose Intravenous Infusion BP 10% w/v, solution for infusion	B. Braun Medical Limited	PA0179/001/028	Solution for infusion	- B05BA - B05BA03	- Anhydrous glucose	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Glucose Intravenous Infusion BP 5% w/v solution for infusion	B. Braun Medical Limited	PA0179/001/003	Solution for infusion	- B05 - B05BA - B05BA03 - V07AB	- Glucose		- Intravenous use
Glycerol 1g Suppositories	Ethypharm	PA0549/028/001	Suppository	- A06AX - A06AX01	- Glycerol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Rectal use
Glycerol Suppositories BP for Adults	Ethypharm	PA0549/028/003	Suppository	- A06AX - A06AX01	- Glycerol		- Rectal use
Glyceryl Trinitrate 5 mg/ml Sterile Concentrate	Pfizer Healthcare Ireland	PA0822/204/001	Concentrate for solution for infusion	- C01DA - C01DA02	- Glyceryl trinitrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Glycopyrronium Bromide 200 micrograms/ml Solution for Injection	MercuryPharm Ltd	PA0857/001/001	Solution for injection	- A03AB - A03AB02	- Glycopyrronium bromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Glycopyrronium bromide 200 micrograms/ml Solution for injection	Ethypharm	PA0549/029/001	Solution for injection	- A03AB - A03AB02	- Glycopyrronium bromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Glycopyrronium Bromide and Neostigmine Metilsulfate 0.5mg / 2.5mg per ml Solution for Injection	MercuryPharm Ltd	PA0857/002/001	Solution for injection	- N07AA - N07AA51	- Glycopyrronium bromide - Neostigmine Metilsulfate		- Intravenous use
GLYPRESSIN 1 mg Powder and Solvent for Solution for Injection	Ferring Ireland Ltd	PA1009/004/001	Powder and solvent for solution for injection	- H01BA - H01BA04	- Terlipressin acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Glypressin 1 mg/ 8.5 ml solution for injection	Ferring Ireland Ltd	PA1009/004/002	Solution for injection	- H01BA - H01BA04	- Terlipressin acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Glytrin 400 micrograms per metered dose Sublingual Spray	Ayrton Saunders (Ireland) Limited	PA22906/002/001	Sublingual spray, solution	- C01DA - C01DA02	- Glyceryl trinitrate		- Sublingual use
Glyxambi	Boehringer Ingelheim International GmbH	EU/1/16/1146/001-009	Film-coated tablet	- A10BD - A10BD19	- Empagliflozin - Linagliptin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Glyxambi	Boehringer Ingelheim International GmbH	EU/1/16/1146/010-018	Film-coated tablet	- A10BD - A10BD19	- Empagliflozin - Linagliptin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Golden Eye 0.1% w/v Eye drops, solution	Cambridge Healthcare Ireland Limited	PA22695/001/001	Eye drops, solution	- S01AX - S01AX15	- Propamidine isetionate		- Ocular use
Golden Eye 0.15% w/w Eye Ointment	Cambridge Healthcare Ireland Limited	PA22695/001/002	Eye ointment	- S01AX - S01AX14	- Dibromopropamidine isethionate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Ocular use
Golpimec 0.5 mg hard capsules	Neuraxpharm Ireland Limited	PA23229/003/001	Capsule, hard	- L04AA27	- Fingolimod	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Gonal-F	Merck Europe B.V.	EU/1/95/001/012	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Gonal-F	Merck Europe B.V.	EU/1/95/001/013	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		
Gonal-F	Merck Europe B.V.	EU/1/95/001/014	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		
Gonal-F	Merck Europe B.V.	EU/1/95/001/015	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		
Gonal-F	Merck Europe B.V.	EU/1/95/001/005	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		
Gonal-F	Merck Europe B.V.	EU/1/95/001/017	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		- Subcutaneous use
Gonal-F	Merck Europe B.V.	EU/1/95/001/018	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		- Subcutaneous use
Gonal-F	Merck Europe B.V.	EU/1/95/001/019	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		- Subcutaneous use
Gonal-F	Merck Europe B.V.	EU/1/95/001/020	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		- Subcutaneous use
Gonal-F	Merck Europe B.V.	EU/1/95/001/021	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		
Gonal-F	Merck Europe B.V.	EU/1/95/001/022	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		- Subcutaneous use
Gonal-F	Serono Limited	EU/1/95/001/023	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		- Subcutaneous use
Gonal-F	Serono Limited	EU/1/95/001/024	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		- Subcutaneous use
Gonal-F	Merck Europe B.V.	EU/1/95/001/025	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		- Subcutaneous use
Gonal-F	Merck Europe B.V.	EU/1/95/001/026	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		- Subcutaneous use
Gonal-F	Merck Europe B.V.	EU/1/95/001/027	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		- Subcutaneous use
Gonal-F	Serono Limited	EU/1/95/001/028	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		- Subcutaneous use
Gonal-F	Serono Limited	EU/1/95/001/029	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		- Subcutaneous use
Gonal-F	Merck Europe B.V.	EU/1/95/001/031	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		- Subcutaneous use
Gonal-F	Merck Europe B.V.	EU/1/95/001/032	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		
GONAL-F	Merck Europe B.V.	EU/1/95/001/033	Solution for injection in pre-filled pen	- G03GA - G03GA05	- Follitropin alfa		
Gonal-F	Merck Europe B.V.	EU/1/95/001/034	Solution for injection	- G03GA - G03GA05	- Follitropin alfa		
Gonal-F - Ampoule	Merck Europe B.V.	EU/1/95/001/004	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		
Gonal-F - Ampoule	Merck Europe B.V.	EU/1/95/001/001	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		
Gonal-F - Ampoule	Merck Europe B.V.	EU/1/95/001/002	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		
Gonal-F Ampoule	Merck Europe B.V.	EU/1/95/001/003	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		
Gonal-F Ampoule	Merck Europe B.V.	EU/1/95/001/010	Powder for solution for injection	- G03GA - G03GA05	- Follitropin alfa		

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Gonal-F Vial	Merck Europe B.V.	EU/1/95/001/006	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		
Gonal-F Vials	Merck Europe B.V.	EU/1/95/001/008	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		
Gonal-F Vials	Merck Europe B.V.	EU/1/95/001/016	Powder and solvent for solution for injection	- G03GA - G03GA05	- Follitropin alfa		
GoResp Digihaler	Teva Pharma B.V.	EU/1/19/1403/001-003	Inhalation powder	- R03AK07	- Budesonide - Formoterol fumarate dihydrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Inhalation use
GoResp Digihaler	Teva Pharma B.V.	EU/1/19/1403/004-005	Inhalation powder	- R03AK07	- Budesonide - Formoterol fumarate dihydrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Inhalation use
Grafalon 20 mg/ml concentrate for solution for infusion	Neovii Biotech GmbH	PA1015/001/001	Concentrate for solution for infusion	- L04AA - L04AA04	- Anti-human t-lymphocyte immunoglobulin from rabbits	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
GRANOCYTE 13 million IU/mL, powder and solvent for solution for injection/infusion, in a pre-filled syringe	Chugai Pharma France	PA22641/002/002	Powder and solvent for solution for injection/infusion	- L03AA - L03AA10	- Lenograstim	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
GRANOCYTE 34 million IU/mL, powder and solvent for solution for injection/infusion, in a pre-filled syringe	Chugai Pharma France	PA22641/002/001	Powder and solvent for solution for injection/infusion	- L03AA - L03AA10	- Lenograstim	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Granpidam	Accord Healthcare S.L.U.	EU/1/16/1137/001-005 Interchangeable List Code: IC0063-003-003	Film-coated tablet		- Sildenafil base (as citrate)	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
GRANUPAS	Eurocept International BV	EU/1/13/896/001	Gastro-resistant granules	- J04AA - J04AA01	- Para-aminosalicylic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
GRAPHITES	A. Nelson & Company Limited	HOR1149/013/001	Not assigned		- Graphites		- Oral use
Grastofil	Accord Healthcare S.L.U.	EU/1/13/877/001-002	Solution for injection/infusion in pre-filled syringe	- L03AA - L03AA02	- Filgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Grastofil	Accord Healthcare S.L.U.	EU/1/13/877/003-004	Solution for injection/infusion in pre-filled syringe	- L03AA - L03AA02	- Filgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Grasustek	Juta Pharma GmbH	EU/1/19/1375/001	Solution for injection	- L03AA - L03AA13		Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
GRAZAX 75,000 SQ-T sublingual lyophilisate	ALK-Abello A/S	PA1255/004/001	Sublingual lyophilisate	- V01AA - V01AA02	- Grass pollen extract (phleum pratense)		- Oromucosal use
GREPID	Pharmathen S.A.	EU/1/09/535/1-16 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- CLOPIDOGREL BESYLATE	Article 10(1) - Generic Application	- Oral use
Griseofulvin 500 mg film-coated tablets	Brown & Burk IR Limited	PA23148/006/001	Film-coated tablet	- D01BA - D01BA01	- Griseofulvin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Guaifenesin 200 mg syrup in sachet	Johnson & Johnson (Ireland) Limited	PA0330/059/001	Syrup in sachet	- R05CA03	- Guaifenesin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Gyno-Pevaryl Once 150 mg Vaginal Pessary	Karo Pharma AB	PA22650/006/001	Pessary	- G01AF - G01AF05	- ECONAZOLE NITRATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Gynoxin 200 mg Vaginal Capsules	Recordati Industria Chimica e Farmaceutica SpA	PA0812/004/001	Vaginal capsule, soft	- G01AF - G01AF12	- Fenticonazole nitrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Gynoxin 600 mg Vaginal Capsules	Recordati Industria Chimica e Farmaceutica SpA	PA0812/004/002	Vaginal capsule, soft	- G01AF - G01AF12	- Fenticonazole nitrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Halaven	Eisai GmbH	EU/1/11/678/001-002	Solution for injection	- L01XX - L01XX41	- Eribulin mesylate		- Intravenous use
Halcion 125 micrograms Tablets	Pfizer Healthcare Ireland	PA0822/129/002	Tablet	- N05CD - N05CD05	- Triazolam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Halcion 250 microgram Tablets	Pfizer Healthcare Ireland	PA0822/129/001	Tablet	- N05CD - N05CD05	- Triazolam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Haldol Decanoate 100mg/ml Solution for Injection	Essential Pharma Limited	PA22587/003/002	Solution for injection	- N05AD - N05AD01	- Haloperidol		- Intramuscular use
Haldol Decanoate 50mg/ml Solution for Injection	Essential Pharma Limited	PA22587/003/001	Solution for injection	- N05AD - N05AD01	- Haloperidol		- Intramuscular use
Half Beta-Prograne 80 mg Prolonged-Release Capsules	Tillomed Pharma GmbH	PA22720/002/002	Prolonged-release capsule, hard	- C07AA - C07AA05	- Propranolol hydrochloride		- Oral use
Half Sinemet CR 25mg/100mg Prolonged-Release Tablets	Organon Pharma (Ireland) Limited	PA23198/004/006	Prolonged-release tablet	- N04BA - N04BA02	- Levodopa - Carbidopa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Haloperidol 5mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/101/001	Solution for injection	- N05AD - N05AD01	- Haloperidol		- Intramuscular use
Hartmann's Solution for Infusion, glass bottle	Fresenius Kabi Deutschland GmbH	PA2059/057/004	Solution for infusion	- B05BB - B05BB01	- Sodium chloride - Potassium chloride - Calciumchloride dihydrate - Sodium lactate (as 50% solution)		- Intravenous use
Hartmann's Solution for Infusion, PPC PSEB bag	Fresenius Kabi Deutschland GmbH	PA2059/057/003	Solution for infusion	- B05BB - B05BB01	- Sodium chloride - Potassium chloride - Calcium chloride dihydrate - Sodium lactate (as 50% solution)		- Intravenous use
Hartmann's Solution for Infusion, PSEB bag	Fresenius Kabi Deutschland GmbH	PA2059/057/002	Solution for infusion	- B05BB - B05BB01	- Sodium chloride - Potassium chloride - Calcium chloride dihydrate - Sodium lactate (as 50% solution)		- Intravenous use
Hartmann's Solution for Infusion, PVC bag	Fresenius Kabi Deutschland GmbH	PA2059/057/001	Solution for infusion	- B05BB - B05BB01	- Sodium chloride - Potassium chloride - Calcium chloride dihydrate - Sodium lactate (as 50% solution)		- Intravenous use
Hartmann's Solution Compound Sodium Lactate Intravenous Infusion BP	Laboratoire AGUETTANT	PA1968/020/001	Solution for infusion	- B05BB - B05BB01	- Sodium chloride - Calcium chloride dihydrate - Potassium chloride - Sodium lactate solution 60%	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Hartmann's Solution for Infusion, PE bottle	Fresenius Kabi Deutschland GmbH	PA2059/057/005	Solution for infusion	- B05BB - B05BB01	- Sodium chloride - Potassium chloride - Calcium chloride dihydrate - Sodium lactate (as 50% solution)		- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Harvoni	Gilead Sciences Ireland UC	EU/1/14/958/001-002	Film-coated tablet	- J05AX - J05AX65	- Sofosbuvir - Ledipasvir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Harvoni	Gilead Sciences Ireland UC	EU/1/14/958/003	Film-coated tablet	- J05AP51	- Ledipasvir - Sofosbuvir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Harvoni	Gilead Sciences Ireland UC	EU/1/14/958/004	Granules	- J05AP51	- Ledipasvir - Sofosbuvir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Harvoni	Gilead Sciences Ireland UC	EU/1/14/958/005	Granules	- J05AP51	- Ledipasvir - Sofosbuvir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Havrix Junior Monodose Vaccine. Hepatitis A Vaccine (Inactivated, Adsorbed). 720 ELISA units/ 0.5ml Suspension for injection in a pre-filled syringe	GlaxoSmithKline (Ireland) Limited	PA1077/026/001	Suspension for injection in pre-filled syringe	- J07BC - J07BC02	- Aluminium - Hepatitis A antigen		- Intramuscular use - Subcutaneous use
Havrix Monodose Vaccine. Hepatitis A Vaccine (inactivated, adsorbed), 1440 ELISA units/ 1ml Suspension for injection in a pre-filled syringe	GlaxoSmithKline (Ireland) Limited	PA1077/026/002	Suspension for injection in pre-filled syringe	- J07BC - J07BC02	- Aluminium - Hepatitis A antigen		- Intramuscular use - Subcutaneous use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/001	Suspension for injection	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/002	Suspension for injection	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/003	Suspension for injection	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/004	Suspension for injection in pre-filled syringe	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/005	Suspension for injection in pre-filled syringe	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/006	Suspension for injection	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/007	Suspension for injection	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/008	Suspension for injection	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/009	Suspension for injection	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/010	Suspension for injection	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/011	Suspension for injection in pre-filled syringe	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/012	Suspension for injection	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/013	Suspension for injection in pre-filled syringe	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/014	Suspension for injection	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/015	Suspension for injection	- J07BC - J07BC01	- Hepatitis b vaccine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/018-025	Suspension for injection	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Sanofi Pasteur MSD Ltd	EU/1/01/183/018-025,30-31	Suspension for injection	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/026-029	Suspension for injection in pre-filled syringe	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HBVAXPRO	Sanofi Pasteur MSD Ltd	EU/1/01/183/026-029,32	Suspension for injection	- J07BC - J07BC01	- Hepatitis b vaccine		- Intramuscular use
HC45 Hydrocortisone Acetate Cream (Hydrocortisone Acetate 1% w/w)	KARO PHARMA AB	PA22650/008/001	Cream	- D07AA - D07AA02	- HYDROCORTISONE ACETATE		- Topical use
Hefiya	Sandoz GmbH	EU/1/18/1287/001-003	Solution for injection in pre-filled syringe	- L04AB - L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Hefiya	Sandoz GmbH	EU/1/18/1287/004-006	Solution for injection in pre-filled pen	- L04AB - L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Hefiya	Sandoz GmbH	EU/1/18/1287/007	Solution for injection in pre-filled syringe	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
HELIOBACTER Test INFAI	INFAI Institut fur biomedizinish	EU/1/97/045/001	Powder for oral solution	- V04CX	- 13c-urea		- Inhalation use
Heliobacter Test INFAI	INFAI Institut fur biomedizinish	EU/1/97/045/003	Powder for oral solution	- V04CX	- 13c-urea		
Hemangiol	Pierre Fabre Dermatologie	EU/1/14/919/001	Oral solution	- C07AA - C07AA05	- PROPRANOLOL HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Hemgenix	CSL Behring GmbH	EU/1/22/1715/001	Concentrate for solution for infusion	- B06	- Etranacogene dezaparvovec	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Hemlibra	Roche Registration GmbH	EU/1/18/1271/001	Solution for injection	- B02BX - B02BX06	- Emicizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Hemlibra	Roche Registration GmbH	EU/1/18/1271/002-004	Solution for injection	- B02BX - B02BX06	- Emicizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Hemosol B0 solution for haemodialysis/haemofiltration	Baxter Holding B.V.	PA2299/051/002	Solution for haemodialysis/haemofiltration	- B05Z	- Magnesium chloride hexahydrate - Calcium chloride dihydrate - Lactic acid - Sodium hydrogen carbonate - Sodium chloride - Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium lactate - Sodium hydrogen carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Haemodialysis - Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Hemosol B0 solution for haemodialysis/haemofiltration	Baxter Holding B.V.	PA2299/051/001	Solution for haemodialysis/haemofiltration	- B05ZB	- Magnesium chloride hexahydrate - Calcium chloride dihydrate - Lactic acid - Sodium hydrogen carbonate - Sodium chloride - Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium lactate - Sodium hydrogen carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Haemodialysis - Intravenous use
Heparin sodium 1,000 I.U./ml Solution for injection or concentrate for solution for infusion, 10ml ampoules	Pinewood Laboratories Ltd	PA0281/229/002	Solution for injection/infusion	- B01AB - B01AB01	- Heparin sodium		- Intravenous use
Heparin sodium 1,000 I.U./ml Solution for injection or concentrate for solution for infusion, 5ml ampoules	Pinewood Laboratories Ltd	PA0281/229/001	Solution for injection/infusion	- B01AB - B01AB01	- Heparin sodium		- Intravenous use
Heparin sodium 1,000 I.U./ml Solution for injection or concentrate for solution for infusion, 5ml vials	Pinewood Laboratories Ltd	PA0281/229/004	Solution for injection/infusion	- B01AB - B01AB01	- Heparin sodium	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Heparin Sodium 10 I.U./ml flushing solution for maintenance of patency of intravenous devices	Pinewood Laboratories Ltd	PA0281/230/001	Irrigation solution	- B01AB - B01AB01	- Heparin sodium	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Heparin sodium 25,000 I.U./ml Solution for injection or concentrate for solution for infusion, 0.2ml ampoules	Pinewood Laboratories Ltd	PA0281/229/003	Solution for injection/infusion	- B01AB - B01AB01	- Heparin sodium	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Heparin sodium 5,000 I.U./ml Solution for injection or concentrate for solution for infusion, 5 ml vials	Pinewood Laboratories Ltd	PA0281/229/005	Solution for injection/infusion	- B01AB - B01AB01	- Heparin sodium	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Heparin Sodium BP 1000 IU/l in 0.9% w/v Sodium Chloride IV Infusion	Baxter Holding B.V.	PA2299/014/001	Solution for infusion	- B01AB - B01AB01	- Heparin sodium - Sodium chloride - Disodium phosphate dodecahydrate - Citric acid monohydrate		- Intravenous use
Heparin Sodium BP 2000 IU/l in 0.9 % w/v Sodium Chloride IV infusion	Baxter Holding B.V.	PA2299/014/002	Solution for infusion	- B01AB - B01AB01	- Heparin sodium - Sodium chloride - Disodium phosphate dodecahydrate - Citric acid monohydrate		- Intravenous use
Hepatect CP 50 IU/ml; solution for infusion	Biotest Pharma GmbH	PA0592/005/004	Solution for infusion	- J06BB - J06BB04	- Human plasma protein - Hbs antibodies	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Hepcludex	Gilead Sciences Ireland UC	EU/1/20/1446/001	Powder for solution for injection	- J05A - J05AX - J05AX28	- Bulevirtide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Heplisav B	Dynavax GmbH	EU/1/20/1503/001	Solution for injection in pre-filled syringe	- J07BC01	- Hepatitis b surface antigen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Herceptin	Roche Registration GmbH	EU/1/00/145/001	Powder for concentrate for solution for infusion	- L01XC - L01XC03	- Trastuzumab		- Intravenous use
Herceptin	Roche Registration GmbH	EU/1/00/145/002	Solution for injection	- L01XC - L01XC03	- Trastuzumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Herwenda	Sandoz GmbH	EU/1/23/1762/001	Powder for concentrate for solution for infusion	- L01FD01	- Trastuzumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Herzuma	Celltrion Healthcare Hungary Kft.	EU/1/17/1257/001	Powder for concentrate for solution for infusion	- L01XC - L01XC03	- Trastuzumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Hetlioz	Vanda Pharmaceuticals Netherlands B.V.	EU/1/15/1008/001	Capsule, hard	- N05CH - N05CH03	- Tasimelteon	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Hexacima	Sanofi Pasteur SA	EU/1/13/828/001-007	Suspension for injection	- J07CA - J07CA09	- Haemophilus influenzae type b capsular polysaccharide - Pertussis toxoid - (polyribosylribitol phosphate) conjugated to tetanous protein - Filamentous haemagglutinin - Type 1 (mahoney) - Diphtheria toxoid - Type 2 (mef-1) - Tetanus toxoid - Type 3 (saukett) - Hepatitis b surface antigen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Hexiprep 2.0% w/v / 70.0% w/v Impregnated Pad	GAMA Healthcare Ireland Ltd	PA23120/001/001	Impregnated pad	- D08AC52	- Chlorhexidine digluconate solution - Isopropyl alcohol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Hexvix 85 mg, powder and solvent for intravesical solution	Photocure ASA	PA1024/003/001	Powder and solvent for intravesical solution	- V04CX	- Hexaminolevulinate hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravesical use
Hexyon	Sanofi Pasteur	EU/1/13/829/001-007	Suspension for injection	- J07CA - J07CA09	- (polyribosylribitol phosphate) conjugated to tetanous protein - Type 1 (mahoney) - Haemophilus influenzae type b polysaccharide - Diphtheria toxoid - Type 2 (mef-1) - Filamentous haemagglutinin - Tetanus toxoid - Pertussis toxoid - Type 3 (saukett) - Hepatitis b surface antigen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Hezkue 12.5 mg/actuation, oral suspension	Aspargo Labs Ireland Limited	PA25240/001/001	Oral suspension	- G04BE03	- Sildenafil citrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Hiberix. Haemophilus Type b (Hib) vaccine.Powder and Solvent for Solution for Injection	GlaxoSmithKline (Ireland) Limited	PA1077/027/001	Powder and solvent for solution for injection	- J07AG51	- Haemophilus influenzae type b polysaccharide - Conjugate of haemophilus influenzae type b capsular polysaccharide (prp) and tetanus toxoid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Hidrasec 100 mg hard capsules	Bioproject Europe Ltd	PA1714/001/001	Capsule, hard	- A07XA - A07XA04	- Racecadotril	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Hidrasec Children 30mg Granules for Oral Suspension	Bioproject Europe Ltd	PA1714/001/003	Granules for oral suspension	- A07XA - A07XA04	- Racecadotril	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Hidrasec Infants 10mg Granules for Oral Suspension	Bioproject Europe Ltd	PA1714/001/002	Granules for oral suspension	- A07XA - A07XA04	- Racecadotril	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Hidrasec Infants and Children 4 mg/mL Oral Suspension	Bioprojet Pharma	PA22580/002/001	Oral suspension	- A07XA04	- Racecadotril	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Hirobriz Breezhaler	Novartis Europharm Limited	EU/1/09/594/1-5	Inhalation powder, hard capsule	- R03AC - R03AC18	- Indacaterol maleate		- Inhalation use
Hirobriz Breezhaler	Novartis Europharm Limited	EU/1/09/594/6-10	Inhalation powder, hard capsule	- R03AC - R03AC18	- Indacaterol maleate		- Inhalation use
Histaclar 10mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/046/001	Film-coated tablet	- R06AX - R06AX13	- Loratadine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Hizentra	CSL Behring GmbH	EU/1/11/687/001-12	Solution for injection	- J06BA01	- Human normal immunoglobulin		- Subcutaneous use
Holland & Barrett Devil's Claw Hard Capsules	Holland & Barrett Limited	TR23157/009/001	Capsule, hard			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Holland & Barrett Echinacea Cold and Flu Hard Capsules	Holland & Barrett Limited	TR23157/007/001	Capsule, hard			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Holland & Barrett Hypericum Hard Capsules	Holland & Barrett Limited	TR23157/003/001	Capsule, hard			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Holland & Barrett Lemon Balm Hard Capsules	Holland & Barrett Limited	TR23157/005/001	Capsule, hard			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Holland & Barrett Milk Thistle Hard Capsules	Holland & Barrett Limited	TR23157/013/001	Capsule, hard			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Holland & Barrett Valerian Hard Capsules	Holland & Barrett Limited	TR23157/001/001	Capsule, hard	- N05CM - N05CM09		Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Holland and Barrett Agnus Castus PMS relief Tablets	Holland & Barrett Limited	TR23157/011/001	Tablet			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Holoclar	Holostem S.r.l.	EU/1/14/987/001	Living tissue equivalent	- S01XA19	- Ex vivo expanded autologous corneal epithelial cells containing stem cells	Full application (Article 8(3) of Directive No 2001/83/EC)	- Implantation
Hukyndra	Stada Arzneimittel AG	EU/1/21/1589/001-006	Solution for injection in pre-filled syringe	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Hukyndra	Stada Arzneimittel AG	EU/1/21/1589/007	Solution for injection in pre-filled syringe	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Hulio	Biosimilar Collaborations Ireland Limited	EU/1/18/1319/001-007	Solution for injection	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Hulio	Biosimilar Collaborations Ireland Limited	EU/1/18/1319/009-010	Solution for injection in pre-filled syringe	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Humalog	Eli Lilly Nederland B.V.	EU/1/96/007/019	Solution for injection	- A10AB - A10AB04	- Insulin lispro		
Humalog	Eli Lilly and Company Limited	EU/1/96/007/039-042	Solution for injection	- A10AB - A10AB04			
Humalog 3ml	Eli Lilly Nederland B.V.	EU/1/96/007/004	Solution for injection in cartridge	- A10AB - A10AB04	- Insulin lispro		
Humalog Mix25	Eli Lilly Nederland B.V.	EU/1/96/007/005	Suspension for injection	- A10AD - A10AD04	- Insulin lispro		- Subcutaneous use
Humalog Mix25	Eli Lilly Nederland B.V.	EU/1/96/007/008	Suspension for injection	- A10AD	- Insulin lispro		- Subcutaneous use
Humalog Mix50	Eli Lilly Nederland B.V.	EU/1/96/007/006	Suspension for injection	- A10AD	- Insulin lispro		- Subcutaneous use
Humalog NPL	Eli Lilly Nederland B.V.	EU/1/96/007/010	Suspension for injection	- A10AD	- Insulin lispro		- Subcutaneous use
Humalog Vials	Eli Lilly Nederland B.V.	EU/1/96/007/002	Solution for injection	- A10AB - A10AB04	- Insulin lispro		- Intravenous use - Subcutaneous use
Human Albumin Baxalta 200 g/l Solution for Infusion	Baxalta Innovations GmbH	PA2004/004/002	Solution for infusion	- B05AA - B05AA01	- Plasma protein containing at least 95% human albumin		- Intravenous use
Human Albumin Baxalta 50 g/l Solution for Infusion	Baxalta Innovations GmbH	PA2004/004/001	Solution for infusion	- B05AA - B05AA01	- Plasma protein containing at least 95% human albumin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Human Albumin CSL Behring, 200 g/l, solution for infusion	CSL Behring GmbH	PA0800/012/001	Solution for infusion	- B05AA01	- Human albumin solution	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Humira	AbbVie Deutschland GmbH & Co. KG	EU/1/03/256/020	Solution for injection in pre-filled syringe	- L04AB - L04AB04	- Adalimumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Humira	AbbVie Deutschland GmbH & Co. KG	EU/1/03/256/022	Solution for injection in pre-filled syringe	- L04AB - L04AB04	- Adalimumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
HUMIRA	AbbVie Deutschland GmbH & Co. KG	EU/1/03/256/1-10	Solution for injection	- L04AB - L04AB04	- Adalimumab		- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Humulin I (Isophane) 100 IU/ml Suspension for Injection in cartridge	Eli Lilly Nederland B.V.	PA2276/002/004	Suspension for injection in cartridge	- A10AC - A10AC01	- Human insulin (recombinant dna origin)		- Subcutaneous use
Humulin I (Isophane) 100 IU/ml Suspension for Injection in vial	Eli Lilly Nederland B.V.	PA2276/002/003	Suspension for injection	- A10AC - A10AC01	- Human insulin (recombinant dna origin)		- Intramuscular use - Subcutaneous use
Humulin I KwikPen (Isophane) 100 IU/ml Suspension for Injection	Eli Lilly Nederland B.V.	PA2276/005/002	Suspension for injection	- A10AC - A10AC01	- Human insulin (recombinant dna origin)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Humulin M3 (Mixture 3) 100 IU/ml Suspension for Injection in cartridge	Eli Lilly Nederland B.V.	PA2276/003/004	Suspension for injection in cartridge	- A10AD - A10AD01	- Human insulin (recombinant dna origin)		- Subcutaneous use
Humulin M3 (Mixture 3) 100 IU/ml Suspension for Injection in vial	Eli Lilly Nederland B.V.	PA2276/003/003	Suspension for injection	- A10AD - A10AD01	- Human insulin (recombinant dna origin)		- Intramuscular use - Subcutaneous use
Humulin M3 KwikPen (mixture 3) 100 IU/ml Suspension for Injection	Eli Lilly Nederland B.V.	PA2276/006/002	Suspension for injection	- A10AD - A10AD01	- Human insulin (recombinant dna origin)		- Subcutaneous use
Humulin M3 KwikPen (mixture 3) 100 IU/ml Suspension for Injection	PCO Manufacturing Ltd.	PPA0465/501/001	Suspension for injection	- A10AD - A10AD01	- Human insulin (recombinant dna origin)		- Subcutaneous use
Humulin S (Soluble) 100 IU/ml Solution for Injection in vial	Eli Lilly Nederland B.V.	PA2276/001/003	Solution for injection in vial	- A10AB - A10AB01	- Human insulin (recombinant dna origin)		- Intramuscular use - Intravenous use - Subcutaneous use
Humulin S (Soluble), 100 IU/ml Solution for Injection in cartridge	Eli Lilly Nederland B.V.	PA2276/001/004	Solution for injection in cartridge	- A10AB01	- Human insulin (recombinant dna origin)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Hyaluronidase 1500 I.U. Powder for Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/231/001	Powder for solution for injection/infusion	- B06AA - B06AA03	- Hyaluronidase	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Hycamtin	Sandoz Pharmaceuticals d.d.	EU/1/96/027/001	Powder for concentrate for solution for infusion	- L01XX - L01XX17	- Topotecan hydrochloride		
Hycamtin	Sandoz Pharmaceuticals d.d.	EU/1/96/027/003	Powder for concentrate for solution for infusion	- L01XX - L01XX17	- Topotecan hydrochloride		
Hycamtin	Sandoz Pharmaceuticals d.d.	EU/1/96/027/004	Powder for concentrate for solution for infusion	- L01XX - L01XX17	- Topotecan (as hydrochloride)		- Intravenous use
Hycamtin	Sandoz Pharmaceuticals d.d.	EU/1/96/027/005	Powder for concentrate for solution for infusion	- L01XX - L01XX17	- Topotecan (as hydrochloride)		- Intravenous use
Hycamtin	Sandoz Pharmaceuticals d.d.	EU/1/96/027/006	Capsule, hard	- L01XX - L01XX17	- Topotecan hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Hycamtin	Sandoz Pharmaceuticals d.d.	EU/1/96/027/007	Capsule, hard	- L01XX - L01XX17	- Topotecan hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Hydrea 500 mg Hard Capsules	CHEPLAPHARM Arzneimittel GmbH	PA2239/021/001	Capsule, hard	- L01XX - L01XX05	- Hydroxycarbamide		- Oral use
Hydrex Surgical Scrub 4.0% w/v Cutaneous Solution	Ecolab Deutschland GmbH	PA1843/001/001	Cutaneous solution	- D08AC - D08AC02	- Chlorhexidine gluconate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Topical
Hydrocortisone 1 % w/w Cream	Ovelle Limited	PA0206/030/001	Cream	- D07AA - D07AA02	- Hydrocortisone	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Hydrocortisone 10 mg Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/003/001	Tablet	- H02AB - H02AB09	- Hydrocortisone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Hydrocortisone 20 mg Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/003/002	Tablet	- H02AB - H02AB09	- Hydrocortisone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Hydrocortisone 5 mg Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/003/003	Tablet	- H02AB09	- Hydrocortisone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Hydrocortone 10 mg Tablets	Teva B.V.	PA1986/054/001	Tablet	- H02AB - H02AB09	- Hydrocortisone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Hydromorphone Hydrochloride 20 mg/ml Solution for Injection / Concentrate for Solution for Infusion	Ethypharm	PA0549/030/001	Solution for injection/infusion	- N02AA - N02AA03	- Hydromorphone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Hydromorphone hydrochloride 20 mg/ml solution for injection/infusion	AS Kalceks	PA2165/023/001	Solution for injection/infusion	- N02AA03	- Hydromorphone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Hydromorphone Hydrochloride 50 mg/ml Solution for Injection / Concentrate for Solution for Infusion	Ethypharm	PA0549/030/002	Solution for injection/infusion	- N02AA - N02AA03	- Hydromorphone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Hydromorphone hydrochloride 50 mg/ml solution for injection/infusion	AS Kalceks	PA2165/023/002	Solution for injection/infusion	- N02AA03	- Hydromorphone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Hydroxocobalamin 1 mg/ml solution for injection	G.L. Pharma GmbH	PA1770/002/001 Interchangeable List Code: IC0121-172-063	Solution for injection		- Hydroxocobalamin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Hydroxocobalamin Basi 1000 microgram/mL solution for injection	Laboratorios Basi Industria Farmaceutica S.A.	PA23303/001/001 Interchangeable List Code: IC0121-172-063	Solution for injection		- Hydroxocobalamin chloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use
Hydroxychloroquine sulfate Accord 200 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/223/001	Film-coated tablet	- P01BA02	- Hydroxychloroquine sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Hydroxyzine hydrochloride 25 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/025/001	Film-coated tablet	- N05BB - N05BB01	- Hydroxyzine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	
Hyftor	Plusultra Pharma GmbH	EU/1/23/1723/001	Gel	- L04AA10	- Sirolimus	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Topical
Hyoscine Hydrobromide Martindale Pharma 600 micrograms/ml Solution for Injection	Ethypharm	PA0549/031/002	Solution for injection	- A04AD	- Hyoscine hydrobromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Hypericum	A. Nelson & Company Limited	HOR1149/015/001	Pillules		- Hypericum perforatum		- Oral use
Hypnovel 10 mg/2 ml Solution for Injection	CHEPLAPHARM Arzneimittel GmbH	PA2239/007/001	Solution for injection	- N05CD - N05CD08	- Midazolam hydrochloride		- Intramuscular use - Intravenous use - Rectal use
Hypnovel 10 mg/5 ml Solution for Injection	CHEPLAPHARM Arzneimittel GmbH	PA2239/007/002	Solution for injection	- N05CD - N05CD08	- Midazolam hydrochloride		- Intramuscular use - Intravenous use - Rectal use
Hypoloc 5 mg tablets	Menarini International Operations Luxembourg S.A.	PA0865/010/001 Interchangeable List Code: IC0082-001-002	Tablet		- Nebivolol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Hypoloc Plus 5 mg/12.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/016/001	Film-coated tablet	- C07BB - C07BB12	- Nebivolol - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Hypoloc Plus 5 mg/25 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/016/002	Film-coated tablet	- C07BB - C07BB12	- Nebivolol - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Hypovase 0.5mg Tablets	Pfizer Healthcare Ireland	PA0822/195/001	Tablet	- C02CA - C02CA01	- Prazosin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
HyQvia	Baxalta Innovations GmbH	EU/1/13/840/001-006	Solution for infusion	- J06BA - J06BA02	- Human normal immunoglobulin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Hyrimoz	Sandoz GmbH	EU/1/18/1286/001-003	Solution for injection in pre-filled syringe	- L04AB - L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Hyrimoz	Sandoz GmbH	EU/1/18/1286/004-006	Solution for injection in pre-filled pen	- L04AB - L04AB04	- Adalimumab		- Subcutaneous use
Hyrimoz	Sandoz GmbH	EU/1/18/1286/007	Solution for injection in pre-filled syringe	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Hytrin 10mg Tablets	Amdipharm Limited	PA1142/005/004	Tablet	- G04CA - G04CA03	- Terazosin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Hytrin 1mg and 2mg Tablets (Starter Pack)	Amdipharm Limited	PA1142/005/001	Tablet	- G04CA - G04CA03	- Terazosin - Terazosin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Hytrin 2mg Tablets	Amdipharm Limited	PA1142/005/002	Tablet	- G04CA - G04CA03	- Terazosin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Hytrin 5mg Tablets	Amdipharm Limited	PA1142/005/003	Tablet	- G04CA - G04CA03	- Terazosin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
IASIBON	Pharmathen S.A.	EU/1/10/659/003	Concentrate for solution for infusion	- M05BA06	- IBANDRONIC ACID	Article 10(1) - Generic Application	- Oral use
IASIBON	Pharmathen S.A.	EU/1/10/659/004	Concentrate for solution for infusion	- M05BA06	- IBANDRONIC ACID	Article 10(1) - Generic Application	- Oral use
IASIBON	Pharmathen S.A.	EU/1/10/659/005-007	Concentrate for solution for infusion	- M05BA06	- IBANDRONIC ACID	Article 10(1) - Generic Application	- Oral use
Iasibon 50 mg film-coated tablets	Pharmathen S.A.	EU/1/10/659/001-002&8-10 Interchangeable List Code: IC0141-023-003	Film-coated tablet		- Ibandronic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ibandronic Acid 150 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/184/001	Film-coated tablet	- M05BA - M05BA06	- Ibandronate sodium monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ibandronic Acid 6 mg Concentrate for Solution for Infusion	Noridem Enterprises Limited	PA1122/018/001	Concentrate for solution for infusion	- M05BA - M05BA06	- Ibandronate sodium monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Ibandronic acid Accord	Accord Healthcare S.L.U.	EU/1/12/798/001	Concentrate for solution for infusion	- M05BA - M05BA06	- Ibandronate sodium monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Ibandronic acid Accord	Accord Healthcare S.L.U.	EU/1/12/798/002-004	Concentrate for solution for infusion	- M05BA - M05BA06	- Ibandronate sodium monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ibandronic acid Accord	Accord Healthcare S.L.U.	EU/1/12/798/005-006	Solution for injection in pre-filled syringe	- M05BA - M05BA06	- Ibandronic acid - Ibandronate sodium monohydrate - Ibandronate sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Ibandronic Acid Clonmel 150 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/240/001 Interchangeable List Code: IC0141-062-003	Film-coated tablet		- Ibandronic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ibandronic Acid Mylan 150 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/111/001	Film-coated tablet	- M05BA - M05BA06	- Ibandronic sodium monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ibandronic Acid Sandoz 50 mg film-coated tablets	Sandoz GmbH	EU/1/11/685/001-005 Interchangeable List Code: IC0141-023-003	Film-coated tablet		- Ibandronic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ibandronic Acid Teva 150 mg film-coated tablets	Teva Pharma B.V.	EU/1/10/642/003-004 Interchangeable List Code: IC0141-062-003	Film-coated tablet		- Ibandronic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ibandronic Acid Teva 50 mg film-coated tablets	Teva Pharma B.V.	EU/1/10/642/001-002 Interchangeable List Code: IC0141-023-003	Film-coated tablet		- Ibandronic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ibrance	Pfizer Europe MA EEIG	EU/1/16/1147/001-002	Capsule, hard	- L01XE33	- Palbociclib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ibrance	Pfizer Europe MA EEIG	EU/1/16/1147/0012-013	Film-coated tablet	- L01XE33	- Palbociclib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ibrance	Pfizer Europe MA EEIG	EU/1/16/1147/003-004	Capsule, hard	- L01XE - L01XE33	- Palbociclib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ibrance	Pfizer Europe MA EEIG	EU/1/16/1147/005-006	Capsule, hard	- L01XE - L01XE33	- Palbociclib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ibrance	Pfizer Europe MA EEIG	EU/1/16/1147/010-011	Film-coated tablet	- L01XE33	- Palbociclib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ibrance	Pfizer Europe MA EEIG	EU/1/16/1147/014-015	Film-coated tablet	- L01XE33	- Palbociclib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ibugel 5% w/w Gel	Dermal Laboratories (Ireland) Limited	PA23128/011/001	Gel	- M02AA - M02AA13	- Ibuprofen		- Topical
Ibuprofen 200 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/165/001	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ibuprofen 200 mg soft capsules	Brillpharma (Ireland) Limited	PA22749/022/004	Capsule, soft	- M01AE - M01AE01	- Ibuprofen ph. eur.	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ibuprofen 200mg Coated Tablets	Chefaro Ireland DAC	PA1186/022/001	Coated tablet	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ibuprofen 400 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/165/002	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ibuprofen 600 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/165/003	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ibuprofen B. Braun 200 mg solution for infusion	B. Braun Melsungen AG	PA0736/041/003	Solution for infusion	- M01AE01	- Ibuprofen	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Ibuprofen B. Braun 400 mg solution for infusion	B. Braun Melsungen AG	PA0736/041/001	Solution for infusion	- M01AE - M01AE01	- Ibuprofen	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Ibuprofen B. Braun 600 mg solution for infusion	B. Braun Melsungen AG	PA0736/041/002	Solution for infusion	- M01AE - M01AE01	- Ibuprofen	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Ibuprofen Banner 100 mg soft chewable capsules	Patheon Softgels B.V.	PA22773/001/001	Chewable capsule, soft	- M01AE01	- Ibuprofen	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Ibuprofen Farmalider 200 mg film-coated tablets	Farmalider, S.A.	PA2090/002/001	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen ph. eur.	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Ibuprofen Gen.Orph	Gen.Orph	EU/1/23/1791/001	Solution for injection	- C01EB16	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Ibuprofen Max 400mg Film-coated Tablets	Chefaro Ireland DAC	PA1186/022/002	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets	Haleon Ireland Limited	PA0678/160/001	Film-coated tablet	- M01AE51	- Ibuprofen - Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
ICANDRA	Novartis Europharm Limited	EU/1/08/484/1-6, 13-15	Film Coated Tablet	- A10BD08			- Oral use
Icandra	Novartis Europharm Limited	EU/1/08/484/7-12, 16-18	Film-coated tablet	- A10BD			- Oral use
Icatibant 30 mg solution for injection in pre-filled syringe	Fresenius Kabi Deutschland GmbH	PA2059/075/001	Solution for injection in pre-filled syringe	- B06AC02	- Icatibant Acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Icatibant Accord	Accord Healthcare S.L.U.	EU/1/21/1567/001-002	Solution for infusion in pre-filled syringe	- B06AC02	- Icatibant	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Icatibant Aguettant 30 mg solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/014/001	Solution for injection in pre-filled syringe	- B06AC02	- Icatibant Acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Iclusig	Incyte Biosciences Distribution B.V.	EU/1/13/839/001-002	Film-coated tablet	- L01XE - L01XE24	- Ponatinib hci	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Iclusig	Incyte Biosciences Distribution B.V.	EU/1/13/839/003-004	Film-coated tablet	- L01XE - L01XE24	- Ponatinib hci	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Iclusig	Incyte Biosciences Distribution B.V.	EU/1/13/839/006	Film-coated tablet	- L01XE - L01XE24	- Ponatinib hci	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Icorvida SR 1.5mg Prolonged-release Tablets	KRKA, d.d., Novo mesto	PA1347/022/001	Prolonged-release tablet	- C03BA - C03BA11	- Indapamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
IDACIO	Fresenius Kabi Deutschland GmbH	EU/1/19/1356/001	Solution for injection	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
IDACIO	Fresenius Kabi Deutschland GmbH	EU/1/19/1356/002	Solution for injection in pre-filled syringe	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
IDACIO	Fresenius Kabi Deutschland GmbH	EU/1/19/1356/003	Solution for injection in pre-filled pen	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Idefirix	Hansa Biopharma AB	EU/1/20/1471/001-002	Powder for concentrate for solution for infusion	- L04AA - L04AA41	- Imlifidase	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
IDELVION	CSL Behring GmbH	EU/1/16/1095/001	Powder and solvent for solution for injection	- B02BD	- Rix-fp	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
IDELVION	CSL Behring GmbH	EU/1/16/1095/002	Powder and solvent for solution for injection	- B02BD	- Rix-fp	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
IDELVION	CSL Behring GmbH	EU/1/16/1095/003	Powder and solvent for solution for injection	- B02BD	- Rix-fp	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
IDELVION	CSL Behring GmbH	EU/1/16/1095/004	Powder and solvent for solution for injection	- B02BD	- Rix-fp	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Idelvion	CSL Behring GmbH	EU/1/16/1095/009	Powder and solvent for solution for injection	- B02BD04	- Albutrepenonacog Alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ideos 500 mg/400 IU Chewable Tablets	Primecrown 2010 Limited	PPA1633/033/001	Chewable tablet	- A12AX	- Cholecalciferol - Calcium carbonate		- Oral use
IDEOS 500mg/400 IU Chewable Tablets	Laboratoire Innotech International	PA1033/001/001	Chewable tablet	- A12AX	- Cholecalciferol - Calcium carbonate		- Oral use
Idrolax 10g, powder for oral solution in a sachet	IPSEN Consumer HealthCare	PA22808/001/001	Powder for oral solution in sachet	- A06AD - A06AD15	- Macrogol 4000	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
IELMAG3 0.2 mg kit for radiopharmaceutical preparation	ROTOP Pharmaka GmbH	PA2226/001/001	Kit for radiopharmaceutical preparation	- V09CA - V09CA03	- Mertiatide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Ifirmacombi	KRKA, d.d., Novo mesto	EU/1/11/673/001-008	Film-coated tablet	- C09DA - C09DA04	- Irbesartan hydrochloride - Hydrochlorothiazide		- Oral use
IFIRMACOMBI	Krka d.d., Novo mesto	EU/1/11/673/009-016	Film-coated tablet	- C09DA04	- IRBESARTAN HYDROCHLORIDE - HYDROCHLOROTHIAZIDE		- Oral use
Ifirmacombi	KRKA, d.d., Novo mesto	EU/1/11/673/017-024	Film-coated tablet	- C09DA - C09DA04	- Irbesartan hydrochloride - Hydrochlorothiazide		- Oral use
Ifirmasta	KRKA, d.d., Novo mesto	EU/1/08/480/13-18	Film-coated tablet	- C09CA - C09CA04	- Irbesartan hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ifirmasta	KRKA, d.d., Novo mesto	EU/1/08/480/1-6	Film-coated tablet	- C09CA - C09CA04	- Irbesartan hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ifirmasta	KRKA, d.d., Novo mesto	EU/1/08/480/7-12	Film-coated tablet	- C09CA - C09CA04	- Irbesartan hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ikervis	Santen OY	EU/1/15/990/001-002	Eye drops, emulsion	- S01XA - S01XA18	- Ciclosporin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Ilaris	Novartis Europharm Limited	EU/1/09/564/004	Solution for injection	- L04AC - L04AC08	- Canakinumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Ilaris	Novartis Europharm Limited	EU/1/09/564/1-2	Powder for solution for injection	- L04AC - L04AC08	- Canakinumab		- Subcutaneous use
Illuzyce	Billev Pharma ApS	EU/1/22/1680/001-006	Radiopharmaceutical precursor, solution	- V10X	- Lutetium (177lu) chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	
Ilumetri	Almirall, S.A.	EU/1/18/1323/001	Solution for injection in pre-filled syringe	- L04AC17	- Tildrakizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Ilumetri	Almirall S.A.	EU/1/18/1323/003	Solution for injection	- L04AC17	- Tildrakizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
ILUVIEN 190 micrograms intravitreal implant in applicator	Alimera Sciences Europe Limited,	PA22620/001/001	Intravitreal implant in applicator	- S01BA15	- Fluocinolone acetonide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravitreal use
Ilvico Cold and Flu film-coated tablets Paracetamol 325 mg Caffeine 30 mg Brompheniramine maleate 3 mg	P&G Health Germany GmbH	PA22703/001/001	Film-coated tablet	- R06AB - R06AB51	- Paracetamol - BROMPHENIRAMINE MALEATE - Caffeine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Imatinib	Accord Healthcare S.L.U.	EU/1/13/845/001-008	Film-coated tablet	- L01XE - L01XE01	- Imatinib mesylate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Imatinib	Accord Healthcare S.L.U.	EU/1/13/845/009-014	Film-coated tablet	- L01X	- Imatinib mesylate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Imatinib Krka d.d 100 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/054/001	Film-coated tablet	- L01XE - L01XE01	- Imatinib mesilate		- Oral use
Imatinib Krka d.d. 400 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/054/002	Film-coated tablet	- L01XE - L01XE01	- Imatinib mesilate		- Oral use
Imatinib Rowex 100mg Film-coated tablets	Rowex Ltd	PA0711/248/001	Film-coated tablet	- L01XE - L01XE01	- Imatinib mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Imatinib Rowex 400mg Film-coated tablets	Rowex Ltd	PA0711/248/002	Film-coated tablet	- L01XE - L01XE01	- Imatinib mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
IMATINIB TEVA	Teva B.V.	EU/1/12/808/001-012	Film-coated tablet	- L01XE01	- IMATINIB MESILATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
IMATINIB TEVA	Teva B.V.	EU/1/12/808/013-020	Film-coated tablet	- L01XE01	- IMATINIB MESILATE	Article 10(1) - Generic Application	- Oral use
IMATINIB TEVA	Teva B.V.	EU/1/12/808/021-032	Capsule, hard	- L01XE01	- IMATINIB MESILATE	Article 10(1) - Generic Application	- Oral use
IMATINIB TEVA	Teva B.V.	EU/1/12/808/033-040	Capsule, hard	- L01XE01	- IMATINIB MESILATE	Article 10(1) - Generic Application	- Oral use
Imbruvica	Janssen-Cilag International NV	EU/1/14/945/001-002	Capsule, hard	- L01XE27	- Ibrutinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Imbruvica	Janssen-Cilag International NV	EU/1/14/945/005	Film-coated tablet	- L01XE27	- Ibrutinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Imbruvica	Janssen-Cilag International NV	EU/1/14/945/006	Film-coated tablet	- L01XE27	- Ibrutinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Imbruvica	Janssen-Cilag International NV	EU/1/14/945/007-008	Film-coated tablet	- L01XE27	- Ibrutinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Imbruvica	Janssen-Cilag International NV	EU/1/14/945/009-010	Film-coated tablet	- L01XE27	- Ibrutinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Imcivree	Rhythm Pharmaceuticals Netherlands B.V	EU/1/21/1564/001	Solution for injection	- A08AA	- Setmelanotide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Imdur 60 mg Prolonged-release Film-coated Tablets	Topridge Pharma (Ireland) Limited	PA2129/001/001	Prolonged-release tablet	- C01DA - C01DA14	- ISOSORBIDE MONONITRATE		- Oral use
Imfinzi	AstraZeneca AB	EU/1/18/1322/001-002	Concentrate for solution for infusion	- L01XC28	- Durvalumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Imigran 10 mg Nasal Spray, Solution	GlaxoSmithKline (Ireland) Limited	PA1077/008/003	Nasal spray, solution	- N02CC - N02CC01	- Sumatriptan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Imigran 20 mg nasal spray, solution	GlaxoSmithKline (Ireland) Limited	PA1077/008/004 Interchangeable List Code: IC0143-003-066	Nasal spray, solution		- Sumatriptan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Imigran 20 mg nasal spray, solution	IMED Healthcare Ltd.	PPA1463/211/001 Interchangeable List Code: IC0143-003-066	Nasal spray, solution		- Sumatriptan	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Nasal use
Imigran 20 mg nasal spray, solution	PCO Manufacturing Ltd.	PPA0465/070/005 Interchangeable List Code: IC0143-003-066	Nasal spray, solution		- Sumatriptan	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Nasal use
Imigran Ftab 100 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/070/004 Interchangeable List Code: IC0143-024-014	Film-coated tablet		- Sumatriptan	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Imigran Ftab 100 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/008/007 Interchangeable List Code: IC0143-024-014	Film-coated tablet		- Sumatriptan succinate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Imigran Ftab 100 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/032/002 Interchangeable List Code: IC0143-024-014	Film-coated tablet		- Sumatriptan	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Imigran Ftab 50 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/008/006 Interchangeable List Code: IC0143-023-014	Film-coated tablet		- Sumatriptan succinate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Imigran Ftab 50 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/070/003 Interchangeable List Code: IC0143-023-014	Film-coated tablet		- Sumatriptan	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Imigran Ftab 50 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/032/001 Interchangeable List Code: IC0143-023-014	Film-coated tablet		- Sumatriptan	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Imipenem/Cilastatin 250 mg/250 mg powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/074/001	Powder for solution for infusion	- J01DH51	- Imipenem - Cilastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Imipenem/Cilastatin 500 mg/500 mg powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/074/002	Powder for solution for infusion	- J01DH51	- Imipenem - Cilastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Imipenem/Cilastatin 500 mg/500 mg powder for solution for infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/005/001	Powder for solution for infusion	- J01DH - J01DH51	- Imipenem - Cilastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Imjudo	AstraZeneca AB	EU/1/22/1713/001-002	Concentrate for solution for infusion	- L01FX20 - L01XC	- Tremelimumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Imlygic	Amgen Europe B.V.	EU/1/15/1064/001	Solution for injection	- L01XC - L01XC19	- Talimogene laherparepvec	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intralesional use
Imlygic	Amgen Europe B.V.	EU/1/15/1064/002	Solution for injection	- L01XC - L01XC19	- Talimogene laherparepvec	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intralesional use
Imnovid	Bristol-Myers Squibb Pharma EEIG	EU/1/13/850/001	Capsule, hard	- L04AX - L04AX06	- Pomalidomide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Imnovid	Bristol-Myers Squibb Pharma EEIG	EU/1/13/850/002	Capsule, hard	- L04AX - L04AX06	- Pomalidomide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Imnovid	Bristol-Myers Squibb Pharma EEIG	EU/1/13/850/003	Capsule, hard	- L04AX - L04AX06	- Pomalidomide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Imnovid	Bristol-Myers Squibb Pharma EEIG	EU/1/13/850/004	Capsule, hard	- L04AX - L04AX06	- Pomalidomide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Imodium 2 mg Capsules	JNTL Consumer Health I (Ireland) Limited	PA23490/025/002	Capsule, hard	- A07DA - A07DA03	- Loperamide hydrochloride		- Oral use
Imodium Instants 2 mg Orodispersible Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/025/001	Orodispersible tablet	- A07DA - A07DA03	- Loperamide hydrochloride		- Oral use
Imodium Instants 2 mg Orodispersible Tablets	IMED Healthcare Ltd.	PPA1463/207/001	Orodispersible tablet	- A07DA - A07DA03	- Loperamide hydrochloride	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Imodium Instants 2 mg Orodispersible Tablets	PCO Manufacturing Ltd.	PPA0465/001/002	Orodispersible tablet	- A07DA - A07DA03	- Loperamide hydrochloride	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Imodium LiquiRelief 2mg Soft Capsules	JNTL Consumer Health I (Ireland) Limited	PA23490/025/003	Capsule, soft	- A07DA - A07DA03	- Loperamide hydrochloride		- Oral use
Imodium Plus 2 mg/125 mg Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/030/001	Tablet	- A07DA - A07DA53	- Loperamide hydrochloride - Simeticone	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Imolieve 2 mg orodispersible tablets	Clonmel Healthcare Ltd	PA0126/305/001	Orodispersible tablet	- A07DA - A07DA03	- Loperamide hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Implanon NXT, 68 mg implant for subdermal use	Organon Pharma (Ireland) Limited	PA23198/017/001	Implant	- G03AC - G03AC08	- Etonogestrel	Full application (Article 8(3) of Directive No 2001/83/EC)	- Implantation
Implanon NXT, 68 mg implant for subdermal use	PCO Manufacturing Ltd.	PPA0465/250/001	Implant	- G03AC08	- Etonogestrel		- Implantation
Implanon NXT, 68 mg implant for subdermal use	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/002/001	Implant	- G03AC - G03AC08	- Etonogestrel		- Subcutaneous use
Implanon NXT, 68 mg implant for subdermal use	IMED Healthcare Ltd.	PPA1463/171/001	Implant	- G03AC08	- Etonogestrel		- Implantation
Imraldi	Samsung Bioepis NL B.V.	EU/1/17/1216/001-004	Solution for injection in pre-filled syringe	- L04AB - L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Imraldi	Samsung Bioepis NL B.V.	EU/1/17/1216/005-008	Solution for injection in pre-filled pen	- L04AB04	- Adalimumab		- Subcutaneous use
Imraldi	Samsung Bioepis NL B.V.	EU/1/17/1216/009	Solution for injection	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Imuger 25 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/032/001	Film-coated tablet	- L04AX - L04AX01	- Azathioprine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Imuger 50 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/032/002	Film-coated tablet	- L04AX - L04AX01	- Azathioprine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Imunovir 500 mg tablets	Kora Corporation Limited trading as Kora Healthcare	PA1748/001/001	Tablet	- J05AX - J05AX05	- Inosine acedoben dimepranol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Imuran 25 mg Film-coated Tablets	Aspen Pharma Trading Limited	PA1691/003/002	Film-coated tablet	- L04AX - L04AX01	- Azathioprine		- Oral use
Imuran 25 mg Film-coated Tablets	IMED Healthcare Ltd.	PPA1463/196/002	Film-coated tablet	- L04AX01	- Azathioprine		- Oral use
Imuran 25 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/077/001	Film-coated tablet	- L04AX01	- Azathioprine		- Oral use
Imuran 50 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/077/002	Film-coated tablet	- L04AX01	- Azathioprine		- Oral use
Imuran 50 mg Film-coated Tablets	IMED Healthcare Ltd.	PPA1463/196/001	Film-coated tablet	- L04AX01	- Azathioprine		- Oral use
Imuran 50 mg Film-coated Tablets	Aspen Pharma Trading Limited	PA1691/003/003	Film-coated tablet	- L04AX - L04AX01	- Azathioprine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Imuran 50 mg Film-coated Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/041/001	Film-coated tablet	- L04AX - L04AX01	- Azathioprine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Imuran 50 mg Powder for Solution for Injection or Infusion	Aspen Pharma Trading Limited	PA1691/003/001	Powder for solution for injection/infusion	- L04AX - L04AX01	- Azathioprine sodium		- Intramuscular use
IMVAGGIS 0.03 mg pessary	Laboratoires Besins International	PA1054/005/001	Pessary	- G03CA - G03CA04	- Estriol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Vaginal use
Imvanex	Bavarian Nordic A/S	EU/1/13/855/001	Suspension for injection	- J07BX	- Mva-bn virus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Inaqovi	Otsuka Pharmaceutical Netherlands B.V.	EU/1/23/1756/001	Film-coated tablet	- L01BC58	- Decitabine - Cedazuridine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Inbrija	Acorda Therapeutics Ireland Limited	EU/1/19/1390/001-002	Inhalation powder, hard capsule	- N04BA01	- Levodopa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Increlex	Ipsen Pharma	EU/1/07/402/001	Solution for injection	- H01AC - H01AC03	- Mecasermin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Incresync	Takeda Pharma A/S	EU/1/13/842/010-018	Film-coated tablet	- A10BD	- Alogliptin (as benzoate) - Pioglitazone (as hydrochloride)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Incresync	Takeda Pharma A/S	EU/1/13/842/01-09	Film-coated tablet	- A10BD - A10BD09	- Alogliptin (as benzoate) - Pioglitazone (as hydrochloride)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Incresync	Takeda Pharma A/S	EU/1/13/842/019-027	Film-coated tablet	- A10BD	- Pioglitazone (as hydrochloride) - Alogliptin (as benzoate)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Incresync	Takeda Pharma A/S	EU/1/13/842/028-036	Film-coated tablet	- A10BD	- Pioglitazone (as hydrochloride) - Alogliptin (as benzoate)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Incruse Ellipta	GlaxoSmithKline (Ireland) Limited	EU/1/14/922/001-003	Inhalation powder, pre-dispensed	- R03BB07	- Umeclidinium bromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Indium (111In) DTPA 37MBq/ml Solution for Injection	Curium Netherlands B.V.	PA0690/009/001	Solution for injection	- V09AX01	- Indium (111 in) - PENTETIC ACID	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intrathecal use
Indium (In111) Chloride 370MBq/ml radiopharmaceutical precursor	Curium Netherlands B.V.	PA0690/008/001	Radiopharmaceutical precursor, solution	- V09AX01	- Indium (111 in)	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Indivina 1 mg/2.5 mg tablets	Orion Corporation	PA1327/005/001	Tablet	- G03FA - G03FA12	- Estradiol valerate - Medroxyprogesterone acetate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Indivina 1 mg/5 mg tablets	Orion Corporation	PA1327/005/002	Tablet	- G03FA - G03FA12	- Estradiol valerate - Medroxyprogesterone acetate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Indivina 2 mg/5 mg tablets	Orion Corporation	PA1327/005/003	Tablet	- G03FA - G03FA12	- Medroxyprogesterone acetate - Estradiol valerate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Indoramin 20 mg Film-coated Tablets	Chemidex Pharma Limited	PA22643/004/001	Film-coated tablet	- C02CA - C02CA02	- Indoramin base		- Oral use
InductOs	Medtronic BioPharma B.V.	EU/1/02/226/001	Powder, solvent and matrix for implantation matrix	- M05BC - M05BC01	- Dibotermin alfa		- Implantation
Inegy 10 mg / 20 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/024/002 Interchangeable List Code: IC0034-051-002	Tablet		- Ezetimibe - Simvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Inegy 10 mg / 80 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/024/004 Interchangeable List Code: IC0034-060-002	Tablet		- Ezetimibe - Simvastatin		- Oral use
Inegy 10 mg/40 mg tablets	Organon Pharma (Ireland) Limited	PA23198/024/003 Interchangeable List Code: IC0034-059-002	Tablet		- Ezetimibe - Simvastatin		- Oral use
Inegy 10mg / 10mg Tablets	Organon Pharma (Ireland) Limited	PA23198/024/001 Interchangeable List Code: IC0034-017-002	Tablet		- Ezetimibe - Simvastatin		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/001	Powder and suspension for suspension for injection	- J07CA - J07CA09	- Haemophilus influenzae - Pertussis toxoid - Tetanus toxoid - Polysaccharide-k - Diphtheria toxoid - Pertactin - Hbs ag - Filamentous haemagglutinin (fha)		
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/002	Powder and suspension for suspension for injection	- J07CA	- Haemophilus influenzae - Hbs ag - Tetanus toxoid - Pertussis toxoid - Filamentous haemagglutinin (fha) - Polysaccharide-k - Diphtheria toxoid - Pertactin		
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/003	Suspension for injection	- J07CA	- Haemophilus influenzae - Pertactin - Diphtheria toxoid - Polysaccharide-k - Tetanus toxoid - Filamentous haemagglutinin (fha) - Hbs ag - Pertussis toxoid		
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/004	Suspension for injection	- J07CA	- Haemophilus influenzae - Pertactin - Diphtheria toxoid - Polysaccharide-k - Tetanus toxoid - Filamentous haemagglutinin (fha) - Hbs ag - Pertussis toxoid		
Infanrix hexa	GlaxoSmithKline Biologicals	EU/1/00/152/005	Powder and suspension for suspension for injection	- J07CA	- Pertactin - Pertussis toxoid - Hbs ag - Diphtheria toxoid - Filamentous haemagglutinin (fha) - Polysaccharide-k - Tetanus toxoid - Haemophilus influenzae		
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/006	Powder and suspension for suspension for injection	- J07CA	- Filamentous haemagglutinin - Polysaccharide-k - Diphtheria toxoid - Haemophilus influenzae - Tetanus toxoid - Pertactin - Pertussis toxoid - Hbs ag	Full application (Article 8(3) of Directive No 2001/83/EC)	
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/007	Suspension for injection	- J07CA	- Haemophilus influenzae - Pertactin - Diphtheria toxoid - Polysaccharide-k - Tetanus toxoid - Filamentous haemagglutinin (fha) - Hbs ag - Pertussis toxoid		

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/008	Suspension for injection	- J07CA	- Haemophilus influenzae - Pertactin - Diphtheria toxoid - Polysaccharide-k - Tetanus toxoid - Filamentous haemagglutinin (fha) - Hbs ag - Pertussis toxoid		
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/009	Suspension for injection	- J07CA	- Haemophilus influenzae - Pertactin - Diphtheria toxoid - Polysaccharide-k - Tetanus toxoid - Filamentous haemagglutinin (fha) - Hbs ag - Pertussis toxoid		
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/010	Suspension for injection	- J07CA	- Haemophilus influenzae - Pertactin - Diphtheria toxoid - Polysaccharide-k - Tetanus toxoid - Filamentous haemagglutinin (fha) - Hbs ag - Pertussis toxoid		
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/011	Suspension for injection	- J07CA	- Haemophilus influenzae - Pertactin - Diphtheria toxoid - Polysaccharide-k - Tetanus toxoid - Filamentous haemagglutinin (fha) - Hbs ag - Pertussis toxoid		
Infanrix hexa	GlaxoSmithKline Biologicals	EU/1/00/152/012	Suspension for injection	- J07CA	- Haemophilus influenzae - Pertactin - Diphtheria toxoid - Polysaccharide-k - Tetanus toxoid - Filamentous haemagglutinin (fha) - Hbs ag - Pertussis toxoid		
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/013	Suspension for injection	- J07CA	- Haemophilus influenzae - Pertactin - Diphtheria toxoid - Polysaccharide-k - Tetanus toxoid - Filamentous haemagglutinin (fha) - Hbs ag - Pertussis toxoid		
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/014	Powder and suspension for suspension for injection	- J07CA	- Haemophilus influenzae - Pertactin - Diphtheria toxoid - Polysaccharide-k - Tetanus toxoid - Filamentous haemagglutinin (fha) - Hbs ag - Pertussis toxoid		

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/015	Suspension for injection	- J07CA	- Haemophilus influenzae - Pertactin - Diphtheria toxoid - Polysaccharide-k - Tetanus toxoid - Filamentous haemagglutinin (fha) - Hbs ag - Pertussis toxoid		
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/016	Powder and suspension for suspension for injection	- J07CA	- Haemophilus influenzae - Pertactin - Diphtheria toxoid - Polysaccharide-k - Tetanus toxoid - Filamentous haemagglutinin (fha) - Hbs ag - Pertussis toxoid		
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/19-20	Powder and suspension for suspension for injection	- J07CA - J07CA09	- Tetanus toxoid (t) - Conjugate of haemophilus influenzae type b capsular polysaccharide (prp) and tetanus toxoid - Pertactin (69 kda outer membrane protein - prn) - Diphtheria toxoid (d) - Inactivated polio virus type 2 - R-dna hepatitis b surface antigen (hbsag) - Inactivated polio virus type 1 - Pertussis toxoid (pt) - Inactivated polio virus type 3 - Filamentous haemagglutinin (fha)		- Intramuscular use
Inflectra	Pfizer Europe MA EEIG	EU/1/13/854/001-005	Powder for concentrate for solution for infusion	- L04AB - L04AB02	- Ct-p13 (infliximab)	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Influvac Tetra, suspension for injection in pre-filled syringe (influenza vaccine, surface antigen, inactivated)	Viatris Healthcare Limited	PA23355/016/001	Suspension for injection in pre-filled syringe	- J07BB - J07BB02	- A/Victoria/2570/2019 (H1N1)pdm09 - like strain (A/Victoria/2570/2019, IVR-215) - A/Darwin/9/2021 (H3N2) - like strain (A/Darwin/9/2021, IVR-228) - B/PHUKET/3073/2013 -LIKE STRAIN (B/PHUKET/3073/2013, WILD TYPE) - B/Austria/1359417/2021 - like strain (B/Michigan/01/2021, wild type)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Infutraze concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/083/001	Concentrate for solution for infusion	- B05XA31	- Copper chloride dihydrate - Manganese chloride tetrahydrate - Potassium iodide - Sodium selenite anhydrous - Zinc chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/001-002	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intraarterial use - Intravenous use - Subcutaneous use
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/003-004	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intraarterial use - Intravenous use - Subcutaneous use
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/005-006	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intraarterial use - Intravenous use - Subcutaneous use
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/007-008	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intraarterial use - Intravenous use - Subcutaneous use
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/009-010	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intraarterial use - Intravenous use - Subcutaneous use
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/069	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/070	Solution for injection in pre-filled syringe	- B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/071	Solution for injection in multidose container	- B01AB05	- Enoxaparin sodium - Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/072	Solution for injection in multidose container	- B01AB05	- Enoxaparin sodium - Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Inlyta	Pfizer Europe MA EEIG	EU/1/12/777/001-003	Film-coated tablet	- L01XE - L01XE17	- Axitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Inlyta	Pfizer Europe MA EEIG	EU/1/12/777/004-006	Film-coated tablet	- L01XE - L01XE17	- Axitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Inlyta	Pfizer Europe MA EEIG	EU/1/12/777/007-009	Film-coated tablet	- L01XE - L01XE17	- Axitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Inlyta	Pfizer Europe MA EEIG	EU/1/12/777/010-012	Film-coated tablet	- L01XE - L01XE17	- Axitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
innohep 10,000 IU in 0.5 ml, solution for injection	Leo Laboratories Limited	PA0046/060/010	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use
innohep 10,000 IU in 0.5 ml, solution for injection	PCO Manufacturing Ltd.	PPA0465/499/003	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use
innohep 10,000 IU/ml solution for injection	Leo Laboratories Limited	PA0046/060/002	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use
innohep 12,000 IU in 0.6 ml, Solution for injection	Leo Laboratories Limited	PA0046/060/013	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use
innohep 14,000 IU in 0.7 ml, solution for injection	Leo Laboratories Limited	PA0046/060/011	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
innohep 14,000 IU in 0.7 ml, solution for injection	PCO Manufacturing Ltd.	PPA0465/499/004	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use
innohep 16,000 IU in 0.8 ml, Solution for injection	Leo Laboratories Limited	PA0046/060/014	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use
innohep 18,000 IU in 0.9 ml, solution for injection	Leo Laboratories Limited	PA0046/060/004	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use
innohep 18,000 IU in 0.9 ml, solution for injection	PCO Manufacturing Ltd.	PPA0465/499/005	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use
innohep 2,500 IU, solution for injection	Leo Laboratories Limited	PA0046/060/008	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use
innohep 20,000 IU/ml Solution for Injection	Leo Laboratories Limited	PA0046/060/003	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use
innohep 3,500 IU, solution for injection	Leo Laboratories Limited	PA0046/060/009	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use
innohep 3,500 IU, solution for injection	PCO Manufacturing Ltd.	PPA0465/499/002	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use
innohep 4,500 IU, solution for injection	PCO Manufacturing Ltd.	PPA0465/499/001	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use
innohep 4,500 IU, solution for injection	Leo Laboratories Limited	PA0046/060/007	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use
innohep 8,000 IU in 0.4 ml, Solution for injection	Leo Laboratories Limited	PA0046/060/012	Solution for injection	- B01AB - B01AB10	- Tinzaparin sodium		- Subcutaneous use
Innovace 10 mg Tablets	PCO Manufacturing Ltd.	PPA0465/462/001	Tablet	- C09AA - C09AA02	- Enalapril maleate		- Oral use
Innovace 10 mg Tablets	IMED Healthcare Ltd.	PPA1463/208/001	Tablet	- C09AA - C09AA02	- Enalapril maleate		- Oral use
Innovace 10 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/005/003	Tablet	- C09AA - C09AA02	- Enalapril maleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Innovace 2.5 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/005/001	Tablet	- C09AA - C09AA02	- Enalapril maleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Innovace 20 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/005/004	Tablet	- C09AA - C09AA02	- Enalapril maleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Innovace 20 mg Tablets	IMED Healthcare Ltd.	PPA1463/208/002	Tablet	- C09AA - C09AA02	- Enalapril maleate		- Oral use
Innovace 5 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/005/002	Tablet	- C09AA - C09AA02	- Enalapril maleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Innozide 20 mg/12.5 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/006/001	Tablet	- C09BA - C09BA02	- Enalapril maleate - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
INOmax	AGA AB	EU/1/01/194/001	Medicinal gas, compressed	- R07AX - R07AX01	- Nitric oxide		
INOmax	INO Therapeutics AB	EU/1/01/194/003-004	Medicinal gas, compressed	- R07AX - R07AX01	- Nitric oxide		
Inovelon	Eisai GmbH	EU/1/06/378/017	Oral suspension	- N03AF - N03AF03	- Rufinamide		- Oral use
Inovelon	Eisai GmbH	EU/1/06/378/1-16	Film-coated tablet	- N03AF - N03AF03	- Rufinamide		- Oral use
Inrebic	Bristol-Myers Squibb Pharmaceuticals uc	EU/1/20/1514/001	Capsule, hard	- L01XE	- Fedratinib dihydrochloride monohydrate - Fedratinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Insomniger 10 mg tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/225/001	Tablet	- N05CD - N05CD07	- Temazepam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Insomniger 20 mg tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/225/002	Tablet	- N05CD - N05CD07	- Temazepam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
INSPRA	B & S Healthcare	DPR1328/016/002	Tablet	- C03DA04	- EPLERENONE		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
INSPRA 25 mg film-coated tablets	Upjohn EESV	PA23055/005/001 Interchangeable List Code: IC0115-022-003	Film-coated tablet		- Eplerenone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
INSPRA 50 mg film-coated tablets	Upjohn EESV	PA23055/005/002 Interchangeable List Code: IC0115-023-003	Film-coated tablet		- Eplerenone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Instanyl	Takeda Danmark A/S	EU/1/09/531/010-013	Nasal spray, solution	- N02AB - N02AB03	- FENTANYL CITRATE		- Nasal use
Instanyl	Takeda Danmark A/S	EU/1/09/531/014-017	Nasal spray, solution	- N02AB - N02AB03	- FENTANYL CITRATE		- Nasal use
Instanyl	Takeda Danmark A/S	EU/1/09/531/018-021	Nasal spray, solution	- N02AB - N02AB03	- FENTANYL CITRATE		- Nasal use
Instanyl	Takeda Danmark A/S	EU/1/09/531/1-3	Nasal spray, solution	- N02AB - N02AB03	- FENTANYL CITRATE		- Nasal use
Instanyl	Takeda Danmark A/S	EU/1/09/531/4-6	Nasal spray, solution	- N02AB - N02AB03	- FENTANYL CITRATE		- Nasal use
Instanyl	Takeda Danmark A/S	EU/1/09/531/7-9	Nasal spray, solution	- N02AB - N02AB03	- FENTANYL CITRATE		- Nasal use
Instillagel 6 ml Urethral, vaginal, rectal and oropharyngeal gel	Farco-Pharma GmbH	PA0328/001/001	Gel	- N01BB - N01BB52	- Lidocaine hydrochloride - Chlorhexidine digluconate (as chlorhexidine digluconate solution (20% w/v) ph.eur. - Methyl parahydroxybenzoate - Propyl parahydroxybenzoate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Urethral use
Instillagel® 11 ml Urethral, vaginal, rectal and oropharyngeal gel	Farco-Pharma GmbH	PA0328/001/002	Gel	- N01BB - N01BB52	- Lidocaine hydrochloride - Chlorhexidine digluconate (as chlorhexidine digluconate solution (20% w/v) ph.eur. - Methyl parahydroxybenzoate - Propyl parahydroxybenzoate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Urethral use
Insulatard	Novo Nordisk A/S	EU/1/02/233/003-004	Suspension for injection	- A10AC - A10AC01	- Insulin human		- Subcutaneous use
Insulatard	Novo Nordisk A/S	EU/1/02/233/1-15	Suspension for injection	- A10AC - A10AC01	- Insulin human		
Insulatard FlexPen	Novo Nordisk A/S	EU/1/02/233/013	Suspension for injection	- A10AC - A10AC01	- Insulin human		
Insulatard InnoLet	Novo Nordisk A/S	EU/1/02/233/010-012	Suspension for injection	- A10AC - A10AC01	- Insulin human		
Insulatard Penfill	Novo Nordisk A/S	EU/1/02/233/005-007	Suspension for injection	- A10AC - A10AC01	- Insulin human		
Insulin aspart Sanofi	Sanofi Winthrop Industrie	EU/1/20/1447/001-005	Solution for injection	- A10AB05	- Insulin aspart	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Insulin aspart Sanofi	Sanofi Winthrop Industrie	EU/1/20/1447/001-007	Solution for injection	- A10AB05	- Insulin aspart	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Insulin lispro Sanofi (previously Admelog)	Sanofi Winthrop Industrie	EU/1/17/1203/001-008	Solution for injection	- A10AB - A10AB04	- Insulin lispro	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/029	Suspension for injection	- A10AC - A10AC01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/037	Suspension for injection	- A10AC - A10AC01	- Insulin human		- Intramuscular use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/069	Solution for injection	- A10AC - A10AC01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/070	Suspension for injection	- A10AC - A10AC01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/071	Suspension for injection	- A10AC - A10AC01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/072	Suspension for injection	- A10AB - A10AB01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/057	Suspension for injection	- A10AC - A10AC01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/058	Suspension for injection	- A10AC - A10AC01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Basal 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/033	Suspension for injection	- A10AC - A10AC01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Basal 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/034	Suspension for injection	- A10AC - A10AC01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Basal 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/035	Suspension for injection	- A10AC - A10AC01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Basal 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/036	Suspension for injection	- A10AC - A10AC01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 15	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/073	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 15	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/074	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 15	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/075	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 15	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/076	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 15	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/059	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 15	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/060	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 15 100 IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/038	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 15 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/039	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 15 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/040	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 15 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/041	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 15 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/042	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 25	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/077	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 25	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/078	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 25	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/079	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 25	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/080	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 25	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/061	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 25	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/062	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 25 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/043	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 25 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/044	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 25 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/045	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 25 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/046	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 25 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/047	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 30	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/170-189	Suspension for injection	- A10AD - A10AD01	- Insulin human hr1799	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Insuman Comb 50	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/081	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 50	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/082	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 50	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/083	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Insuman Comb 50	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/084	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 50	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/063	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 50	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/064	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 50 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/048	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 50 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/049	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 50 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/050	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 50 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/051	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Comb 50 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/052	Suspension for injection	- A10AD - A10AD01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Implantable	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/202-203	Solution for infusion	- A10AB - A10AB01	- Insulin human	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraperitoneal use
Insuman Infusat 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/053	Solution for injection	- A10AB - A10AB01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Infusat 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/054	Solution for injection in cartridge	- A10AB - A10AB01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/055	Solution for injection in cartridge	- A10AB - A10AB01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/056	Solution for injection in cartridge	- A10AB - A10AB01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/030	Solution for injection in cartridge	- A10AB - A10AB01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/031	Solution for injection	- A10AB - A10AB01	- Insulin human		- Intramuscular use - Subcutaneous use
INSUMAN RAPID	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/028	Solution for injection	- A10AB - A10AB01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/065	Solution for injection	- A10AB - A10AB01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/066	Solution for injection	- A10AB - A10AB01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/067	Solution for injection	- A10AB - A10AB01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/068	Solution for injection	- A10AB - A10AB01	- Insulin human		- Intramuscular use - Subcutaneous use
Insuman Rapid 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/032	Solution for injection	- A10AB - A10AB01	- Insulin human		- Intramuscular use - Subcutaneous use
Integrilin	GlaxoSmithKline (Ireland) Limited	EU/1/99/109/001	Solution for infusion	- B01AC16	- Eptifibatide		- Intra-venous
Integrilin	GlaxoSmithKline (Ireland) Limited	EU/1/99/109/002	Solution for injection	- B01AC - B01AC16	- Eptifibatide		- Intravenous use
Intelence	Janssen-Cilag International NV	EU/1/08/468/002	Tablet	- J05AG - J05AG04	- Etravirine		- Oral use
Intelence	Janssen-Cilag International NV	EU/1/08/468/003	Tablet	- J05AG - J05AG04	- Etravirine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Intelence	Janssen-Cilag International NV	EU/1/08/468/1	Tablet	- J05AG - J05AG04	- Etravirine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Intralipid 20 % w/v Emulsion for Infusion Biofine bag	Fresenius Kabi Deutschland GmbH	PA2059/041/005	Emulsion for infusion	- B05BA - B05BA02	- Soya bean oil, refined		- Intravenous use
Intralipid 20% w/v Emulsion for Infusion, Glass Bottle	Fresenius Kabi Deutschland GmbH	PA2059/041/001	Emulsion for infusion	- B05BA - B05BA02	- Soya bean oil		- Intravenous use
Intrarosa	Endoceutics S.A.	EU/1/17/1255/001	Pessary	- G03	- Prasterone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Intratect 100 g/L, solution for infusion	Biotest Pharma GmbH	PA0592/007/002	Solution for infusion	- J06BA - J06BA02	- Human plasma protein	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Intratect 50 g/L, solution for infusion	Biotest Pharma GmbH	PA0592/007/001	Solution for infusion	- J06BA - J06BA02	- Human plasma protein >96% immunoglobulins	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
IntronA	Schering Plough Europe	EU/1/99/127/001	Powder and solvent for solution for injection	- L03AB - L03AB05	- Interferon alfa-2b		- Intravenous use - Subcutaneous use
INTRONA	Schering Plough Europe	EU/1/99/127/036	Solution for Injection	- L03AB05	- INTERFERON ALFA-2B		- Subcutaneous
INTRONA	Schering Plough Europe	EU/1/99/127/038	Solution for Injection	- L03AB05	- INTERFERON ALFA-2B		- Subcutaneous
Intuniv	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/15/1040/001-002	Prolonged-release tablet	- C02AC - C02AC02	- GUANFACINE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Intuniv	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/15/1040/003-005	Prolonged-release tablet	- C02AC - C02AC02	- GUANFACINE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Intuniv	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/15/1040/006-007	Prolonged-release tablet	- C02AC - C02AC02	- GUANFACINE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Intuniv	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/15/1040/008-009	Prolonged-release tablet	- C02AC - C02AC02	- GUANFACINE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Invanz	Merck Sharp & Dohme BV,	EU/1/02/216/001	Concentrate for solution for infusion	- J01DH - J01DH03	- Ertapenem sodium		
INVEGA 12 mg prolonged-release tablets	Janssen-Cilag International NV	EU/1/07/395/16-20	Prolonged-release tablet	- N05AX - N05AX13	- Paliperidone		- Oral use
INVEGA 3 mg prolonged-release tablets	Janssen-Cilag International NV	EU/1/07/395/1-5 Interchangeable List Code: IC0130-045-024	Prolonged-release tablet		- Paliperidone		- Oral use
INVEGA 6 mg prolonged-release tablets	Janssen-Cilag International NV	EU/1/07/395/6-10 Interchangeable List Code: IC0130-046-024	Prolonged-release tablet		- Paliperidone		- Oral use
INVEGA 9 mg prolonged-release tablets	Janssen-Cilag International NV	EU/1/07/395/11-15 Interchangeable List Code: IC0130-178-024	Prolonged-release tablet		- Paliperidone		- Oral use
Invokana	Janssen-Cilag International NV	EU/1/13/884/001-004	Film-coated tablet	- A10BK - A10BK02	- Canagliflozin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Invokana	Janssen-Cilag International NV	EU/1/13/884/005-008	Film-coated tablet	- A10BK - A10BK02	- Canagliflozin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Iodine Liniment Strong, Cutaneous SolutionIodine 10% w/vPotassium Iodide 6% w/v	Ovelle Limited	PA0206/026/001	Cutaneous solution	- D08AG - D08AG03	- Potassium iodide - Iodine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical use
Iodine Tincture (Alcoholic Iodine Solution BP), Cutaneous SolutionIodine 2.5% w/vPotassium Iodide 2.5% w/v	Ovelle Limited	PA0206/025/001	Cutaneous solution	- D08AG - D08AG03	- Potassium iodide - Iodine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical use
Iomeron 150 mgI/ml Solution for Injection	Bracco Imaging spa	PA1826/006/001	Solution for injection	- V08AB - V08AB10	- Iomeprol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Iomeron 200 mgI/ml Solution for Injection	Bracco Imaging spa	PA1826/006/002	Solution for injection	- V08AB - V08AB10	- Iomeprol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraarterial use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Iomeron 250 mgI/ml Solution for Injection	Bracco Imaging spa	PA1826/006/003	Solution for injection	- V08AB - V08AB10	- Iomeprol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraarterial use - Intravenous use
Iomeron 300 mgI/ml Solution for Injection	Bracco Imaging spa	PA1826/006/004	Solution for injection	- V08AB - V08AB10	- Iomeprol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraarterial use - Intraarticular use - Intravenous use
Iomeron 350 mgI/ml Solution for Injection	Bracco Imaging spa	PA1826/006/005	Solution for injection	- V08AB - V08AB10	- Iomeprol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Iomeron 400 mgI/ml Solution for Injection	Bracco Imaging spa	PA1826/006/006	Solution for injection	- V08AB - V08AB10	- Iomeprol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ionolyte solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/042/001	Solution for infusion	- B05BB - B05BB01	- Sodium acetate trihydrate - Sodium chloride - Potassium chloride - Magnesium chloride hexahydrate - Sodium hydroxide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
IOPIDINE 1%w/v Eye Drops, Solution	Essential Pharma Limited	PA22587/002/002	Eye drops, solution	- S01EA - S01EA03	- Apraclonidine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use - Topical use
Iopidine 5 mg/ml Eye Drops, Solution	Essential Pharma Limited	PA22587/002/001	Eye drops, solution	- S01EA - S01EA03	- Apraclonidine hydrochloride		- Ocular use
Ipramol Steri-Neb 0.5 mg/2.5 mg per 2.5 ml nebuliser solution	Teva B.V.	PA1986/082/001 Interchangeable List Code: IC0081-136-052	Nebuliser solution		- Ipratropium bromide - SALBUTAMOL SULFATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Inhalation use
Ipratropium bromide/Salbutamol Neutec 0.5/2.5 mg per 2.5 ml nebuliser solution	Neutec Inhaler Ireland Limited	PA23030/003/001 Interchangeable List Code: IC0081-136-052	Nebuliser solution		- Ipratropium bromide monohydrate - SALBUTAMOL SULFATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Ipratropium Steri-Neb 250 micrograms/ml Nebuliser solution	Teva B.V.	PA1986/083/001	Nebuliser solution	- R03BB - R03BB01	- Ipratropium bromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	
IPV Infanrix suspension for injection in pre-filled syringe Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed)	GlaxoSmithKline (Ireland) Limited	PA1077/108/001	Suspension for injection in pre-filled syringe	- J07CA02	- Pertussis toxoid - Filamentous haemagglutinin - Pertactin - Diphtheria toxoid - Tetanus toxoid - Polio virus type 1 inactivated - Polio virus type 2 inactivated - Polio virus type 3 inactivated	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
IPV-Boostrix–Suspension for injection in a pre-filled syringeDiphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content)	GlaxoSmithKline (Ireland) Limited	PA1077/101/001	Suspension for injection in pre-filled syringe	- J07CA02	- Diphtheria toxoid - Tetanus toxoid - Pertussis toxoid - Filamentous haemagglutinin - Pertactin - Type 1 (mahoney) - Type 2 (mef-1) - Type 3 (saukett)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Irbesartan Accord 150 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/037/002	Film-coated tablet	- C09CA - C09CA04	- Irbesartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Irbesartan Accord 300 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/037/003	Film-coated tablet	- C09CA - C09CA04	- Irbesartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Irbesartan Accord 75 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/037/001	Film-coated tablet	- C09CA - C09CA04	- Irbesartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Irbesartan Clonmel 150mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/205/002	Film-coated tablet	- C09CA - C09CA04	- Irbesartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Irbesartan Clonmel 300mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/205/003	Film-coated tablet	- C09CA - C09CA04	- Irbesartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Irbesartan Clonmel 75mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/205/001	Film-coated tablet	- C09CA - C09CA04	- Irbesartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Irbesartan HCT Winthrop	Zentiva k.s.	EU/1/06/377/006-010	Tablet	- C09DA - C09DA04	- Irbesartan - Hydrochlorothiazide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Irbesartan HCT Winthrop	Zentiva k.s.	EU/1/06/377/23-28	Tablet	- C09DA - C09DA04	- Irbesartan - Hydrochlorothiazide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Irbesartan HCT Winthrop	Zentiva k.s.	EU/1/06/377/6-10,17-22	Tablet	- C09DA - C09DA04	- Irbesartan - Hydrochlorothiazide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Irbesartan HCT Zentiva	Zentiva k.s.	EU/1/06/377/1-5,11-16	Tablet	- C09DA - C09DA04	- Hydrochlorothiazide - Irbesartan	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Irbesartan HCT Zentiva	Zentiva k.s.	EU/1/06/377/001-005	Tablet	- C09DA - C09DA04	- Hydrochlorothiazide - Irbesartan	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Irbesartan Rowa 150 mg tablets	Rowa Pharmaceuticals Limited	PA0074/080/002	Tablet	- C09CA - C09CA04	- Irbesartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Irbesartan Rowa 300 mg tablets	Rowa Pharmaceuticals Limited	PA0074/080/003	Tablet	- C09CA - C09CA04	- Irbesartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Irbesartan Rowa 75 mg tablets	Rowa Pharmaceuticals Limited	PA0074/080/001	Tablet	- C09CA - C09CA04	- Irbesartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
IRBESARTAN TEVA	Teva B.V.	EU/1/09/576/1-13	Film-coated tablet	- C09CA04	- IRBESARTAN	Article 10(1) - Generic Application	- Oral use
IRBESARTAN TEVA	Teva B.V.	EU/1/09/576/14-26	Film-coated tablet	- C09CA04	- IRBESARTAN	Article 10(1) - Generic Application	- Oral use
IRBESARTAN TEVA	Teva B.V.	EU/1/09/576/27-39	Film-coated tablet	- C09CA04	- IRBESARTAN	Article 10(1) - Generic Application	- Oral use
Irbesartan Winthrop	Zentiva k.s.	EU/1/06/376/001-005	Tablet	- C09CA - C09CA04	- Irbesartan	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Irbesartan Winthrop	Zentiva k.s.	EU/1/06/376/11-15	Tablet	- C09CA - C09CA04	- Irbesartan	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Irbesartan Winthrop	Zentiva k.s.	EU/1/06/376/1-5	Tablet	- C09CA - C09CA04	- Irbesartan	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Irbesartan Winthrop	Zentiva k.s.	EU/1/06/376/16-21	Film-coated tablet	- C09CA - C09CA04	- Irbesartan		- Oral use
Irbesartan Winthrop	Zentiva k.s.	EU/1/06/376/22-27	Film-coated tablet	- C09CA - C09CA04	- Irbesartan		- Oral use
Irbesartan Winthrop	Zentiva k.s.	EU/1/06/376/28-33	Film-coated tablet	- C09CA - C09CA04	- Irbesartan		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Irbesartan Winthrop	Zentiva k.s.	EU/1/06/376/6-10	Tablet	- C09CA - C09CA04	- Irbesartan	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
IRBESARTAN/HYDROCHLOROTHIAZIDE TEVA	Teva B.V.	EU/1/09/583/1-24	Film-coated tablet	- C09DA04	- IRBESARTAN - HYDROCHLOROTHIAZIDE, MICRONISED	Article 10(1) - Generic Application	- Oral use
IRBESARTAN/HYDROCHLOROTHIAZIDE TEVA	Teva B.V.	EU/1/09/583/25-48	Film-coated tablet	- C09DA04	- IRBESARTAN - HYDROCHLOROTHIAZIDE, MICRONISED	Article 10(1) - Generic Application	- Oral use
IRBESARTAN/HYDROCHLOROTHIAZIDE TEVA	Teva B.V.	EU/1/09/583/49-72	Film-coated tablet	- C09DA04	- IRBESARTAN - HYDROCHLOROTHIAZIDE, MICRONISED	Article 10(1) - Generic Application	- Oral use
Iressa	AstraZeneca AB	EU/1/09/526/001-002	Film-coated tablet	- L01XE - L01XE02	- Gefitinib		- Oral use
Ireven 150mg prolonged-release capsules, hard	Pharmathen S.A.	PA1368/002/002 Interchangeable List Code: IC0026-062-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ireven 75 mg prolonged-release capsules, hard	Pharmathen S.A.	PA1368/002/001 Interchangeable List Code: IC0026-028-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Iricryn 0.3 mg/ml eye drops, solution	Farmaprojects S.A.	PA1391/006/001	Eye drops, solution	- S01EE03	- Bimatoprost	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Irinotecan 20 mg/ml Concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/044/001	Concentrate for solution for infusion	- L01XX - L01XX09	- Irinotecan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/108/001	Concentrate for solution for infusion	- L01XX - L01XX19	- Irinotecan hydrochloride trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Irinotecan Hydrochloride 20 mg/mL concentrate for solution for infusion	Teva B.V.	PA1986/068/001	Concentrate for solution for infusion	- L01XX - L01XX19	- Irinotecan hydrochloride trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Irish Botanica Echinacea Oral Liquid	Irish Botanica	TR1723/001/001	Oral solution		- TINCTURE FROM DRIED ECHINACEA PURPUREA (L.) MOENCH RADIX (1:3)	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Iruxol Mono 1.2U/g Ointment	Smith & Nephew GmbH	PA22696/001/001	Ointment	- D03BA - D03BA52	- Protease - Clostridiopeptidase a	Competence of personnel (Article 23 of Directive No 2010/63/EU)	- Topical
Iscover	Sanofi Winthrop Industrie	EU/1/98/070/001 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- Clopidogrel hydrogensulfate		- Oral use
Iscover	Sanofi Winthrop Industrie	EU/1/98/070/8-10 Interchangeable List Code: IC0005-029-003	Film-coated tablet		- Clopidogrel hydrogensulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Isentress	Merck Sharp & Dohme BV,	EU/1/07/436/003	Chewable tablet	- J05AX - J05AX08	- Raltegravir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Isentress	Merck Sharp & Dohme BV	EU/1/07/436/004	Chewable tablet	- J05AX - J05AX08	- Raltegravir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Isentress	Merck Sharp & Dohme BV	EU/1/07/436/005	Granules for oral suspension	- J05AX - J05AX08	- Raltegravir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Isentress	Merck Sharp & Dohme BV	EU/1/07/436/006	Film-coated tablet	- J05AX - J05AX08	- Raltegravir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Isentress	Merck Sharp & Dohme BV,	EU/1/07/436/1-2	Film-coated tablet	- J05AX - J05AX08	- Raltegravir potassium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Isoket 1mg/ml Concentrate for solution for injection or infusion, 10 ml Ampoule	Merus Labs Luxco II S.à.R.L.	PA2118/003/001	Concentrate for solution for injection/infusion	- C01DA - C01DA08	- Isosorbide dinitrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intracoronary use - Intravenous use
Isomel SR	Dexcel Pharma GmbH	PA2261/002/001	Prolonged-release tablet	- C01DA - C01DA14	- Isosorbid-5-mononitrat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Isomonit Retard 60 mg Prolonged-release tablets	Rowex Ltd	PA0711/023/001	Prolonged-release tablet	- C01DA - C01DA14	- ISOSORBIDE MONONITRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Isoprenaline hydrochloride Macure 0.2 mg/ml concentrate for solution for infusion	Macure Pharma ApS	PA23199/001/001	Concentrate for solution for infusion	- C01CA02	- ISOPRENALINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Isoptin 2.5mg/ml Solution for Injection or Infusion	Mylan IRE Healthcare Limited	PA2010/003/004	Solution for injection/infusion	- C08DA - C08DA01	- Verapamil hydrochloride		- Intravenous use
Isoptin 40 mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/003/001	Film-coated tablet	- C08DA - C08DA01	- Verapamil hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Isoptin 80 mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/003/002	Film-coated tablet	- C08DA - C08DA01	- Verapamil hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Isoptin SR 240 mg Prolonged-Release Tablets	Mylan IRE Healthcare Limited	PA2010/003/005	Prolonged-release tablet	- C08DA - C08DA01	- Verapamil hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Isotretinoin 10 mg soft capsules	Rowex Ltd	PA0711/312/002	Capsule, soft	- D10BA01	- Isotretinoin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Isotretinoin 20 mg soft capsules	Rowex Ltd	PA0711/312/003	Capsule, soft	- D10BA01	- Isotretinoin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Isotretinoin GAP 10 mg capsule, soft	Gap S.A.	PA22735/002/001	Capsule, soft	- D10BA01	- Isotretinoin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Isotretinoin GAP 20 mg capsule, soft	Gap S.A.	PA22735/002/002	Capsule, soft	- D10BA01	- Isotretinoin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Isotretinoin SUN 10 mg soft capsules	Sun Pharmaceutical Industries Europe B.V.	PA2050/007/001	Capsule, soft	- D10BA01	- Isotretinoin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Isotretinoin SUN 20 mg soft capsules	Sun Pharmaceutical Industries Europe B.V.	PA2050/007/002	Capsule, soft	- D10BA01	- Isotretinoin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Istin 10 mg hard capsule	Upjohn EESV	PA23055/012/004	Capsule, hard	- C08CA01	- Amlodipine besilate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Istin 10 mg tablets	Upjohn EESV	PA23055/012/002 Interchangeable List Code: IC0045-002-008	Tablet		- Amlodipine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Istin 10 mg tablets	PCO Manufacturing Ltd.	PPA0465/065/002 Interchangeable List Code: IC0045-002-008	Tablet		- Amlodipine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Istin 5 mg hard capsule	Upjohn EESV	PA23055/012/003	Capsule, hard	- C08CA01	- Amlodipine besilate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Istin 5 mg tablets	Upjohn EESV	PA23055/012/001 Interchangeable List Code: IC0045-001-008	Tablet		- Amlodipine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Istin 5 mg tablets	PCO Manufacturing Ltd.	PPA0465/065/001 Interchangeable List Code: IC0045-001-008	Tablet		- Amlodipine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Isturisa	Recordati Rare Diseases	EU/1/19/1407/001	Film-coated tablet	- H02CA - H02CA02	- Osilodrostat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Isturisa	Recordati Rare Diseases	EU/1/19/1407/002	Film-coated tablet	- H02CA - H02CA02	- Osilodrostat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Isturisa	Recordati Rare Diseases	EU/1/19/1407/003	Film-coated tablet	- H02CA - H02CA02	- Osilodrostat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Itami 140 mg medicated plaster	Fidia Farmaceutici S.p.A.	PA0814/002/001	Medicated plaster	- M02AA - M02AA15	- Diclofenac sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Itoco 20 mg/ml eye drops, solution	Farmaprojects S.A.	PA1391/003/001	Eye drops, solution	- S01EC03	- Dorzolamide hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Itraconazole 10mg/ml oral solution	Athlone Pharmaceuticals Limited	PA1418/004/001	Oral solution	- J02AC - J02AC02	- Itraconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
ITULAZAX 12 SQ-Bet sublingual lyophilisate	ALK-Abello A/S	PA1255/007/001	Oral lyophilisate	- V01AA - V01AA05	- Betula verrucosa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Ivabradine Accord	Accord Healthcare S.L.U.	EU/1/17/1190/001-007	Film-coated tablet	- C01EB - C01EB17	- Ivabradine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ivabradine Accord	Accord Healthcare S.L.U.	EU/1/17/1190/008-014	Film-coated tablet	- C01EB - C01EB17	- Ivabradine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ivabradine Anpharm	Anpharm Przedsiebiorstwo Farmaceutyczne S.A	EU/1/15/1041/001-007	Film-coated tablet	- C01EB - C01EB17	- Ivabradine hydrochloride	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Ivabradine Anpharm	Anpharm Przedsiebiorstwo Farmaceutyczne S.A	EU/1/15/1041/008-014	Film-coated tablet	- C01EB - C01EB17	- Ivabradine hydrochloride	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ivabradine Krka 5 mg Film-coated Tablets	KRKA, d.d., Novo mesto	PA1347/065/001	Film-coated tablet	- C01EB - C01EB17	- Ivabradine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ivabradine Krka 7.5 mg Film-coated Tablets	KRKA, d.d., Novo mesto	PA1347/065/002	Film-coated tablet	- C01EB - C01EB17	- Ivabradine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ivabradine Rowex 5 mg Film-coated Tablets	Rowex Ltd	PA0711/265/001	Film-coated tablet	- C01EB - C01EB17	- Ivabradine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ivabradine Rowex 7.5 mg Film-coated Tablets	Rowex Ltd	PA0711/265/002	Film-coated tablet	- C01EB - C01EB17	- Ivabradine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ivabradine Zentiva	Zentiva k.s.	EU/1/16/1144/001-007	Film-coated tablet	- C01EB - C01EB17	- Ivabradine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
IVABRADINE ZENTIVA	Zentiva k.s.	EU/1/16/1144/008-014	Film-coated tablet	- C01EB17	- IVABRADINE HYDROCHLORIDE	Article 10(1) - Generic Application	- Oral use
IVEMEND	Merck Sharp & Dohme BV,	EU/1/07/437/001-2	Powder for solution for infusion	- A04AD - A04AD12	- Fosaprepitant dimeglumine		- Intravenous use
Ivemend	Merck Sharp & Dohme BV,	EU/1/07/437/003-004	Powder for solution for infusion	- A04AD - A04AD12	- Fosaprepitant dimeglumine		
Ivozall	Aenova Holding GmbH	EU/1/19/1396/001	Concentrate for solution for infusion	- L01BB06	- Clofarabine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Ixiaro	Intercell Austria AG	EU/1/08/501/1-2	Suspension for injection	- J07BA - J07BA02	- Inactivated je virus		- Intramuscular use
IXPRIM 37.5 mg/325 mg, film coated-tablets	Grunenthal Pharma Ltd	PA2242/006/001 Interchangeable List Code: IC0077-133-014	Film-coated tablet		- Tramadol hydrochloride - Paracetamol	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
IXPRIM effervescent 37.5 mg/325 mg effervescent tablets	Grunenthal Pharma Ltd	PA2242/006/002	Effervescent tablet	- N02AJ - N02AJ13	- Paracetamol - Tramadol hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Izba	Novartis Europharm Limited	EU/1/13/905/001-002	Eye drops, solution	- S01EE - S01EE04	- Travoprost	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Jakavi	Novartis Europharm Limited	EU/1/12/773/001	Tablet	- L01XE - L01XE18	- Ruxolitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jakavi	Novartis Europharm Limited	EU/1/12/773/002	Tablet	- L01XE - L01XE18	- Ruxolitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jakavi	Novartis Europharm Limited	EU/1/12/773/003	Tablet	- L01XE - L01XE18	- Ruxolitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jakavi	Novartis Europharm Limited	EU/1/12/773/013-016	Tablet	- L01XE - L01XE18	- Ruxolitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jalra	Novartis Europharm Limited	EU/1/08/485/1-11	Tablet	- A10BD08	- Vildagliptin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Janumet	Merck Sharp & Dohme BV	EU/1/08/455/008-014 Interchangeable List Code: IC0070-122-003	Film-coated tablet		- Sitagliptin phosphate - Metformin Hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Janumet	Merck Sharp & Dohme BV,	EU/1/08/455/1-7 Interchangeable List Code: IC0070-121-003	Film-coated tablet		- Sitagliptin phosphate - Metformin Hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Janumet	Merck Sharp & Dohme BV	EU/1/08/455/8-14 Interchangeable List Code: IC0070-122-003	Film-coated tablet		- Sitagliptin phosphate - Metformin Hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Januvia 100 mg film-coated tablets	Merck Sharp & Dohme BV	EU/1/07/383/13-18 Interchangeable List Code: IC0131-024-003	Film-coated tablet		- Sitagliptin phosphate monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Januvia 25 mg film-coated tablets	Merck Sharp & Dohme BV,	EU/1/07/383/1-6 Interchangeable List Code: IC0131-022-003	Film-coated tablet		- Sitagliptin phosphate monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Januvia 50 mg film-coated tablets	Merck Sharp & Dohme BV	EU/1/07/383/7-12 Interchangeable List Code: IC0131-023-003	Film-coated tablet		- Sitagliptin phosphate monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jardiance	Boehringer Ingelheim International GmbH	EU/1/14/930/001-009	Film-coated tablet	- A10BK - A10BK03	- Empagliflozin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jardiance	Boehringer Ingelheim International GmbH	EU/1/14/930/010-018	Film-coated tablet	- A10BX - A10BX12	- Empagliflozin		
Javlor	Pierre Fabre Medicament	EU/1/09/550/1-12	Concentrate for solution for infusion	- L01CA - L01CA05	- Vinflunine ditartrate		- Intravenous use
Jaydess 13.5 mg intrauterine delivery system	Bayer Limited	PA1410/068/001	Intrauterine delivery system	- G02BA - G02BA03	- Levonorgestrel, micronized	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intrauterine use
Jayempi	Nova Laboratories Ireland Limited	EU/1/21/1557/001	Oral suspension	- L04AX01	- Azathioprine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Jaypirca	Eli Lilly Nederland B.V.	EU/1/23/1738/001-003	Film-coated tablet	- L01EL05	- Pirtobrutinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jaypirca	Eli Lilly Nederland B.V.	EU/1/23/1738/004-009	Film-coated tablet	- L01EL05	- Pirtobrutinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jcovden	Janssen-Cilag International NV	EU/1/20/1525/001	Suspension for injection	- J07BX - J07BX03	- Adenovirus serotype 26 vector encoding SARS-CoV-2 spike protein	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Jemperli	GlaxoSmithKline (Ireland) Limited	EU/1/21/1538/001	Concentrate for solution for infusion	- L01XC - L01XC40	- Dostarlimab	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Jentadueto	Boehringer Ingelheim International GmbH	EU/1/12/780/001-014	Film-coated tablet	- A10BD - A10BD11	- Linagliptin - Metformin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jentadueto	Boehringer Ingelheim International GmbH	EU/1/12/780/015-028	Film-coated tablet	- A10BD - A10BD11	- Metformin - Linagliptin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jevtana	Sanofi Winthrop Industrie	EU/1/11/676/001	Concentrate and solvent for solution for infusion	- L01CD - L01CD04	- Cabazitaxel		- Intravenous use
Jext 150 micrograms solution for injection in pre-filled pen	ALK-Abello A/S	PA1255/006/001	Solution for injection in pre-filled pen	- C01CA - C01CA24	- Adrenaline	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Jext 300 micrograms solution for injection in pre-filled pen	ALK-Abello A/S	PA1255/006/002	Solution for injection in pre-filled pen	- C01CA - C01CA24	- Adrenaline	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intramuscular use
Jinarc	Otsuka Pharmaceutical Netherlands B.V.	EU/1/15/1000/001-002	Tablet	- C03XA - C03XA01	- Tolvaptan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jinarc	Otsuka Pharmaceutical Netherlands B.V.	EU/1/15/1000/003-004	Tablet	- C03XA - C03XA01	- Tolvaptan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jinarc	Otsuka Pharmaceutical Netherlands B.V.	EU/1/15/1000/005-007	Tablet	- C03XA - C03XA01	- Tolvaptan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jinarc	Otsuka Pharmaceutical Netherlands B.V.	EU/1/15/1000/008-010	Tablet	- C03XA - C03XA01	- Tolvaptan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jinarc	Otsuka Pharmaceutical Netherlands B.V.	EU/1/15/1000/011-013	Tablet	- C03XA - C03XA01	- Tolvaptan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jivi	Bayer AG	EU/1/18/1324/001	Powder and solvent for solution for injection	- B02BD02	- DAMOCTOCOG ALFA PEGOL	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Jivi	Bayer AG	EU/1/18/1324/002	Powder and solvent for solution for injection	- B02BD02	- DAMOCTOCOG ALFA PEGOL	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Jivi	Bayer AG	EU/1/18/1324/003	Powder and solvent for solution for injection	- B02BD02	- DAMOCTOCOG ALFA PEGOL	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Jivi	Bayer AG	EU/1/18/1324/004	Powder and solvent for solution for injection	- B02BD02	- DAMOCTOCOG ALFA PEGOL	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Jivi	Bayer AG	EU/1/18/1324/005	Powder and solvent for solution for injection	- B02BD02	- DAMOCTOCOG ALFA PEGOL	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Jorveza	Dr. Falk Pharma GmbH	EU/1/17/1254/001-005	Orodispersible tablet	- A07EA - A07EA06	- Budesonide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jorveza	Dr. Falk Pharma GmbH	EU/1/17/1254/007-011	Orodispersible tablet	- A07EA06	- Budesonide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Juluca	ViiV Healthcare BV	EU/1/18/1282/001-002	Film-coated tablet	- J05AR21	- Dolutegravir - Rilpivirine hydrochloride - Sodium starch glycolate ep - Iron oxide yellow (E172)		- Oral use
Junior Parapaed Paracetamol Oral Suspension 120 mg/5 ml	Pinewood Laboratories Ltd	PA0281/002/001	Oral suspension	- N02BE - N02BE01	- Paracetamol		- Oral use
Junyelt, Concentrate for solution for infusion	Laboratoire AGUETTANT	PA1968/006/001	Concentrate for solution for infusion	- B05XA - B05XA31	- Zinc gluconate - Copper gluconate - Manganese Gluconate - Potassium iodide - Sodium selenite	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Jylamvo	Therakind (Europe) Limited	EU/1/17/1172/001	Oral solution	- L01BA - L01BA01	- Methotrexate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Jyseleca	Galapagos NV	EU/1/20/1480/001-002	Film-coated tablet	- L04AA - L04AA45	- Filgotinib maleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Jyseleca	Galapagos NV	EU/1/20/1480/003-004	Film-coated tablet	- L04AA - L04AA45	- Filgotinib maleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kabiven emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/045/003	Emulsion for infusion	- B05BA - B05BA10	- Soya bean oil - Glucose monohydrate - Alanine - Arginine - Aspartic Acid - Glutamic acid - Glycine - Histidine - Isoleucine - Leucine - Lysine hydrochloride - Methionine - Phenylalanine - Proline - Serine - Threonine - Tryptophan - Tyrosine - Valine - Calcium chloride 2 h2o - Sodium glycerophosphate anhydrous - Magnesium sulphate 7h2o - Potassium chloride - Sodium acetate 3 H20 - Amino acids - Nitrogen - Fat - Glucose - Glucose (dextrose) - Sodium - Potassium - Magnesium - Calcium - Phosphate - Sulphate - Chloride - Acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Kabiven Peripheral emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/045/004	Emulsion for infusion	- B05BA - B05BA10	- Soya bean oil - Glucose anhydrous - Alanine - Arginine - Aspartic Acid - Glutamic acid - Glycine - Histidine - Isoleucine - Leucine - Lysine - Methionine - Phenylalanine - Proline - Serine - Threonine - Tryptophan - Tyrosine - Valine - Calcium chloride - Sodium glycerophosphate anhydrous - Magnesium sulfate - Potassium chloride - Sodium acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Kadcyla	Roche Registration GmbH	EU/1/13/885/001	Powder for concentrate for solution for infusion	- L01FD03	- Trastuzumab emtansine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Kadcyla	Roche Registration GmbH	EU/1/13/885/002	Powder for concentrate for solution for infusion	- L01FD03	- Trastuzumab emtansine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Kaftrio	Vertex Pharmaceuticals (Ireland) Limited	EU/1/20/1468/001	Film-coated tablet	- R07AX32	- TEZACAFTOR - Ivacaftor - VX-445	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kaftrio	Vertex Pharmaceuticals (Ireland) Limited	EU/1/20/1468/002	Film-coated tablet	- R07AX32	- Ivacaftor - TEZACAFTOR - Elexacaftor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kalcipos-D forte 500 mg/800 IU chewable tablets	Viatris Healthcare Limited	PA23355/015/002	Chewable tablet	- A12AX	- Calcium - Cholecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Kalcipos-D forte 500 mg/800 IU film-coated tablets	Viatris Healthcare Limited	PA23355/015/001	Film-coated tablet	- A12AX	- Calcium - Cholecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Kaletra	AbbVie Deutschland GmbH & Co. KG	EU/1/01/172/003	Oral solution	- J05AE - J05AE03	- Ritonavir - Lopinavir		- Oral use
Kaletra	AbbVie Deutschland GmbH & Co. KG	EU/1/01/172/006	Film-coated tablet	- J05AE - J05AE06	- Ritonavir - Lopinavir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kaletra	AbbVie Deutschland GmbH & Co. KG	EU/1/01/172/4-5,7-8	Film-coated tablet	- J05AE - J05AE03	- Lopinavir - Ritonavir		
Kalms Day film-coated tablets	LanesHealth (Ireland) Limited	TR22702/002/001	Film-coated tablet	- N05CM	- Valerian dry hydroalcoholic extract - Hops dry extract	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Kalms Night Film-Coated Tablets	LanesHealth (Ireland) Limited	TR22702/001/001	Film-coated tablet	- N05CM	- Valerian dry hydroalcoholic extract	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Kalydeco	Vertex Pharmaceuticals (Ireland) Limited	EU/1/12/782/001-002	Film-coated tablet	- R07AX02	- Ivacaftor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kalydeco	Vertex Pharmaceuticals (Ireland) Limited	EU/1/12/782/003	Granules in sachet	- R07AX02	- Ivacaftor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kalydeco	Vertex Pharmaceuticals (Ireland) Limited	EU/1/12/782/004	Granules in sachet	- R07AX	- Ivacaftor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kalydeco	Vertex Pharmaceuticals (Ireland) Limited	EU/1/12/782/005	Film-coated tablet	- R07AX02	- Ivacaftor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kalydeco	Vertex Pharmaceuticals (Ireland) Limited	EU/1/12/782/007	Film-coated tablet	- R07AX02	- Ivacaftor	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kalydeco	Vertex Pharmaceuticals (Ireland) Limited	EU/1/12/782/008	Granules	- R07AX02	- Ivacaftor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kamiren 4 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/038/001 Interchangeable List Code: IC0021-008-024	Prolonged-release tablet		- Doxazosin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Kanjinti	Amgen Europe B.V.	EU/1/18/1281/001	Powder for concentrate for solution for infusion	- L01XC - L01XC03	- Trastuzumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Kanjinti	Amgen Europe B.V.	EU/1/18/1281/002	Powder for concentrate for solution for infusion	- L01XC - L01XC03	- Trastuzumab		- Intravenous use
KANUMA	Alexion Europe SAS	EU/1/15/1033/001	Concentrate for solution for infusion	- A16AB - A16AB14	- Sebelipase alfa	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Kapake 15mg/500mg Tablets	Galen Pharma Ireland Limited	PA22680/002/001	Tablet	- N02AJ - N02AJ06	- Paracetamol - Codeine phosphate hemihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Kapake 30mg/500mg Tablets	Galen Pharma Ireland Limited	PA22680/002/002	Tablet	- N02AJ - N02AJ06	- Paracetamol - Codeine phosphate		- Oral use
Kapruvia	Vifor France	EU/1/22/1643/001-002	Solution for injection	- V03AX	- Difelikefalin Acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/001	Tablet	- C09CA - C09CA04	- Irbesartan		
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/001-003	Tablet	- C09CA - C09CA04	- Irbesartan	Full application (Article 8(3) of Directive No 2001/83/EC)	
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/004	Tablet	- C09CA - C09CA04	- Irbesartan		
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/004-006	Tablet	- C09CA - C09CA04	- Irbesartan	Full application (Article 8(3) of Directive No 2001/83/EC)	
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/007	Tablet	- C09CA - C09CA04	- Irbesartan		
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/007-009	Tablet	- C09CA - C09CA04	- Irbesartan	Full application (Article 8(3) of Directive No 2001/83/EC)	
Karvezide	Sanofi Winthrop Industrie	EU/1/98/085/001	Tablet	- C09DA - C09DA04	- Irbesartan - Hydrochlorothiazide		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Karvezide	Sanofi Winthrop Industrie	EU/1/98/085/001-003	Tablet	- C09DA - C09DA04	- Irbesartan - Hydrochlorothiazide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Karvezide	Sanofi Winthrop Industrie	EU/1/98/085/004	Tablet	- C09DA04	- Irbesartan - Hydrochlorothiazide		- Oral use
Karvezide	Sanofi Winthrop Industrie	EU/1/98/085/004-006	Tablet		- Irbesartan - Hydrochlorothiazide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Karvezide	Sanofi Winthrop Industrie	EU/1/98/085/023-028	Film-coated tablet	- C09DA - C09DA04	- Irbesartan - Hydrochlorothiazide		- Oral use
KARVEZIDE	sanofi-aventis groupe	EU/1/98/85/23-28	Tablets	- C09DA04	- IRBESARTAN - HYDROCHLOROTHIAZIDE		- Oral use
Kauliv	Strides Pharma (Cyprus) Limited	EU/1/22/1710/001-002	Solution for injection in cartridge	- H05AA02	- Teriparatide	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Kay-Cee-L Syrup 7.5% w/v	Elara Pharmaservices Europe Limited	PA22637/004/001	Oral solution	- A12BA - A12BA01	- Potassium chloride		- Oral use
Keflex 125 mg/5 ml Powder for Oral Suspension	Flynn Pharma Limited	PA1226/002/002	Powder for oral suspension	- J01DB - J01DB01	- Cephalexin monohydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Keflex 250 mg Hard Capsules	Flynn Pharma Limited	PA1226/002/001	Capsule, hard	- J01DB - J01DB01	- Cefalexin Anhydrous		- Oral use
Keflex 250 mg/5 ml Powder for Oral Suspension	Flynn Pharma Limited	PA1226/002/003	Powder for oral suspension	- J01DB - J01DB01	- Cefalexin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Keflex 500 mg Film-Coated Tablets	Flynn Pharma Limited	PA1226/002/004	Film-coated tablet	- J01DB - J01DB01	- Cefalexin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Kemadrin 5 mg Tablets	Aspen Pharma Trading Limited	PA1691/005/001	Tablet	- N04AA - N04AA04	- Procyclidine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kemadrin 5 mg tablets	PCO Manufacturing Ltd.	PPA0465/494/001	Tablet	- N04AA - N04AA04	- Procyclidine hydrochloride		- Oral use
Kengrexal	Chiesi Farmaceutici S.p.A.	EU/1/15/994/001	Powder for concentrate for solution for injection/infusion	- B01AC	- Cangrelor tetrasodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Kentera	Teva B.V.	EU/1/03/270/004-005	Gel in sachet	- G04BD - G04BD04	- Oxybutynin hydrochloride		- Transdermal use
Kentera	Teva B.V.	EU/1/03/270/1-2	Transdermal patch	- G04BD - G04BD04	- Oxybutynin		- Transdermal use
Keppra	UCB Pharma SA	EU/1/00/146/030	Concentrate for solution for infusion	- N03AX - N03AX14	- Levetiracetam		
KEPPRA	UCB Pharma S.A.	EU/1/00/146/006-013	Film Coated Tablet	- N03AX14	- LEVETIRACETAM		
KEPPRA	UCB Pharma S.A.	EU/1/00/146/014-019	Film Coated Tablet	- N03AX14	- LEVETIRACETAM		
KEPPRA	UCB Pharma S.A.	EU/1/00/146/020-026	Film Coated Tablet	- N03AX14	- LEVETIRACETAM		
Keppra 100 mg/ml oral solution	UCB Pharma S.A.	EU/1/00/146/027 Interchangeable List Code: IC0119-171-019	Oral solution		- Levetiracetam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Keppra levetiracetam	UCB Pharma SA	EU/1/00/146/001	Film-coated tablet	- N03AX - N03AX14	- Levetiracetam		
Keral 25 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/002/002	Film-coated tablet	- M01AE - M01AE17	- Dexketoprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Keral 25 mg granules in sachet	Menarini International Operations Luxembourg S.A.	PA0865/002/007	Granules in sachet	- M01AE17	- Dexketoprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Keral 25 mg oral solution in sachet	Menarini International Operations Luxembourg S.A.	PA0865/002/006	Oral solution in sachet	- M01AE - M01AE17	- Dexketoprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Keral 25mg granules for oral solution	Menarini International Operations Luxembourg S.A.	PA0865/002/005	Granules for oral solution	- M01AE - M01AE17	- Dexketoprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Keral 50 mg/2ml solution for injection/infusion	Menarini International Operations Luxembourg S.A.	PA0865/002/003	Solution for injection/infusion	- M01AE - M01AE17	- Dexketoprofen trometamol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Kerendia	Bayer AG	EU/1/21/1616/001-005	Film-coated tablet	- C03DA - C03DA05	- Finerenone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kerendia	Bayer AG	EU/1/21/1616/006-010	Film-coated tablet	- C03DA - C03DA05	- Finerenone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kesimpta	Novartis Europharm Limited	EU/1/21/1532/001-002	Solution for injection in pre-filled syringe	- L01XC10	- Ofatumumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Kesimpta	Novartis Europharm Limited	EU/1/21/1532/003-004	Solution for injection in pre-filled pen	- L01XC10 - L04AA	- Ofatumumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Ketalar 10mg/ml Solution for Injection/Infusion	Pfizer Healthcare Ireland	PA0822/013/001	Solution for injection/infusion	- N01AX - N01AX03	- Ketamine hydrochloride		- Intravenous use
Ketalar 50 mg/ml Solution for Injection/Infusion	Pfizer Healthcare Ireland	PA0822/013/002	Solution for injection/infusion	- N01AX - N01AX03	- Ketamine hydrochloride		- Intravenous use
Ketoconazole HRA	HRA Pharma Rare Diseases	EU/1/14/965/001	Tablet	- J02AB - J02AB02	- Ketoconazole	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Ketofall 0.25 mg/ml eye drops, solution in single-dose container	Pharma Stulln GmbH	PA1815/002/001	Eye drops, solution in single-dose container	- S01GX - S01GX08	- Ketotifen hydrogen fumarate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Ketopine 20mg/g Shampoo	Pinewood Laboratories Ltd	PA0281/125/001	Shampoo	- D01AC - D01AC08	- Ketoconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Cutaneous use
Ketovite Liquid	Taw Pharma (Ireland) Ltd	PA23081/012/001	Oral solution	- A11BA	- Vitamin a palmitate - Ergocalciferol - Choline chloride - Cyanocobalamin		- Oral use
Kevzara	Sanofi Winthrop Industrie	EU/1/17/1196/001-002	Solution for injection	- L04AC - L04AC14	- Sarilumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Kevzara	Sanofi Winthrop Industrie	EU/1/17/1196/003-008	Solution for injection	- L04AC - L04AC14	- Sarilumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Keytruda	Merck Sharp & Dohme BV,	EU/1/15/1024/002	Concentrate for solution for infusion	- L01XC - L01XC18	- Pembrolizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Kigabeq	Orphelia Pharma SA	EU/1/18/1302/001	Soluble tablet	- N03AG04	- Vigabatrin	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Kigabeq	Orphelia Pharma SA	EU/1/18/1302/002	Soluble tablet	- N03AG04	- Vigabatrin	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
KIMMTRAK	Immunocore Ireland Limited	EU/1/22/1630/001	Concentrate for solution for infusion	- L01	- Tebentafusp	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Kineret	Swedish Orphan Biovitrum AB	EU/1/02/203/005-007	Solution for injection in pre-filled syringe	- L04AC - L04AC03	- Anakinra	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Kinpeygo	Stada Arzneimittel AG	EU/1/22/1657/001	Modified-release capsule, hard	- A07EA - A07EA06	- Budesonide micronised	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Kinzalkomb 40 mg/12.5 mg tablets	Bayer AG	EU/1/02/214/1-5 Interchangeable List Code: IC0050-099-039	Tablet		- Telmisartan - Hydrochlorothiazide		- Oral use
Kinzalkomb 80 mg/12.5 mg tablets	Bayer AG	EU/1/02/214/006-010 Interchangeable List Code: IC0050-081-039	Tablet		- Telmisartan - Hydrochlorothiazide		- Oral use
Kinzalkomb 80 mg/25 mg tablets	Bayer AG	EU/1/02/214/11-15 Interchangeable List Code: IC0050-100-039	Tablet		- Hydrochlorothiazide - Telmisartan	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Kinzalmono 20 mg tablets	Bayer AG	EU/1/98/091/009-012 Interchangeable List Code: IC0049-003-014	Tablet		- Telmisartan		- Oral use
Kinzalmono 40 mg tablets	Bayer AG	EU/1/98/091/001-004 Interchangeable List Code: IC0049-004-014	Tablet		- Telmisartan		- Oral use
Kinzalmono 80 mg tablets	Bayer AG	EU/1/98/091/005-008 Interchangeable List Code: IC0049-005-014	Tablet		- Telmisartan		- Oral use
Kiovig	Baxter AG	EU/1/05/329/001-006	Solution for infusion	- J06BA - J06BA02	- Human normal immunoglobulin		- Intravenous use
Kirsty	Biosimilar Collaborations Ireland Limited	EU/1/20/1506/001-007	Solution for injection	- A10AB05	- Insulin aspart (iasp)	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Kisplyx	Eisai GmbH	EU/1/16/1128/001	Capsule, hard	- L01XE - L01XE29	- Lenvatinib mesilate	Full application (Article 8(3) of Directive No 2001/83/EC)	
Kisplyx	Eisai GmbH	EU/1/16/1128/002	Capsule, hard	- L01XE - L01XE29	- Lenvatinib mesilate	Full application (Article 8(3) of Directive No 2001/83/EC)	
Kisqali	Novartis Europharm Limited	EU/1/17/1221/001-012	Film-coated tablet	- L01X	- Ribociclib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
KIVEXA	ViiV Healthcare BV	EU/1/04/298/1-2	Film-coated tablet	- J05AR - J05AR02	- Abacavir sulfate - Lamivudine		- Unknown
Klacid 250 mg film-coated tablets	Viatris Healthcare Limited	PA23355/013/001 Interchangeable List Code: IC0072-130-003	Film-coated tablet		- Clarithromycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Klacid 250mg/5ml Granules for Oral Suspension	Viatris Healthcare Limited	PA23355/013/006	Granules for oral suspension	- J01FA - J01FA09	- Clarithromycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Klacid Forte 500 mg film-coated tablets	Viatris Healthcare Limited	PA23355/013/002 Interchangeable List Code: IC0072-117-003	Film-coated tablet		- Clarithromycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Klacid IV 500mg Powder for Concentrate for Solution for Infusion	Viatris Healthcare Limited	PA23355/013/003	Powder for concentrate for solution for infusion	- J01FA - J01FA09	- Clarithromycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Klacid LA 500mg Modified release tablets	Viatris Healthcare Limited	PA23355/013/004 Interchangeable List Code: IC0072-117-050	Modified-release tablet		- Clarithromycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Klacid Paediatric Suspension 125mg/5ml, Granules for Oral Suspension	Viatris Healthcare Limited	PA23355/013/005	Granules for oral suspension	- J01FA - J01FA09	- Clarithromycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Klaram LA 500 mg prolonged-release tablets	Accord Healthcare Ireland Ltd.	PA2315/133/001 Interchangeable List Code: IC0072-117-050	Prolonged-release tablet		- Clarithromycin citrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Klariger 500 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/093/002 Interchangeable List Code: IC0072-117-003	Film-coated tablet		- Clarithromycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Klean-Prep Powder for oral Solution	Helsinn Birex Pharmaceuticals Limited	PA0294/017/001	Powder for oral solution	- A06AD - A06AD65	- Sodium chloride - Potassium chloride - Macrogol 3350 - Sodium bicarbonate - Sodium sulfate anhydrous		- Oral use
Kliogest 2 mg/1 mg film-coated tablets	Novo Nordisk A/S	PA0218/022/001	Film-coated tablet	- G03FA - G03FA01	- Estradiol - Norethisterone acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Klisyri	Almirall, S.A.	EU/1/21/1558/001	Ointment	- D06BX03	- Tirbanibulin	Full application (Article 8(3) of Directive No 2001/83/EC)	
KOGENATE Bayer	Bayer AG	EU/1/00/143/001	Powder and solvent for solution for injection	- B02BD - B02BD02	- Octocog alfa - R-dna (baby hamster kidney expression system)		- Intravenous use
Kogenate Bayer	Bayer Schering Pharma AG	EU/1/00/143/002	Powder and solvent for solution for injection	- B02BD - B02BD02	- Octocog alfa		- Intravenous use
Kogenate Bayer	Bayer Schering Pharma AG	EU/1/00/143/003	Powder and solvent for solution for injection	- B02BD - B02BD02	- Octocog alfa		- Intravenous use
KOGENATE BAYER	Bayer Schering Pharma AG	EU/1/00/143/004	Powder and solvent for solution for injection	- B02BD - B02BD02	- Octocog alfa		
Kogenate Bayer	Bayer Schering Pharma AG	EU/1/00/143/005	Powder and solvent for solution for injection	- B02BD - B02BD02	- Octocog alfa		- Intravenous use
Kogenate Bayer	Bayer Schering Pharma AG	EU/1/00/143/006	Powder and solvent for solution for injection	- B02BD - B02BD02	- Octocog alfa		- Intravenous use
Kogenate Bayer	Bayer Schering Pharma AG	EU/1/00/143/012-013	Powder and solvent for solution for injection	- B02BD - B02BD02	- Octocog alfa		- Intravenous use
Kogenate Bayer	Bayer Schering Pharma AG	EU/1/00/143/10-11	Powder and solvent for solution for injection	- B02BD - B02BD02	- Octocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Komboglyze	AstraZeneca AB	EU/1/11/731/001-006	Film-coated tablet	- A10BD10	- Saxagliptin - METFORMIN HYDROCHLORIDE		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Komboglyze	AstraZeneca AB	EU/1/11/731/007-012	Film-coated tablet	- A10BD10	- METFORMIN HYDROCHLORIDE - Saxagliptin		- Oral use
Konakion MM Ampoules 10 mg/ml Solution for Injection and Oral Solution	CHEPLAPHARM Arzneimittel GmbH	PA2239/002/001	Solution for injection	- B02BA - B02BA01	- Phytomenadione		- Intravenous use - Oral use
Konakion MM Paediatric Ampoules 2 mg/ 0.2 ml oral solution or solution for injection	CHEPLAPHARM Arzneimittel GmbH	PA2239/002/002	Solution for injection	- B02BA - B02BA01	- Phytomenadione		- Intramuscular use - Intravenous use - Oral use
Konverge 20 mg/5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/017/001	Film-coated tablet	- C09DB - C09DB02	- Olmesartan medoxomil - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Konverge 40 mg/10 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/017/003	Film-coated tablet	- C09DB - C09DB02	- Olmesartan medoxomil - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Konverge 40 mg/5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/017/002	Film-coated tablet	- C09DB - C09DB02	- Olmesartan medoxomil - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Konverge Plus 20 mg/5 mg/12.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/019/001	Film-coated tablet	- C09DX - C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Konverge Plus 40mg/10mg/12.5mg film coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/019/003	Film-coated tablet	- C09DX - C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Konverge Plus 40mg/10mg/25mg film coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/019/005	Film-coated tablet	- C09DX - C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Konverge Plus 40mg/5mg/12.5mg film coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/019/002	Film-coated tablet	- C09DX - C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Konverge Plus 40mg/5mg/25mg film coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/019/004	Film-coated tablet	- C09DX - C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Kopen 250mg Tablets	Athlone Pharmaceuticals Limited	PA1418/014/003	Tablet	- J01CE - J01CE02	- Phenoxymethylpenicillin potassium		- Oral use
Kopen Sugar Free 125mg/5ml Powder for Oral Solution	Athlone Pharmaceuticals Limited	PA1418/014/001	Powder for oral solution	- J01CE - J01CE02	- Phenoxymethylpenicillin potassium		- Oral use
Kopen Sugar Free 250mg/5ml Powder for Oral Solution	Athlone Pharmaceuticals Limited	PA1418/014/002	Powder for oral solution	- J01CE - J01CE02	- Phenoxymethylpenicillin potassium		- Oral use
Koselugo	AstraZeneca AB	EU/1/21/1552/001	Capsule, hard	- L01EE04 - L01XE	- Selumetinib Sulfate	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Koselugo	AstraZeneca AB	EU/1/21/1552/002	Capsule, hard	- L01EE04 - L01XE	- Selumetinib Sulfate	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kovaltry	Bayer AG	EU/1/15/1076/001-002	Powder and solvent for solution for injection	- B02BD - B02BD02	- Octocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Kovaltry	Bayer Pharma AG	EU/1/15/1076/003-004	Powder and solvent for solution for injection	- B02BD - B02BD02	- Octocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Kovaltry	Bayer Pharma AG	EU/1/15/1076/005-006	Powder and solvent for solution for injection	- B02BD - B02BD02	- Octocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Kovaltry	Bayer Pharma AG	EU/1/15/1076/007-008	Powder and solvent for solution for injection	- B02BD - B02BD02	- Octocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Kovaltry	Bayer Pharma AG	EU/1/15/1076/009-010	Powder and solvent for solution for injection	- B02BD - B02BD02	- Octocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
KryptoScan, [81m Kr] Radionuclide generator	Curium Netherlands B.V.	PA0690/007/001	Radionuclide generator	- V09EX01	- Krypton (81m kr)	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
Kuvan	BioMarin International Limited	EU/1/08/481/004	Powder for oral solution	- A16AX07	- Sapropterin hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kuvan	BioMarin International Limited	EU/1/08/481/005	Powder for oral solution	- A16AX07	- Sapropterin hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kuvan	BioMarin International Limited	EU/1/08/481/1-3	Soluble tablet	- A16AX07	- Sapropterin dihydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kwells 300 microgram Tablets	Dexcel Pharma GmbH	PA2261/006/001	Tablet	- A04AD - A04AD01	- Hyoscine hydrobromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Kyleena 19.5 mg intrauterine delivery system	PCO Manufacturing Ltd.	PPA0465/476/001	Intrauterine delivery system	- G02BA - G02BA03	- Levonorgestrel		- Intrauterine use
Kyleena 19.5 mg intrauterine delivery system	IMED Healthcare Ltd.	PPA1463/186/001	Intrauterine delivery system	- G02BA - G02BA03	- Levonorgestrel		- Intrauterine use
Kyleena 19.5 mg intrauterine delivery system	Bayer Limited	PA1410/081/001	Intrauterine delivery system	- G02BA - G02BA03	- Levonorgestrel, micronized	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intrauterine use
Kymriah	Novartis Europharm Limited	EU/1/18/1297/001	Dispersion for infusion	- L01	- AUTOGLAS T CELLS TRANSDUCED WITH LENTIVIRAL VECTOR CONTAINING A CHIMERIC ANTIGEN RECEPTOR DIRECTED AGAINST CD1	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Kyntheum (previously known Brodalumab)	LEO Pharma A/S	EU/1/16/1155/001	Solution for injection in pre-filled syringe	- L04AC - L04AC12	- Brodalumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Kyprolis	Amgen Europe B.V.	EU/1/15/1060/001	Powder for solution for injection	- L01XX - L01XX45	- Carfilzomib		- Intravenous use
Kytril 1 mg/1 ml solution for injection	Atnahs Pharma Netherlands B.V.	PA22657/003/001	Solution for injection	- A04AA - A04AA02	- Granisetron hydrochloride		- Intravenous use
Kytril 1mg film-coated tablets	Atnahs Pharma Netherlands B.V.	PA22657/003/003	Film-coated tablet	- A04AA - A04AA02	- Granisetron hydrochloride		- Oral use
Kytril 2mg film-coated tablets	Atnahs Pharma Netherlands B.V.	PA22657/003/004	Film-coated tablet	- A04AA - A04AA02	- Granisetron hydrochloride		- Oral use
Kytril 3 mg/3 ml solution for injection	Atnahs Pharma Netherlands B.V.	PA22657/003/002	Solution for injection	- A04AA - A04AA02	- Granisetron hydrochloride		- Intravenous use
Labetalol 5 mg/ml solution for injection/ infusion	S.A.L.F. S.p.A. Laboratorio Farmacologico	PA22760/001/001	Solution for injection/infusion	- C07AG01	- Labetalol hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lacosamide Accord	Accord Healthcare S.L.U.	EU/1/17/1230/001-004	Film-coated tablet	- N03AX - N03AX18	- Lacosamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lacosamide Accord	Accord Healthcare S.L.U.	EU/1/17/1230/005-008	Film-coated tablet	- N03AX - N03AX18	- Lacosamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lacosamide Accord	Accord Healthcare S.L.U.	EU/1/17/1230/009-012	Film-coated tablet	- N03AX - N03AX18	- Lacosamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lacosamide Accord	Accord Healthcare S.L.U.	EU/1/17/1230/013-016	Film-coated tablet	- N03AX - N03AX18	- Lacosamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lacosamide Accord	Accord Healthcare S.L.U.	EU/1/17/1230/026-027	Solution for infusion	- N03AX18	- Lacosamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Lacosamide Adroiq	Extrovis EU Kft.	EU/1/23/1732/001	Solution for infusion	- N03AX18	- Lacosamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Lacosamide Ascend 10 mg/ml syrup	Ascend GmbH	PA23429/001/001	Syrup	- N03AX18	- Lacosamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lacosamide Fresenius Kabi 10 mg/ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/078/001	Solution for infusion	- N03AX18	- Lacosamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Lacosamide Krka 100 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/099/002	Film-coated tablet	- N03AX18	- Lacosamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lacosamide Krka 150 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/099/003	Film-coated tablet	- N03AX18	- Lacosamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lacosamide Krka 200 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/099/004	Film-coated tablet	- N03AX18	- Lacosamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lacosamide Krka 50 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/099/001	Film-coated tablet	- N03AX18	- Lacosamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lacosamide UCB	UCB Pharma S.A.	EU/1/19/1383/001-002	Solution for infusion	- N03AX18	- Lacosamide	Informed consent application (Article 10c of Directive No 2001/83/EC)	
Lacosamide UCB	UCB Pharma S.A.	EU/1/19/1383/003	Syrup	- N03AX18	- Lacosamide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Lacosamide UCB	UCB Pharma S.A.	EU/1/19/1383/004-009	Film-coated tablet	- N03AX18	- Lacosamide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intravenous use - Oral use
Lacosamide UCB	UCB Pharma S.A.	EU/1/19/1383/010-015	Film-coated tablet	- N03AX18	- Lacosamide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intravenous use - Oral use
Lacosamide UCB	UCB Pharma S.A.	EU/1/19/1383/016-021	Film-coated tablet	- N03AX18	- Lacosamide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intravenous use - Oral use
Lacosamide UCB	UCB Pharma S.A.	EU/1/19/1383/022-027	Film-coated tablet	- N03AX18	- Lacosamide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intravenous use - Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lactecon 3.335g/5ml oral solution	Mylan IRE Healthcare Limited	PA2010/014/001	Oral solution	- A06AD - A06AD11	- Lactulose	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Lactulose 10 g/15 ml Oral Solution Sachet	Fresenius Kabi Austria GmbH	PA0773/004/001	Oral solution	- A06AD - A06AD11	- Lactulose	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lactulose Fresenius 670mg/ml oral solution	Fresenius Kabi Austria GmbH	PA0773/003/001 Interchangeable List Code: IC0099-151-019	Oral solution		- Lactulose	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Laevolac Plum 10 g/15 ml oral solution	Fresenius Kabi Austria GmbH	PA0773/005/001	Oral solution	- A06AD - A06AD11	- Lactulose	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lamictal 100 mg chewable/dispersible tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/009	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lamictal 100 mg chewable/dispersible tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/003/005	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 100 mg chewable/dispersible tablets	PCO Manufacturing Ltd.	PPA0465/443/003	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine	ZZZ PPA	- Oral use
Lamictal 100 mg chewable/dispersible tablets.	IMED Healthcare Ltd.	PPA1463/066/002	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 100 mg tablets	IMED Healthcare Ltd.	PPA1463/066/005	Tablet	- N03AX09	- Lamotrigine		- Oral use
Lamictal 100 mg tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/003/003	Tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 100 mg Tablets	Merit Pharmaceuticals Limited	PPA23080/014/002	Tablet	- N03AX09	- Lamotrigine		- Oral use
Lamictal 100 mg tablets	Originalis B.V.	PPA2306/024/001	Tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 100 mg Tablets	PCO Manufacturing Ltd.	PPA0465/092/010	Tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 100 mg tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/003	Tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 2 mg chewable/dispersible tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/005	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lamictal 200 mg chewable/dispersible tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/010	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lamictal 200 mg chewable/dispersible tablets	PCO Manufacturing Ltd.	PPA0465/092/009	Chewable/dispersible tablet	- N03AX09	- Lamotrigine		- Oral use
Lamictal 200 mg chewable/dispersible tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/003/006	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 200 mg chewable/dispersible tablets.	IMED Healthcare Ltd.	PPA1463/066/003	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 200 mg tablets	IMED Healthcare Ltd.	PPA1463/066/009	Tablet	- N03AX09	- Lamotrigine		- Oral use
Lamictal 200 mg Tablets	PCO Manufacturing Ltd.	PPA0465/092/013	Tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 200 mg tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/004	Tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 25 mg chewable/dispersible tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/007	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 25 mg chewable/dispersible tablets	PCO Manufacturing Ltd.	PPA0465/443/001	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine	ZZZ PPA	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lamictal 25 mg chewable/dispersible tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/003/001	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 25 mg chewable/dispersible tablets.	IMED Healthcare Ltd.	PPA1463/066/006	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 25 mg tablets	IMED Healthcare Ltd.	PPA1463/066/004	Tablet	- N03AX09	- Lamotrigine		- Oral use
Lamictal 25 mg tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/003/007	Tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 25 mg tablets	Merit Pharmaceuticals Limited	PPA23080/014/001	Tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 25 mg Tablets	PCO Manufacturing Ltd.	PPA0465/092/011	Tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 25 mg tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/001	Tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 5 mg chewable/dispersible tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/006	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lamictal 5 mg chewable/dispersible tablets	PCO Manufacturing Ltd.	PPA0465/092/005	Chewable/dispersible tablet	- N03AX09	- Lamotrigine		- Oral use
Lamictal 50 mg chewable/dispersible tablets	PCO Manufacturing Ltd.	PPA0465/443/002	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine	ZZZ PPA	- Oral use
Lamictal 50 mg chewable/dispersible tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/003/004	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 50 mg chewable/dispersible tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/008	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lamictal 50 mg chewable/dispersible tablets.	IMED Healthcare Ltd.	PPA1463/066/001	Chewable/dispersible tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 50 mg tablets	IMED Healthcare Ltd.	PPA1463/066/008	Tablet	- N03AX09	- Lamotrigine		- Oral use
Lamictal 50 mg tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/003/002	Tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 50 mg Tablets	PCO Manufacturing Ltd.	PPA0465/092/012	Tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamictal 50 mg tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/002	Tablet	- N03AX - N03AX09	- Lamotrigine		- Oral use
Lamisil 1% w/w Cream	PCO Manufacturing Ltd.	PPA0465/151/001	Cream	- D01AE - D01AE15	- Terbinafine hydrochloride	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Cutaneous use
Lamisil 1% w/w Cream	IMED Healthcare Ltd.	PPA1463/192/001	Cream	- D01A - D01AE15	- Terbinafine hydrochloride	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Cutaneous use
Lamisil 1% w/w Cream	Karo Pharma AB	PA22650/009/001	Cream	- D01AE - D01AE15	- Terbinafine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Lamisil 250 mg Tablets	IMED Healthcare Ltd.	PPA1463/157/001	Tablet	- D01BA - D01BA02	- Terbinafine		- Oral use
Lamisil 250 mg Tablets	PCO Manufacturing Ltd.	PPA0465/096/001	Tablet	- D01BA02	- Terbinafine	ZZZ PPA	- Oral use
Lamisil 250 mg Tablets	Novartis Ireland Limited	PA0896/015/001	Tablet	- D01BA - D01BA02	- Terbinafine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lamisil AT Cream	Karo Pharma AB	PA22650/009/002	Cream	- D01AE - D01AE15	- Terbinafine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lamisil Once 1% cutaneous solution	Karo Pharma AB	PA22650/009/003	Cutaneous solution	- D01AE - D01AE15	- Terbinafine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
LAMIVUDINE TEVA	Teva B.V.	EU/1/09/566/1-5	Film-coated tablet	- J05AF05	- LAMIVUDINE	Article 10(1) - Generic Application	- Oral use
LAMIVUDINE TEVA PHARMA B.V.	Teva B.V.	EU/1/09/596/1-7	Film-coated tablet	- J05AF05	- LAMIVUDINE	Article 10(1) - Generic Application	- Oral use
LAMIVUDINE TEVA PHARMA B.V.	Teva B.V.	EU/1/09/596/8-14	Film-coated tablet	- J05AF05	- LAMIVUDINE	Article 10(1) - Generic Application	- Oral use
Lamotrigine SyriMed 5mg/ml Oral Suspension	Syri Pharma Limited t/a Thame Laboratories	PA22697/018/001	Oral suspension	- N03AX09	- Lamotrigine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
LAMZEDE	Chiesi Farmaceutici S.p.A.	EU/1/17/1258/001-003	Powder for solution for infusion	- A16AB - A16AB15	- Velmanase alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Lanoxin 250 microgram Tablets	Aspen Pharma Trading Limited	PA1691/001/004	Tablet	- C01AA - C01AA05	- Digoxin		- Oral use
Lanoxin 500 micrograms/2ml Solution for Injection	Aspen Pharma Trading Limited	PA1691/001/001	Solution for injection	- C01AA - C01AA05	- Digoxin		- Intramuscular use
Lanoxin PG 50 micrograms/ml Elixir	Aspen Pharma Trading Limited	PA1691/001/002	Oral solution	- C01AA - C01AA05	- Digoxin		- Oral use
Lanoxin PG 62.5 microgram Tablets	Aspen Pharma Trading Limited	PA1691/001/003	Tablet	- C01AA - C01AA05	- Digoxin		- Oral use
Lansoprazole 15 mg gastro-resistant capsules, hard	Accord Healthcare Ireland Ltd.	PA2315/128/001 Interchangeable List Code: IC0008-032-033	Gastro-resistant capsule, hard		- Lansoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lansoprazole 30 mg gastro-resistant capsules, hard	Accord Healthcare Ireland Ltd.	PA2315/128/002 Interchangeable List Code: IC0008-033-033	Gastro-resistant capsule, hard		- Lansoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lansoprazole Krka 15 mg Gastro-resistant Capsules, hard	KRKA, d.d., Novo mesto	PA1347/062/001 Interchangeable List Code: IC0008-032-033	Gastro-resistant capsule, hard		- Lansoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lansoprazole Krka 30 mg Gastro-resistant Capsules, hard	KRKA, d.d., Novo mesto	PA1347/062/002 Interchangeable List Code: IC0008-033-033	Gastro-resistant capsule, hard		- Lansoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lansoprazole Pinewood 15mg Gastro-resistant Capsules, Hard	Pinewood Laboratories Ltd	PA0281/151/001 Interchangeable List Code: IC0008-032-033	Gastro-resistant capsule, hard		- Lansoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lansoprazole Pinewood 30mg Gastro-resistant Capsules, Hard	Pinewood Laboratories Ltd	PA0281/151/002 Interchangeable List Code: IC0008-033-033	Gastro-resistant capsule, hard		- Lansoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lansoprazole Teva Pharma 15 mg gastro-resistant capsules, hard	Teva B.V.	PA1986/008/001 Interchangeable List Code: IC0008-032-033	Gastro-resistant capsule, hard		- Lansoprazole	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Lansoprazole Teva Pharma 30 mg gastro-resistant capsules, hard	Teva B.V.	PA1986/008/002 Interchangeable List Code: IC0008-033-033	Gastro-resistant capsule, hard		- Lansoprazole	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
LANTUS	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/001	Solution for injection	- A10AE - A10AE04	- Insulin glargine		- Subcutaneous use
Lantus	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/002	Solution for injection	- A10AE - A10AE04	- Insulin glargine		- Subcutaneous use
Lantus	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/003	Solution for injection	- A10AE - A10AE04	- Insulin glargine		- Subcutaneous use
Lantus	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/004	Solution for injection	- A10AE - A10AE04	- Insulin glargine		- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lantus	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/005	Solution for injection in cartridge	- A10AE - A10AE04	- Insulin glargine		- Subcutaneous use
Lantus	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/006	Solution for injection in cartridge	- A10AE - A10AE04	- Insulin glargine		- Subcutaneous use
Lantus	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/007	Solution for injection in cartridge	- A10AE - A10AE04	- Insulin glargine		- Subcutaneous use
Lantus	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/8-37	Solution for injection	- A10AE - A10AE04	- Insulin glargine		- Subcutaneous use
Lanvis 40mg Tablets	Aspen Pharma Trading Limited	PA1691/006/001	Tablet	- L01BB - L01BB03	- Tioguanine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Lanzol 15 mg hard gastro-resistant capsules	Rowex Ltd	PA0711/067/001 Interchangeable List Code: IC0008-032-033	Gastro-resistant capsule, hard		- Lansoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lanzol 30 mg hard gastro-resistant capsules	Rowex Ltd	PA0711/067/002 Interchangeable List Code: IC0008-033-033	Gastro-resistant capsule, hard		- Lansoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Larig 100 mg Dispersible Tablets	Rowex Ltd	PA0711/085/004	Dispersible tablet	- N03AX - N03AX09	- Lamotrigine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Larig 200 mg Dispersible Tablets	Rowex Ltd	PA0711/085/005	Dispersible tablet	- N03AX - N03AX09	- Lamotrigine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Larig 25 mg Dispersible Tablets	Rowex Ltd	PA0711/085/002	Dispersible tablet	- N03AX - N03AX09	- Lamotrigine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Larig 50 mg Dispersible Tablets	Rowex Ltd	PA0711/085/003	Dispersible tablet	- N03AX - N03AX09	- Lamotrigine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lartruvo	Eli Lilly Nederland B.V.	EU/1/16/1143/001	Concentrate for solution for infusion	- L01XC - L01XC27	- Olaratumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Lasix 20mg/2ml Solution for Injection or Infusion	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/052/002	Solution for injection/infusion	- C03CA - C03CA01	- Frusemide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Lassar's Cream.Zinc Oxide 23% w/w & Salicylic Acid 2% w/w	Ovelle Limited	PA0206/014/002	Cream	- D02AF	- Zinc oxide - Salicylic acid		- Topical use
Lassar's PasteZinc Oxide 24% w/w & Salicylic Acid 2% w/w	Ovelle Limited	PA0206/014/001	Cutaneous paste	- D02AF	- Zinc oxide - Salicylic acid		- Topical use
Lataneau Plus 50 microgram/ml + 5 mg/ml Eye Drops, Solution	Alapis S.A.	PA1608/001/001 Interchangeable List Code: IC0100-153-045	Eye drops, solution		- Timolol - Latanoprost	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Latanoprost/Timolol Zentiva 50 microgram/ml + 5 mg/ml eye drops solution	Zentiva k.s.	PA1701/002/001 Interchangeable List Code: IC0100-153-045	Eye drops, solution		- Latanoprost - Timolol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Latuda	Aziende Chimiche Riunite Angelini Francesco	EU/1/14/913/001-007	Film-coated tablet	- N05AE - N05AE05	- Lurasidone hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Latuda	Aziende Chimiche Riunite Angelini Francesco	EU/1/14/913/008-014	Film-coated tablet	- N05AE - N05AE05	- Lurasidone hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Latuda	Aziende Chimiche Riunite Angelini Francesco	EU/1/14/913/015-021	Film-coated tablet	- N05AE - N05AE05	- Lurasidone hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Laventair Ellipta	GlaxoSmithKline (Ireland) Limited	EU/1/14/899/001-003	Inhalation powder, pre-dispensed	- R03AL03	- Umeclidinium bromide - Vilanterol trifenatate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Laxido Orange, powder for oral solution	Galen Pharma Ireland Limited	PA22680/001/001	Powder for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium chloride - Sodium hydrogen carbonate - Potassium chloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Laxido Paediatric Plain, 6.9 g sachet, powder for oral solution	Galen Pharma Ireland Limited	PA22680/001/003	Powder for oral solution in sachet	- A06AD - A06AD65	- Macrogol 3350 - Sodium chloride - Sodium hydrogen carbonate - Potassium chloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Laxido, powder for oral solution	Galen Pharma Ireland Limited	PA22680/001/002	Powder for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium chloride - Sodium hydrogen carbonate - Potassium chloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Laxose (Lactulose Solution BP) 3.35g/5ml Oral Solution	Pinewood Laboratories Ltd	PA0281/079/001 Interchangeable List Code: IC0099-151-019	Oral solution		- Lactulose	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Lecalpin 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/186/001 Interchangeable List Code: IC0020-002-003	Film-coated tablet		- Lercanidipine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lecalpin 20 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/186/002 Interchangeable List Code: IC0020-003-003	Film-coated tablet		- Lercanidipine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lecigon 20 mg/ml + 5 mg/ml + 20 mg/ml intestinal gel	Lobsor Pharmaceuticals AB	PA23144/001/001	Intestinal gel	- N04BA03	- Levodopa - Carbidopa monohydrate - Entacapone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intestinal use
Ledaga	Helsinn Birex Pharmaceuticals Limited	EU/1/16/1171/001	Gel	- L01AA - L01AA05	- CHLORMETHINE HYDROCHLORIDE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Leflunomide 10 mg film-coated tablets	Morningside Healthcare (Malta) Limited	PA23142/009/001	Film-coated tablet	- L04AA - L04AA13	- Leflunomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Leflunomide 20mg film-coated tablets	Morningside Healthcare (Malta) Limited	PA23142/009/002	Film-coated tablet	- L04AA - L04AA13	- Leflunomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Leflunomide medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/10/637/001-004	Film-coated tablet	- L04AA - L04AA13	- Leflunomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Leflunomide medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/10/637/005-009	Film-coated tablet	- L04AA - L04AA13	- Leflunomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Leflunomide medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/10/637/010-012	Film-coated tablet	- L04AA - L04AA13	- Leflunomide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
LEFLUNOMIDE RATIOPHARM	Ratiopharm GmbH	EU/1/10/654/003-004	Film-coated tablet	- L04AA13			- Oral use
Leflunomide Winthrop	Zentiva k.s.	EU/1/09/604/10	Film-coated tablet	- L04AA - L04AA13	- Leflunomide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Leflunomide Winthrop	Zentiva k.s.	EU/1/09/604/1-4	Film-coated tablet	- L04AA - L04AA13	- Leflunomide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Leflunomide Winthrop	Zentiva k.s.	EU/1/09/604/5-9	Film-coated tablet	- L04AA - L04AA13	- Leflunomide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Lemsip Chesty Cough 50mg/5ml Oral Solution	Reckitt Benckiser Ireland Ltd	PA0979/026/001	Oral solution	- R05CA - R05CA03	- Guaifenesin		- Oral use
Lemsip Cold & Flu Headcold 500 mg Powder for Oral Solution	Reckitt Benckiser Ireland Ltd	PA0979/014/001	Powder for oral solution	- N02BE - N02BE01	- Paracetamol		- Oral use
Lemsip Cold & Flu Hot Lemon 500 mg Powder for Oral Solution	Reckitt Benckiser Ireland Ltd	PA0979/013/001	Powder for oral solution	- N02BE - N02BE01	- Paracetamol		- Oral use
Lemsip Cough and Cold Capsules with CaffeineParacetamol 500mgGuaifenesin 100mgCaffeine 25mg	Reckitt Benckiser Ireland Ltd	PA0979/029/001	Capsule, hard	- N02BE - N02BE51	- Paracetamol - Guaifenesin - Caffeine anhydrous	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Lemsip Decongestant & Flu Capsules with CaffeineParacetamol 500mgPhenylephine Hydrochloride 6.1mgCaffeine 25mg	Reckitt Benckiser Ireland Ltd	PA0979/027/001	Capsule, hard	- N02BE - N02BE51	- Paracetamol - Phenylephrine hydrochloride - Caffeine anhydrous	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Lemsip Dry Cough 0.25ml/5ml Oral Solution	Reckitt Benckiser Ireland Ltd	PA0979/025/001	Oral solution	- R05X	- Glycerol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Lemsip Max Cold and Flu Blackcurrant 1000 mg Powder for Oral Solution	Reckitt Benckiser Ireland Ltd	PA0979/021/003	Powder for oral solution	- N02BE - N02BE01	- Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Lemsip Max Cold and Flu Hot Lemon 1000mg Powder for Oral Solution	Reckitt Benckiser Ireland Ltd	PA0979/021/001	Powder for oral solution	- N02BE - N02BE01	- Paracetamol		- Oral use
Lemsip Max Cough & Cold Powder for Oral Solution Paracetamol 1000 mg Guaifenesin 200 mg	Reckitt Benckiser Ireland Ltd	PA0979/028/001	Powder for oral solution	- N02BE - N02BE51	- Paracetamol - Guaifenesin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Lemsip Max Sinus & Flu Hot Lemon Powder for Oral Solution	Reckitt Benckiser Ireland Ltd	PA0979/020/001	Powder for oral solution	- N02BE - N02BE51	- Paracetamol - PSEUDOEPHEDRINE HYDROCHLORIDE	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Lemsip Multirelief capsules Paracetamol 500mg Phenylephrine hydrochloride 6.1mg Guaifenesin 100mg	Reckitt Benckiser Ireland Ltd	PA0979/053/001	Capsule, hard	- N02BE - N02BE51	- Paracetamol - Phenylephrine hydrochloride - Guaifenesin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Lemtrada	Sanofi Belgium	EU/1/13/869/001	Concentrate for solution for infusion	- L04AA - L04AA34	- Alemtuzumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Lenalidomide Accord 10 mg hard capsules	Accord Healthcare S.L.U.	EU/1/18/1316/006-007 Interchangeable List Code: IC0125-002-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lenalidomide Accord 15 mg hard capsules	Accord Healthcare S.L.U.	EU/1/18/1316/008-009 Interchangeable List Code: IC0125-032-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Accord 2.5 mg hard capsules	Accord Healthcare S.L.U.	EU/1/18/1316/001-002 Interchangeable List Code: IC0125-018-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Accord 20 mg hard capsules	Accord Healthcare S.L.U.	EU/1/18/1316/010 Interchangeable List Code: IC0125-003-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Accord 25 mg hard capsules	Accord Healthcare S.L.U.	EU/1/18/1316/011 Interchangeable List Code: IC0125-022-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Accord 5 mg hard capsules	Accord Healthcare S.L.U.	EU/1/18/1316/003-004 Interchangeable List Code: IC0125-001-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Accord 7.5 mg hard capsules	Accord Healthcare S.L.U.	EU/1/18/1316/005 Interchangeable List Code: IC0125-041-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Clonmel 10 mg hard capsules	Clonmel Healthcare Ltd	PA0126/320/004 Interchangeable List Code: IC0125-002-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Clonmel 15 mg hard capsules	Clonmel Healthcare Ltd	PA0126/320/005 Interchangeable List Code: IC0125-032-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Clonmel 2.5 mg hard capsules	Clonmel Healthcare Ltd	PA0126/320/001 Interchangeable List Code: IC0125-018-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Clonmel 20 mg hard capsules	Clonmel Healthcare Ltd	PA0126/320/006 Interchangeable List Code: IC0125-003-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Clonmel 25 mg hard capsules	Clonmel Healthcare Ltd	PA0126/320/007 Interchangeable List Code: IC0125-022-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Clonmel 5 mg hard capsules	Clonmel Healthcare Ltd	PA0126/320/002 Interchangeable List Code: IC0125-001-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Clonmel 7.5 mg hard capsules	Clonmel Healthcare Ltd	PA0126/320/003 Interchangeable List Code: IC0125-041-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Grindeks 10 mg hard capsules	AS Grindeks	PA22992/004/004 Interchangeable List Code: IC0125-002-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lenalidomide Grindeks 15 mg hard capsules	AS Grindeks	PA22992/004/005 Interchangeable List Code: IC0125-032-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Grindeks 2.5 mg hard capsules	AS Grindeks	PA22992/004/001 Interchangeable List Code: IC0125-018-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Grindeks 20 mg hard capsules	AS Grindeks	PA22992/004/006 Interchangeable List Code: IC0125-003-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Grindeks 25 mg hard capsules	AS Grindeks	PA22992/004/007 Interchangeable List Code: IC0125-022-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Grindeks 5 mg hard capsules	AS Grindeks	PA22992/004/002 Interchangeable List Code: IC0125-001-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Grindeks 7.5 mg hard capsules	AS Grindeks	PA22992/004/003 Interchangeable List Code: IC0125-041-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Krka 10 mg hard capsules	KRKA, d.d., Novo mesto	EU/1/20/1519/007-008 Interchangeable List Code: IC0125-002-001	Capsule, hard		- Lenalidomide hydrochloride hydrate - Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Krka 15 mg hard capsules	KRKA, d.d., Novo mesto	EU/1/20/1519/009-010 Interchangeable List Code: IC0125-032-001	Capsule, hard		- Lenalidomide hydrochloride hydrate - Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Krka 2.5 mg hard capsules	KRKA, d.d., Novo mesto	EU/1/20/1519/001-002 Interchangeable List Code: IC0125-018-001	Capsule, hard		- Lenalidomide hydrochloride hydrate - Lenalidomide	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Krka 20 mg hard capsules	KRKA, d.d., Novo mesto	EU/1/20/1519/011-012 Interchangeable List Code: IC0125-003-001	Capsule, hard		- Lenalidomide hydrochloride hydrate - Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Krka 25 mg hard capsules	KRKA, d.d., Novo mesto	EU/1/20/1519/013-014 Interchangeable List Code: IC0125-022-001	Capsule, hard		- Lenalidomide hydrochloride hydrate - Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Krka 5 mg hard capsules	KRKA, d.d., Novo mesto	EU/1/20/1519/003-004 Interchangeable List Code: IC0125-001-001	Capsule, hard		- Lenalidomide hydrochloride hydrate - Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Krka 7.5 mg hard capsules	KRKA, d.d., Novo mesto	EU/1/20/1519/005-006 Interchangeable List Code: IC0125-041-001	Capsule, hard		- Lenalidomide hydrochloride hydrate - Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lenalidomide Mylan 10 mg hard capsules	Mylan IRE Healthcare Limited	EU/1/20/1490/009-010 Interchangeable List Code: IC0125-002-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Mylan 15 mg hard capsules	Mylan IRE Healthcare Limited	EU/1/20/1490/011-012 Interchangeable List Code: IC0125-032-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Mylan 2.5 mg hard capsules	Mylan IRE Healthcare Limited	EU/1/20/1490/001-003 Interchangeable List Code: IC0125-018-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Mylan 20 mg hard capsules	Mylan IRE Healthcare Limited	EU/120/1490/013-015 Interchangeable List Code: IC0125-003-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Mylan 25 mg hard capsules	Mylan IRE Healthcare Limited	EU/1/20/1490/016-018 Interchangeable List Code: IC0125-022-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Mylan 5 mg hard capsules	Mylan IRE Healthcare Limited	EU/1/20/1490/004-005 Interchangeable List Code: IC0125-001-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Mylan 7.5 mg hard capsules	Mylan IRE Healthcare Limited	EU/1/20/1490/006-008 Interchangeable List Code: IC0125-041-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Rowex 10 mg hard capsules	Rowex Ltd	PA0711/302/004 Interchangeable List Code: IC0125-002-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Rowex 15 mg hard capsules	Rowex Ltd	PA0711/302/005 Interchangeable List Code: IC0125-032-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Rowex 2.5 mg hard capsules	Rowex Ltd	PA0711/302/001 Interchangeable List Code: IC0125-018-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Rowex 20 mg hard capsules	Rowex Ltd	PA0711/302/006 Interchangeable List Code: IC0125-003-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Rowex 25 mg hard capsules	Rowex Ltd	PA0711/302/007 Interchangeable List Code: IC0125-022-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Rowex 5 mg hard capsules	Rowex Ltd	PA0711/302/002 Interchangeable List Code: IC0125-001-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lenalidomide Rowex 7.5 mg hard capsules	Rowex Ltd	PA0711/302/003 Interchangeable List Code: IC0125-041-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Teva 10 mg hard capsules	Teva B.V.	PA1986/051/004 Interchangeable List Code: IC0125-002-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Teva 15 mg hard capsules	Teva B.V.	PA1986/051/005 Interchangeable List Code: IC0125-032-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Teva 2.5 mg hard capsules	Teva B.V.	PA1986/051/001 Interchangeable List Code: IC0125-018-001	Capsule, hard		- Lenalidomide hydrochloride hydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Teva 20 mg hard capsules	Teva B.V.	PA1986/051/006 Interchangeable List Code: IC0125-003-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Teva 25 mg hard capsules	Teva B.V.	PA1986/051/007 Interchangeable List Code: IC0125-022-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Teva 5 mg hard capsules	Teva B.V.	PA1986/051/002 Interchangeable List Code: IC0125-001-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenalidomide Teva 7.5 mg hard capsules	Teva B.V.	PA1986/051/003 Interchangeable List Code: IC0125-041-001	Capsule, hard		- Lenalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lenvima	Eisai GmbH	EU/1/15/1002/001	Capsule, hard	- L01X	- Lenvatinib mesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lenvima	Eisai GmbH	EU/1/15/1002/002	Capsule, hard	- L01X	- Lenvatinib mesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lenzetto 1.53 mg/spray, Transdermal Spray, Solution	Gedeon Richter Plc	PA1330/017/001	Transdermal spray, solution	- G03CA - G03CA03	- Estradiol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Leonore 100 micrograms/20 micrograms coated tablets	Rowex Ltd	PA0711/127/001	Coated tablet	- G03AA - G03AA07	- Levonorgestrel - Ethinylestradiol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Leqvio	Novartis Europharm Limited	EU/1/20/1494/001	Solution for injection in pre-filled syringe	- C10AX - C10AX16	- Inclisiran	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Lercanidipine Clonmel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/187/001 Interchangeable List Code: IC0020-002-003	Film-coated tablet		- Lercanidipine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lercanidipine Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/187/002 Interchangeable List Code: IC0020-003-003	Film-coated tablet		- Lercanidipine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lercanidipine Mylan 10 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/155/001 Interchangeable List Code: IC0020-002-003	Film-coated tablet		- Lercanidipine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lercanidipine Mylan 20mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/155/002 Interchangeable List Code: IC0020-003-003	Film-coated tablet		- Lercanidipine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lercaril 10 mg/10 mg film-coated tablets	Recordati Ireland Limited	PA1404/002/001	Film-coated tablet	- C09BB - C09BB02	- Lercanidipine hydrochloride - Enalapril maleate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Lercaril 10 mg/10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/472/001	Film-coated tablet	- C09BB - C09BB02	- Enalapril maleate - Lercanidipine hydrochloride		- Oral use
Lercaril 10 mg/10 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/198/001	Film-coated tablet	- C09BB - C09BB02	- Lercanidipine hydrochloride - Enalapril maleate		- Oral use
Lercaril 20 mg/10 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/198/002	Film-coated tablet	- C09BB - C09BB02	- Lercanidipine hydrochloride - Enalapril maleate		- Oral use
Lercaril 20 mg/10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/472/002	Film-coated tablet	- C09BB - C09BB02	- Enalapril maleate - Lercanidipine hydrochloride	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Lercaril 20 mg/10 mg film-coated tablets	Recordati Ireland Limited	PA1404/002/002	Film-coated tablet	- C09BB - C09BB02	- Enalapril maleate - Lercanidipine hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Lercaril 20 mg/20 mg Film-coated Tablets	Recordati Ireland Limited	PA1404/002/003	Film-coated tablet	- C09BB - C09BB02	- Enalapril maleate - Lercanidipine hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Lercaril 20 mg/20 mg Film-coated Tablets	PCO Manufacturing Ltd.	PPA0465/472/003	Film-coated tablet	- C09BB - C09BB02	- Enalapril maleate - Lercanidipine hydrochloride	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Lescol XL 80 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/404/001	Prolonged-release tablet	- C10AA04	- Fluvastatin	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Lescol XL 80 mg Prolonged-release tablets	Ethyx Pharmaceuticals	PA23517/001/001	Prolonged-release tablet	- C10AA - C10AA04	- Fluvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lescol XL 80 mg Prolonged-release tablets	IMED Healthcare Ltd.	PPA1463/101/001	Prolonged-release tablet	- C10AA04	- Fluvastatin		- Oral use
Lestace 10 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/008/003	Tablet	- C09AA - C09AA03	- Lisinopril Dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lestace 20 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/008/004	Tablet	- C09AA - C09AA03	- Lisinopril Dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lestace 5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/008/002	Tablet	- C09AA - C09AA03	- Lisinopril Dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Letrozole 2.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/109/001 Interchangeable List Code: IC0117-018-003	Film-coated tablet		- Letrozole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Letrozole 2.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/198/001 Interchangeable List Code: IC0117-018-003	Film-coated tablet		- Letrozole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Letrozole Bluefish 2.5 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/013/001 Interchangeable List Code: IC0117-018-003	Film-coated tablet		- Letrozole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Letrozole Mylan 2.5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/116/001 Interchangeable List Code: IC0117-018-003	Film-coated tablet		- Letrozole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Letrozole Synthon 2.5 mg film-coated tablets	Synthon BV	PA0840/009/001 Interchangeable List Code: IC0117-018-003	Film-coated tablet		- Letrozole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Letrozole Teva 2.5 mg film-coated tablets	Teva Pharma B.V.	PA0749/085/001 Interchangeable List Code: IC0117-018-003	Film-coated tablet		- Letrozole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Letybo	Croma-Pharma GmbH	PA0846/001/001	Powder for solution for injection	- M03AX01	- Clostridium Botulinum Neurotoxin Type A (900 KD)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Letzo 2.5 mg film-coated tablets	Rowex Ltd	PA0711/190/001 Interchangeable List Code: IC0117-018-003	Film-coated tablet		- Letrozole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Leucovorin-Teva 10mg/ml Concentrate for Solution for Infusion	Teva Pharma B.V.	PA0749/001/001	Concentrate for solution for infusion	- V03AF - V03AF03	- Folinic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Leukeran 2 mg film-coated tablets	Aspen Pharma Trading Limited	PA1691/007/001	Film-coated tablet	- L01AA - L01AA02	- Chlorambucil		- Oral use
Leuprex 3, 5mg Implant	Rowex Ltd	PA0711/188/001	Implant	- L02AE - L02AE02	- Leuprorelin acetate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Levemir	Novo Nordisk A/S	EU/1/04/278/010-011	Solution for injection in pre-filled pen	- A10AE - A10AE05	- Insulin determir		- Subcutaneous use
LEVEMIR (INSULIN DETEMIR)	Novo Nordisk A/S	EU/1/04/278/1-9	Solution for injection	- A10AE - A10AE05	- Insulin detemir		
Levetiracetam 100 mg / mL Concentrate for solution for infusion	Noridem Enterprises Limited	PA1122/026/001	Concentrate for solution for infusion	- N03AX14	- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Levetiracetam 100 mg/ml concentrate for solution for infusion	Esteve Pharmaceuticals GmbH	PA22709/002/001	Concentrate for solution for infusion	- N03AX14	- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Levetiracetam Accor	Accord Healthcare S.L.U.	EU/1/11/712/001-007	Film-coated tablet	- N03AX - N03AX14	- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levetiracetam Accor	Accord Healthcare S.L.U.	EU/1/11/712/008-013	Film-coated tablet	- N03AX - N03AX14	- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levetiracetam Accor	Accord Healthcare S.L.U.	EU/1/11/712/015-021	Film-coated tablet	- N03AX - N03AX14	- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levetiracetam Accor	Accord Healthcare S.L.U.	EU/1/11/712/022-028	Film-coated tablet	- N03AX - N03AX14	- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
LEVETIRACETAM ACTAVIS	Actavis Group PTC ehf	EU/1/11/713/001-010	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
LEVETIRACETAM ACTAVIS	Actavis Group PTC ehf	EU/1/11/713/011-020	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Article 10(1) - Generic Application	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
LEVETIRACETAM ACTAVIS	Actavis Group PTC ehf	EU/1/11/713/021-030	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Article 10(1) - Generic Application	- Oral use
LEVETIRACETAM ACTAVIS	Actavis Group PTC ehf	EU/1/11/713/031-040	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Article 10(1) - Generic Application	- Oral use
Levetiracetam Actavis Group 100 mg/ml oral solution	Actavis Group hf	EU/1/11/738/001-003 Interchangeable List Code: IC0119-171-019	Oral solution		- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levetiracetam Bluefish 1000 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/020/003	Film-coated tablet	- N03AX - N03AX14	- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levetiracetam Bluefish 250 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/020/001	Film-coated tablet	- N03AX - N03AX14	- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levetiracetam Bluefish 500 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/020/002	Film-coated tablet	- N03AX - N03AX14	- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levetiracetam Brillpharma 100 mg/ml oral solution	Brillpharma (Ireland) Limited	PA22749/019/001 Interchangeable List Code: IC0119-171-019	Oral solution		- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levetiracetam Clonmel 100 mg/ml oral solution	Clonmel Healthcare Ltd	PA0126/368/001 Interchangeable List Code: IC0119-171-019	Oral solution		- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levetiracetam Clonmel 1000 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/326/003	Film-coated tablet	- N03AX14	- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levetiracetam Clonmel 250 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/326/001	Film-coated tablet	- N03AX14	- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levetiracetam Clonmel 500 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/326/002	Film-coated tablet	- N03AX14	- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levetiracetam Hospira	Pfizer Europe MA EEIG	EU/1/13/889/001-002	Concentrate for solution for infusion	- N03AX - N03AX14	- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
LEVETIRACETAM RATIOPHARM	Ratiopharm GmbH	EU/1/11/702/004-009	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Article 10(1) - Generic Application	- Oral use
LEVETIRACETAM RATIOPHARM	Ratiopharm GmbH	EU/1/11/702/010-017	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Article 10(1) - Generic Application	- Oral use
LEVETIRACETAM RATIOPHARM	Ratiopharm GmbH	EU/1/11/702/018-024	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Article 10(1) - Generic Application	- Oral use
LEVETIRACETAM RATIOPHARM	Ratiopharm GmbH	EU/1/11/702/025-031	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Article 10(1) - Generic Application	- Oral use
Levetiracetam ratiopharm 100 mg/ml oral solution	Ratiopharm GmbH	EU/1/11/702/001-003 Interchangeable List Code: IC0119-171-019	Oral solution		- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
LEVETIRACETAM SUN	Sun Phamaceutical Industries Europe B.V.	EU/1/11/741/001	Concentrate for solution for infusion	- N03AX14	- LEVETIRACETAM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intra-venous
LEVETIRACETAM TEVA	Teva B.V.	EU/1/11/701/001-004	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Article 10(1) - Generic Application	- Oral use
LEVETIRACETAM TEVA	Teva B.V.	EU/1/11/701/008-014	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Article 10(1) - Generic Application	- Oral use
LEVETIRACETAM TEVA	Teva Pharma B.V.	EU/1/11/701/015-021	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
LEVETIRACETAM TEVA	Teva B.V.	EU/1/11/701/022-028	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Article 10(1) - Generic Application	- Oral use
Levetiracetam Thame 100 mg/ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/012/001 Interchangeable List Code: IC0119-171-019	Oral solution		- Levetiracetam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levitra	Bayer Schering Pharma AG	EU/1/03/248/013-15	Orodispersible tablet	- G04BE - G04BE09	- Vardenafil hydrochloride trihydrate		- Oral use
LEVITRA	Bayer AG	EU/1/03/248/1-12	Film-coated tablet	- G04BE - G04BE09	- Vardenafil (as hydrochloride trihydrate)		- Oral use
Levobupivacaine 0.625 mg/ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/009/001	Solution for infusion	- N01BB - N01BB10	- Levobupivacaine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use
Levobupivacaine 1.25 mg/mL solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/009/002	Solution for infusion	- N01BB - N01BB10	- Levobupivacaine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use
Levobupivacaine 2.5 mg/mL solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/009/003	Solution for injection/infusion	- N01BB - N01BB10	- Levobupivacaine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use - Infiltration - Intrathecal use - Perineural use
Levobupivacaine 5.0 mg/mL solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/009/004	Solution for injection/infusion	- N01BB - N01BB10	- Levobupivacaine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use - Infiltration - Intrathecal use - Perineural use
Levobupivacaine 7.5 mg/mL solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/009/005	Solution for injection/infusion	- N01BB - N01BB10	- Levobupivacaine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use - Infiltration - Intrathecal use - Perineural use
Levocetirizine dihydrochloride 5 mg Film-Coated Tablets	Brillpharma (Ireland) Limited	PA22749/003/001 Interchangeable List Code: IC0095-001-003	Film-coated tablet		- Levocetirizine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levocetirizine Glenmark 5 mg Film-coated Tablets	Glenmark Arzneimittel GmbH	PA22645/003/001 Interchangeable List Code: IC0095-001-003	Film-coated tablet		- Levocetirizine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levocetirizine Krka 5mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/043/001 Interchangeable List Code: IC0095-001-003	Film-coated tablet		- Levocetirizine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levodopa/carbidopa/ Entacapone Orion	Orion Corporation	EU/1/11/706/007-011	Film-coated tablet	- N04BA - N04BA03	- Levodopa - Carbidopa monohydrate - Entacapone	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Levodopa/carbidopa/ Entacapone Orion	Orion Corporation	EU/1/11/706/012-017	Film-coated tablet	- N04BA - N04BA03	- Levodopa - Entacapone - Carbidopa monohydrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Levodopa/carbidopa/ Entacapone Orion	Orion Corporation	EU/1/11/706/018-022	Film-coated tablet	- N04BA - N04BA03	- Levodopa - Entacapone - Carbidopa monohydrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Levodopa/carbidopa/ Entacapone Orion	Orion Corporation	EU/1/11/706/023-028	Film-coated tablet	- N04BA - N04BA03	- Levodopa - Carbidopa monohydrate - Entacapone	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Levodopa/carbidopa/ Entacapone Orion	Orion Corporation	EU/1/11/706/029-033	Film-coated tablet	- N04BA - N04BA03	- Entacapone - Levodopa - Carbidopa monohydrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Levodopa/Carbidopa /Entacapone Orion	Orion Corporation	EU/1/11/706/034-38	Film-coated tablet	- N04BA - N04BA03	- Entacapone - Carbidopa monohydrate - Levodopa	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Levodopa/Carbidopa /Entacapone Sandoz	Orion Corporation	EU/1/13/859/001-006	Film-coated tablet	- N04BA - N04BA03	- Carbidopa monohydrate - Entacapone - Levodopa	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Levodopa/Carbidopa /Entacapone Sandoz	Orion Corporation	EU/1/13/859/007-011	Film-coated tablet	- N04BA - N04BA03	- Entacapone - Carbidopa monohydrate - Levodopa	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Levodopa/Carbidopa /Entacapone Sandoz	Orion Corporation	EU/1/13/859/012-017	Film-coated tablet	- N04BA - N04BA03	- Carbidopa monohydrate - Entacapone - Levodopa	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Levodopa/Carbidopa /Entacapone Sandoz	Orion Corporation	EU/1/13/859/018-022	Film-coated tablet	- N04BA - N04BA03	- Entacapone - Carbidopa monohydrate - Levodopa	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Levodopa/Carbidopa /Entacapone Sandoz	Orion Corporation	EU/1/13/859/023-028	Film-coated tablet	- N04BA - N04BA03	- Levodopa - Carbidopa monohydrate - Entacapone	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Levodopa/Carbidopa /Entacapone Sandoz	Orion Corporation	EU/1/13/859/029-033	Film-coated tablet	- N04BA - N04BA03	- Entacapone - Carbidopa monohydrate - Levodopa	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Levodopa/Carbidopa /Entacapone Sandoz	Orion Corporation	EU/1/13/859/034-038	Film-coated tablet	- N04BA - N04BA03	- Entacapone - Carbidopa monohydrate - Levodopa	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Levofloxacin 5mg/ml solution for infusion	Noridem Enterprises Limited	PA1122/013/001	Solution for infusion	- J01MA - J01MA12	- Levofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Levofloxacin 5mg/ml solution for infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/008/001	Solution for infusion	- J01MA - J01MA12	- Levofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Levofloxacin 5mg/ml solution for infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/008/002	Solution for infusion	- J01MA - J01MA12	- Levofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Levofloxacin 5mg/ml solution for infusion, freeflex bags	Fresenius Kabi Deutschland GmbH	PA2059/010/002	Solution for infusion	- J01MA - J01MA12	- Levofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Levofloxacin 5mg/ml solution for infusion, LDPE bottles	Fresenius Kabi Deutschland GmbH	PA2059/010/001	Solution for infusion	- J01MA - J01MA12	- Levofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Levofloxacin Bluefish 250 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/019/001	Film-coated tablet	- J01MA - J01MA12	- Levofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levofloxacin Bluefish 500 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/019/002	Film-coated tablet	- J01MA - J01MA12	- Levofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levofloxacin Krka 250 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/048/001	Film-coated tablet	- J01MA - J01MA12	- Levofloxacin hemihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levofloxacin Krka 500 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/048/002	Film-coated tablet	- J01MA - J01MA12	- Levofloxacin hemihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levonorgestrel Rowex 1.5mg Tablet	Rowex Ltd	PA0711/267/001	Tablet	- G03AD - G03AD01	- Levonorgestrel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levosert 52 mg intrauterine delivery system	Gedeon Richter Plc	PA1330/022/001	Intrauterine delivery system	- G02BA - G02BA03	- Levonorgestrel	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intrauterine use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Levosert SHI 52mg Intrauterine Delivery System	Gedeon Richter Plc	PA1330/022/002	Intrauterine delivery system	- G02BA03	- Levonorgestrel	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intrauterine use
Levosimendan 2.5 mg/ml concentrate for solution for infusion	AS Kalceks	PA2165/015/001	Concentrate for solution for infusion	- C01CX08	- Levosimendan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Levothyroxine 100 micrograms per 5 ml oral solution	Amdipharm Limited	PA1142/029/004	Oral solution	- H03AA - H03AA01	- Levothyroxine sodium	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Levothyroxine 25 micrograms per 5 ml oral solution	Amdipharm Limited	PA1142/029/002	Oral solution	- H03AA01	- Levothyroxine sodium	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Levothyroxine 50 micrograms per 5 ml oral solution	Amdipharm Limited	PA1142/029/003	Oral solution	- H03AA - H03AA01	- Levothyroxine sodium	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Levothyroxine sodium Aristo 100 micrograms tablets	Aristo Pharma GmbH	PA1983/004/003	Tablet	- H03AA - H03AA01	- Levothyroxine sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levothyroxine sodium Aristo 112 microgram tablets	Aristo Pharma GmbH	PA1983/004/009	Tablet	- H03AA01	- Levothyroxine Sodium Anhydrous EP	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Levothyroxine sodium Aristo 125 micrograms tablets	Aristo Pharma GmbH	PA1983/004/006	Tablet	- H03AA01	- Levothyroxine Sodium Anhydrous EP	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Levothyroxine sodium Aristo 137 microgram tablets	Aristo Pharma GmbH	PA1983/004/010	Tablet	- H03AA01	- Levothyroxine Sodium Anhydrous EP	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Levothyroxine sodium Aristo 150 micrograms tablets	Aristo Pharma GmbH	PA1983/004/007	Tablet	- H03AA01	- Levothyroxine Sodium Anhydrous EP	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Levothyroxine sodium Aristo 175 microgram tablets	Aristo Pharma GmbH	PA1983/004/011	Tablet	- H03AA01	- Levothyroxine Sodium Anhydrous EP	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Levothyroxine sodium Aristo 200 micrograms tablets	Aristo Pharma GmbH	PA1983/004/004	Tablet	- H03AA - H03AA01	- Levothyroxine sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levothyroxine sodium Aristo 25 micrograms tablets	Aristo Pharma GmbH	PA1983/004/001	Tablet	- H03AA - H03AA01	- Levothyroxine sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levothyroxine sodium Aristo 50 micrograms tablets	Aristo Pharma GmbH	PA1983/004/002	Tablet	- H03AA - H03AA01	- Levothyroxine sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levothyroxine sodium Aristo 75 micrograms tablets	Aristo Pharma GmbH	PA1983/004/005	Tablet	- H03AA01	- Levothyroxine Sodium Anhydrous EP	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Levothyroxine sodium Aristo 88 microgram tablets	Aristo Pharma GmbH	PA1983/004/008	Tablet	- H03AA01	- Levothyroxine Sodium Anhydrous EP	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Levothyroxine Teva 100 micrograms Tablets	Teva Pharma B.V.	PA0749/143/003	Tablet	- H03AA - H03AA01	- Levothyroxine sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Levothyroxine Teva 25 micrograms Tablets	Teva Pharma B.V.	PA0749/143/001	Tablet	- H03AA - H03AA01	- Levothyroxine sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Levothyroxine Teva 50 micrograms Tablets	Teva Pharma B.V.	PA0749/143/002	Tablet	- H03AA - H03AA01	- Levothyroxine sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lexapro 10 mg film-coated tablets	H. Lundbeck A/S	PA0805/002/002 Interchangeable List Code: IC0071-002-003	Film-coated tablet		- Escitalopram	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lexapro 10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/129/001 Interchangeable List Code: IC0071-002-003	Film-coated tablet		- Escitalopram	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Lexapro 15 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/129/004 Interchangeable List Code: IC0071-032-003	Film-coated tablet		- Escitalopram	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Lexapro 15 mg film-coated tablets	H. Lundbeck A/S	PA0805/002/003 Interchangeable List Code: IC0071-032-003	Film-coated tablet		- Escitalopram	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lexapro 20 mg film-coated tablets	H. Lundbeck A/S	PA0805/002/004 Interchangeable List Code: IC0071-003-003	Film-coated tablet		- Escitalopram	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lexapro 20 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/129/002 Interchangeable List Code: IC0071-003-003	Film-coated tablet		- Escitalopram	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Lexapro 5 mg film-coated tablets	H. Lundbeck A/S	PA0805/002/001 Interchangeable List Code: IC0071-001-003	Film-coated tablet		- Escitalopram	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lexotan 1.5mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/008/001	Tablet	- N05BA - N05BA08	- Bromazepam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lexotan 3mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/008/002	Tablet	- N05BA - N05BA08	- Bromazepam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Leydex 100 mg Orodispersible Tablets	Leyden Delta BV	PA2241/001/004	Orodispersible tablet	- N05AH - N05AH02	- Clozapine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Leydex 12.5 mg Orodispersible Tablets	Leyden Delta BV	PA2241/001/001	Orodispersible tablet	- N05AH - N05AH02	- Clozapine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Leydex 200 mg Orodispersible Tablets	Leyden Delta BV	PA2241/001/005	Orodispersible tablet	- N05AH - N05AH02	- Clozapine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Leydex 25 mg Orodispersible tablet	Leyden Delta BV	PA2241/001/002	Orodispersible tablet	- N05AH - N05AH02	- Clozapine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Leydex 50 mg Orodispersible Tablets	Leyden Delta BV	PA2241/001/003	Orodispersible tablet	- N05AH - N05AH02	- Clozapine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
LG-octaplas, Powder and solvent for solution for infusion	Octapharma (IP) SPRL	PA2219/002/002	Powder and solvent for solution for infusion	- B05AA	- Human plasma protein	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
LG-octaplas, solution for infusion	Octapharma (IP) SPRL	PA2219/002/001	Solution for infusion	- B05AA	- Human plasma protein	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Libmeldy	Orchard Therapeutics (Netherlands) B.V.	EU/1/20/1493/001	Dispersion for infusion	- A16AB21	- Autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Libmyris	Stada Arzneimittel AG	EU/1/21/1590/001-006	Solution for injection in pre-filled syringe	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Libmyris	Stada Arzneimittel AG	EU/1/21/1590/007	Solution for injection in pre-filled syringe	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Librium 10mg Hard Capsule	Mylan IRE Healthcare Limited	PA2010/041/002	Capsule, hard	- N05BA - N05BA02	- CHLORDIAZEPOXIDE HYDROCHLORIDE		- Oral use
Librium 5mg Hard Capsules	Mylan IRE Healthcare Limited	PA2010/041/001	Capsule, hard	- N05BA - N05BA02	- CHLORDIAZEPOXIDE HYDROCHLORIDE		- Oral use
Libtayo	Regeneron Ireland U.C.	EU/1/19/1376/001	Concentrate for solution for infusion	- L01XC33	- CEMIPLIMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Licomep 10 mg hard gastro-resistant capsules	Laboratorios LICONSA, S.A.	PA1239/026/001 Interchangeable List Code: IC0010-002-016	Gastro-resistant capsule, hard		- Omeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Licomep 20 mg hard gastro-resistant capsules	Laboratorios LICONSA, S.A.	PA1239/026/002 Interchangeable List Code: IC0010-003-016	Gastro-resistant capsule, hard		- Omeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Licomep 40 mg hard gastro-resistant capsules	Laboratorios LICONSA, S.A.	PA1239/026/003 Interchangeable List Code: IC0010-004-016	Gastro-resistant capsule, hard		- Omeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lidbree 42 mg/mL intrauterine gel	Gedeon Richter Plc	PA1330/025/001	Intrauterine gel	- N01BB02	- Lidocaine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intracervical use - Intrauterine use
Lidocaine 10 mg/ ml (1% w/v) solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/009/001	Solution for injection in pre-filled syringe	- N01BB - N01BB02	- Lidocaine hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Infiltration
Lidocaine 20 mg/ ml (2% w/v) solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/009/002	Solution for injection in pre-filled syringe	- N01BB - N01BB02	- Lidocaine hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Infiltration
Lidocaine Hydrochloride 1% w/v Solution for Injection	Fresenius Kabi Deutschland GmbH	PA2059/003/001	Solution for injection	- N01BB02	- Lidocaine Hydrochloride Monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use - Intramuscular use - Intravenous use - Subcutaneous use
Lidocaine Hydrochloride 2% w/v Solution for Injection	Fresenius Kabi Deutschland GmbH	PA2059/003/002	Solution for injection	- N01BB02	- Lidocaine Hydrochloride Monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use - Intramuscular use - Intravenous use - Subcutaneous use
Lidocaine hydrochloride 20 mg/ml, solution for injection/infusion	Laboratoire AGUETTANT	PA1968/012/001	Solution for injection/infusion	- N01BB02	- Lidocaine Hydrochloride Monohydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Epidural use - Infiltration - Intramuscular use - Intravenous use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v) solution for injection	Noridem Enterprises Limited	PA1122/027/001	Solution for injection	- N01BB02	- Lidocaine Hydrochloride Monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use - Intradermal use - Intramuscular use - Intravenous use - Perineural use - Subcutaneous use - Submucosal use
Lidocaine hydrochloride Noridem 20 mg / mL (2 % w/v) solution for injection	Noridem Enterprises Limited	PA1122/027/002	Solution for injection	- N01BB02	- Lidocaine Hydrochloride Monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use - Intradermal use - Intramuscular use - Intravenous use - Perineural use - Subcutaneous use - Submucosal use
Lifmior	Pfizer Europe MA EEIG	EU/1/16/1165/001	Powder and solvent for solution for injection	- L04AB - L04AB01	- Etanercept	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Lifmior	Pfizer Europe MA EEIG	EU/1/16/1165/002-004	Powder and solvent for solution for injection	- L04AB - L04AB01	- Etanercept	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Lifmior	Pfizer Europe MA EEIG	EU/1/16/1165/005-007	Solution for injection in pre-filled syringe	- L04AB - L04AB01	- Etanercept	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Lifmior	Pfizer Europe MA EEIG	EU/1/16/1165/008-010	Solution for injection in pre-filled syringe	- L04AB - L04AB01	- Etanercept	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Lifmior	Pfizer Europe MA EEIG	EU/1/16/1165/011-013	Solution for injection in pre-filled pen	- L04AB - L04AB01	- Etanercept	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Lignospan Special (20 mg/12.5 microgram per ml) Solution for Injection 1.8 ml	Septodont	PA0196/013/001	Solution for injection	- N01BB - N01BB52	- Adrenaline (epinephrine) - Lidocaine Hydrochloride, anhydrous		- Infiltration - Perineural use
Lignospan Special (20 mg/12.5 microgram per ml) Solution for Injection 2.2 ml	Septodont	PA0196/013/002	Solution for injection	- N01BB - N01BB52	- Lidocaine Hydrochloride, anhydrous - Adrenaline (epinephrine)		- Infiltration - Perineural use
Linagliptin Clonmel 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/334/001	Film-coated tablet	- A10BH05	- Linagliptin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Linagliptin Viatris	Viatris Limited	PA23266/013/001	Film-coated tablet	- A10BH05	- Linagliptin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Linezolid 2 mg/ ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/011/001	Solution for infusion	- J01XX - J01XX08	- Linezolid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Linezolid 2 mg/ml solution for infusion	KRKA, d.d., Novo mesto	PA1347/057/002	Solution for infusion	- J01XX - J01XX08	- Linezolid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Linezolid 2 mg/ml solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/104/003	Solution for infusion	- J01XX - J01XX08	- Linezolid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Linezolid 600 mg Film-Coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/104/001	Film-coated tablet	- J01XX - J01XX08	- Linezolid (form iii)	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Linezolid 600 mg Film-Coated Tablets	Rowex Ltd	PA0711/230/001	Film-coated tablet	- J01XX - J01XX08	- Linezolid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Linezolid Clonmel 600 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/238/001	Film-coated tablet	- J01XX - J01XX08	- Linezolid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Linezolid Krka 600 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/057/001	Film-coated tablet	- J01XX - J01XX08	- Linezolid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Linezolid Teva 600 mg film-coated tablets	Teva Pharma B.V.	PA0749/204/001	Film-coated tablet	- J01XX - J01XX08	- Linezolid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lioresal 10 mg Tablets	Novartis Ireland Limited	PA0896/017/001	Tablet	- M03BX - M03BX01	- Baclofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lioresal 5mg/5ml Oral solution	Novartis Ireland Limited	PA0896/017/002	Oral solution	- M03BX - M03BX01	- Baclofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lipantil Micro 200 mg hard capsules	Mylan IRE Healthcare Limited	PA2010/015/002	Capsule, hard	- C10AB - C10AB05	- Fenofibrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lipantil Micro 200 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/471/001	Capsule, hard	- C10AB - C10AB05	- Fenofibrate		- Oral use
Lipantil Micro 67 mg hard capsules.	Mylan IRE Healthcare Limited	PA2010/015/001	Capsule, hard	- C10AB - C10AB05	- Fenofibrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lipantil Supra 145 mg film-coated tablet	PCO Manufacturing Ltd.	PPA0465/409/001	Film-coated tablet	- C10AB - C10AB05	- Fenofibrate		- Oral use
Lipantil Supra 145mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/015/003	Film-coated tablet	- C10AB - C10AB05	- Fenofibrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lipantil Supra 215 mg, film-coated tablet	Mylan IRE Healthcare Limited	PA2010/015/004	Film-coated tablet	- C10AB - C10AB05	- Fenofibrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lipertance 10mg/5mg/5mg film-coated tablets	Les Laboratoires Servier	PA0568/028/001	Film-coated tablet	- C10BX - C10BX11	- Atorvastatin - Perindopril arginine - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Lipertance 20mg/10mg/10mg film-coated tablets	Les Laboratoires Servier	PA0568/028/004	Film-coated tablet	- C10BX - C10BX11	- Atorvastatin - Perindopril arginine - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Lipertance 20mg/10mg/5mg film-coated tablets	Les Laboratoires Servier	PA0568/028/003	Film-coated tablet	- C10BX - C10BX11	- Atorvastatin - Perindopril arginine - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Lipertance 20mg/5mg/5mg film-coated tablets	Les Laboratoires Servier	PA0568/028/002	Film-coated tablet	- C10BX - C10BX11	- Atorvastatin - Perindopril arginine - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Lipertance 40mg/10mg/10mg film-coated tablets	Les Laboratoires Servier	PA0568/028/005	Film-coated tablet	- C10BX - C10BX11	- Atorvastatin - Perindopril arginine - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Lipiodol Ultra Fluid 38% w/w Solution for injection	Guerbet	PA0686/004/001	Solution for injection	- V08AD	- organically combined iodine.	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intrathecal use - Intravenous use
Lipitor 10 mg chewable tablets	Upjohn EESV	PA23055/017/006	Chewable tablet	- C10AA - C10AA05	- Atorvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lipitor 10 mg film-coated tablets	Upjohn EESV	PA23055/017/001 Interchangeable List Code: IC0001-002-003	Film-coated tablet		- Atorvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lipitor 10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/075/001 Interchangeable List Code: IC0001-002-003	Film-coated tablet		- Atorvastatin	ZZZ PPA	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lipitor 20 mg chewable tablets	Upjohn EESV	PA23055/017/007	Chewable tablet	- C10AA - C10AA05	- Atorvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lipitor 20 mg film-coated tablets	Upjohn EESV	PA23055/017/002 Interchangeable List Code: IC0001-003-003	Film-coated tablet		- Atorvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lipitor 20 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/075/002 Interchangeable List Code: IC0001-003-003	Film-coated tablet		- Atorvastatin	ZZZ PPA	- Oral use
Lipitor 40 mg chewable tablets	Upjohn EESV	PA23055/017/008	Chewable tablet	- C10AA - C10AA05	- Atorvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lipitor 40 mg film-coated tablets	Upjohn EESV	PA23055/017/003 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lipitor 40 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/075/003 Interchangeable List Code: IC0001-004-003	Film-coated tablet		- Atorvastatin	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Lipitor 5 mg chewable tablets	Upjohn EESV	PA23055/017/005	Chewable tablet	- C10AA - C10AA05	- Atorvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lipitor 80 mg film-coated tablets	Upjohn EESV	PA23055/017/004 Interchangeable List Code: IC0001-005-003	Film-coated tablet		- Atorvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lipitor 80 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/075/004 Interchangeable List Code: IC0001-005-003	Film-coated tablet		- Atorvastatin	ZZZ PPA	- Oral use
Lipocomb 10 mg/10 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/460/001 Interchangeable List Code: IC0111-017-009	Capsule, hard		- Ezetimibe - Rosuvastatin		- Oral use
Lipocomb 10 mg/10 mg hard capsules	EGIS Pharmaceuticals PLC	PA1470/004/001 Interchangeable List Code: IC0111-017-009	Capsule, hard		- Rosuvastatin zinc - Ezetimibe	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Lipocomb 20 mg/10 mg hard capsules	EGIS Pharmaceuticals PLC	PA1470/004/002 Interchangeable List Code: IC0111-061-009	Capsule, hard		- Rosuvastatin zinc - Ezetimibe	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Lipocomb 20 mg/10 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/460/002 Interchangeable List Code: IC0111-061-009	Capsule, hard		- Rosuvastatin - Ezetimibe		- Oral use
Lipocomb 40 mg/10 mg hard capsules	EGIS Pharmaceuticals PLC	PA1470/004/003 Interchangeable List Code: IC0111-093-009	Capsule, hard		- Rosuvastatin zinc - Ezetimibe	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Liposic 2 mg/g eye gel	Bausch + Lomb Ireland Limited	PA23259/009/001	Eye gel	- S01XA - S01XA20	- Carbomer	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Ocular use
Liprolog	Eli Lilly and Company Limited	EU/1/01/195/028-029	Not assigned	- A10AB - A10AB04			
Liprolog	Eli Lilly Nederland B.V.	EU/1/01/195/22-27	Suspension for injection	- A10AB - A10AB04	- Insulin lispro		

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Liprolog	Eli Lilly Nederland B.V.	EU/1/01/195/001	Solution for injection	- A10AB - A10AB04	- Insulin lispro		- Subcutaneous use
Liprolog	Eli Lilly Nederland B.V.	EU/1/01/195/002	Solution for injection	- A10AB - A10AB04	- Insulin lispro		- Subcutaneous use
Liprolog Mix25	Eli Lilly Nederland B.V.	EU/1/01/195/003	Suspension for injection	- A10AB - A10AB04	- Insulin lispro		- Subcutaneous use
Liprolog Mix25 Pen	Eli Lilly Nederland B.V.	EU/1/01/195/006	Suspension for injection	- A10AB - A10AB04	- Insulin lispro		- Subcutaneous use
Liprolog Mix50	Eli Lilly Nederland B.V.	EU/1/01/195/004	Suspension for injection	- A10AB - A10AB04	- Insulin lispro		- Subcutaneous use
Liprolog Mix50 Pen	Eli Lilly Nederland B.V.	EU/1/01/195/007	Suspension for injection	- A10AB - A10AB04	- Insulin lispro		- Subcutaneous use
Liprolog-Pen	Eli Lilly Nederland B.V.	EU/1/01/195/005	Solution for injection	- A10AB - A10AB04	- Insulin lispro		- Subcutaneous use
Liquid Medical Oxygen 100 % Medicinal gas, cryogenic	SOL S.p.A.	PA1848/005/002	Not assigned	- V03AN - V03AN01	- Oxygen	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
Liquid Medical Oxygen 100% Medicinal gas, cryogenic	SOL S.p.A.	PA1848/005/001	Not assigned	- V03AN - V03AN01	- Oxygen	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
LIQUIVISC 2.5 mg/g eye gel	Laboratoires Thea	PA1107/002/001	Eye gel	- S01XA - S01XA20	- Carbomer	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Lisinopril 1mg/ml Oral Solution	Taw Pharma (Ireland) Ltd	PA23081/013/001	Oral solution	- C09AA - C09AA03	- Lisinopril Dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lisinopril Grindeks 10 mg tablets	AS Grindeks	PA22992/018/002	Tablet	- C09AA03	- Lisinopril Dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lisinopril Grindeks 20 mg tablets	AS Grindeks	PA22992/018/003	Tablet	- C09AA03	- Lisinopril Dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lisinopril Grindeks 5 mg tablets	AS Grindeks	PA22992/018/001	Tablet	- C09AA03	- Lisinopril Dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lisopress 10 mg tablets	Gedeon Richter Plc	PA1330/013/003	Tablet	- C09AA - C09AA03	- Lisinopril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lisopress 2.5 mg tablets	Gedeon Richter Plc	PA1330/013/001	Tablet	- C09AA - C09AA03	- Lisinopril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lisopress 20 mg tablets	Gedeon Richter Plc	PA1330/013/004	Tablet	- C09AA - C09AA03	- Lisinopril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lisopress 5 mg tablets	Gedeon Richter Plc	PA1330/013/002	Tablet	- C09AA - C09AA03	- Lisinopril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lispril 10 mg Tablets	Rowex Ltd	PA0711/047/003	Tablet	- C09AA - C09AA03	- Lisinopril (as dihydrate)	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lispril 20 mg Tablets	Rowex Ltd	PA0711/047/004	Tablet	- C09AA - C09AA03	- Lisinopril (as dihydrate)	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lispril 5 mg Tablets	Rowex Ltd	PA0711/047/002	Tablet	- C09AA - C09AA03	- Lisinopril Dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lispril-Hydrochlorothiazide 10 mg/12.5 mg tablets	Rowex Ltd	PA0711/051/001	Tablet	- C09BA - C09BA03	- Lisinopril Dihydrate - Hydrochlorothiazide		- Oral use
Lispril-Hydrochlorothiazide 20 mg/12.5 mg tablets	Rowex Ltd	PA0711/051/002	Tablet	- C09BA - C09BA03	- Lisinopril Dihydrate - Hydrochlorothiazide		- Oral use
LITAK	Lipomed GmbH	EU/1/04/275/001-002	Solution for injection	- L01BB - L01BB04	- Cladribine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Litfulo	Pfizer Europe MA EEIG	EU/1/23/1755/001-003	Capsule, hard	- L04AA - L04AF08	- Ritlecitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lithium Chloride 0.15 mmol/ml. Solution for Injection	LiDCO Netherlands B.V.	PA23039/001/001	Solution for injection	- N05AN - N05AN01	- Lithium chloride		- Intravenous use
Livazo 1mg film-coated tablets	Kowa Pharmaceutical Europe GmbH	PA2324/001/001	Film-coated tablet	- C10AA - C10AA08	- Pitavastatin calcium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Livazo 2mg film-coated tablets	Kowa Pharmaceutical Europe GmbH	PA2324/001/002	Film-coated tablet	- C10AA - C10AA08	- Pitavastatin calcium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Livazo 4mg film-coated tablets	Kowa Pharmaceutical Europe GmbH	PA2324/001/003	Film-coated tablet	- C10AA - C10AA08	- Pitavastatin calcium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Livial 2.5 mg tablets	Organon Pharma (Ireland) Limited	PA23198/021/001	Tablet	- G03CX - G03CX01	- Tibolone		- Oral use
LIVMARLI	Mirum Pharmaceuticals International B.V.	EU/1/22/1704/001	Oral solution	- A05AX - A05AX04	- Maralixibat Chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
LIVOGIVA	Theramex Ireland Limited	EU/1/20/1462/001-002	Solution for injection in pre-filled pen	- H05AA02	- Teriparatide	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Livtencity	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/22/1672/001-002	Film-coated tablet	- J05AX10	- Maribavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lixiana	Daiichi Sankyo Europe GmbH	EU/1/15/993/001	Film-coated tablet	- B01AF - B01AF03	- Edoxaban tosilate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lixiana	Daiichi Sankyo Europe GmbH	EU/1/15/993/002	Film-coated tablet	- B01AF - B01AF03	- Edoxaban tosilate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lixiana	Daiichi Sankyo Europe GmbH	EU/1/15/993/003	Film-coated tablet	- B01AF - B01AF03	- Edoxaban tosilate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Locametz	Advanced Accelerator Applications	EU/1/22/1692/001	Kit for radiopharmaceutical preparation	- V09I - V09IX14	- Gozetotide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Loceryl 5% w/v Medicated Nail Lacquer	PCO Manufacturing Ltd.	PPA0465/234/001	Medicated nail lacquer	- D01AE - D01AE16	- Amorolfine		- Cutaneous use
Loceryl 5% w/v Medicated Nail Lacquer	IMED Healthcare Ltd.	PPA1463/081/001	Medicated nail lacquer	- D01AE - D01AE16	- Amorolfine		- Cutaneous use
Loceryl 5% w/v Medicated Nail Lacquer	Galderma International	PA22743/009/001	Medicated nail lacquer	- D01AE - D01AE16	- Amorolfine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Loceryl 5% w/v Medicated Nail Lacquer	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/036/001	Medicated nail lacquer	- D01AE - D01AE16	- Amorolfine		- Topical

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Locoid Cream 0.1 % w/w	CHEPLAPHARM Arzneimittel GmbH	PA2239/019/001	Cream	- D07AB - D07AB02	- Hydrocortisone butyrate		- Topical use
Locoid Lipocream 0.1% w/w Cream	CHEPLAPHARM Arzneimittel GmbH	PA2239/019/002	Cream	- D07AB - D07AB02	- Hydrocortisone butyrate		- Topical use
Logynon Tablets	Bayer Limited	PA1410/005/001	Coated tablet	- G03AB - G03AB03	- Levonorgestrel micronized - Levonorgestrel micronized - Levonorgestrel micronized - Ethinylestradiol micronized - Ethinylestradiol micronized		- Oral use
Lojuxta	Amryt Pharmaceuticals DAC	EU/1/13/851/001	Capsule, hard	- C10AX - C10AX12	- Lomitapide mesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lojuxta	Amryt Pharmaceuticals DAC	EU/1/13/851/002	Capsule, hard	- C10AX - C10AX12	- Lomitapide mesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lojuxta	Amryt Pharmaceuticals DAC	EU/1/13/851/003	Capsule, hard	- C10AX - C10AX12	- Lomitapide mesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lojuxta	Amryt Pharmaceuticals DAC	EU/1/13/851/004	Capsule, hard	- C10AX - C10AX12	- Lomitapide mesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lojuxta	Amryt Pharmaceuticals DAC	EU/1/13/851/005	Capsule, hard	- C10AX - C10AX12	- Lomitapide mesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lojuxta	Amryt Pharmaceuticals DAC	EU/1/13/851/006	Capsule, hard	- C10AX - C10AX12	- Lomitapide mesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lokelma	AstraZeneca AB	EU/1/17/1173/001-002	Powder for oral suspension	- V03AE - V03AE10	- Sodium zirconium cyclosilicate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lokelma	AstraZeneca AB	EU/1/17/1173/003-004	Powder for oral suspension	- V03AE - V03AE10	- Sodium zirconium cyclosilicate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lomexin 2% w/v Cutaneous Spray, Solution	Recordati Industria Chimica e Farmaceutica SpA	PA0812/002/005	Cutaneous spray, solution	- D01AC - D01AC12	- Fenticonazole nitrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Lomexin 2% w/w Cream	Recordati Industria Chimica e Farmaceutica SpA	PA0812/002/001	Cream	- D01AC - D01AC12	- Fenticonazole nitrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Loniten 5 mg tablets	Pfizer Healthcare Ireland	PA0822/130/001	Tablet	- C02DC - C02DC01	- Minoxidil		- Oral use
Lonquex	Teva B.V.	EU/1/13/856/001-002	Solution for injection in pre-filled syringe	- L03AA - L03AA14	- Xm22 drug substance lipegfilgrastim	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Lonsurf	Les Laboratoires Servier	EU/1/16/1096/001-003	Film-coated tablet	- L01BC - L01BC59	- Trifluridine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lonsurf	Les Laboratoires Servier	EU/1/16/1096/004-006	Film-coated tablet	- L01BC	- Trifluridine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lopid 300 mg capsules, hard	Pfizer Healthcare Ireland	PA0822/014/001	Capsule, hard	- C10AB - C10AB04	- Gemfibrozil		- Oral use
Lopid 600 mg film-coated tablet	PCO Manufacturing Ltd.	PPA0465/320/001	Film-coated tablet	- C10AB - C10AB04	- Gemfibrozil		- Oral use
Lopid 600 mg film-coated tablets	Pfizer Healthcare Ireland	PA0822/014/002	Film-coated tablet	- C10AB - C10AB04	- Gemfibrozil		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lopinavir/Ritonavir Mylan	Mylan Pharmaceuticals Limited	EU/1/15/1067/001-003	Film-coated tablet	- J05AE - J05AE03	- Lopinavir - Ritonavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lopinavir/Ritonavir Mylan	Mylan Pharmaceuticals Limited	EU/1/15/1067/004-008	Film-coated tablet	- J05AR - J05AR10	- Lopinavir - Ritonavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lorat 10mg Tablets	Rowex Ltd	PA0711/088/001	Tablet	- R06AX - R06AX13	- Loratadine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Loratadine 10 mg Tablets	Azure Pharmaceuticals Ltd	PA22871/008/001	Tablet	- R06AX13	- Loratadine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Loratadine Accord 10 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/246/001	Tablet	- R06AX13	- Loratadine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Loravis 50 microgram/ml eye drops, solution	Farmaprojects S.A.	PA1391/007/001 Interchangeable List Code: IC0096-152-045	Eye drops, solution		- Latanoprost	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Lorazepam 1mg tablets	Morningside Healthcare (Malta) Limited	PA23142/007/001	Tablet	- N05BA - N05BA06	- Lorazepam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lorazepam 2.5 mg tablets	Morningside Healthcare (Malta) Limited	PA23142/007/002	Tablet	- N05BA - N05BA06	- Lorazepam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lorazepam Macure 4 mg/ml solution for injection	Macure Pharma ApS	PA23199/002/001	Solution for injection	- N05BA06	- Lorazepam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Lorviqua	Pfizer Europe MA EEIG	EU/1/19/1355/001	Film-coated tablet	- L01 - L01XE44	- LORLATINIB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lorviqua	Pfizer Europe MA EEIG	EU/1/19/1355/002	Film-coated tablet	- L01 - L01XE44	- LORLATINIB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Losamel 20 mg gastro-resistant tablets	Clonmel Healthcare Ltd	PA0126/115/001 Interchangeable List Code: IC0010-003-016	Gastro-resistant tablet		- Omeprazole		- Oral use
Losartan Clonmel 100 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/355/002 Interchangeable List Code: IC0003-024-003	Film-coated tablet		- Losartan potassium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan Clonmel 50 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/355/001 Interchangeable List Code: IC0003-023-003	Film-coated tablet		- Losartan potassium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan Krka 100 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/020/003 Interchangeable List Code: IC0003-024-003	Film-coated tablet		- Losartan potassium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan Krka 25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/020/001 Interchangeable List Code: IC0003-022-003	Film-coated tablet		- Losartan potassium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Losartan Krka 50 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/020/002 Interchangeable List Code: IC0003-023-003	Film-coated tablet		- Losartan potassium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Losartan Potassium 100 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/059/003 Interchangeable List Code: IC0003-024-003	Film-coated tablet		- Losartan potassium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan Potassium 25 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/059/001 Interchangeable List Code: IC0003-022-003	Film-coated tablet		- Losartan potassium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Losartan Potassium 50 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/059/002 Interchangeable List Code: IC0003-023-003	Film-coated tablet		- Losartan potassium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan Potassium Pinewood 100 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/154/003 Interchangeable List Code: IC0003-024-003	Film-coated tablet		- Losartan potassium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan Potassium Pinewood 50 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/154/002 Interchangeable List Code: IC0003-023-003	Film-coated tablet		- Losartan potassium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan Rowa 100mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/082/003 Interchangeable List Code: IC0003-024-003	Film-coated tablet		- Losartan potassium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan Rowa 50mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/082/002 Interchangeable List Code: IC0003-023-003	Film-coated tablet		- Losartan potassium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan Teva 100 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/090/004 Interchangeable List Code: IC0003-024-003	Film-coated tablet		- Losartan potassium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan Teva 50 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/090/003 Interchangeable List Code: IC0003-023-003	Film-coated tablet		- Losartan potassium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan/Hydrochlorothiazide Clonmel 100 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/354/002 Interchangeable List Code: IC0031-027-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan/Hydrochlorothiazide Clonmel 50 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/354/001 Interchangeable List Code: IC0031-025-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan/Hydrochlorothiazide Krka 100 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/040/002 Interchangeable List Code: IC0031-026-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan/Hydrochlorothiazide Krka 100 mg/25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/040/003 Interchangeable List Code: IC0031-027-003	Film-coated tablet		- Losartan potassium - Hydrocholothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan/Hydrochlorothiazide Krka 50 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/040/001 Interchangeable List Code: IC0031-025-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losartan/Hydrochlorothiazide Teva 100mg/25mg Film-Coated Tablets	Teva Pharma B.V.	PA0749/026/002 Interchangeable List Code: IC0031-027-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Losartan/Hydrochlorothiazide Teva 50mg/12.5mg Film-Coated Tablets	Teva Pharma B.V.	PA0749/026/001 Interchangeable List Code: IC0031-025-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Losec Control 20 mg gastro-resistant tablets	Bayer Limited	PA1410/066/001	Gastro-resistant tablet	- A02BC - A02BC01	- Omeprazole	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Losec MUPS 10 mg gastro-resistant tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/009/001 Interchangeable List Code: IC0010-002-016	Gastro-resistant tablet		- Omeprazole magnesium		- Oral use
Losec MUPS 10 mg gastro-resistant tablets	PCO Manufacturing Ltd.	PPA0465/423/003 Interchangeable List Code: IC0010-002-016	Gastro-resistant tablet		- Omeprazole		- Oral use
Losec MUPS 20 mg gastro-resistant tablets	PCO Manufacturing Ltd.	PPA0465/423/001 Interchangeable List Code: IC0010-003-016	Gastro-resistant tablet		- Omeprazole		- Oral use
Losec MUPS 20 mg gastro-resistant tablets	IMED Healthcare Ltd.	PPA1463/141/001 Interchangeable List Code: IC0010-003-016	Gastro-resistant tablet		- Omeprazole		- Oral use
Losec MUPS 20 mg gastro-resistant tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/009/002 Interchangeable List Code: IC0010-003-016	Gastro-resistant tablet		- Omeprazole		- Oral use
Losec MUPS 40 mg gastro-resistant tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/009/003 Interchangeable List Code: IC0010-004-016	Gastro-resistant tablet		- Omeprazole		- Oral use
Lotanos Comp 100 mg/25 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/072/002 Interchangeable List Code: IC0031-027-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Lotanos Comp 50 mg/12.5 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/072/001 Interchangeable List Code: IC0031-025-003	Film-coated tablet		- Losartan potassium - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lotemax 0.5% w/v eye drops, suspension	Dr. Gerhard Mann, chem.-pharm. Fabrik GmbH	PA1245/001/001	Eye drops, suspension	- S01BA - S01BA14	- Loteprednol etabonate		- Ocular use
Lovtelar 800 mg film-coated tablets	Pharmathen S.A.	PA1368/022/001	Film-coated tablet	- V03AE02	- Sevelamer carbonate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Low Centyl K 1.25 mg/573 mg modified-release tablets	KARO PHARMA AB	PA22650/002/001	Modified-release tablet	- C03AB - C03AB01	- Bendroflumethiazide - Potassium chloride		- Oral use
Loxentia 20mg hard gastro-resistant capsule	KRKA, d.d., Novo mesto	PA1347/051/001 Interchangeable List Code: IC0091-003-006	Gastro-resistant capsule, hard		- Duloxetine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Loxentia 40mg hard gastro-resistant capsule	KRKA, d.d., Novo mesto	PA1347/051/003 Interchangeable List Code: IC0091-004-006	Gastro-resistant capsule, hard		- Duloxetine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lucentis	Novartis Europharm Limited	EU/1/06/374/002-004	Solution for injection	- S01LA - S01LA04	- Ranibizumab		- Intravitreal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
LuMark	IDB Holland B.V.,	EU/1/15/1013/001	Radiopharmaceutical precursor, solution	- V10X	- Lutetium, isotope of mass 177	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravitreal use
Lumeblue	Alfasigma S.p.A	EU/1/20/1470/001	Prolonged-release tablet	- V04CX	- Methylthioninium chloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Lumigan	AbbVie Deutschland GmbH & Co. KG	EU/1/02/205/001-2	Eye drops, solution	- S01EE - S01EE03	- Bimatoprost		- Ocular use
Lumigan	AbbVie Deutschland GmbH & Co. KG	EU/1/02/205/3-4	Eye drops, solution	- S01EE - S01EE03	- Bimatoprost		- Ocular use
Luminity	Lantheus EU Limited	EU/1/06/361/01-2	Gas and solvent for dispersion for injection/infusion	- V08DA - V08DA04	- Perflutren		
Lumykras	Amgen Europe B.V.	EU/1/21/1603/001-003	Film-coated tablet	- L01XX73	- Sotorasib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lunsumio	Roche Registration GmbH	EU/1/22/1649/001	Concentrate for solution for infusion	- L01FX25	- Mosunetuzumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Lunsumio	Roche Registration GmbH	EU/1/22/1649/002	Concentrate for solution for infusion	- L01FX25 - L01XC	- Mosunetuzumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Lupkynis	Otsuka Pharmaceutical Netherlands B.V.	EU/1/22/1678/001	Capsule, soft	- L04AD03	- Voclosporin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lustral 100 mg film-coated tablets	Upjohn EESV	PA23055/001/002 Interchangeable List Code: IC0064-024-003	Film-coated tablet		- Sertraline	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lustral 100 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/202/001 Interchangeable List Code: IC0064-024-003	Film-coated tablet		- Sertraline		- Oral use
Lustral 100 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/062/002 Interchangeable List Code: IC0064-024-003	Film-coated tablet		- Sertraline hydrochloride	ZZZ PPA	- Oral use
Lustral 50 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/062/001 Interchangeable List Code: IC0064-023-003	Film-coated tablet		- Sertraline hydrochloride	ZZZ PPA	- Oral use
Lustral 50 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/202/002 Interchangeable List Code: IC0064-023-003	Film-coated tablet		- Sertraline		- Oral use
Lustral 50 mg film-coated tablets	Upjohn EESV	PA23055/001/001 Interchangeable List Code: IC0064-023-003	Film-coated tablet		- Sertraline	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lutathera	Advanced Accelerator Applications	EU/1/17/1226/001	Solution for infusion	- V10XX - V10XX04	- 177lu-dotao-tyr3-octeeotate		- Intravenous use
Lutinus 100 mg vaginal tablets	Ferring Ireland Ltd	PA1009/022/001	Vaginal tablet	- G03DA - G03DA04	- Progesterone		- Vaginal use
Lutrate 1 month Depot 3.75 mg powder and solvent for prolonged-release suspension for injection	GP-PHARM, S.A.	PA1766/002/001	Powder and solvent for prolonged-release suspension for injection	- L02AE - L02AE02	- Leuprorelin acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lutrate 3 month Depot 22.5 mg powder and solvent for prolonged-release suspension for injection	GP-PHARM, S.A.	PA1766/002/002	Powder and solvent for prolonged-release suspension for injection	- L02AE - L02AE02	- Leuprorelin acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Luveris	Merck Europe B.V.	EU/1/00/155/001	Powder and solvent for solution for infusion	- G03GA - G03GA07	- Lutropin alfa		- Subcutaneous use
Luveris	Merck Europe B.V.	EU/1/00/155/002	Powder and solvent for solution for injection	- G03GA07	- Lutropin alfa		- Subcutaneous use
Luveris	Merck Europe B.V.	EU/1/00/155/003	Powder and solvent for solution for injection	- G03GA07	- Lutropin alfa		- Subcutaneous use
Luveris	Merck Europe B.V.	EU/1/00/155/004	Powder and solvent for solution for injection	- G03GA07	- Lutropin alfa		- Subcutaneous use
Luveris	Merck Europe B.V.	EU/1/00/155/005	Powder and solvent for solution for injection	- QG03GA07	- Lutropin alfa		- Subcutaneous use
Luveris	Merck Europe B.V.	EU/1/00/155/006	Powder and solvent for solution for injection	- G03GA07	- Lutropin alfa		- Subcutaneous use
Luveris	Merck Europe B.V.	EU/1/00/155/007	Solution for injection	- G03GA - G03GA07	- Lutropin alfa		- Subcutaneous use
Luxturna	Novartis Ireland Limited	EU/1/18/1331/001	Concentrate and solvent for solution for injection	- S01XA27	- VORETIGENE NEPARVOVEC	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subretinal use
Lycimor 300 mg Capsules, Hard	Teva B.V.	PA1986/118/001	Capsule, hard	- J01AA - J01AA04	- Lymecycline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Lyclear 5% w/w Dermal Cream	GlaxoSmithKline (Ireland) Limited	PA1077/066/001	Cream	- P03AC - P03AC04	- Permethrin		- Cutaneous use
Lyclear Creme Rinse 1% w/w Cutaneous solution	Chefaro Ireland DAC	PA1186/003/001	Cutaneous solution	- P03AC - P03AC04	- Permethrin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical
Lydisilka	Estetra SPRL	EU/1/21/1548/001-004	Film-coated tablet	- G03AA - G03AA18	- Estetrol monohydrate - Estetrol - Drospirenone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
LYFNUA	Merck Sharp & Dohme BV,	EU/1/21/1613/001-004	Film-coated tablet	- R05DB - R05DB29	- Gefapixant	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lymphoseek	Norgine B.V.	EU/1/14/955/001	Kit for radiopharmaceutical preparation	- V09IA	- Tilmanocept	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intra-dermal - Subcutaneous
Lymphoseek	Navidea Biopharmaceuticals Europe Ltd	EU/1/14/955/001-002	Kit for radiopharmaceutical preparation	- V09IA	- Tilmanocept	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intradermal use - Subcutaneous use
Lynparza	AstraZeneca AB	EU/1/14/959/002-003	Film-coated tablet	- L01XX - L01XX46	- Olaparib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lynparza	AstraZeneca AB	EU/1/14/959/004-005	Film-coated tablet	- L01XX - L01XX46	- Olaparib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lyrica 100 mg hard capsules	Upjohn EESV	EU/1/04/279/014-016 Interchangeable List Code: IC0110-024-001	Capsule, hard		- Pregabalin	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lyrica 150 mg hard capsules	Upjohn EESV	EU/1/04/279/017-019 Interchangeable List Code: IC0110-062-001	Capsule, hard		- Pregabalin	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lyrica 20 mg/ml oral solution	Upjohn EESV	EU/1/04/279/044 Interchangeable List Code: IC0110-128-019	Oral solution		- Pregabalin	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lyrica 200 mg hard capsules	Upjohn EESV	EU/1/04/279/020-022 Interchangeable List Code: IC0110-067-001	Capsule, hard		- Pregabalin	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lyrica 225 mg hard capsules	Upjohn EESV	EU/1/04/279/033-035 Interchangeable List Code: IC0110-064-001	Capsule, hard		- Pregabalin	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lyrica 25 mg hard capsules	Upjohn EESV	EU/1/04/279/001-005 Interchangeable List Code: IC0110-022-001	Capsule, hard		- Pregabalin	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lyrica 300 mg hard capsules	Upjohn EESV	EU/1/04/279/023-025 Interchangeable List Code: IC0110-029-001	Capsule, hard		- Pregabalin	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lyrica 50 mg hard capsules	Upjohn EESV	EU/1/04/279/006-010 Interchangeable List Code: IC0110-023-001	Capsule, hard		- Pregabalin	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lyrica 75 mg hard capsules	Upjohn EESV	EU/1/04/279/011-013 Interchangeable List Code: IC0110-028-001	Capsule, hard		- Pregabalin	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
LysaKare	Advanced Accelerator Applications	EU/1/19/1381/001	Solution for infusion	- V03AF11	- L-lysine hydrochloride - L-arginine hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
LYSODREN	HRA Pharma Rare Diseases	EU/1/04/273/001	Tablet	- L01XX - L01XX23	- Mitotane		
Lytgobi	Taiho Pharma Netherlands B.V.	EU/1/23/1741/001-003	Film-coated tablet	- L01XE51	- Futibatinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Lyumjev	Eli Lilly Nederland B.V.	EU/1/20/1422/001-012	Solution for injection	- A10AB04	- Insulin lispro	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Lyumjev	Eli Lilly Nederland B.V.	EU/1/20/1422/013-015	Solution for injection in pre-filled pen	- A10AB04	- Insulin lispro	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Lyumjev	Eli Lilly Nederland B.V.	EU/1/20/1422/016-017	Solution for injection	- A10AB04	- Insulin lispro	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Lyxumia	Sanofi-Aventis Groupe	EU/1/12/811/001	Solution for injection in pre-filled pen	- A10BX - A10BX10	- Lixisenatide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Lyxumia	Sanofi-Aventis Groupe	EU/1/12/811/002-005	Solution for injection in pre-filled pen	- A10BX - A10BX10	- Lixisenatide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Maalox 200mg/175mg per 5ml Oral Suspension	Opella Healthcare France SAS T/A Sanofi	PA23180/009/001	Oral suspension	- A02AD - A02AD01	- Magnesium hydroxide - Aluminium hydroxide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Maalox 400mg/400mg Chewable Tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/009/002	Chewable tablet	- A02AD - A02AD01	- Magnesium hydroxide - Aluminium oxide, hydrated	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Maalox Plus 200 mg/175 mg/25 mg Oral Suspension	Opella Healthcare France SAS T/A Sanofi	PA23180/008/001	Oral suspension	- A02AF - A02AF02	- Aluminium hydroxide - Magnesium hydroxide - Simeticone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Maalox Plus Chewable Tablets 200mg/200mg/25mg	Opella Healthcare France SAS T/A Sanofi	PA23180/008/002	Chewable tablet	- A02AF - A02AF02	- ALUMINIUM OXIDE, HYDRATED PH. EUR - MAGNESIUM HYDROXIDE PH. EUR. - Dimeticone ph. eur. (as simeticone ph. eur.)		- Oral use
MABTHERA	Roche Registration GmbH	EU/1/98/067/001	Concentrate for solution for infusion	- L01XC02	- Rituximab		- Intravenous use - Subcutaneous use
Mabthera	Roche Registration GmbH	EU/1/98/067/002	Concentrate for solution for infusion	- L01XC02	- Rituximab		- Subcutaneous use
MabThera	Roche Registration GmbH	EU/1/98/067/003	Solution for injection	- L01XC02	- Rituximab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
MabThera	Roche Registration GmbH	EU/1/98/067/004	Solution for injection	- L01XC02	- Rituximab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
MACI	Genzyme Europe B.V.	EU/1/13/847/001	Implant	- M09AX02	- AUTOLOGOUS CHONDROCYTES	Article 8(3) - Full new Application	
MacroBID 100mg Prolonged-Release Capsules	Amdipharm Limited	PA1142/033/001	Prolonged-release capsule, hard	- J01XE - J01XE01	- Nitrofurantoin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Macrodantin 100mg Capsules, hard	Amdipharm Limited	PA1142/031/002	Capsule, hard	- J01XE - J01XE01	- Nitrofurantoin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Macrodantin 50mg, Capsules, hard	Amdipharm Limited	PA1142/031/001	Capsule, hard	- J01XE - J01XE01	- Nitrofurantoin		- Oral use
Macrolief 13.8g sachet, powder for oral solution	Rowex Ltd	PA0711/224/001	Powder for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium chloride - Sodium hydrogen carbonate - Potassium chloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Madopar 100 mg/25 mg dispersible tablet	Roche Products (Ireland) Ltd	PA2307/004/003	Dispersible tablet	- N04BA - N04BA02	- Levodopa - Benserazide		- Oral use
Madopar 200 mg/50 mg hard capsules	Roche Products (Ireland) Ltd	PA2307/004/001	Capsule, hard	- N04BA - N04BA02	- Levodopa - Benserazide		- Oral use
Madopar 50 mg/12.5 mg dispersible tablet	Roche Products (Ireland) Ltd	PA2307/004/002	Dispersible tablet	- N04BA - N04BA02	- Levodopa - Benserazide		- Oral use
Magmedi 97 mg tablets	Kora Corporation Limited trading as Kora Healthcare	PA1748/004/001	Tablet	- A12CC04	- Magnesium	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Magnaspartate 243 mg powder for oral solution	Kora Corporation Limited trading as Kora Healthcare	PA1748/002/001	Powder for oral solution	- A12CC - A12CC05	- Magnesium aspartate dihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Magnesium Sulfate 38.5% w/w Cutaneous Paste	Foran Healthcare Limited,	PA0484/021/001	Cutaneous paste	- D11AX - D11AX05	- Magnesium sulfate dried	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Cutaneous use
Magnesium Sulfate 50 % w/v Solution for Injection/Concentrate for solution for infusion	Ethypharm	PA0549/020/001	Solution for injection/infusion	- B05XA - B05XA05	- Magnesium sulphate heptahydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Magnesium Verla 5 mmol granules for oral solution	Rowa Pharmaceuticals Limited	PA0074/062/001	Granules for oral solution	- A12CC05	- Magnesium	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Maintelyte solution for infusion	Baxter Holding B.V.	PA2299/045/001	Solution for infusion	- B05BB02	- Sodium chloride - GLUCOSE MONOHYDRATE PH. EUR. - Sodium acetate, trihydrate - POTASSIUM CHLORIDE PH. EUR. - MAGNESIUM CHLORIDE HEXAHYDRATE PH. EUR.	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Majoven XL 150mg Prolonged Release Capsules, Hard	Brillpharma (Ireland) Limited	PA22749/014/003 Interchangeable List Code: IC0026-062-030	Prolonged-release capsule, hard		- Venlafaxine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Majoven XL 37.5mg Prolonged Release Capsules, Hard	Brillpharma (Ireland) Limited	PA22749/014/001 Interchangeable List Code: IC0026-063-030	Prolonged-release capsule, hard		- Venlafaxine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Majoven XL 75 mg prolonged-release capsules, hard	Brillpharma (Ireland) Limited	PA22749/014/002 Interchangeable List Code: IC0026-028-030	Prolonged-release capsule, hard		- Venlafaxine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Malarone 250mg/100mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/111/001	Film-coated tablet	- P01BB - P01BB51	- Atovaquone - PROGUANIL HYDROCHLORIDE	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Manerix 150 mg Film-coated Tablets	Mylan IRE Healthcare Limited	PA2010/023/001	Film-coated tablet	- N06AG - N06AG02	- Moclobemide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mannitol 10% Solution for Infusion BP	Baxter Holding B.V.	PA2299/006/001	Solution for infusion	- B05BC - B05BC01	- Mannitol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Mannitol 15% w/v solution for infusion	Baxter Holding B.V.	PA2299/006/002	Solution for infusion	- B05BC - B05BC01	- Mannitol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Marcain 0.25% w/v with Adrenaline (Epinephrine, 5 micrograms per ml) (1:200,000) Solution for Injection	Aspen Pharma Trading Limited	PA1691/025/001	Solution for injection	- N01BB - N01BB51	- Bupivacaine hydrochloride - Adrenaline tartrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Marcain 0.5% w/v with Adrenaline (Epinephrine, 5 micrograms per ml) (1:200,000) Solution for Injection	Aspen Pharma Trading Limited	PA1691/025/002	Solution for injection	- N01BB - N01BB51	- Adrenaline tartrate - Bupivacaine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Marcain Heavy Steripack 0.5% w/v Solution for Injection	Aspen Pharma Trading Limited	PA1691/024/003	Solution for injection	- N01BB - N01BB01	- Bupivacaine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intrathecal use
Marcain Polyamp Steripack 0.25% w/v Solution for Injection	Aspen Pharma Trading Limited	PA1691/024/001	Solution for injection	- N01BB - N01BB01	- Bupivacaine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intrathecal use
Marcain Polyamp Steripack 0.5% w/v Solution for Injection	Aspen Pharma Trading Limited	PA1691/024/002	Solution for injection	- N01BB - N01BB01	- Bupivacaine hydrochloride		- Intrathecal use
Marixino	KRKA, d.d., Novo mesto	EU/1/13/820/001-013 Interchangeable List Code: IC0022-002-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE		- Oral use
Marixino	Krka d.d., Novo mesto	EU/1/13/820/014-026 Interchangeable List Code: IC0022-003-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Marviol 150/30 microgram Tablets	Organon Pharma (Ireland) Limited	PA23198/018/001	Tablet	- G03AA - G03AA09	- Desogestrel - Ethinylestradiol		- Oral use
MATEVER	Pharmathen S.A.	EU/1/11/711/001-006	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
MATEVER	Pharmathen S.A.	EU/1/11/711/007-014	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Article 10(1) - Generic Application	- Oral use
MATEVER	Pharmathen S.A.	EU/1/11/711/015-022	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Article 10(1) - Generic Application	- Oral use
MATEVER	Pharmathen S.A.	EU/1/11/711/023-029	Film-coated tablet	- N03AX14	- LEVETIRACETAM	Article 10(1) - Generic Application	- Oral use
MATEVER	Pharmathen S.A.	EU/1/11/711/030	Concentrate for solution for infusion	- N03AX14	- LEVETIRACETAM	Article 10(1) - Generic Application	- Oral use
Matrifen, 100 micrograms/hour Transdermal patch	Takeda Products Ireland Ltd	PA2229/007/005	Transdermal patch	- N02AB - N02AB03	- Fentanyl		- Transdermal use
Matrifen, 12 micrograms/hour Transdermal patch	Takeda Products Ireland Ltd	PA2229/007/001	Transdermal patch	- N02AB - N02AB03	- Fentanyl		- Transdermal use
Matrifen, 25 micrograms/hour Transdermal patch	Takeda Products Ireland Ltd	PA2229/007/002	Transdermal patch	- N02AB - N02AB03	- Fentanyl		- Transdermal use
Matrifen, 50 micrograms/hour Transdermal patch	Takeda Products Ireland Ltd	PA2229/007/003	Transdermal patch	- N02AB - N02AB03	- Fentanyl		- Transdermal use
Matrifen, 75 micrograms/hour Transdermal patch	Takeda Products Ireland Ltd	PA2229/007/004	Transdermal patch	- N02AB - N02AB03	- Fentanyl		- Transdermal use
Mavenclad	Merck Europe B.V.	EU/1/17/1212/001-006	Tablet	- L04AA	- Cladribine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Maviret	AbbVie Deutschland GmbH & Co. KG	EU/1/17/1213/001	Film-coated tablet	- J05AX	- Pibrentasvir - Glecaprevir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Maviret	AbbVie Deutschland GmbH & Co. KG	EU/1/17/1213/003	Coated granules in sachet	- J05A - J05AP57	- Glecaprevir - Pibrentasvir	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Maxibar 98.45% w/w powder for oral suspension	Bracco Imaging spa	PA1826/002/001	Powder for oral suspension	- V08BA - V08BA01	- Barium sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Powder for oral/rectal suspension
Maxidex 0.1% w/v Eye Drops, Suspension	Novartis Ireland Limited	PA0896/018/001	Eye drops, suspension	- S01BA - S01BA01	- Dexamethasone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Maxilief Effervescent Tablets Paracetamol 500mg Codeine Phosphate Hemihydrate 8mg Caffeine 30mg	Clonmel Healthcare Ltd	PA0126/113/001	Effervescent tablet	- N02BE - N02BE51	- Paracetamol - Codeine phosphate hemihydrate - Caffeine		- Oral use
Maxitrol 0.1% w/v, 6000 IU/ml, 3500 IU/ml eye drops, suspension	Novartis Ireland Limited	PA0896/019/001	Eye drops, suspension	- S01CA - S01CA01	- Dexamethasone - Polymyxin b sulfate - Neomycin sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Maxolon 10 mg Tablets	Amdipharm Limited	PA1142/011/003	Tablet	- A03FA - A03FA01	- Metoclopramide hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Maxolon 5 mg/ml Solution for Injection	Amdipharm Limited	PA1142/011/001	Solution for injection	- A03FA - A03FA01	- Metoclopramide hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Mayzent	Novartis Europharm Limited	EU/1/19/1414/001-002	Film-coated tablet	- L04AA42	- Siponomid - SIPONIMOD FUMARIC ACID	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mayzent	Novartis Europharm Limited	EU/1/19/1414/003	Film-coated tablet	- L04AA42	- Siponomid - SIPONIMOD FUMARIC ACID	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mayzent	Novartis Europharm Limited	EU/1/19/1414/007-008	Film-coated tablet	- L04AA42	- SIPONIMOD FUMARIC ACID	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mebeverine hydrochloride 135 mg Film-coated Tablets	Azure Pharmaceuticals Ltd	PA22871/006/001	Film-coated tablet	- A03AA04	- Mebeverine hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Medical Air	BOC Gases Ireland Ltd	PA0208/009/001	Medicinal gas, compressed	- V03AN - V03AN01	- Oxygen	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
Medical Carbon Dioxide	BOC Gases Ireland Ltd	PA0208/006/001	Medicinal gas, liquefied	- V03AN - V03AN02	- Carbon dioxide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
Medical Helium	BOC Gases Ireland Ltd	PA0208/008/001	Medicinal gas, compressed	- V03AN - V03AN03	- Helium		- Inhalation use
Medical Liquid Oxygen	BOC Gases Ireland Ltd	PA0208/002/001	Medicinal gas, cryogenic	- V03AN - V03AN01	- Oxygen		- Inhalation use
Medical Nitrous Oxide	BOC Gases Ireland Ltd	PA0208/001/001	Medicinal gas, liquefied	- N01AX - N01AX13	- Nitrous oxide		- Inhalation use
Medical Oxygen	BOC Gases Ireland Ltd	PA0208/003/001	Medicinal gas, compressed	- V03AN - V03AN01	- Oxygen	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
Medical Oxygen	Air Liquide Healthcare Ireland Limited	PA22852/001/001	Medicinal gas, compressed	- V03AN - V03AN01	- Oxygen	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
Medical Oxygen 100% Medicinal gas, compressed	SOL S.p.A.	PA1848/005/003	Medicinal gas, compressed	- V03AN - V03AN01	- Oxygen	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
Medical Oxygen/Carbon Dioxide mixtures	BOC Gases Ireland Ltd	PA0208/004/001	Medicinal gas, compressed	- V03AN - V03AN01 - V03AN02	- Oxygen - Carbon dioxide		- Extracorporeal use
Medicinal air synthetic SOL 21.75% v/v medicinal gas, compressed	SOL S.p.A.	PA1848/002/001	Medicinal gas, compressed	- V03AN - V03AN01	- Oxygen	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Medijel oromucosal gelLidocaine hydrochloride 0.66% w/wAminoacridine hydrochloride 0.05% w/w	Phoenix Labs	PA1113/022/001	Oromucosal gel	- D08AA - N01BB52	- Aminacrine hydrochloride - Lignocaine hydrochloride		- Oromucosal use
Medikinet 10 mg tablets	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/007	Tablet	- N06BA - N06BA04	- Methylphenidate hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Medikinet 20 mg tablets	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/008	Tablet	- N06BA - N06BA04	- Methylphenidate hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Medikinet 5 mg tablets	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/006	Tablet	- N06BA - N06BA04	- Methylphenidate hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Medikinet MR 10mg modified – release capsules, hard	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/002	Modified-release capsule, hard	- N06BA - N06BA04	- Methylphenidate hydrochloride - Methylphenidate hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Medikinet MR 20mg modified – release capsules, hard	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/003	Modified-release capsule, hard	- N06BA - N06BA04	- Methylphenidate hydrochloride - Methylphenidate hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Medikinet MR 30mg modified – release capsules, hard	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/004	Modified-release capsule, hard	- N06BA - N06BA04	- Methylphenidate hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Medikinet MR 40mg modified – release capsules, hard	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/005	Modified-release capsule, hard	- N06BA - N06BA04	- Methylphenidate hydrochloride - Methylphenidate hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Medikinet MR 5mg modified – release capsules, hard	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/001	Modified-release capsule, hard	- N06BA - N06BA04	- Methylphenidate hydrochloride - Methylphenidate hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Medirax 2.5 mg nasal spray, solution in single-dose container	Medir B.V.	PA22954/001/001	Nasal spray, solution in single-dose container	- N05CD08	- Midazolam hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Nasal use
Medirax 3.75 mg nasal spray, solution in single-dose container	Medir B.V.	PA22954/001/002	Nasal spray, solution in single-dose container	- N05CD08	- Midazolam hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Nasal use
Medirax 5 mg nasal spray, solution in single-dose container	Medir B.V.	PA22954/001/003	Nasal spray, solution in single-dose container	- N05CD08	- Midazolam hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Nasal use
Medispray oromucosal spray, solution Chlorhexidine digluconate 2 mg/ml Lidocaine hydrochloride 0.5 mg/ml	Clonmel Healthcare Ltd	PA0126/300/001	Oromucosal spray, solution	- R02AA - R02AA05	- Lidocaine hydrochloride - Chlorhexidine digluconate solution	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oromucosal use
Medithyme Cough Syrup	Clonmel Healthcare Ltd	TR0126/319/001	Syrup			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
MEFAC 250 mg Hard Capsules	Rowa Pharmaceuticals Limited	PA0074/015/001	Capsule, hard	- M01AG - M01AG01	- Mefenamic acid		- Oral use
MEFAC 500 mg Film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/015/002	Film-coated tablet	- M01AG - M01AG01	- Mefenamic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Megace 160 mg Tablets	IMED Healthcare Ltd.	PPA1463/191/001	Tablet	- L02AB - L02AB01	- Megestrol acetate	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Megace 160 mg tablets	PCO Manufacturing Ltd.	PPA0465/323/002	Tablet	- L02AB - L02AB01	- Megestrol acetate		- Oral use
Megace 160 mg tablets	PharmaSwiss Ceska republika s.r.o.	PA1696/002/001	Tablet	- L02AB - L02AB01	- Megestrol acetate		- Oral use
Megace 40 mg/ml oral suspension	PCO Manufacturing Ltd.	PPA0465/323/001	Oral suspension	- L02AB - L02AB01	- Megestrol acetate		- Oral use
Megace 40 mg/ml Oral Suspension	IMED Healthcare Ltd.	PPA1463/161/001	Oral suspension	- L02AB - L02AB01	- Megestrol acetate		- Oral use
Megace 40 mg/ml oral suspension	Originalis B.V.	PPA2306/016/001	Oral suspension	- L02AB01	- Megestrol acetate		- Oral use
Megace 40 mg/ml Oral Suspension	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/027/001	Oral suspension	- L02AB - L02AB01	- Megestrol acetate		- Oral use
Megace 40 mg/ml Oral Suspension	Bausch Health Ireland Limited	PA22698/024/001	Oral suspension	- L02AB - L02AB01	- Megestrol acetate		- Oral use
Megalotect 100 U/mL solution for infusion	Biotest Pharma GmbH	PA0592/008/001	Solution for infusion	- J06BB09	- Human Cytomegalovirus Immunoglobulin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Mekinist 0.5 mg film-coated tablets	Novartis Europharm Limited	EU/1/14/931/01-02	Film-coated tablet	- L01XE25	- Trametinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mekinist 1 mg film-coated tablets	Novartis Europharm Limited	EU/1/14/931/03-04	Film-coated tablet	- L01XE25	- Trametinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mekinist 2 mg film-coated tablets	Novartis Europharm Limited	EU/1/14/931/05-06	Film-coated tablet	- L01XE - L01XE25	- Trametinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mektovi	Pierre Fabre Medicament	EU/1/18/1315/001	Film-coated tablet	- L01XE41	- BINMETINIB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Meladura 2 mg prolonged-release tablets	Bluefish Pharmaceuticals AB	PA1436/047/001	Prolonged-release tablet	- N05CH01	- Melatonin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Melatonin Neurim	RAD Neurim Pharmaceuticals EEC SARL	EU/1/22/1694/001-004	Prolonged-release tablet	- N05CH01	- Melatonin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Melatonin Pharma Nord 3 mg film-coated tablets	Pharma Nord ApS	PA1242/002/001	Film-coated tablet	- N05CH01	- Melatonin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Meldonium 500 mg hard capsules	AS Grindeks	PA22992/025/001	Capsule, hard	- C01EB22	- Meldonium dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Melfen 200mg Film-coated tablets	Clonmel Healthcare Ltd	PA0126/012/001	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen ph. eur.	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Melfen 400mg Film-coated tablets	Clonmel Healthcare Ltd	PA0126/012/002	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen ph. eur.	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Meloxicam Chanelle Medical 15 mg Tablets	Chanelle Medical Unlimited Company	PA0688/005/002	Tablet	- M01AC - M01AC06	- Meloxicam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Meloxicam Chanelle Medical 7.5 mg Tablets	Chanelle Medical Unlimited Company	PA0688/005/001	Tablet	- M01AC - M01AC06	- Meloxicam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Melphalan Tillomed 50 mg powder and solvent for solution for injection/infusion	Tillomed Pharma GmbH	PA22720/006/001	Powder and solvent for solution for injection/infusion	- L01AA - L01AA03	- Melphalan Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Memantine Accord	Accord Healthcare S.L.U.	EU/1/13/880/001-008 Interchangeable List Code: IC0022-002-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE		- Oral use
Memantine Accord	Accord Healthcare S.L.U.	EU/1/13/880/013 Interchangeable List Code: IC0022-106-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE		- Oral use
Memantine Accord	Accord Healthcare S.L.U.	EU/1/13/880/09-12 Interchangeable List Code: IC0022-003-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE		- Oral use
Memantine Clonmel 10mg Film-coated Tablet	Clonmel Healthcare Ltd	PA0126/255/002 Interchangeable List Code: IC0022-002-003	Film-coated tablet		- Memantine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Memantine Clonmel 10mg/ml Oral Solution	Clonmel Healthcare Ltd	PA0126/255/001 Interchangeable List Code: IC0022-107-019	Oral solution		- Memantine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Memantine Grindeks 10 mg film-coated tablets	AS Grindeks	PA22992/003/001 Interchangeable List Code: IC0022-002-003	Film-coated tablet		- Memantine Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Memantine hydrochloride Pinewood 10 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/166/001 Interchangeable List Code: IC0022-002-003	Film-coated tablet		- Memantine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Memantine hydrochloride Pinewood 20 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/166/002 Interchangeable List Code: IC0022-003-003	Film-coated tablet		- Memantine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Memantine LEK	Pharmathen S.A.	EU/1/13/826/001-006 Interchangeable List Code: IC0022-002-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Memantine LEK	Pharmathen S.A.	EU/1/13/826/007-011 Interchangeable List Code: IC0022-003-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Memantine Merz	Merz Pharmaceuticals GmbH	EU/1/12/799/001-012 Interchangeable List Code: IC0022-002-003	Film-coated tablet		- Memantine (free base) - MEMANTINE HYDROCHLORIDE	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Memantine Merz	Merz Pharmaceuticals GmbH	EU/1/12/799/013-024 Interchangeable List Code: IC0022-003-003	Film-coated tablet		- Memantine (free base) - MEMANTINE HYDROCHLORIDE	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Memantine Merz	Merz Pharmaceuticals GmbH	EU/1/12/799/025-026 Interchangeable List Code: IC0022-106-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE - Memantine (free base)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Memantine Merz	Merz Pharmaceuticals GmbH	EU/1/12/799/027-029 Interchangeable List Code: IC0022-107-019	Oral solution		- MEMANTINE HYDROCHLORIDE - Memantine (free base)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Memantine Mylan	Mylan Pharmaceuticals Limited	EU/1/13/827/001-018 Interchangeable List Code: IC0022-002-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Memantine Mylan	Mylan Pharmaceuticals Limited	EU/1/13/827/019-036 Interchangeable List Code: IC0022-003-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Memantine Ratiopharm	Ratiopharm GmbH	EU/1/13/836/001-12 Interchangeable List Code: IC0022-002-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
MEMANTINE RATIOPHARM	Ratiopharm GmbH	EU/1/13/836/013-22 Interchangeable List Code: IC0022-003-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE	Article 10(1) - Generic Application	- Oral use
MEMANTINE RATIOPHARM	Ratiopharm GmbH	EU/1/13/836/023 Interchangeable List Code: IC0022-106-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE	Article 10(1) - Generic Application	- Oral use
Menitorix powder and solvent for solution for injection. Haemophilus type b and Meningococcal group C conjugate vaccine	GlaxoSmithKline (Ireland) Limited	PA1077/116/001	Powder and solvent for solution for injection	- J07AG53	- Conjugate of haemophilus influenzae type b capsular polysaccharide (polyribosylribitol phosphate) and tetanus - Conjugate of neisseria meningitides c capsular polysaccharide and tetanus toxoid (mean tt/ps ratio :1)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Menjugate 10 micrograms suspension for injection Meningococcal group C conjugate vaccine	GSK Vaccines S.r.l.	PA0919/004/003	Suspension for injection in pre-filled syringe	- J07AH - J07AH05	- Meningococcal group c oligosaccharide - Corynebacterium diphtheriae crm197 protein	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Menjugate 10 micrograms suspension for injection Meningococcal group C conjugate vaccine	GSK Vaccines S.r.l.	PA0919/004/004	Suspension for injection	- J07AH - J07AH05	- Meningococcal group c oligosaccharide - Corynebacterium diphtheriae crm197 protein	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Menoforce Sage tablets	A.Vogel Ireland Limited	TR2309/004/001	Tablet			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
MENOPUR 1200 IU Powder and Solvent for Solution for Injection	Ferring Ireland Ltd	PA1009/015/003	Powder and solvent for solution for injection	- G03GA - G03GA02	- Menotrophin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
MENOPUR 1200 IU Powder and Solvent for Solution for Injection	PCO Manufacturing Ltd.	PPA0465/453/002	Powder and solvent for solution for injection	- G03GA02	- Menotrophin	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Subcutaneous use
MENOPUR 600 IU Powder and Solvent for Solution for Injection	PCO Manufacturing Ltd.	PPA0465/453/001	Powder and solvent for solution for injection	- G03GA02	- Menotrophin	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Subcutaneous use
MENOPUR 600 IU Powder and Solvent for Solution for Injection	Ferring Ireland Ltd	PA1009/015/002	Powder and solvent for solution for injection	- G03GA - G03GA02	- Menotrophin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
MENOPUR® 75 IU Powder and Solvent for Solution for Injection	Ferring Ireland Ltd	PA1009/015/001	Powder and solvent for solution for injection	- G03GA - G03GA02	- Menotrophin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Menotrophin Ferring 1200 IU solution for injection in a pre-filled pen	Ferring Ireland Ltd	PA1009/030/003	Solution for injection in pre-filled pen	- G03GA02	- Menotrophin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Menotrophin Ferring 600 IU solution for injection in a pre-filled pen	Ferring Ireland Ltd	PA1009/030/002	Solution for injection in pre-filled pen	- G03GA02	- Menotrophin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Menotrophin Ferring 75 IU powder and solvent for solution for injection.	Ferring Ireland Ltd	PA1009/030/001	Powder and solvent for solution for injection	- G03GA02	- Menotrophin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Menquadfi	Sanofi Pasteur	EU/1/20/1483/001-002	Solution for injection	- J07AH08	- Neisseria Meningitidis Group A Polysaccharide - Neisseria Meningitis Group W135 Polysaccharide - N. Meningitidis Group Y Polysaccharide - Tetanus toxoid - N. Meningitidis Group C Polysaccharide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Menthol & Wintergreen Cream	Ovelle Limited	PA0206/022/001	Cream	- M02AC	- Turpentine oil - Oleoresin capsicum - Methyl salicylate - Levomenthol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical use
Mentholatum Deep Heat Cream	The Mentholatum Company (Ireland) Limited	PA25197/001/001	Cream	- M02AC	- Methyl salicylate - Racementhol - Eucalyptus oil - Turpentine oil		- Topical use
Mentholatum Deep Heat Spray, cutaneous spray solution	The Mentholatum Company (Ireland) Limited	PA25197/002/001	Cutaneous spray, solution	- M02AC	- Ethyl salicylate - Hydroxyethyl Salicylate - Methyl salicylate - Methyl nicotinate		- Cutaneous use
Menveo	GSK Vaccines S.r.l.	EU/1/10/614/002-003	Powder and solution for solution for injection	- J07AH - J07AH08	- Meningococcal group y oligosacchardie - Meningococcal group a oligosaccharide - Meningococcal group c oligosaccharide - Meningococcal group w-135 oligosaccharide		- Intramuscular use
MEPACT	Takeda France SAS	EU/1/08/502/001	Powder for concentrate for dispersion for infusion	- L03AX - L03AX15	- Mifamurtide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Mepsevii	Ultragenyx Germany GmbH	EU/1/18/1301/001	Concentrate for solution for infusion	- A16AB18	- RECOMBINANT HUMAN BETA GLUCURONIDASE; RHGUS	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Meptid 100 mg/ml Solution for Injection	Almirall, S.A.	PA0968/005/001	Solution for injection	- N02AX - N02AX05	- Meptazinol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intrathecal use - Intravenous use
Meptid 200 mg film-coated Tablets	Almirall, S.A.	PA0968/005/002	Film-coated tablet	- N02AX - N02AX05	- Meptazinol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mercaptopurine Silver Pharma 50 mg tablets	Silver Pharma S.L.	PA23137/001/001	Tablet	- L01BB02	- Mercaptopurine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mercilon 150/20 microgram Tablets	Organon Pharma (Ireland) Limited	PA23198/019/001	Tablet	- G03AA - G03AA09	- Desogestrel - Ethinylestradiol		- Oral use
Meronem I.V. 1g Powder for solution for injection or infusion	Pfizer Healthcare Ireland	PA0822/190/002	Powder for solution for injection/infusion	- J01DH - J01DH02	- Meropenem	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem 1 g powder for solution for injection or infusion	Rowex Ltd	PA0711/314/002	Powder for solution for injection/infusion	- J01DH02	- Meropenem Trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Meropenem 1 g powder for solution for injection or infusion	Venus Pharma GmbH	PA1610/001/002	Powder for solution for injection/infusion	- J01DH - J01DH02	- Meropenem Trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem 1 g powder for solution for injection or infusion	Fresenius Kabi Deutschland GmbH	PA2059/012/002	Powder for solution for injection/infusion	- J01DH - J01DH02	- Meropenem Trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem 1 g powder for solution for injection or infusion	Acino AG	PA2168/002/002	Powder for solution for injection/infusion	- J01DH - J01DH02	- Meropenem Trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem 1 g powder for solution for injection/infusion	AS Kalceks	PA2165/016/002	Powder for solution for injection/infusion	- J01DH02	- Meropenem Trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem 1 g powder for solution for injection/infusion	Steriscience B.V.	PA23431/001/002	Powder for solution for injection/infusion	- J01DH02	- Meropenem Trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem 1g Powder for Solution for Injection or Infusion	Noridem Enterprises Limited	PA1122/015/002	Powder for solution for injection/infusion	- J01DH - J01DH02	- Meropenem	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem 1g powder for solution for injection/infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/006/002	Powder for solution for injection/infusion	- J01DH - J01DH02	- Meropenem	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem 2 g powder for solution for injection/infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/006/003	Powder for solution for injection/infusion	- J01DH02	- Meropenem Trihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Meropenem 500 mg powder for solution for injection or infusion	Rowex Ltd	PA0711/314/001	Powder for solution for injection/infusion	- J01DH02	- Meropenem Trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Meropenem 500 mg powder for solution for injection or infusion	Fresenius Kabi Deutschland GmbH	PA2059/012/001	Powder for solution for injection/infusion	- J01DH - J01DH02	- Meropenem Trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem 500 mg powder for solution for injection or infusion	Venus Pharma GmbH	PA1610/001/001	Powder for solution for injection/infusion	- J01DH - J01DH02	- Meropenem	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem 500 mg powder for solution for injection or infusion	Acino AG	PA2168/002/001	Powder for solution for injection/infusion	- J01DH - J01DH02	- Meropenem Trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Meropenem 500 mg powder for solution for injection/infusion	AS Kalceks	PA2165/016/001	Powder for solution for injection/infusion	- J01DH02	- Meropenem Trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem 500 mg powder for solution for injection/infusion	Steriscience B.V.	PA23431/001/001	Powder for solution for injection/infusion	- J01DH02	- Meropenem Trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem 500mg Powder for Solution for Injection or Infusion	Noridem Enterprises Limited	PA1122/015/001	Powder for solution for injection/infusion	- J01DH - J01DH02	- Meropenem	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem 500mg powder for solution for injection/infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/006/001	Powder for solution for injection/infusion	- J01DH - J01DH02	- Meropenem	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem ACS Dobfar 1 g powder for solution for injection/infusion	ACS Dobfar S.p.A.	PA23451/001/002	Powder for solution for injection/infusion	- J01DH02	- Meropenem	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem ACS Dobfar 500 mg powder for solution for injection/infusion	ACS Dobfar S.p.A.	PA23451/001/001	Powder for solution for injection/infusion	- J01DH02	- Meropenem	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem Aurobindo 1g Powder for solution for injection or infusion	Eugia Pharma (Malta) Limited	PA23467/002/002	Powder for solution for injection/infusion	- J01DH - J01DH02	- Meropenem	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem Aurobindo 500mg Powder for solution for injection or infusion	Eugia Pharma (Malta) Limited	PA23467/002/001	Powder for solution for injection/infusion	- J01DH - J01DH02	- Meropenem	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem Star Pharmasin 1 g Powder for solution for injection/infusion	Star Pharmasin Ltd	PA22689/001/002	Powder for solution for injection/infusion	- J01DH02	- Meropenem Trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meropenem Star Pharmasin 500 mg Powder for solution for injection/infusion	Star Pharmasin Ltd	PA22689/001/001	Powder for solution for injection/infusion	- J01DH02	- Meropenem Trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Meroponia 1,000 mg Powder for Solution for Injection or Infusion	Clonmel Healthcare Ltd	PA0126/225/002	Powder for solution for injection/infusion	- J01DH - J01DH02	- Meropenem	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Mestinon 60 mg tablets	PCO Manufacturing Ltd.	PPA0465/492/001	Tablet	- N07AA - N07AA02	- Pyridostigmine bromide		- Oral use
Mestinon 60 mg Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/028/001	Tablet	- N07AA - N07AA02	- Pyridostigmine bromide		- Oral use
Mestinon 60mg Tablets	Mylan IRE Healthcare Limited	PA2010/052/001	Tablet	- N07AA - N07AA02	- Pyridostigmine bromide		- Oral use
Metalyse	Boehringer Ingelheim International GmbH	EU/1/00/169/004	Powder and solvent for solution for injection	- B01AD	- Tenecteplase		- Intravenous use
Metalyse	Boehringer Ingelheim International GmbH	EU/1/00/169/005	Powder and solvent for solution for injection	- B01AD	- Tenecteplase		- Intravenous use
Metalyse	Boehringer Ingelheim International GmbH	EU/1/00/169/006	Powder and solvent for solution for injection	- B01AD	- Tenecteplase		- Intravenous use
Metaperex 400 IU soft capsules	Kora Corporation Limited trading as Kora Healthcare	PA1748/005/001	Capsule, soft	- A11HA03	- Rrr alpha-tocoferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Metaraminol 10 mg/ml Solution for Injection or Infusion	Global Harvest Pharmaceuticals (Ireland) Limited	PA22893/001/001	Solution for injection/infusion	- C01CA - C01CA09	- METARAMINOL TARTRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Metformin Accord 1000 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/245/003 Interchangeable List Code: IC0067-119-003	Film-coated tablet		- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metformin Accord 500 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/245/001 Interchangeable List Code: IC0067-117-003	Film-coated tablet		- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metformin Accord 850 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/245/002 Interchangeable List Code: IC0067-118-003	Film-coated tablet		- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metformin Aurobindo 1000 mg film-coated tablets	Aurobindo Pharma (Malta) Limited	PA1445/021/003 Interchangeable List Code: IC0067-119-003	Film-coated tablet		- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metformin Aurobindo 500 mg film-coated tablets	Aurobindo Pharma (Malta) Limited	PA1445/021/001 Interchangeable List Code: IC0067-117-003	Film-coated tablet		- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metformin Aurobindo 850 mg film-coated tablets	Aurobindo Pharma (Malta) Limited	PA1445/021/002 Interchangeable List Code: IC0067-118-003	Film-coated tablet		- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metformin Bluefish 1000 mg, film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/009/003 Interchangeable List Code: IC0067-119-003	Film-coated tablet		- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metformin Bluefish 500 mg, Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/009/001 Interchangeable List Code: IC0067-117-003	Film-coated tablet		- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metformin Bluefish 850 mg, film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/009/002 Interchangeable List Code: IC0067-118-003	Film-coated tablet		- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metformin Hydrochloride 500mg/5ml Oral Solution	Taw Pharma (Ireland) Limited	PA23081/008/001	Oral solution	- A10BA - A10BA02	- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metformin Pinewood 1000 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/213/003 Interchangeable List Code: IC0067-119-003	Film-coated tablet		- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metformin Pinewood 500 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/213/001 Interchangeable List Code: IC0067-117-003	Film-coated tablet		- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metformin Pinewood 850 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/213/002 Interchangeable List Code: IC0067-118-003	Film-coated tablet		- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metformin Teva 1000 mg Film-coated tablets	Teva Pharma B.V.	PA0749/185/003 Interchangeable List Code: IC0067-119-003	Film-coated tablet		- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metformin Teva 500 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/185/001 Interchangeable List Code: IC0067-117-003	Film-coated tablet		- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Metformin Teva 850 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/185/002 Interchangeable List Code: IC0067-118-003	Film-coated tablet		- Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Methacholine chloride 100 mg Powder for nebuliser solution	Acic Europe Limited	PA2326/001/001	Powder for nebuliser solution	- V04CX - V04CX03	- Methacholine Chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
Methadone hydrochloride 1 mg/ml oral solution	Alkaloid - INT d.o.o	PA2128/002/001	Oral solution	- N07BC02	- Methadone hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Methadone Hydrochloride 5 mg tablets	Ascot Laboratories (Ireland) Limited	PA23163/002/001	Tablet	- N07BC - N07BC02	- Methadone hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution	Taw Pharma (Ireland) Limited	PA23081/011/001	Oral solution	- N07BC - N07BC02	- Methadone hydrochloride		- Oral use
Methadone Mixture DTF (Sugar Free) 1 mg in 1 ml Oral Solution	Ethypharm	PA0549/032/001	Oral solution	- N07BC - N07BC02	- Methadone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Methocarbamol 750 mg film-coated tablets	HBS Healthcare	PA2238/001/001	Film-coated tablet	- M03BA - M03BA03	- Methocarbamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Methofill 10 mg solution for injection in pre-filled injector	Accord Healthcare Ireland Ltd.	PA2315/060/003	Solution for injection in pre-filled injector	- L01BA - L01BA01	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Methofill 12.5 mg solution for injection in pre-filled injector	Accord Healthcare Ireland Ltd.	PA2315/060/004	Solution for injection in pre-filled injector	- L01BA - L01BA01	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Methofill 15 mg solution for injection in pre-filled injector	Accord Healthcare Ireland Ltd.	PA2315/060/005	Solution for injection in pre-filled injector	- L01BA - L01BA01	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Methofill 17.5 mg solution for injection in pre-filled injector	Accord Healthcare Ireland Ltd.	PA2315/060/006	Solution for injection in pre-filled injector	- L01BA - L01BA01	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Methofill 20 mg solution for injection in pre-filled injector	Accord Healthcare Ireland Ltd.	PA2315/060/007	Solution for injection in pre-filled injector	- L01BA - L01BA01	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Methofill 22.5 mg solution for injection in pre-filled injector	Accord Healthcare Ireland Ltd.	PA2315/060/008	Solution for injection in pre-filled injector	- L01BA - L01BA01	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Methofill 25 mg solution for injection in pre-filled injector	Accord Healthcare Ireland Ltd.	PA2315/060/009	Solution for injection in pre-filled injector	- L01BA - L01BA01	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Methofill 27.5 mg solution for injection in pre-filled injector	Accord Healthcare Ireland Ltd.	PA2315/060/010	Solution for injection in pre-filled injector	- L01BA - L01BA01	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Methofill 30 mg solution for injection in pre-filled injector	Accord Healthcare Ireland Ltd.	PA2315/060/011	Solution for injection in pre-filled injector	- L01BA - L01BA01	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Methofill 50 mg/mL solution for injection in pre-filled syringe	Accord Healthcare Ireland Ltd.	PA2315/060/001	Solution for injection in pre-filled syringe	- L04AX - L04AX03	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
Methofill 7.5 mg solution for injection in pre-filled injector	Accord Healthcare Ireland Ltd.	PA2315/060/002	Solution for injection in pre-filled injector	- L01BA - L01BA01	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Methotrexate 1 g/10 ml Injection	Pfizer Healthcare Ireland	PA0822/206/006	Solution for injection	- L01BA - L01BA01	- Methotrexate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Methotrexate 10 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/062/002 Interchangeable List Code: IC0098-002-002	Tablet		- Methotrexate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Methotrexate 10 mg tablets	Morningside Healthcare (Malta) Limited	PA23142/005/001 Interchangeable List Code: IC0098-002-002	Tablet		- Methotrexate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Methotrexate 100 mg/ml concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/061/002	Concentrate for solution for infusion	- L01BA - L01BA01	- Methotrexate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Methotrexate 2.5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/062/001 Interchangeable List Code: IC0098-018-002	Tablet		- Methotrexate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Methotrexate 2.5 mg Tablets	Amdipharm Limited	PA1142/030/001 Interchangeable List Code: IC0098-018-002	Tablet		- Methotrexate		- Oral use
Methotrexate 2.5mg tablets	Morningside Healthcare (Malta) Limited	PA23142/005/002 Interchangeable List Code: IC0098-018-002	Tablet		- Methotrexate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Methotrexate 25mg/ml Solution for Injection	Accord Healthcare Ireland Ltd.	PA2315/061/001	Solution for injection	- L01BA - L01BA01	- Methotrexate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intraarterial use - Intramuscular use - Intrathecal use - Intravenous use
Methotrexate 5 g/50 ml Injection	Pfizer Healthcare Ireland	PA0822/206/007	Solution for injection	- L01BA - L01BA01	- Methotrexate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Methotrexate 5 mg/2 ml Injection	Pfizer Healthcare Ireland	PA0822/206/001	Solution for injection	- L01BA - L01BA01	- Methotrexate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Methotrexate 500 mg/20 ml Injection	Pfizer Healthcare Ireland	PA0822/206/003	Solution for injection	- L01BA - L01BA01	- Methotrexate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Methotrexate 50mg/2ml Injection	Pfizer Healthcare Ireland	PA0822/206/002	Solution for injection	- L01BA - L01BA01	- Methotrexate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Methotrexate Orion 10 mg tablets	Orion Corporation	PA1327/019/002 Interchangeable List Code: IC0098-002-002	Tablet		- Methotrexate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Methotrexate Orion 2.5 mg tablets	Orion Corporation	PA1327/019/001 Interchangeable List Code: IC0098-018-002	Tablet		- Methotrexate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Methoxyflurane 99.9%, 3 ml inhalation vapour, liquid	Medical Developments MD&P Limited	PA22745/003/001	Inhalation vapour, liquid	- N02BG09	- Methoxyflurane	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Methoxyflurane Medical Developments MD&P 99.9%, 3 ml inhalation vapour, liquid	Medical Developments MD&P Limited	PA22745/002/001	Inhalation vapour, liquid	- N02BG09	- Methoxyflurane	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Methylthioninium Chloride Proveblue	Provepharm SAS	EU/1/11/682/001	Solution for injection	- V03AB - V03AB17	- Methylthioninium chloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Metoclopramide 5mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/084/001	Solution for injection	- A03FA - A03FA01	- Metoclopramide hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Metoclopramide hydrochloride 10 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/204/001	Tablet	- A03FA - A03FA01	- Metoclopramide hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Metocor 100 mg Tablets	Rowex Ltd	PA0711/008/002	Tablet	- C07AB - C07AB02	- METOPROLOL TARTRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metocor 50 mg Tablets	Rowex Ltd	PA0711/008/001	Tablet	- C07AB - C07AB02	- METOPROLOL TARTRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Metoject 10 mg solution for injection in pre-filled pen	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/014/003	Solution for injection in pre-filled pen	- L01BA - L01BA01	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Metoject 10 mg solution for injection in pre-filled pen	IMED Healthcare Ltd.	PPA1463/172/002	Solution for injection in pre-filled pen	- L01BA - L01BA01	- Methotrexate		- Subcutaneous use
Metoject 10 mg solution for injection in pre-filled pen	PCO Manufacturing Ltd.	PPA0465/436/002	Solution for injection in pre-filled pen	- L01BA - L01BA01	- Methotrexate	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Subcutaneous use
Metoject 15 mg solution for injection in pre-filled pen	PCO Manufacturing Ltd.	PPA0465/436/003	Solution for injection in pre-filled pen	- L01BA - L01BA01	- Methotrexate	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Subcutaneous use
Metoject 15 mg solution for injection in pre-filled pen	IMED Healthcare Ltd.	PPA1463/172/003	Solution for injection in pre-filled pen	- L01BA - L01BA01	- Methotrexate		- Subcutaneous use
Metoject 15 mg solution for injection in pre-filled pen	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/014/004	Solution for injection in pre-filled pen	- L01BA - L01BA01	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Metoject 20 mg solution for injection in pre-filled pen	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/014/005	Solution for injection in pre-filled pen	- L01BA - L01BA01	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Metoject 20 mg solution for injection in pre-filled pen	IMED Healthcare Ltd.	PPA1463/172/004	Solution for injection in pre-filled pen	- L01BA - L01BA01	- Methotrexate		- Subcutaneous use
Metoject 20 mg solution for injection in pre-filled pen	PCO Manufacturing Ltd.	PPA0465/436/004	Solution for injection in pre-filled pen	- L01BA - L01BA01	- Methotrexate	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Subcutaneous use
Metoject 25 mg solution for injection in pre-filled pen	PCO Manufacturing Ltd.	PPA0465/436/005	Solution for injection in pre-filled pen	- L01BA - L01BA01	- Methotrexate	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Subcutaneous use
Metoject 25 mg solution for injection in pre-filled pen	IMED Healthcare Ltd.	PPA1463/172/005	Solution for injection in pre-filled pen	- L01BA - L01BA01	- Methotrexate		- Subcutaneous use
Metoject 25 mg solution for injection in pre-filled pen	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/014/006	Solution for injection in pre-filled pen	- L01BA - L01BA01	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Metoject 50 mg/ml Solution for Injection, pre-filled syringe	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/014/001	Solution for injection in pre-filled syringe	- L04AX - L04AX03	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
Metoject 50 mg/ml Solution for Injection, pre-filled syringe	PCO Manufacturing Ltd.	PPA0465/436/001	Solution for injection in pre-filled syringe	- L04AX03	- Methotrexate		- Subcutaneous use
Metoject 7.5 mg solution for injection in pre-filled pen	IMED Healthcare Ltd.	PPA1463/172/001	Solution for injection in pre-filled pen	- L01BA - L01BA01	- Methotrexate		- Subcutaneous use
Metoject 7.5 mg solution for injection in pre-filled pen	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/014/002	Solution for injection in pre-filled pen	- L01BA - L01BA01	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Metopirone 250mg Soft capsules	HRA Pharma Rare Diseases	PA22888/001/001	Capsule, soft	- V04CD - V04CD01	- Metyrapone		- Oral use
Metronidazole 5 mg/ml solution for infusion	B. Braun Melsungen AG	PA0736/002/001	Solution for infusion	- J01XD - J01XD01	- Metronidazole		- Intravenous use
Metvix 160 mg/g cream	Galderma International	PA22743/010/001	Cream	- L01XD - L01XD03	- METHYL AMINOLEVULINATE HYDROCHLORIDE		- Topical use
Mevlyq	Yes Pharmaceutical Development Services GmbH	EU/1/23/1789/001	Solution for injection	- L01XX41	- Eribulin mesylate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Mezavant XL 1200 mg gastro-resistant, prolonged release tablets	IMED Healthcare Ltd.	PPA1463/093/001	Prolonged-release tablet	- A07EC - A07EC02	- Mesalazine		- Oral use
Mezavant XL 1200 mg gastro-resistant, prolonged release tablets	Originalis B.V.	PPA2306/023/001	Prolonged-release tablet	- A07EC - A07EC02	- Mesalazine		- Oral use
Mezavant XL 1200 mg gastro-resistant, prolonged release tablets	PCO Manufacturing Ltd.	PPA0465/289/001	Prolonged-release tablet	- A07EC - A07EC02	- Mesalazine	ZZZ PPA	- Oral use
Mezavant XL 1200 mg gastro-resistant, prolonged release tablets	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/004/001	Prolonged-release tablet	- A07EC - A07EC02	- Mesalazine		- Oral use
Miacalcic 100 IU/ml solution for injection and infusion	Essential Pharma (M) Limited	PA22644/004/001	Solution for injection/infusion	- H05BA - H05BA01	- Calcitonin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
Miacalcic 50 IU/ml solution for injection and infusion	Essential Pharma (M) Limited	PA22644/004/002	Solution for injection/infusion	- H05BA - H05BA01	- Calcitonin		- Intramuscular use - Intravenous use - Subcutaneous use
MIBG (123I) 74 MBq/mL solution for injection	Curium Netherlands B.V.	PA0690/005/001	Solution for injection	- V09IX - V09IX01	- Iobenguane	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Micardis 20 mg tablets	Boehringer Ingelheim International GmbH	EU/1/98/090/009-012 Interchangeable List Code: IC0049-003-014	Tablet		- Telmisartan		- Oral use
Micardis 40 mg tablets	Boehringer Ingelheim International GmbH	EU/1/98/090/001-004 Interchangeable List Code: IC0049-004-014	Tablet		- Telmisartan		- Oral use
Micardis 80 mg tablets	Boehringer Ingelheim International GmbH	EU/1/98/090/005-008 Interchangeable List Code: IC0049-005-014	Tablet		- Telmisartan		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
MicardisPlus 40 mg/12.5 mg tablets	Boehringer Ingelheim International GmbH	EU/1/02/213/001-005 Interchangeable List Code: IC0050-099-039	Tablet		- Telmisartan - Hydrochlorothiazide		- Oral use
MicardisPlus 80 mg/12.5 mg tablets	Boehringer Ingelheim International GmbH	EU/1/02/213/006-010 Interchangeable List Code: IC0050-081-039	Tablet		- Telmisartan - Hydrochlorothiazide		- Oral use
MicardisPlus 80 mg/25 mg tablets	Boehringer Ingelheim International GmbH	EU/1/02/213/17-23 Interchangeable List Code: IC0050-100-039	Tablet		- Telmisartan - Hydrochlorothiazide		- Oral use
Micolette Micro-Enema Rectal Solution	Pinewood Laboratories Ltd	PA0281/115/001	Rectal solution	- A06AG	- Sodium citrate - Sodium lauryl sulphoacetate - Glycerol		- Rectal use
Microlax Rectal Solution Sodium Citrate 450mg/5ml Sodium Lauryl Sulphoacetate 45mg/5ml	JNTL Consumer Health I (Ireland) Limited	PA23490/017/001	Rectal solution	- A06AG - A06AG11	- Sodium citrate - Sodium lauryl sulfoacetate		- Rectal use
Microlite 100/20 microgram Tablets	Bayer Limited	PA1410/007/001	Tablet	- G03AA - G03AA07	- Ethinylestradiol - Levonorgestrel	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Midazolam 1 mg/ml Solution for Injection or Infusion	Accord Healthcare Ireland Ltd.	PA2315/063/001	Solution for injection/infusion	- N05CD - N05CD08	- Midazolam	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Midazolam 1 mg/ml solution for injection/infusion	AS Kalceks	PA2165/012/002	Solution for injection/infusion	- N05CD08	- Midazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Rectal use
Midazolam 1 mg/ml solution for injection/infusion in pre-filled syringe	Accord Healthcare Ireland Ltd.	PA2315/220/001	Solution for injection/infusion in pre-filled syringe	- N05CD08	- Midazolam	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Rectal use
Midazolam 2 mg/ml Solution for injection or infusion	Accord Healthcare Ireland Ltd.	PA2315/063/005	Solution for injection/infusion	- N05CD - N05CD08	- Midazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Midazolam 5 mg/ml Solution for injection or infusion	Accord Healthcare Ireland Ltd.	PA2315/063/006	Solution for injection/infusion	- N05CD - N05CD08	- Midazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Midazolam 5 mg/ml Solution for Injection or Infusion	Accord Healthcare Ireland Ltd.	PA2315/063/002	Solution for injection/infusion	- N05CD - N05CD08	- Midazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Midazolam 5 mg/ml solution for injection/infusion	AS Kalceks	PA2165/012/001	Solution for injection/infusion	- N05CD08	- Midazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Rectal use
Midazolam Rowa 10 mg oromucosal solution	Rowa Pharmaceuticals Limited	PA0074/099/004	Oromucosal solution	- N05CD08	- Midazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use
Midazolam Rowa 2.5 mg oromucosal solution	Rowa Pharmaceuticals Limited	PA0074/099/001	Oromucosal solution	- N05CD08	- Midazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use
Midazolam Rowa 5 mg oromucosal solution	Rowa Pharmaceuticals Limited	PA0074/099/002	Oromucosal solution	- N05CD08	- Midazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use
Midazolam Rowa 7.5 mg oromucosal solution	Rowa Pharmaceuticals Limited	PA0074/099/003	Oromucosal solution	- N05CD08	- Midazolam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Midodrine Hydrochloride 2.5 mg tablets	Milstein C.V.	PA23215/001/001 Interchangeable List Code: IC0120-018-002	Tablet		- Midodrine hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Midodrine Hydrochloride 5 mg tablets	Milstein C.V.	PA23215/001/002 Interchangeable List Code: IC0120-001-002	Tablet		- Midodrine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Midodrine Hydrochloride Morningside 2.5 mg tablets	Morningside Healthcare (Malta) Limited	PA23142/008/001 Interchangeable List Code: IC0120-018-002	Tablet		- Midodrine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Midodrine Hydrochloride Morningside 5 mg tablets	Morningside Healthcare (Malta) Limited	PA23142/008/002 Interchangeable List Code: IC0120-001-002	Tablet		- Midodrine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Midodrine Tillomed 2.5 mg tablets	Tillomed Pharma GmbH	PA23169/002/001 Interchangeable List Code: IC0120-018-002	Tablet		- Midodrine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Midodrine Tillomed 5 mg tablets	Tillomed Pharma GmbH	PA23169/002/002 Interchangeable List Code: IC0120-001-002	Tablet		- Midodrine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Midon 2.5 mg tablets	PCO Manufacturing Ltd.	PPA0465/276/001 Interchangeable List Code: IC0120-018-002	Tablet		- Midodrine hydrochloride		- Oral use
Midon 2.5 mg Tablets	Originalis B.V.	PPA2306/032/001	Tablet	- C01CA - C01CA17	- Midodrine hydrochloride		- Oral use
Midon 2.5 mg tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/013/002 Interchangeable List Code: IC0120-018-002	Tablet		- Midodrine hydrochloride		- Oral use
Midon 2.5 mg tablets	Merit Pharmaceuticals Limited	PPA23080/024/001 Interchangeable List Code: IC0120-018-002	Tablet		- Midodrine hydrochloride		- Oral use
Midon 2.5 mg tablets	IMED Healthcare Ltd.	PPA1463/160/001 Interchangeable List Code: IC0120-018-002	Tablet		- Midodrine hydrochloride		- Oral use
Midon 2.5 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/016/001 Interchangeable List Code: IC0120-018-002	Tablet		- Midodrine hydrochloride		- Oral use
Midon 5 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/016/002 Interchangeable List Code: IC0120-001-002	Tablet		- Midodrine hydrochloride		- Oral use
Midon 5 mg tablets	IMED Healthcare Ltd.	PPA1463/160/002 Interchangeable List Code: IC0120-001-002	Tablet		- Midodrine hydrochloride		- Oral use
Midon 5 mg tablets	Merit Pharmaceuticals Limited	PPA23080/024/002 Interchangeable List Code: IC0120-001-002	Tablet		- Midodrine hydrochloride		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Midon 5 mg tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/013/001 Interchangeable List Code: IC0120-001-002	Tablet		- Midodrine hydrochloride		- Oral use
Midon 5 mg tablets	Originalis B.V.	PPA2306/029/001 Interchangeable List Code: IC0120-001-002	Tablet		- Midodrine hydrochloride	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Midon 5 mg Tablets	PCO Manufacturing Ltd.	PPA0465/276/002 Interchangeable List Code: IC0120-001-002	Tablet		- Midodrine hydrochloride		- Oral use
Mifegyne 200 mg tablets	EXELGYN	PA22946/001/001	Tablet	- G03XB01	- Mifepristone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mifegyne 600 mg tablets	EXELGYN	PA22946/001/002	Tablet	- G03XB01	- Mifepristone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Miglustat Dipharma	Dipharma B.V.	EU/1/18/1346/001	Capsule, hard	- A16AX - A16AX06	- Miglustat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Miglustat GenOrph	Gen.Orph	EU/1/17/1232/001	Capsule, hard	- A16AX - A16AX06	- Miglustat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Migraleve Film-coated Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/014/003	Film-coated tablet	- N02BE - N02BE51	- BUCLIZINE HYDROCHLORIDE - Paracetamol - Codeine phosphate hemihydrate		- Oral use
Migraleve Pink Film-coated Tablets Paracetamol 500mg Codeine Phosphate 8mg Buclizine Hydrochloride 6.25mg	JNTL Consumer Health I (Ireland) Limited	PA23490/014/001	Film-coated tablet	- N02BE - N02BE51	- Paracetamol - Codeine phosphate hemihydrate - BUCLIZINE HYDROCHLORIDE		- Oral use
Migraleve Yellow Film-coated Tablets Paracetamol 500mg Codeine phosphate 8mg	JNTL Consumer Health I (Ireland) Limited	PA23490/014/002	Film-coated tablet	- N02BE - N02BE51	- Paracetamol - Codeine phosphate hemihydrate		- Oral use
Migsun 85 mg/500 mg film-coated tablets	Orion Corporation	PA1327/022/001	Film-coated tablet	- N02CC	- Sumatriptan succinate - Naproxen sodium	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Milk of Magnesia Traditional Mint Flavoured Liquid, 415 mg/5 ml, oral suspension	Chefaro Ireland DAC	PA1186/010/001	Oral suspension	- A02AA - A02AA04	- Magnesium hydroxide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Milrinone 1 mg/ml Solution for Injection/Infusion	Pinewood Laboratories Ltd	PA0281/244/001	Solution for injection/infusion	- C01CE - C01CE02	- Milrinone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Mimpara	Amgen Europe B.V.	EU/1/04/292/013	Granules	- H05BX - H05BX01	- Cinacalcet hydrochloride	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mimpara	Amgen Europe B.V.	EU/1/04/292/014	Granules	- H05BX - H05BX01	- Cinacalcet hydrochloride	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mimpara	Amgen Europe B.V.	EU/1/04/292/015	Granules	- H05BX - H05BX01	- Cinacalcet hydrochloride	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Mimpara 30 mg film-coated tablets	Amgen Europe B.V.	EU/1/04/292/001-004 Interchangeable List Code: IC0134-033-003	Film-coated tablet		- Cinacalcet hydrochloride	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mimpara 60 mg film-coated tablets	Amgen Europe B.V.	EU/1/04/292/005-008 Interchangeable List Code: IC0134-127-003	Film-coated tablet		- Cinacalcet hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mimpara 90 mg film-coated tablets	Amgen Europe B.V.	EU/1/04/292/009-012 Interchangeable List Code: IC0134-166-003	Film-coated tablet		- Cinacalcet hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
MINESSE 60 micrograms/15 micrograms film-coated tablet	Pfizer Healthcare Ireland	PA0822/144/001	Film-coated tablet	- G03AA - G03AA10	- Gestodene - Ethinylestradiol		- Oral use
Minims Artificial Tears 0.35% w/w + 0.44% w/w Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/013/001	Eye drops, solution	- S01AX - S01AX07	- Sodium chloride - Hydroxyethylcellulose	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical
Minims Atropine Sulphate 1% Eye Drops, solution	Bausch + Lomb Ireland Limited	PA23259/007/001	Eye drops, solution	- S01FA - S01FA01	- Atropine sulfate		- Ocular use
Minims Chloramphenicol 0.5% Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/010/001	Eye drops, solution	- S01AA - S01AA01	- Chloramphenicol		- Ocular use
Minims Cyclopentolate Hydrochloride 1% w/v Eye Drops, solution	Bausch + Lomb Ireland Limited	PA23259/011/001	Eye drops, solution	- S01FA - S01FA04	- Cyclopentolate hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Minims Fluorescein Sodium 1%, w/v Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/012/001	Eye drops, solution	- S01JA - S01JA01	- Fluorescein sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Minims Fluorescein Sodium 2%, w/v Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/012/002	Eye drops, solution	- S01JA - S01JA01	- Fluorescein sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Minims Lidocaine Hydrochloride 4% w/v & Fluorescein Sodium 0.25% w/v Eye Drops, solution	Bausch + Lomb Ireland Limited	PA23259/014/001	Eye drops, solution	- S01JA - S01JA51	- Fluorescein sodium - Lidocaine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Minims Oxybuprocaine Hydrochloride 0.4% w/v Eye Drops Solution	Bausch + Lomb Ireland Limited	PA23259/015/001	Eye drops, solution	- S01HA - S01HA02	- Oxybuprocaine hydrochloride		- Ocular use
Minims Phenylephrine Hydrochloride 2.5% w/v eye drops, solution	Bausch + Lomb Ireland Limited	PA23259/016/001	Eye drops, solution	- S01GA - S01GA05	- Phenylephrine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Minims Pilocarpine Nitrate 2% w/v, Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/017/001	Eye drops, solution	- S01EB - S01EB01	- Pilocarpine nitrate		- Ocular use
Minims Povidone Iodine 5% w/v Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/018/001	Eye drops, solution	- S01AX - S01AX18	- Iodinated povidone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Minims Prednisolone Sodium Phosphate 0.5% w/v Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/019/001	Eye drops, solution	- S01BA - S01BA04	- Prednisolone sodium phosphate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Minims Proxymetacaine hydrochloride 0.5% w/v, Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/020/001	Eye drops, solution	- S01HA - S01HA04	- PROXYMETACAINE HYDROCHLORIDE		- Ocular use
Minims Saline 0.9% w/v Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/021/001	Eye drops, solution	- S01AX - S01AX03	- Sodium chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use - Topical use
Minims Tetracaine Hydrochloride 0.5% w/v Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/022/001	Eye drops, solution	- S01HA - S01HA03	- Tetracaine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Minims Tetracaine Hydrochloride 1% w/v Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/022/002	Eye drops, solution	- S01HA - S01HA03	- Tetracaine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Minims Tropicamide 0.5 % w/v Eye drops, solution	Bausch + Lomb Ireland Limited	PA23259/023/001	Eye drops, solution	- S01FA - S01FA06	- Tropicamide		- Ocular use
Minims Tropicamide 1% w/v Eye drops, solution	Bausch + Lomb Ireland Limited	PA23259/023/002	Eye drops, solution	- S01FA - S01FA06	- Tropicamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Minjuvi	MorphoSys AG	EU/1/21/1570/001	Powder for concentrate for solution for infusion	- L01XC - L01XC35	- Tafasitamab	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Minocin SA 100 mg Modified Release Capsules	Mylan IRE Healthcare Limited	PA2010/060/001	Modified-release capsule, hard	- J01AA - J01AA08	- Minocycline hydrochloride		- Oral use
Minosil 100mg Modified-release Capsules	Pinewood Laboratories Ltd	PA0281/132/001	Modified-release capsule, hard	- J01AA - J01AA08	- Minocycline hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Minoxidil for men 5% w/v cutaneous solution	Careforsons Ireland Limited	PA22753/001/001	Cutaneous solution	- D11AX01	- Minoxidil	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Cutaneous use
Minulet 75 micrograms/30 micrograms coated tablets	Pfizer Healthcare Ireland	PA0822/093/001	Coated tablet	- G03AA - G03AA10	- Ethinyloestradiol - Gestodene	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Miochol®-E, 20mg, Powder and Solvent for instillation solution for intraocular use	Dr. Gerhard Mann, chem.-pharm. Fabrik GmbH	PA1245/002/001	Powder and solvent for intraocular instillation solution	- S01EB - S01EB09	- Acetylcholine chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Miofen 200mg Film-coated Tablet	Alter Pharma	PA22983/001/001	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Miofen 400mg Film-coated Tablet	Alter Pharma	PA22983/001/002	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Miofen 600mg Film-coated Tablet	Alter Pharma	PA22983/001/003	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Miramel 0.088 mg tablets	Clonmel Healthcare Ltd	PA0126/173/001	Tablet	- N04BC - N04BC05	- Pramipexole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Miramel 0.18 mg tablets	Clonmel Healthcare Ltd	PA0126/173/002	Tablet	- N04BC - N04BC05	- Pramipexole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Miramel 0.7 mg tablets	Clonmel Healthcare Ltd	PA0126/173/003	Tablet	- N04BC - N04BC05	- Pramipexole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Mirap 15 mg Film-Coated Tablets	Rowex Ltd	PA0711/062/001 Interchangeable List Code: IC0061-032-015	Film-coated tablet		- Mirtazapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mirap 30 mg Film-Coated Tablets	Rowex Ltd	PA0711/062/002 Interchangeable List Code: IC0061-033-015	Film-coated tablet		- Mirtazapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mirap 45 mg Film-Coated Tablets	Rowex Ltd	PA0711/062/003 Interchangeable List Code: IC0061-110-015	Film-coated tablet		- Mirtazapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mirap DisTab 15 mg Orodispersible Tablets	Rowex Ltd	PA0711/094/001 Interchangeable List Code: IC0061-032-015	Orodispersible tablet		- Mirtazapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mirap DisTab 30 mg Orodispersible Tablets	Rowex Ltd	PA0711/094/002 Interchangeable List Code: IC0061-033-015	Orodispersible tablet		- Mirtazapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mirap DisTab 45 mg Orodispersible Tablets	Rowex Ltd	PA0711/094/003 Interchangeable List Code: IC0061-110-015	Orodispersible tablet		- Mirtazapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/001	Tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate	New active substance (Article 8(3) of Directive No 2001/83/EC)	
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/003	Tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate	New active substance (Article 8(3) of Directive No 2001/83/EC)	
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/005	Tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate	New active substance (Article 8(3) of Directive No 2001/83/EC)	
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/011	Tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/028-30	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate, milled		- Oral use
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/031-33	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate, milled		- Oral use
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/13-15	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate, milled		- Oral use
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/16-18	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate, milled		- Oral use
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/19-21	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate, milled		- Oral use
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/22-24	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate, milled		- Oral use
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/25-27	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate, milled		- Oral use
Mircera	Roche Registration GmbH	EU/1/07/400/008	Solution for injection in pre-filled syringe	- B03XA03	- Methoxy peg-epoetin beta	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Mircera	Roche Registration GmbH	EU/1/07/400/009	Solution for injection in pre-filled syringe	- B03XA03	- Methoxy peg-epoetin beta	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Mircera	Roche Registration GmbH	EU/1/07/400/10	Solution for injection in pre-filled syringe	- B03XA03	- Methoxy peg-epoetin beta	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Mircera	Roche Registration GmbH	EU/1/07/400/11	Solution for injection in pre-filled syringe	- B03XA03	- Methoxy peg-epoetin beta	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Mircera	Roche Registration GmbH	EU/1/07/400/12	Solution for injection in pre-filled syringe	- B03XA03	- Methoxy peg-epoetin beta	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Mircera	Roche Registration GmbH	EU/1/07/400/13	Solution for injection in pre-filled syringe	- B03XA03	- Methoxy peg-epoetin beta	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Mircera	Roche Registration GmbH	EU/1/07/400/17	Solution for injection in pre-filled syringe	- B03XA03	- Methoxy peg-epoetin beta	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Mircera	Roche Registration GmbH	EU/1/07/400/18	Solution for injection in pre-filled syringe	- B03XA03	- Methoxy peg-epoetin beta	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Mircera	Roche Registration GmbH	EU/1/07/400/19	Solution for injection in pre-filled syringe	- B03XA03	- Methoxy peg-epoetin beta	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Mircera	Roche Registration GmbH	EU/1/07/400/20	Solution for injection in pre-filled syringe	- B03XA03	- Methoxy peg-epoetin beta	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Mircera	Roche Registration GmbH	EU/1/07/400/21	Solution for injection in pre-filled syringe	- B03XA03	- Methoxy peg-epoetin beta	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Mirena 52 mg Intrauterine Delivery System	PCO Manufacturing Ltd.	PPA0465/292/001	Intrauterine delivery system	- G02BA03	- Levonorgestrel		- Intrauterine use
Mirena 52 mg Intrauterine Delivery System	IMED Healthcare Ltd.	PPA1463/111/001	Intrauterine delivery system	- G02BA - G02BA03	- Levonorgestrel		- Intrauterine use
Mirena 52 mg intrauterine delivery system	Bayer Limited	PA1410/008/001	Intrauterine delivery system	- G02BA - G02BA03	- Levonorgestrel	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intrauterine use
Mirena 52 mg intrauterine delivery system	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/049/001	Intrauterine delivery system	- G02BA - G02BA03	- Levonorgestrel		- Intrauterine use
Mirpresoc 20 mg Tablets	Laboratorios LICONSA, S.A.	PA1239/017/001 Interchangeable List Code: IC0049-003-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mirpresoc 40 mg Tablets	Laboratorios LICONSA, S.A.	PA1239/017/002 Interchangeable List Code: IC0049-004-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mirpresoc 80 mg Tablets	Laboratorios LICONSA, S.A.	PA1239/017/003 Interchangeable List Code: IC0049-005-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mirtazapine 15 mg Film-Coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/072/001 Interchangeable List Code: IC0061-032-015	Film-coated tablet		- Mirtazapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mirtazapine 30 mg Film-Coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/072/002 Interchangeable List Code: IC0061-033-015	Film-coated tablet		- Mirtazapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Mirtazapine 45 mg Film-Coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/072/003 Interchangeable List Code: IC0061-110-015	Film-coated tablet		- Mirtazapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mirtazapine Bluefish 15 mg orodispersible tablets	Bluefish Pharmaceuticals AB	PA1436/001/001 Interchangeable List Code: IC0061-032-015	Orodispersible tablet		- Mirtazapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mirtazapine Bluefish 30 mg orodispersible tablets	Bluefish Pharmaceuticals AB	PA1436/001/002 Interchangeable List Code: IC0061-033-015	Orodispersible tablet		- Mirtazapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mirtazapine Bluefish 45 mg orodispersible tablets	Bluefish Pharmaceuticals AB	PA1436/001/003 Interchangeable List Code: IC0061-110-015	Orodispersible tablet		- Mirtazapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mirvaso	Galderma International S.A.S.	EU/1/13/904/001-003	Gel	- D11AX	- Brimonidine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
MisoOne 400 microgram tablets	EXELGYN	PA22946/002/001	Tablet	- G02AD06	- Misoprostol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mistra 2mg/0.03mg Film-Coated Tablets	Gedeon Richter Plc	PA1330/018/001	Film-coated tablet	- G03AA - G03AA16	- Dienogest - Ethinylestradiol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mitomycin medac 40 mg powder and solvent for intravesical solution	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/016/002	Powder and solvent for intravesical solution	- L01DC - L01DC03	- Mitomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravesical use
Mitoxana 1 g Powder for Sterile Concentrate	Baxter Holding B.V.	PA2299/028/001	Powder for concentrate for solution for infusion	- L01AA - L01AA06	- Ifosfamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Mitoxana 2 g Powder for Sterile Concentrate	Baxter Holding B.V.	PA2299/028/002	Powder for concentrate for solution for infusion	- L01AA - L01AA06	- Ifosfamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Mivacron 2mg/ml Solution for Injection	Aspen Pharma Trading Limited	PA1691/031/001	Solution for injection	- M03AC - M03AC10	- Mivacurium chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Mixtard	Novo Nordisk A/S	EU/1/02/231/003-35,37	Suspension for injection	- A10AD - A10AD01	- Insulin human - Insulin human		- Subcutaneous use
Mixtard	Novo Nordisk A/S	EU/1/02/231/1-25	Suspension for injection	- A10AD - A10AD01	- Insulin human		
M-M-RVAXPRO	Merck Sharp & Dohme BV,	EU/1/06/337/1-13	Powder and solvent for suspension for injection	- J07BD - J07BD52	- Mumps virus live attenuated jeryl lynn strain - Rubella virus (wistar ra 27/3 strain) live attenuated - Measles virus live attenuated derived from the edmonston b strain	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Modafinil Bluefish 100 mg tablets	Bluefish Pharmaceuticals AB	PA1436/031/001 Interchangeable List Code: IC0138-024-002	Tablet		- Modafinil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Modafinil Bluefish 200 mg tablets	Bluefish Pharmaceuticals AB	PA1436/031/002 Interchangeable List Code: IC0138-067-002	Tablet		- Modafinil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Modigraf	Astellas Pharma Europe BV	EU/1/09/523/001	Granules for oral suspension	- L04AD - L04AD02	- Tacrolimus	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Modigraf	Astellas Pharma Europe BV	EU/1/09/523/002	Granules for oral suspension	- L04AD - L04AD02	- Tacrolimus	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Modrasone Cream 0.05% w/w	Morningside Healthcare (Malta) Limited	PA23142/011/001	Cream	- D07AB - D07AB10	- Alclometasone dipropionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Modrasone Ointment 0.05% w/w	Morningside Healthcare (Malta) Limited	PA23142/011/002	Ointment	- D07AB - D07AB10	- Alclometasone dipropionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Mogadon 5 mg Tablets	Mylan IRE Healthcare Limited	PA2010/024/001	Tablet	- N05CD - N05CD02	- Nitrazepam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Molaxole powder for oral solution	Viatris Healthcare Limited	PA23355/007/001	Powder for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium chloride - Sodium hydrogen carbonate - Potassium chloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Molipaxin 100mg Capsules	Neuraxpharm Ireland Limited	PA23229/011/002	Capsule, hard	- N06AX - N06AX05	- Trazodone hydrochloride	Competence of personnel (Article 23 of Directive No 2010/63/EU)	- Oral use
Molipaxin 150mg Film-coated Tablets	Neuraxpharm Ireland Limited	PA23229/011/003	Film-coated tablet	- N06AX - N06AX05	- Trazodone hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Molipaxin 50mg Capsules	Neuraxpharm Ireland Limited	PA23229/011/001	Capsule, hard	- N06AX - N06AX05	- Trazodone hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Mometasone 50 microgram/dose, Nasal spray, Suspension	Rowex Ltd	PA0711/196/001	Nasal spray, suspension	- R01AD - R01AD09	- Mometasone furoate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Nasal use
Monadia 50mcg/actuation Nasal spray, suspension	Diapharm GmbH & Co. KG	PA1958/008/001	Nasal spray, suspension	- R01AD09	- Mometasone furoate monohydrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Nasal use
Monopost Unidose 50 micrograms/ml eye drops, solution in single-dose container	Laboratoires Thea	PA1107/007/001 Interchangeable List Code: IC0096-152-059	Eye drops, solution in single-dose container		- Latanoprost	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Monopost Unidose 50 micrograms/ml eye drops, solution in single-dose container	IMED Healthcare Ltd.	PPA1463/153/001 Interchangeable List Code: IC0096-152-059	Eye drops, solution in single-dose container		- Latanoprost		- Ocular use
Monopost Unidose 50 micrograms/ml eye drops, solution in single-dose container	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/029/001 Interchangeable List Code: IC0096-152-059	Eye drops, solution in single-dose container		- Latanoprost		- Ocular use
Monopost Unidose 50 micrograms/ml eye drops, solution in single-dose container	PCO Manufacturing Ltd.	PPA0465/449/001 Interchangeable List Code: IC0096-152-059	Eye drops, solution in single-dose container		- Latanoprost		- Ocular use
Monotrim 10 mg/ml Oral Suspension	Taw Pharma (Ireland) Ltd	PA23081/014/001	Oral suspension	- J01EA - J01EA01	- Trimethoprim		- Oral use
Monotrim 100 mg Tablets	Chemidex Pharma Limited	PA22643/002/002	Tablet	- J01EA - J01EA01	- Trimethoprim		- Oral use
Monotrim 200 mg Tablets	Chemidex Pharma Limited	PA22643/002/003	Tablet	- J01EA - J01EA01	- Trimethoprim		- Oral use
Monover 100 mg/ml solution for injection/infusion (ampoules)	Pharmacosmos A/S	PA0982/002/001	Solution for injection/infusion	- B03AC	- Iron	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Monover 100 mg/ml solution for injection/infusion (vials)	Pharmacosmos A/S	PA0982/002/002	Solution for injection/infusion	- B03AC	- Iron		- Intravenous use
Monovo 1mg/g Cream	Almirall Hermal GmbH	PA1548/002/001	Cream	- D07AC - D07AC13	- Mometasone furoate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Montelair 10 mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/215/003 Interchangeable List Code: IC0023-002-003	Film-coated tablet		- Montelukast	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelair 4 mg Chewable Tablets	Clonmel Healthcare Ltd	PA0126/215/001 Interchangeable List Code: IC0023-008-007	Chewable tablet		- Montelukast	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelair 5 mg Chewable Tablets	Clonmel Healthcare Ltd	PA0126/215/002 Interchangeable List Code: IC0023-001-007	Chewable tablet		- Montelukast	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
MONTELUKAST 10 mg Film-Coated Tablets	Aurobindo Pharma (Malta) Limited	PA1445/015/001 Interchangeable List Code: IC0023-002-003	Film-coated tablet		- Montelukast sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelukast 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/039/003 Interchangeable List Code: IC0023-002-003	Film-coated tablet		- Montelukast	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelukast 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/110/003 Interchangeable List Code: IC0023-002-003	Film-coated tablet		- Montelukast	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelukast 4 mg chewable tablets	KRKA, d.d., Novo mesto	PA1347/039/001 Interchangeable List Code: IC0023-008-007	Chewable tablet		- Montelukast	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelukast 5 mg chewable tablets	KRKA, d.d., Novo mesto	PA1347/039/002 Interchangeable List Code: IC0023-001-007	Chewable tablet		- Montelukast	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelukast Bluefish 10 mg Film-coated Tablets	Bluefish Pharmaceuticals AB	PA1436/032/001 Interchangeable List Code: IC0023-002-003	Film-coated tablet		- Montelukast sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelukast Bluefish 4 mg chewable tablets	Bluefish Pharmaceuticals AB	PA1436/033/001 Interchangeable List Code: IC0023-008-007	Chewable tablet		- Montelukast sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelukast Bluefish 5 mg chewable tablets	Bluefish Pharmaceuticals AB	PA1436/033/002 Interchangeable List Code: IC0023-001-007	Chewable tablet		- Montelukast sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelukast Mylan 10 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/119/001 Interchangeable List Code: IC0023-002-003	Film-coated tablet		- Montelukast	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelukast Mylan 4 mg Chewable Tablet	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/131/001 Interchangeable List Code: IC0023-008-007	Chewable tablet		- Montelukast	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Montelukast Mylan 5 mg Chewable Tablet	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/131/002 Interchangeable List Code: IC0023-001-007	Chewable tablet		- Montelukast	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelukast Paediatric 4mg Chewable Tablets	Accord Healthcare Ireland Ltd.	PA2315/110/001 Interchangeable List Code: IC0023-008-007	Chewable tablet		- Montelukast sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
MONTELUKAST Paediatric 5 mg Chewable Tablets	Aurobindo Pharma (Malta) Limited	PA1445/015/003 Interchangeable List Code: IC0023-001-007	Chewable tablet		- Montelukast	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelukast Paediatric 5mg Chewable Tablets	Accord Healthcare Ireland Ltd.	PA2315/110/002 Interchangeable List Code: IC0023-001-007	Chewable tablet		- Montelukast	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelukast Teva 10 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/048/003 Interchangeable List Code: IC0023-002-003	Film-coated tablet		- Montelukast	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelukast Teva 4 mg Chewable Tablet	Teva Pharma B.V.	PA0749/048/001 Interchangeable List Code: IC0023-008-007	Chewable tablet		- Montelukast	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelukast Teva 4 mg GranulesFor children from 6 months to 5 years of age	Teva Pharma B.V.	PA0749/048/004 Interchangeable List Code: IC0023-008-041	Granules		- Montelukast sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Montelukast Teva 5 mg Chewable Tablet	Teva Pharma B.V.	PA0749/048/002 Interchangeable List Code: IC0023-001-007	Chewable tablet		- Montelukast	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Monuril 3 g granules for oral solution	Zambon S.p.A.	PA1441/002/002	Granules for oral solution	- J01XX - J01XX01	- Fosfomycin trometamol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Monuril 3 g granules for oral solution	PCO Manufacturing Ltd.	PPA0465/485/001	Granules for oral solution	- J01XX - J01XX01	- FOSFOMYCIN TROMETAMOL		- Oral use
Monuril 3 g granules for oral solution	IMED Healthcare Ltd.	PPA1463/213/001	Granules for oral solution	- J01XX01	- Fosfomycin	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Monuril 3 g granules for oral solution	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/044/001	Granules for oral solution	- J01XX - J01XX01	- Fosfomycin		- Oral use
Morphine sulfate 10mg/ml Solution for Injection	AS Kalceks	PA2165/003/001	Solution for injection	- N02AA01	- Morphine sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
Morphine Sulfate 10mg/ml Solution for injection	Ethypharm	PA0549/023/001	Solution for injection	- N02AA - N02AA01	- Morphine sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
Morphine sulfate 15mg/ml Solution for Injection	AS Kalceks	PA2165/003/002	Solution for injection	- N02AA01	- Morphine sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
Morphine sulfate 30mg/ml Solution for Injection	AS Kalceks	PA2165/003/003	Solution for injection	- N02AA01	- Morphine sulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
Morphine Sulfate 30mg/ml, Solution for injection	Ethypharm	PA0549/023/002	Solution for injection	- N02AA - N02AA01	- Morphine sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Morphine Sulphate 10mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/020/001	Solution for injection	- N02AA - N02AA01	- Morphine sulfate		- Intramuscular use - Intravenous use - Subcutaneous use
Morphine Sulphate 1mg/5ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/020/003	Solution for injection	- N02AA - N02AA01	- Morphine sulfate		- Intrathecal use - Intravenous use
Morphine Sulphate 30 mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/020/004	Solution for injection	- N02AA - N02AA01	- Morphine sulfate		- Intramuscular use - Intravenous use - Subcutaneous use
Morphine Sulphate 60 mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/020/008	Solution for injection	- N02AA - N02AA01	- Morphine sulfate		- Intramuscular use - Intravenous use - Subcutaneous use
Morsadex 50 mg/2 ml solution for injection/infusion	AS Kalceks	PA2165/002/001	Solution for injection/infusion	- M01AE - M01AE17	- Dexketoprofen trometamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Motilium 10 mg Film-Coated Tablets	PCO Manufacturing Ltd.	PPA0465/272/002	Film-coated tablet	- A03FA - A03FA03	- Domperidone		- Oral use
Motilium 10mg Film-Coated Tablets	IMED Healthcare Ltd.	PPA1463/195/001	Film-coated tablet	- A03FA - A03FA03	- Domperidone	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Motilium 10mg Film-Coated Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/022/002	Film-coated tablet	- A03FA - A03FA03	- Domperidone		- Oral use
Motilium 1mg/ml Oral Suspension	JNTL Consumer Health I (Ireland) Limited	PA23490/039/001	Oral suspension	- A03FA - A03FA03	- Domperidone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Motilium Fastmelts 10mg Orodispersible Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/022/001	Orodispersible tablet	- A03FA - A03FA03	- Domperidone		- Oral use
Motilium Rx 10 mg Film-coated Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/039/002 Interchangeable List Code: IC0085-002-014	Film-coated tablet		- Domperidone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Motusol Max 2 % w/w gel	Teva B.V.	PA1986/093/002	Gel	- M02AA15	- Diclofenac sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Motusol Rx 1 % w/w gel	Teva B.V.	PA1986/093/001 Interchangeable List Code: IC0056-115-043	Gel		- Diclofenac sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Mounjaro	Eli Lilly Nederland B.V.	EU/1/22/1685/001-003	Solution for injection in pre-filled pen	- A10B	- Tirzepatide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Mounjaro	Eli Lilly Nederland B.V.	EU/1/22/1685/004-006	Solution for injection in pre-filled pen	- A10B	- Tirzepatide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Mounjaro	Eli Lilly Nederland B.V.	EU/1/22/1685/007-009	Solution for injection in pre-filled pen	- A10B	- Tirzepatide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Mounjaro	Eli Lilly Nederland B.V.	EU/1/22/1685/010-012	Solution for injection in pre-filled pen	- A10B	- Tirzepatide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Mounjaro	Eli Lilly Nederland B.V.	EU/1/22/1685/013-015	Solution for injection in pre-filled pen	- A10B	- Tirzepatide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Mounjaro	Eli Lilly Nederland B.V.	EU/1/22/1685/016-018	Solution for injection in pre-filled pen	- A10B	- Tirzepatide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Moventig	Kyowa Kirin Holdings B.V.	EU/1/14/962/001-003	Film-coated tablet	- A06AH03	- Naloxegol oxalate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Moventig	Kyowa Kirin Holdings B.V.	EU/1/14/962/004-007	Film-coated tablet	- A06AH03	- Naloxegol oxalate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Movicol Paediatric Chocolate Flavour 6.9 g sachet powder for oral solution	Norgine Healthcare B.V.	PA23265/001/002	Powder for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium bicarbonate - Sodium chloride - Potassium chloride		- Oral use
Movicol 13.8 g sachet powder for oral solution	Norgine Healthcare B.V.	PA23265/001/005	Powder for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium bicarbonate - Sodium chloride - Potassium chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Movicol 13.8g sachet, powder for oral solution	Novalus Healthcare Limited	PPA1925/002/001	Powder for oral solution	- A06AD65	- Macrogol 3350 - Sodium bicarbonate - Sodium chloride - Potassium chloride	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Movicol Chocolate 13.9 g sachet powder for oral solution	Norgine Healthcare B.V.	PA23265/001/001	Powder for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium bicarbonate - Sodium chloride - Potassium chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Movicol Liquid Orange Flavour, Concentrate for Oral Solution	Norgine Healthcare B.V.	PA23265/002/001	Concentrate for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium chloride - Sodium hydrogen carbonate - Potassium chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Movicol Paediatric Plain 6.9 g sachet powder for oral solution	Norgine Healthcare B.V.	PA23265/001/003	Powder for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium bicarbonate - Sodium chloride - Potassium chloride		- Oral use
Movicol Plain 13.7 g sachet powder for oral solution	Norgine Healthcare B.V.	PA23265/001/004	Powder for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium bicarbonate - Sodium chloride - Potassium chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Movicol Ready to Take 13.9 g/25 ml oral solution in sache	Norgine Healthcare B.V.	PA23265/002/002	Oral solution in sachet	- A06AD - A06AD65	- Macrogol 3350 - Sodium chloride - Sodium hydrogen carbonate - Potassium chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Moviprep Orange, powder for oral solution	Norgine B.V.	PA1336/001/002	Powder for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium sulfate anhydrous - Sodium chloride - Potassium chloride - Ascorbic acid - Sodium ascorbate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
MOVIPREP powder for oral solution	PCO Manufacturing Ltd.	PPA0465/428/001	Powder for oral solution	- A06AD - A06AD65	- Sodium ascorbate - Ascorbic acid - Potassium chloride - Sodium chloride - Sodium sulphate anhydrous - Macrogol 3350		- Oral use
Moviprep, powder for oral solution	Primecrown 2010 Limited	PPA1633/070/001	Powder for oral solution	- A06AD - A06AD65	- Potassium chloride - Ascorbic acid - Sodium sulfate anhydrous - Macrogol 3350 - Sodium chloride - Sodium ascorbate		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Moviprep, powder for oral solution	Norgine B.V.	PA1336/001/001	Powder for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium sulfate anhydrous - Sodium chloride - Potassium chloride - Ascorbic acid - Sodium ascorbate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
MOVIPREP, powder for oral solution	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/034/001	Powder for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium sulphate anhydrous - Sodium chloride - Potassium chloride - Ascorbic acid - Sodium ascorbate		- Oral use
MOVYMIA	Stada Arzneimittel AG	EU/1/16/1161/001-002	Solution for injection	- H05AA - H05AA02	- Teriparatide	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Moxifloxacin 400 mg/250 ml Solution for Infusion, FreeFlex bags	Fresenius Kabi Deutschland GmbH	PA2059/013/002	Solution for infusion	- J01MA - J01MA14	- Moxifloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Moxifloxacin 400 mg/250 ml Solution for Infusion, KabiPac bottles	Fresenius Kabi Deutschland GmbH	PA2059/013/001	Solution for infusion	- J01MA - J01MA14	- Moxifloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Mozobil	Genzyme Europe B.V.	EU/1/09/537/001	Solution for injection	- L03AX - L03AX16	- Plerixafor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
MST Continus 10 mg Prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/004/002	Prolonged-release tablet	- N02AA - N02AA01	- Morphine sulfate		- Oral use
MST Continus 100mg Prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/004/006	Prolonged-release tablet	- N02AA - N02AA01	- Morphine sulfate		- Oral use
MST Continus 15 mg Prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/004/003	Prolonged-release tablet	- N02AA - N02AA01	- Morphine sulfate		- Oral use
MST Continus 30 mg Prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/004/004	Prolonged-release tablet	- N02AA - N02AA01	- Morphine sulfate		- Oral use
MST Continus 5 mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/004/001	Prolonged-release tablet	- N02AA - N02AA01	- Morphine sulfate		- Oral use
MST Continus 60 mg Prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/004/005	Prolonged-release tablet	- N02AA - N02AA01	- Morphine sulfate		- Oral use
Mubucho 111 mg film-coated tablets	Zentiva k.s.	PA1701/003/006	Film-coated tablet	- L01XE06	- Dasatinib	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Mubucho 16 mg film-coated tablets	Zentiva k.s.	PA1701/003/001	Film-coated tablet	- L01XE06	- Dasatinib	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Mubucho 40 mg film-coated tablets	Zentiva k.s.	PA1701/003/002	Film-coated tablet	- L01XE06	- Dasatinib	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Mubucho 55 mg film-coated tablets	Zentiva k.s.	PA1701/003/003	Film-coated tablet	- L01XE06	- Dasatinib	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Mubucho 63 mg film-coated tablets	Zentiva k.s.	PA1701/003/004	Film-coated tablet	- L01XE06	- Dasatinib	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Mubucho 79 mg film-coated tablets	Zentiva k.s.	PA1701/003/005	Film-coated tablet	- L01XE06	- Dasatinib	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Mucotex 250 mg/5 ml syrup	Amdeepcha (Malta) Ltd	PA23153/001/001	Syrup	- R05CB03	- Carbocisteine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Mulpleo	Shionogi B.V.	EU/1/18/1348/001	Film-coated tablet	- B02BX07	- LUSUTROMBOPAG	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Multaq	Sanofi Winthrop Industrie	EU/1/09/591/1-4	Film-coated tablet	- C01BD - C01BD07	- Dronedarone hydrochloride		- Oral use
multiBic 2 mmol/l potassium solution for haemodialysis/haemofiltration	Fresenius Medical Care Deutschland GmbH	PA1350/009/002	Solution for haemodialysis/haemofiltration	- B05ZB	- Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Glucose monohydrate - Sodium hydrogen carbonate - Potassium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Haemodialysis - Intravenous use
multiBic 4 mmol/l potassium solution for haemodialysis/haemofiltration	Fresenius Medical Care Deutschland GmbH	PA1350/009/003	Solution for haemodialysis/haemofiltration	- B05ZB	- Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Glucose monohydrate - Sodium hydrogen carbonate - Potassium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Haemodialysis - Intravascular use
multiBic potassium-free solution for haemodialysis/haemofiltration	Fresenius Medical Care Deutschland GmbH	PA1350/009/001	Solution for haemodialysis/haemofiltration	- B05ZB	- Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Glucose monohydrate - Sodium hydrogen carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Haemodialysis - Intravenous use
MultiHance 529 mg/ml solution for injection in pre-filled syringe	Bracco Imaging spa	PA1826/001/002	Solution for injection in pre-filled syringe	- V08CA - V08CA08	- Gadobenate dimeglumine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
MultiHance, 0.5M solution for injection	Bracco Imaging spa	PA1826/001/001	Solution for injection	- V08CA - V08CA08	- Gadobenate dimeglumine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Murexal 10 mg/mL solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/010/001	Solution for injection in pre-filled syringe	- M03AB - M03AB01	- Suxamethonium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Murine irritation & redness relief, 0.012% w/v, eye drops solution	Elara Pharmaservices Europe Limited	PA22637/008/001	Eye drops, solution	- S01GA - S01GA01	- Naphazoline hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Ocular use
MVABEA	Janssen-Cilag International NV	EU/1/20/1445/001	Suspension for injection	- J07BX02	- MVA-BN-FILO	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
MVASI	Amgen Technology (Ireland) UC	EU/1/17/1246/001-002	Concentrate for solution for infusion	- L01XC07	- Bevacizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Myalepta	Amryt Pharmaceuticals DAC	EU/1/18/1276/001-002	Powder for solution for injection	- A16AA	- Metreleptin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Mybufen 200 mg Film-coated Tablets	Bluefish Pharmaceuticals AB	PA1436/039/001	Film-coated tablet	- M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mybufen Max 400 mg Film-coated Tablets	Bluefish Pharmaceuticals AB	PA1436/039/002	Film-coated tablet	- M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mycamine	Astellas Pharma GmbH	EU/1/08/448/001	Powder for solution for infusion	- J02AX - J02AX05	- Micafungin sodium		- Intravenous use
Mycamine 100 mg powder for solution for infusion	Astellas Pharma GmbH	EU/1/08/448/002	Powder for solution for infusion	- J02AX - J02AX05	- Micafungin sodium		- Intravenous use
Mycapssa	FGK Representative Service GmbH	EU/1/22/1690/001	Gastro-resistant capsule, hard	- H01CB02	- OCTREOTIDE ACETATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Myclausen	Herbert J. Passauer GmbH & Co. KG	EU/1/10/647/001-002	Film-coated tablet	- L04AA - L04AA06	- Mycophenolate mofetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Myclausen	Herbert J. Passauer GmbH & Co. KG	EU/1/10/647/003-004	Capsule, hard	- L04AA - L04AA06	- Mycophenolate mofetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mycobutin 150mg Hard Capsules	Pfizer Healthcare Ireland	PA0822/109/001	Capsule, hard	- J04AB - J04AB04	- Rifabutin		- Oral use
Mycolat 250 mg hard capsules	Rowex Ltd	PA0711/129/001	Capsule, hard	- L04AA - L04AA06	- Mycophenolate mofetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mycolat 500 mg Film-coated tablets	Rowex Ltd	PA0711/129/002	Film-coated tablet	- L04AA - L04AA06	- Mycophenolate mofetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mycophenolate Mofetil 500 mg film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/192/001	Film-coated tablet	- L04AA - L04AA06	- Mycophenolate mofetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mycophenolate Mofetil 500 mg Film-coated Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/039/001	Film-coated tablet	- L04AA - L04AA06	- MYCOPHENOLATE MOFETIL		- Oral use
Mycophenolate Mofetil Accord 250 mg capsules	Accord Healthcare Ireland Ltd.	PA2315/064/001	Capsule, hard	- L04AA - L04AA06	- Mycophenolate mofetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mycophenolate mofetil Clonmel 250 mg capsules hard	Clonmel Healthcare Ltd	PA0126/195/001	Capsule, hard	- L04AA - L04AA06	- Mycophenolate mofetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mycophenolate mofetil Clonmel 500 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/195/002	Film-coated tablet	- L04AA - L04AA06	- Mycophenolate mofetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mycophenolate mofetil Teva	Teva B.V.	EU/1/07/439/1-2	Capsule, hard	- L04AA - L04AA06	- Mycophenolate mofetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mycophenolate mofetil Teva	Teva Pharma B.V.	EU/1/07/439/3-4	Film-coated tablet	- L04AA - L04AA06	- Mycophenolate mofetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mycostatin 100,000 units/ml Oral Suspension (Ready Mixed)	Substipharm	PA1677/007/007	Oral suspension	- A07AA - A07AA02	- Nystatin	Full application (Article 8(3) of Directive No 2001/83/EC)	
Mydrilate 0.5% w/v Eye Drops	Esteve Pharmaceuticals GmbH	PA22709/003/001	Eye drops, solution	- S01FA - S01FA04	- Cyclopentolate hydrochloride		- Ocular use
Mydrilate 1.0% w/v Eye Drops	Esteve Pharmaceuticals GmbH	PA22709/003/002	Eye drops, solution	- S01FA - S01FA04	- Cyclopentolate hydrochloride		- Ocular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Myfenax	Teva B.V.	EU/1/07/438/1-2	Capsule, hard	- L04AA - L04AA06	- Mycophenolate mofetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Myfenax	Teva B.V.	EU/1/07/438/3-4	Film-coated tablet	- L04AA - L04AA06	- Mycophenolate mofetil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Myfortic 180 mg gastro-resistant tablets	Novartis Ireland Limited	PA0896/023/001	Gastro-resistant tablet	- L04AA - L04AA06	- Mycophenolic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Myfortic 360 mg gastro-resistant tablets	Novartis Ireland Limited	PA0896/023/002	Gastro-resistant tablet	- L04AA - L04AA06	- Mycophenolic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Myfortic 360 mg gastro-resistant tablets	PCO Manufacturing Ltd.	PPA0465/505/001	Gastro-resistant tablet	- L04AA06	- Mycophenolate sodium		- Oral use
Mykronor 5 micrograms/ml, solution for injection/infusion	Laboratoire AGUETTANT	PA1968/013/001	Solution for injection/infusion	- C01CA03	- Noradrenaline tartrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Myleran 2 mg film-coated tablets	Aspen Pharma Trading Limited	PA1691/008/001	Film-coated tablet	- L01AB - L01AB01	- Busulfan		- Oral use
Mylotarg	Pfizer Europe MA EEIG	EU/1/18/1277/001	Powder for concentrate for solution for infusion	- L01XC - L01XC05	- Gemtuzumab ozogamicin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Myocet	Teva B.V.	EU/1/00/141/001	Powder, dispersion and solvent for concentrate for dispersion for infusion	- L01DB - L01DB01	- DOXORUBICIN HYDROCHLORIDE		- Intravenous use
MYOVIEW 230 micrograms kit for radiopharmaceutical preparation	GE Healthcare AS	PA0735/012/001	Kit for radiopharmaceutical preparation	- V09GA - V09GA02	- Tetrofosmin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Myozyme	Genzyme Europe B.V.	EU/1/06/333/1-3	Powder for concentrate for solution for infusion	- A16AB - A16AB07	- Alglucosidase alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Myrelez 120 mg solution for injection in pre-filled syringe	Amdipharm Limited	PA1142/039/003	Solution for injection in pre-filled syringe	- H01CB03	- Lanreotide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Myrelez 60 mg solution for injection in pre-filled syringe	Amdipharm Limited	PA1142/039/001	Solution for injection in pre-filled syringe	- H01CB03	- Lanreotide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Myrelez 90 mg solution for injection in pre-filled syringe	Amdipharm Limited	PA1142/039/002	Solution for injection in pre-filled syringe	- H01CB03	- Lanreotide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Mysildecard ((previously known as Sildenafil Mylan Pharma))	Viatris Limited	EU/1/16/1134/001-003 Interchangeable List Code: IC0063-003-003	Film-coated tablet		- Sildenafil citrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Mysimba	Orexigen Therapeutics Ireland Limited	EU/1/14/988/001	Prolonged-release tablet	- A08AA - A08AA62	- Naltrexone hydrochloride - BUPROPION HYDROCHLORIDE	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Mysoline 250 mg Tablets	IMED Healthcare Ltd.	PPA1463/179/001	Tablet	- N03AA - N03AA03	- Primidone		- Oral use
Mysoline 250mg Tablets	Laboratoires SERB	PA1777/001/001	Tablet	- N03AA - N03AA03	- Primidone		- Oral use
Myzaar 100 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/087/003 Interchangeable List Code: IC0003-024-003	Film-coated tablet		- Losartan potassium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Myzaar 50 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/087/002 Interchangeable List Code: IC0003-023-003	Film-coated tablet		- Losartan potassium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nabumetone Tillomed 500 mg Film-coated Tablets	Tillomed Pharma GmbH	PA22720/001/001	Film-coated tablet	- M01AX - M01AX01	- Nabumetone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nacsys 600 mg Effervescent Tablets	Alpex Pharma (Irl) Limited	PA2166/001/001	Effervescent tablet	- R05CB - R05CB01	- Acetylcysteine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Naglazyme	BioMarin International Limited	EU/1/05/324/001	Concentrate for solution for infusion	- A16AB08	- Galsulfase		- Intravenous use
Nailderm 250 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/068/001	Tablet	- D01BA - D01BA02	- Terbinafine hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Naloxone Accord	Accord Healthcare Ireland Ltd.	PA2315/254/001	Solution for injection in pre-filled syringe	- V03AB15	- Naloxone hydrochloride dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Naloxone Hydrochloride 400 micrograms/ml Solution for Injection or Infusion	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/111/002	Solution for injection/infusion	- V03AB - V03AB15	- NALOXONE HYDROCHLORIDE		- Intramuscular use - Intravenous use - Subcutaneous use
Naltrexone 50 mg film-coated tablets	Aop Orphan Pharmaceuticals GmbH	PA0934/003/001	Film-coated tablet	- N07BB - N07BB04	- Naltrexone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Naltrexone Hydrochloride 50mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/111/001	Film-coated tablet	- N07BB - N07BB04	- Naltrexone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Namuscla	Lupin Europe GmbH	EU/1/18/1325/001-004	Capsule, hard	- C01BB02	- Mexiletine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Nanocis 0.24 mg kit for radiopharmaceutical preparation	CIS bio International	PA0677/006/001	Kit for radiopharmaceutical preparation	- V09DB	- Rhenium sulphide		- Intravenous use
Naprosyn EC 250mg Gastro-resistant Tablets	Atnahs Pharma Netherlands B.V.	PA22657/002/001	Gastro-resistant tablet	- M01AE - M01AE02	- Naproxen	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Naprosyn EC 500mg Gastro-resistant Tablets	Atnahs Pharma Netherlands B.V.	PA22657/002/002	Gastro-resistant tablet	- M01AE - M01AE02	- Naproxen	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Naproxen 250 mg Gastro-resistant Tablets	Azure Pharmaceuticals Ltd	PA22871/007/001	Gastro-resistant tablet	- M01AE02	- Naproxen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Naproxen 500 mg Gastro-resistant Tablets	Azure Pharmaceuticals Ltd	PA22871/007/003	Gastro-resistant tablet	- M01AE02	- Naproxen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Naratriptan 2.5 mg film-coated tablet	Renata Pharmaceuticals (Ireland) Limited	PA22865/008/001	Film-coated tablet	- N02CC02	- Naratriptan hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Naraverg 2.5 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/065/001	Film-coated tablet	- N02CC - N02CC02	- Naratriptan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Naropin 10 mg/ml solution for injection	Aspen Pharma Trading Limited	PA1691/026/003	Solution for injection	- N01BB - N01BB09	- Ropivacaine Hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intrathecal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Naropin 2 mg/ml solution for injection	Aspen Pharma Trading Limited	PA1691/026/001	Solution for injection	- N01BB - N01BB09	- Ropivacaine Hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intrathecal use
Naropin 7.5 mg/ml solution for injection	Aspen Pharma Trading Limited	PA1691/026/002	Solution for injection	- N01BB - N01BB09	- Ropivacaine Hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intrathecal use
NASACORT 55 micrograms/dose nasal spray, suspension	Lexon (UK) Ltd	PPA1097/032/001	Nasal spray, suspension	- R01AD11	- Triamcinolone acetonide		- Nasal use
NASACORT 55 micrograms/dose, nasal spray, suspension	Opella Healthcare France SAS T/A Sanofi	PA23180/001/001	Nasal spray, suspension	- R01AD - R01AD11	- Triamcinolone acetonide		- Nasal use
Nasacort Allergy 55 micrograms/dose nasal spray, suspension	Opella Healthcare France SAS T/A Sanofi	PA23180/001/002	Nasal spray, suspension	- R01AD - R01AD11	- Triamcinolone acetonide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Nasal use
Naseptin 0.1% & 0.5% w/w Nasal Cream	Alliance Pharma (Ireland) Limited	PA2325/009/001	Nasal cream	- D06AX - D06AX04	- Chlorhexidine Dihydrochloride - Neomycin sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Nasobec 50 Micrograms Aqueous Nasal Spray	Teva B.V.	PA1986/055/001	Nasal spray, suspension	- R01AD01	- Beclometasone dipropionate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intranasal use
Nasofan Aqueous 50 microgram Nasal Spray Suspension	Teva B.V.	PA1986/084/001	Nasal spray, suspension	- R01AD - R01AD08	- Fluticasone propionate		- Nasal use
NASONEX 50 micrograms/actuation Nasal Spray, Suspension	Organon Pharma (Ireland) Limited	PA23198/011/001	Nasal spray, suspension	- R01AD - R01AD09	- Mometasone furoate		- Nasal use
NASONEX 50 micrograms/actuation Nasal Spray, Suspension	PCO Manufacturing Ltd.	PPA0465/146/001	Nasal spray, suspension	- R01AD - R01AD09	- Mometasone furoate	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Nasal use
NASONEX 50 micrograms/actuation Nasal Spray, Suspension	IMED Healthcare Ltd.	PPA1463/102/001	Nasal spray, suspension	- R01AD09	- Mometasone furoate		- Nasal use
Nasonex 50 micrograms/actuation Nasal Spray, Suspension	Merit Pharmaceuticals Limited	PPA23080/001/001	Nasal spray, suspension	- R01AD - R01AD09	- Mometasone furoate		- Nasal use
Nasorinit 137 micrograms/50 micrograms per actuation nasal spray, suspension	Clonmel Healthcare Ltd	PA0126/358/001	Nasal spray, suspension	- R01AD58	- Azelastine hydrochloride - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Nasal use
Nasusaf 137 micrograms/50 micrograms per actuation nasal spray, suspension	Teva B.V.	PA1986/109/001	Nasal spray, suspension	- R01AD58	- Azelastine hydrochloride - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Nasal use
Nat. mur. 6X	New Vistas Healthcare Ltd	HOR0652/001/001	Oral solution		- Nat mur 6x		- Oral use
Natpar	Shire Pharmaceuticals Ireland Limited	EU/1/15/1078/001	Powder and solvent for solution for injection	- H05AA - H05AA03	- Parathyroid hormone (rdna)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Natpar	Shire Pharmaceuticals Ireland Limited	EU/1/15/1078/002	Powder and solvent for solution for injection	- H05AA - H05AA03	- Parathyroid hormone (rdna)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Natpar	Shire Pharmaceuticals Ireland Limited	EU/1/15/1078/003	Powder and solvent for solution for injection	- H05AA - H05AA03	- Parathyroid hormone (rdna)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Natpar	Shire Pharmaceuticals Ireland Limited	EU/1/15/1078/004	Powder and solvent for solution for injection	- H05AA - H05AA03	- Parathyroid hormone (rdna)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Natrilix SR 1.5 mg, prolonged-release film-coated tablets	Les Laboratoires Servier	PA0568/005/001	Prolonged-release tablet	- C03BA - C03BA11	- Indapamide		- Oral use
Nature's Bounty Agnus Castus PMS Relief Tablets	Holland & Barrett Limited	TR23157/012/001	Tablet			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Nature's Bounty Devil's Claw Hard Capsules	Holland & Barrett Limited	TR23157/010/001	Capsule, hard			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Nature's Bounty Echinacea Cold and Flu Hard Capsules	Holland & Barrett Limited	TR23157/008/001	Capsule, hard			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Nature's Bounty Hypericum Hard Capsules	Holland & Barrett Limited	TR23157/004/001	Capsule, hard			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Nature's Bounty Lemon Balm Hard Capsules	Holland & Barrett Limited	TR23157/006/001	Capsule, hard			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Nature's Bounty Milk Thistle Hard Capsules	Holland & Barrett Limited	TR23157/014/001	Capsule, hard			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Nature's Bounty Valerian Hard Capsules	Holland & Barrett Limited	TR23157/002/001	Capsule, hard	- N05CM - N05CM09		Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Natures Aid Echineeze Echinacea tablets	Clonmel Healthcare Ltd	TR0126/311/001	Tablet			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Natures Aid Jointeeze Devil's Claw	Clonmel Healthcare Ltd	TR0126/318/001	Tablet	- V03AX	- Devil's claw dry extract	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Natures Aid Premeeze Agnus Castus hard capsules	Clonmel Healthcare Ltd	TR0126/312/001	Capsule, hard			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Natures Aid Sleepeeze Valerian Tablets	Clonmel Healthcare Ltd	TR0126/316/001	Film-coated tablet	- V03AX		Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
NAVELBINE 10 mg/ml concentrate for solution for infusion	Pierre Fabre Medicament	PA0329/011/003	Concentrate for solution for infusion	- L01CA - L01CA04	- Vinorelbine		- Intrathecal use
NAVELBINE 20 mg soft capsule	Pierre Fabre Medicament	PA0329/011/001	Capsule, soft	- L01CA - L01CA04	- Vinorelbine tartrate		- Oral use
NAVELBINE 30 mg soft capsule	Pierre Fabre Medicament	PA0329/011/002	Capsule, soft	- L01CA - L01CA04	- Vinorelbine		- Oral use
NAVELBINE 80 mg soft capsule	Pierre Fabre Medicament	PA0329/011/004	Capsule, soft	- L01CA - L01CA04	- Vinorelbine tartrate		- Oral use
Nebido 1000 mg/4 ml, solution for injection	Grunenthal Pharma Ltd	PA2242/015/001	Solution for injection	- G03BA - G03BA03	- Testosterone Undecanoate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Nebilet 5 mg tablets	Menarini International Operations Luxembourg S.A.	PA0865/005/001 Interchangeable List Code: IC0082-001-002	Tablet		- Nebivolol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Nebilet Plus 5 mg/12.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/015/001	Film-coated tablet	- C07BB - C07BB12	- Nebivolol - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Nebilet Plus 5 mg/25 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/015/002	Film-coated tablet	- C07BB - C07BB12	- Nebivolol - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Nebimel 5 mg tablets	Clonmel Healthcare Ltd	PA0126/165/001 Interchangeable List Code: IC0082-001-002	Tablet		- Nebivolol hydrochloride		- Oral use
Nebivolol 10mg tablets	Glenmark Arzneimittel GmbH	PA22645/002/001	Tablet	- C07AB - C07AB12	- Nebivolol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Nebivolol Accord 5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/247/001 Interchangeable List Code: IC0082-001-002	Tablet		- Nebivolol hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nebivolol Teva 5 mg Tablets	Teva Pharma B.V.	PA0749/078/001 Interchangeable List Code: IC0082-001-002	Tablet		- Nebivolol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nebol 5 mg Tablets	Rowex Ltd	PA0711/120/001 Interchangeable List Code: IC0082-001-002	Tablet		- Nebivolol hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nefopam Hydrochloride 30 mg Film-coated Tablets	Brown & Burk IR Limited	PA23148/007/001	Film-coated tablet	- N02BG - N02BG06	- Nefopam hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Nefrosol solution for haemofiltration	B. Braun Avitum AG	PA2146/001/001	Solution for haemofiltration	- B05ZB	- Sodium chloride ph.eur. - Sodium hydrogen carbonate - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Glucose monohydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Nefrosol with 2 mmol/l Potassium solution for haemofiltration	B. Braun Avitum AG	PA2146/001/002	Solution for haemofiltration	- B05ZB	- Sodium chloride ph.eur. - Sodium hydrogen carbonate - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Glucose monohydrate - Potassium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Nefrosol with 4 mmol/l Potassium solution for haemofiltration	B. Braun Avitum AG	PA2146/001/003	Solution for haemofiltration	- B05ZB	- Sodium chloride ph.eur. - Sodium hydrogen carbonate - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Glucose monohydrate - Potassium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
NeisVac-C 0.5 ml Suspension for injection in pre-filled syringe. Meningococcal Group C Polysaccharide Conjugate Vaccine Adsorbed	Pfizer Healthcare Ireland	PA0822/183/001	Suspension for injection in pre-filled syringe	- J07AH	- Neisseria meningitidis c - Tetanus toxoid		- Intravenous use
Nelsons Arnicare Arnica Cream	Pharmaceutical Business Consultants Limited	HOA23352/003/001	Cream		- Arnica montana	National Rules Authorisation (Article 16.2 Directive 2001/83/EC.)	- Topical
Nelsons Rhus tox Cream	A. Nelson & Company Limited	HOA1149/010/001	Cream		- Rhus toxicodendron (ghp)	National Rules Authorisation (Article 16.2 Directive 2001/83/EC.)	- Topical
NEMDATINE	Actavis Group PTC ehf	EU/1/13/824/001-002	Film-coated tablet	- N06DX01	- MEMANTINE HYDROCHLORIDE	Article 10(1) - Generic Application	- Oral use
Nemdatine	Actavis Group hf	EU/1/13/824/003-010 Interchangeable List Code: IC0022-002-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
NEMDATINE	Actavis Group PTC ehf	EU/1/13/824/011-013	Film-coated tablet	- N06DX01	- MEMANTINE HYDROCHLORIDE	Article 10(1) - Generic Application	- Oral use
Nemdatine	Actavis Group PTC ehf	EU/1/13/824/014-017 Interchangeable List Code: IC0022-003-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
NEMDATINE	Actavis Group PTC ehf	EU/1/13/824/018 Interchangeable List Code: IC0022-106-003	Film-coated tablet		- MEMANTINE HYDROCHLORIDE - MEMANTINE HYDROCHLORIDE - MEMANTINE HYDROCHLORIDE - MEMANTINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Neoclarityn	N.V. Organon	EU/1/00/161/001	Film-coated tablet	- R06AX	- Desloratidine		- Oral use
Neoclarityn	N.V. Organon	EU/1/00/161/001-013	Film-coated tablet	- R06AX	- Desloratidine	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Neoclarityn	N.V. Organon	EU/1/00/161/59-67	Oral solution	- R06AX - R06AX27	- Desloratadine, micronized		- Oral use
Neo-Cytamen 1000 micrograms/ml Solution for Injection	RPH Pharmaceuticals AB	PA1638/004/001 Interchangeable List Code: IC0121-172-063	Solution for injection		- Hydroxocobalamin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
Neofordex	Laboratoires CTRS	EU/1/15/1053/001	Tablet	- H02AB - H02AB02	- Dexamethasone acetate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
NeoMercazole 20 mg Tablets	Amdipharm Limited	PA1142/002/002	Tablet	- H03BB - H03BB01	- Carbimazole		- Oral use
NeoMercazole 5 mg Tablets	Amdipharm Limited	PA1142/002/001	Tablet	- H03BB - H03BB01	- Carbimazole		- Oral use
Neophyr 1000 ppm mol/mol, medicinal gas, compressed	SOL S.p.A.	PA1848/001/001	Medicinal gas, compressed	- R07AX - R07AX01	- Nitric oxide	Authorisation of breeders, suppliers and users (Article 20 of Directive No 2010/63/EU)	- Inhalation use
Neophyr 225 ppm mol/mol, medicinal gas, compressed	SOL S.p.A.	PA1848/001/003	Medicinal gas, compressed	- R07AX - R07AX01	- Nitric oxide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
Neophyr 450 ppm mol/mol, medicinal gas, compressed	SOL S.p.A.	PA1848/001/002	Medicinal gas, compressed	- R07AX - R07AX01	- Nitric oxide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
Neoral 100 mg/ml concentrate for oral solution	Novartis Ireland Limited	PA0896/024/004	Concentrate for oral solution	- L04AD - L04AD01	- Ciclosporin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Neoral 100mg Soft Capsules	Novartis Ireland Limited	PA0896/024/003	Capsule, soft	- L04AD - L04AD01	- Ciclosporin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Neoral 25 mg Soft Capsules	Novartis Ireland Limited	PA0896/024/001	Capsule, soft	- L04AD - L04AD01	- Ciclosporin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Neoral 50mg Soft Capsules	Novartis Ireland Limited	PA0896/024/002	Capsule, soft	- L04AD - L04AD01	- Ciclosporin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
NEORECORMON	Roche Registration Limited	EU/1/97/31/45-46	Solution for injection	- B03XA01	- Epoetin beta		
NeoRecormon	Roche Registration GmbH	EU/1/97/031/019	Powder and solvent for concentrate for solution for infusion	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
NeoRecormon	Roche Registration GmbH	EU/1/97/031/025	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
NeoRecormon	Roche Registration GmbH	EU/1/97/031/026	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
NeoRecormon	Roche Registration GmbH	EU/1/97/031/029	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
NeoRecormon	Roche Registration GmbH	EU/1/97/031/030	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
NeoRecormon	Roche Registration GmbH	EU/1/97/031/031	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
NeoRecormon	Roche Registration GmbH	EU/1/97/031/032	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
NeoRecormon	Roche Registration GmbH	EU/1/97/031/033	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
NeoRecormon	Roche Registration GmbH	EU/1/97/031/034	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
NeoRecormon	Roche Registration GmbH	EU/1/97/031/035	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
NeoRecormon	Roche Registration GmbH	EU/1/97/031/036	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
NeoRecormon	Roche Registration GmbH	EU/1/97/031/037	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
NeoRecormon	Roche Registration GmbH	EU/1/97/031/038	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
NeoRecormon	Roche Registration GmbH	EU/1/97/031/041	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
NeoRecormon	Roche Registration GmbH	EU/1/97/031/042	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
NeoRecormon	Roche Registration GmbH	EU/1/97/031/043	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
NeoRecormon	Roche Registration GmbH	EU/1/97/031/044	Solution for injection in pre-filled syringe	- B03XA01	- Epoetin beta		- Intravenous use - Subcutaneous use
Neotigason 10 mg capsules	Teva B.V.	PA1986/113/001	Capsule, hard	- D05BB - D05BB02	- Acitretin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Neotigason 25 mg capsules	Teva B.V.	PA1986/113/002	Capsule, hard	- D05BB - D05BB02	- Acitretin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Neotigason 25 mg capsules	Originalis B.V.	PPA2306/020/001	Capsule, hard	- D05BB - D05BB02	- Acitretin		- Oral use
Neparvis	Novartis Europharm Limited	EU/1/16/1103/001	Film-coated tablet	- C09DX - C09DX04	- Sacubitril valsartan	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Neparvis	Novartis Europharm Limited	EU/1/16/1103/002-004	Film-coated tablet	- C09DX - C09DX04	- Sacubitril valsartan	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Neparvis	Novartis Europharm Limited	EU/1/16/1103/005-007	Film-coated tablet	- C09DX - C09DX04	- Sacubitril valsartan	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Neparvis	Novartis Europharm Limited	EU/1/16/1103/018	Granules	- C09DX - C09DX04	- Sacubitril - Valsartan	Full application - Known active substance (Article 12(3) of Directive No 2001/82/EC)	- Oral use
Neparvis	Novartis Europharm Limited	EU/1/16/1103/019	Granules	- C09DX04 - QC09DX04	- Sacubitril - Valsartan	Full application - Known active substance (Article 12(3) of Directive No 2001/82/EC)	- Oral use
Nepexto	Biosimilar Collaborations Ireland Limited	EU/1/120/1436/001-002	Solution for injection in pre-filled syringe	- L04AB - L04AB01	- Etanercept	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Nepexto	Biosimilar Collaborations Ireland Limited	EU/1/120/1436/003-004	Solution for injection in pre-filled syringe	- L04AB - L04AB01	- Etanercept	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Nepexto	Biosimilar Collaborations Ireland Limited	EU/1/20/1436/005-006	Solution for injection in pre-filled pen	- L04AB - L04AB01	- Etanercept	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Nerlynx	Pierre Fabre Medicament	EU/1/18/1311/001	Film-coated tablet	- L01XE45	- Neratinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Neulasta	Amgen Europe B.V.	EU/1/02/227/001-002	Solution for injection	- L03AA - L03AA13	- Pegfilgrastim		- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Neupogen 30 MU (0.3 mg/ml) Solution for injection filgrastim	Amgen Europe B.V.	PA1026/001/001	Solution for injection	- L03AA - L03AA02	- Filgrastim	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Neupogen Singleject 30 MU/0.5 ml Solution for injection in a pre-filled syringe filgrastim	Amgen Europe B.V.	PA1026/001/007	Solution for injection in pre-filled syringe	- L03AA - L03AA02	- Filgrastim	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Neupogen Singleject 48 MU/0.5 ml Solution for injection in a pre-filled syringe filgrastim	Amgen Europe B.V.	PA1026/001/008	Solution for injection in pre-filled syringe	- L03AA - L03AA02	- Filgrastim	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Neupro	Schwarz Pharma Limited	EU/1/05/331/10-12,32-37	Transdermal patch	- N04BC	- Rotigotine		
Neupro	UCB Pharma SA	EU/1/05/331/1-3,14-20	Transdermal patch	- N04BC - N04BC09	- Rotigotine		- Not Currently Available
Neupro	UCB Pharma SA	EU/1/05/331/38-46	Transdermal patch	- N04BC - N04BC09	- Rotigotine		- Transdermal use
Neupro	Schwarz Pharma Limited	EU/1/05/331/4-6,21-25	Transdermal patch	- N04BC	- Rotigotine		
Neupro	UCB Pharma SA	EU/1/05/331/47-55	Transdermal patch	- N04BC - N04BC09	- Rotigotine		- Transdermal use
Neupro	Schwarz Pharma Limited	EU/1/05/331/7-9,26-31	Transdermal patch	- N04BC	- Rotigotine		- Not Currently Available
Neuraceq	Life Molecular Imaging GmbH	EU/1/13/906/001	Solution for injection	- V09AX - V09AX06	- Florbetaben	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Neurontin 100 mg hard capsules	Upjohn EESV	PA23055/004/001 Interchangeable List Code: IC0109-024-001	Capsule, hard		- Gabapentin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Neurontin 300 mg hard capsules	Upjohn EESV	PA23055/004/002 Interchangeable List Code: IC0109-029-001	Capsule, hard		- Gabapentin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Neurontin 300 mg Hard Capsules	PCO Manufacturing Ltd.	PPA0465/097/001 Interchangeable List Code: IC0109-029-001	Capsule, hard		- Gabapentin	ZZZ PPA	- Oral use
Neurontin 400 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/097/002 Interchangeable List Code: IC0109-068-001	Capsule, hard		- Gabapentin	ZZZ PPA	- Oral use
Neurontin 400 mg hard capsules	Upjohn EESV	PA23055/004/003 Interchangeable List Code: IC0109-068-001	Capsule, hard		- Gabapentin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Neurontin 600 mg film-coated tablets	Upjohn EESV	PA23055/004/004 Interchangeable List Code: IC0109-168-003	Film-coated tablet		- Gabapentin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Neurontin 800 mg film-coated tablets	Upjohn EESV	PA23055/004/005 Interchangeable List Code: IC0109-169-003	Film-coated tablet		- Gabapentin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Neurostil 100 mg capsules, hard	Teva Pharma B.V.	PA0749/164/001 Interchangeable List Code: IC0109-024-001	Capsule, hard		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Neurostil 300 mg capsules, hard	Teva Pharma B.V.	PA0749/164/002 Interchangeable List Code: IC0109-029-001	Capsule, hard		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Neurostil 400 mg capsules, hard	Teva Pharma B.V.	PA0749/164/003 Interchangeable List Code: IC0109-068-001	Capsule, hard		- Gabapentin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Neutrogena T/Gel Shampoo 5 mg/ml	Johnson & Johnson (Ireland) Limited	PA0330/014/001	Shampoo	- D05AA	- Coal tar		- Cutaneous use
Nevanac	Novartis Europharm Limited	EU/1/07/433/001	Eye drops, suspension	- S01BC - S01BC10	- Nepafenac	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Nevanac	Novartis Europharm Limited	EU/1/07/433/002	Eye drops, suspension	- S01BC - S01BC10	- Nepafenac	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Nexavar	Bayer AG	EU/1/06/342/01	Film-coated tablet	- L01XE - L01XE05	- Sorafenib (as tosylate)		
Nexazole 20 mg hard gastro-resistant capsules	Pinewood Laboratories Ltd	PA0281/146/001 Interchangeable List Code: IC0004-003-016	Gastro-resistant capsule, hard		- Esomeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nexazole 40 mg hard gastro-resistant capsules	Pinewood Laboratories Ltd	PA0281/146/002 Interchangeable List Code: IC0004-004-016	Gastro-resistant capsule, hard		- Esomeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nexium 10 mg gastro-resistant granules for oral suspension, sachet	Grunenthal Pharma Ltd	PA2242/013/001	Gastro-resistant granules for oral suspension in sachet	- A02BC - A02BC05	- Esomeprazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Nexium 20 mg gastro-resistant tablets	Grunenthal Pharma Ltd	PA2242/013/002 Interchangeable List Code: IC0004-003-016	Gastro-resistant tablet		- Esomeprazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Nexium 20 mg gastro-resistant tablets	PCO Manufacturing Ltd.	PPA0465/083/001 Interchangeable List Code: IC0004-003-016	Gastro-resistant tablet		- Esomeprazole	ZZZ PPA	- Oral use
Nexium 20 mg gastro-resistant tablets	Originalis B.V.	PPA2306/025/001 Interchangeable List Code: IC0004-003-016	Gastro-resistant tablet		- Esomeprazole		- Oral use
Nexium 20 mg gastro-resistant tablets	Merit Pharmaceuticals Limited	PPA23080/003/001 Interchangeable List Code: IC0004-003-016	Gastro-resistant tablet		- Esomeprazole		- Oral use
Nexium 20 mg gastro-resistant tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/015/001 Interchangeable List Code: IC0004-003-016	Gastro-resistant tablet		- Esomeprazole		- Oral use
Nexium 20 mg gastro-resistant tablets	IMED Healthcare Ltd.	PPA1463/002/001 Interchangeable List Code: IC0004-003-016	Gastro-resistant tablet		- Esomeprazole	ZZZ PPA	- Oral use
Nexium 40 mg gastro-resistant tablets	IMED Healthcare Ltd.	PPA1463/002/002 Interchangeable List Code: IC0004-004-016	Gastro-resistant tablet		- Esomeprazole	ZZZ PPA	- Oral use
Nexium 40 mg gastro-resistant tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/015/002 Interchangeable List Code: IC0004-004-016	Gastro-resistant tablet		- Esomeprazole		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Nexium 40 mg gastro-resistant tablets	Merit Pharmaceuticals Limited	PPA23080/003/002 Interchangeable List Code: IC0004-004-016	Gastro-resistant tablet		- Esomeprazole		- Oral use
Nexium 40 mg gastro-resistant tablets	Originalis B.V.	PPA2306/025/002 Interchangeable List Code: IC0004-004-016	Gastro-resistant tablet		- Esomeprazole		- Oral use
Nexium 40 mg gastro-resistant tablets	PCO Manufacturing Ltd.	PPA0465/083/002 Interchangeable List Code: IC0004-004-016	Gastro-resistant tablet		- Esomeprazole	ZZZ PPA	- Oral use
Nexium 40 mg gastro-resistant tablets	Grunenthal Pharma Ltd	PA2242/013/003 Interchangeable List Code: IC0004-004-016	Gastro-resistant tablet		- Esomeprazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Nexium Control	GlaxoSmithKline Dungarvan Limited	EU/1/13/860/001-002	Gastro-resistant tablet	- A02BC - A02BC05	- Esomeprazole magnesium trihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Nexium Control	GlaxoSmithKline Dungarvan Limited	EU/1/13/860/003	Gastro-resistant capsule, hard	- A02BC - A02BC05	- Esomeprazole magnesium trihydrate		- Oral use
Nexium I.V. 40 mg Powder for solution for injection/infusion	Grunenthal Pharma Ltd	PA2242/013/004	Powder for solution for injection/infusion	- A02BC - A02BC05	- Esomeprazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
NexoBrid	MediWound Germany GmbH	EU/1/12/803/001	Powder and gel for gel	- D03BA03	- Partially purified bromelain	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
NexoBrid	MediWound Germany GmbH	EU/1/12/803/002	Powder and gel for gel	- D03BA03	- Partially purified bromelain	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Nexpovio	Karyopharm Europe GmbH	EU/1/21/1537/001-004	Film-coated tablet	- L01XX66	- Selinexor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Nexviadyme	Genzyme Europe B.V.	EU/1/21/1579/001-004	Powder for concentrate for solution for infusion	- A16	- Avalglucosidase Alfa	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
NGENLA	Pfizer Europe MA EEIG	EU/1/21/1617/001	Solution for injection	- H01AC08	- Somatrogon	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
NGENLA	Pfizer Europe MA EEIG	EU/1/21/1617/002	Solution for injection	- H01AC08	- Somatrogon	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Nicam 4% w/w Gel	Dermal Laboratories (Ireland) Limited	PA23128/012/001	Gel	- D10AX	- Nicotinamide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Topical
Nicorandil 10mg Tablets	Dexcel Pharma GmbH	PA2261/003/001	Tablet	- C01DX - C01DX16	- Nicorandil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nicorandil 20mg Tablets	Dexcel Pharma GmbH	PA2261/003/002	Tablet	- C01DX - C01DX16	- Nicorandil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nicorette 15mg Inhaler	JNTL Consumer Health I (Ireland) Limited	PA23490/019/010	Inhalation vapour, impregnated plug	- N07BA - N07BA01	- Nicotine		- Oromucosal use
Nicorette 2mg Medicated Chewing-gum	JNTL Consumer Health I (Ireland) Limited	PA23490/019/014	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine		- Oromucosal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Nicorette 4mg Medicated Chewing-gum	JNTL Consumer Health I (Ireland) Limited	PA23490/019/015	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine		- Oromucosal use
Nicorette Cools 2mg Lozenge	JNTL Consumer Health I (Ireland) Limited	PA23490/019/011	Compressed lozenge	- N07BA - N07BA01	- Nicotine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use
Nicorette Cools 4mg Lozenge	JNTL Consumer Health I (Ireland) Limited	PA23490/019/012	Compressed lozenge	- N07BA - N07BA01	- Nicotine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use
Nicorette Freshfruit 2mg Medicated Chewing Gum	JNTL Consumer Health I (Ireland) Limited	PA23490/019/003	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine		- Oral use
Nicorette Freshfruit 4mg Medicated Chewing Gum	JNTL Consumer Health I (Ireland) Limited	PA23490/019/004	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine		- Oral use
Nicorette Freshmint 2mg Medicated Chewing Gum	JNTL Consumer Health I (Ireland) Limited	PA23490/019/001	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine		- Oral use
Nicorette Freshmint 4 mg Medicated Chewing Gum	JNTL Consumer Health I (Ireland) Limited	PA23490/019/002	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine		- Oral use
Nicorette Fruit 2 mg Lozenges	JNTL Consumer Health I (Ireland) Limited	PA23490/019/017	Compressed lozenge	- N07BA - N07BA01	- Nicotine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use
Nicorette Fruit 4 mg Lozenges	JNTL Consumer Health I (Ireland) Limited	PA23490/019/018	Compressed lozenge	- N07BA - N07BA01	- Nicotine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use
Nicorette Icy White 2mg Medicated Chewing Gum	JNTL Consumer Health I (Ireland) Limited	PA23490/019/008	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine	ZZZ --Unknown--	- Oromucosal use
Nicorette Icy White 4mg Medicated Chewing Gum	JNTL Consumer Health I (Ireland) Limited	PA23490/019/009	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine	ZZZ --Unknown--	- Oromucosal use
Nicorette Invisi 10 mg/16 hours transdermal patch	PCO Manufacturing Ltd.	PPA0465/187/007	Transdermal patch	- N07BA - N07BA01	- Nicotine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Transdermal use
Nicorette Invisi 10 mg/16 hours Transdermal Patch	IMED Healthcare Ltd.	PPA1463/210/001	Transdermal patch	- N07AB01	- Nicotine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Transdermal use
Nicorette Invisi 10mg/16 hours Transdermal Patch	JNTL Consumer Health I (Ireland) Limited	PA23490/019/005	Transdermal patch	- N07BA - N07BA01	- Nicotine	Complete application (stand-alone) - Annex of Council Regulation (EEC) No 2309/93	- Transdermal use
Nicorette Invisi 15 mg/16 hours Transdermal Patch	IMED Healthcare Ltd.	PPA1463/210/002	Transdermal patch	- N07BA01	- Nicotine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Transdermal use
Nicorette Invisi 15 mg/16 hours transdermal patch	PCO Manufacturing Ltd.	PPA0465/187/008	Transdermal patch	- N07BA - N07BA01	- Nicotine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Transdermal use
Nicorette Invisi 15mg/16 hours Transdermal Patch	JNTL Consumer Health I (Ireland) Limited	PA23490/019/006	Transdermal patch	- N07BA - N07BA01	- Nicotine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Nicorette Invisi 15mg/16 hours Transdermal Patch	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/051/001	Transdermal patch	- N07BA - N07BA01	- Nicotine		- Transdermal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Nicorette Invisi Extra Strength 25 mg/16 hours transdermal patch	PCO Manufacturing Ltd.	PPA0465/187/009	Transdermal patch	- N07BA - N07BA01	- Nicotine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Transdermal use
Nicorette Invisi Extra Strength 25 mg/16 hours Transdermal Patch	IMED Healthcare Ltd.	PPA1463/210/003	Transdermal patch	- N07BA01	- Nicotine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Transdermal use
Nicorette Invisi Extra Strength 25mg/16 hours Transdermal Patch	JNTL Consumer Health I (Ireland) Limited	PA23490/019/007	Transdermal patch	- N07BA - N07BA01	- Nicotine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Nicorette Quickmist 1 mg/spray oromucosal spray, solution	JNTL Consumer Health I (Ireland) Limited	PA23490/019/013	Oromucosal spray, solution	- N07BA - N07BA01	- Nicotine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oromucosal use
Nicorette QuickMist Cool Berry 1 mg/spray, oromucosal spray, solution	JNTL Consumer Health I (Ireland) Limited	PA23490/019/016	Oromucosal spray, solution	- N07BA - N07BA01	- Nicotine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oromucosal use
Nicospray 1 mg/spray oromucosal spray, solution	Clonmel Healthcare Ltd	PA0126/309/001	Oromucosal spray, solution	- N07BA01	- Nicotine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use
Nicotinell Cool Mint 2 mg, medicated chewing-gum	Haleon Ireland Limited	PA0678/125/001	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine		- Oral use
Nicotinell Cool Mint 4 mg, medicated chewing-gum	Haleon Ireland Limited	PA0678/125/002	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine		- Oral use
Nicotinell Fruit 2 mg, medicated chewing-gums	Haleon Ireland Limited	PA0678/124/001	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine		- Oral use
Nicotinell Fruit 4 mg, medicated chewing-gum	Haleon Ireland Limited	PA0678/124/002	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine		- Oral use
Nicotinell Mint 1 mg compressed lozenge	Haleon Ireland Limited	PA0678/123/004	Compressed lozenge	- N07BA - N07BA01	- Nicotine		- Oromucosal use
Nicotinell Mint 2 mg compressed lozenge	Haleon Ireland Limited	PA0678/123/005	Compressed lozenge	- N07BA - N07BA01	- Nicotine		- Oromucosal use
Nicotinell Rapid Relief 1 mg/spray oromucosal spray, solution	Haleon Ireland Limited	PA0678/158/001	Oromucosal spray, solution	- N07BA01	- Nicotine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nicotinell Spearmint 2 mg medicated chewing-gum	Haleon Ireland Limited	PA0678/134/001	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use
Nicotinell Spearmint 4 mg medicated chewing-gum	Haleon Ireland Limited	PA0678/134/002	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use
Nicotinell Tropical Fruit 2 mg medicated chewing-gum	Haleon Ireland Limited	PA0678/135/001	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use
Nicotinell Tropical Fruit 4 mg medicated chewing-gum	Haleon Ireland Limited	PA0678/135/002	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use
Nicotinell TTS 10, 7mg/24 hours Transdermal Patch	Haleon Ireland Limited	PA0678/123/001	Transdermal patch	- N07BA - N07BA01	- Nicotine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Transdermal use
Nicotinell TTS 20, 14mg/24 hours Transdermal Patch	Haleon Ireland Limited	PA0678/123/002	Transdermal patch	- N07BA - N07BA01	- Nicotine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Transdermal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Nicotinell TTS 30, 21mg/24 hours Transdermal Patch	Haleon Ireland Limited	PA0678/123/003	Transdermal patch	- N07BA - N07BA01	- Nicotine	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Transdermal use
Night Nurse Capsules Paracetamol 500 mg Promethazine Hydrochloride 10 mg Dextromethorphan Hydrobromide 7.5 mg	Haleon Ireland Limited	PA0678/021/001	Capsule, hard	- N02BE - N02BE51	- Paracetamol - Promethazine hydrochloride - Dextromethorphan hydrobromide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Night Nurse Cold Remedy oral solution Paracetamol 1000 mg/20 ml Promethazine Hydrochloride 20 mg/20 ml Dextromethorphan Hydrobromide 15 mg/20 ml	Haleon Ireland Limited	PA0678/014/001	Oral solution	- N02BE - N02BE51	- Paracetamol - Promethazine hydrochloride - Dextromethorphan hydrobromide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Nilemdo	Daiichi Sankyo Europe GmbH	EU/1/20/1425/001-006	Film-coated tablet	- C01AX15 - C10A	- Bempedoic Acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Nimbex 2mg/ml solution for injection/infusion	Aspen Pharma Trading Limited	PA1691/030/001	Solution for injection/infusion	- M03AC - M03AC11	- Cisatracurium Besilate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Nimenrix	Pfizer Europe MA EEIG	EU/1/12/767/001-007	Powder and solvent for solution for injection	- J07AH - J07AH08	- N.meningitidis serogroup a polysaccharide conjugated to tetanus toxoid - N.meningitidis serogroup c polysaccharide conjugated to tetanus toxoid - N.meningitidis serogroup w polysaccharide conjugated to tetanus toxoid - N.meningitidis serogroup y polysaccharide conjugated to tetanus toxoid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Nimotop 0.02% w/v Concentrate for Solution for Infusion	Bayer Limited	PA1410/030/002	Concentrate for solution for infusion	- C08CA - C08CA06	- Nimodipine		- Intravenous use
Nimotop 30 mg film-coated tablets	Bayer Limited	PA1410/030/001	Film-coated tablet	- C08CA - C08CA06	- Nimodipine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Nimvastid	KRKA, d.d., Novo mesto	EU/1/09/525/14-19	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Nimvastid	KRKA, d.d., Novo mesto	EU/1/09/525/1-7	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Nimvastid	KRKA, d.d., Novo mesto	EU/1/09/525/20-25	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
NIMVASTID	Krka d.d., Novo mesto	EU/1/09/525/26-31	Orodispersible Tablet	- N06DA03	- RIVASTIGMINE HYDROGEN TARTRATE		- Oral use
NIMVASTID	Krka d.d., Novo mesto	EU/1/09/525/32-36	Orodispersible Tablet	- N06DA03	- RIVASTIGMINE HYDROGEN TARTRATE		- Oral use
NIMVASTID	Krka d.d., Novo mesto	EU/1/09/525/37-41	Orodispersible Tablet	- N06DA03	- RIVASTIGMINE HYDROGEN TARTRATE		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
NIMVASTID	Krka d.d., Novo mesto	EU/1/09/525/42-46	Orodispersible Tablet	- N06DA03	- RIVASTIGMINE HYDROGEN TARTRATE		- Oral use
Nimvastid	KRKA, d.d., Novo mesto	EU/1/09/525/8-13	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
NINLARO	Takeda Pharma A/S	EU/1/16/1094/001	Capsule, hard	- L01XX - L01XX50	- Ixazomib citrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
NINLARO	Takeda Pharma A/S	EU/1/16/1094/002	Capsule, hard	- L01XX - L01XX50	- Ixazomib citrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
NINLARO	Takeda Pharma A/S	EU/1/16/1094/003	Capsule, hard	- L01XX - L01XX50	- Ixazomib citrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Nintedanib Clonmel 100 mg soft capsules	Clonmel Healthcare Ltd	PA0126/383/001	Capsule, soft	- L01EX09	- Nintedanib esylate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nintedanib Clonmel 150 mg soft capsules	Clonmel Healthcare Ltd	PA0126/383/002	Capsule, soft	- L01EX09	- Nintedanib esylate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Niopam 300, Solution for injection, glass bottles	Bracco Imaging spa	PA1826/004/003	Solution for injection	- V08AB - V08AB04	- Iopamidol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Niopam 340, Solution for Injection, glass bottles	Bracco Imaging spa	PA1826/004/004	Solution for injection	- V08AB - V08AB04	- Iopamidol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Niopam 370, Solution for Injection, glass bottles	Bracco Imaging spa	PA1826/004/005	Solution for injection	- V08AB - V08AB04	- Iopamidol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
NIPENT 10 mg powder for solution for injection, powder for solution for infusion	Pfizer Healthcare Ireland	PA0822/228/001	Powder for solution for injection/infusion	- L01XX - L01XX08	- Pentostatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
NiQuitin 14mg/24hrs transdermal patches	Chefaro Ireland DAC	PA1186/018/002	Transdermal patch	- N07BA - N07BA01	- Nicotine		- Transdermal use
NiQuitin 2 mg Mint Lozenge	Chefaro Ireland DAC	PA1186/018/009	Compressed lozenge	- N07BA - N07BA01	- Nicotine		- Oral use
NiQuitin 21mg/24hrs transdermal patches	Chefaro Ireland DAC	PA1186/018/003	Transdermal patch	- N07BA - N07BA01	- Nicotine		- Transdermal use
NiQuitin 2mg Lozenge	Chefaro Ireland DAC	PA1186/018/007	Compressed lozenge	- N07BA01	- Nicotine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
NiQuitin 4 mg Lozenge	Chefaro Ireland DAC	PA1186/018/008	Compressed lozenge	- N07BA01	- Nicotine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
NiQuitin 4 mg Mint Lozenge	Chefaro Ireland DAC	PA1186/018/010	Compressed lozenge	- N07BA - N07BA01	- Nicotine		- Oral use
NiQuitin 7mg/24hrs transdermal patches	Chefaro Ireland DAC	PA1186/018/001	Transdermal patch	- N07BA - N07BA01	- Nicotine		- Transdermal use
NiQuitin CLEAR 14mg/24 hrs transdermal patch	Chefaro Ireland DAC	PA1186/018/005	Transdermal patch	- N07BA01	- Nicotine		- Transdermal use
NiQuitin CLEAR 21mg/24 hrs transdermal patch	Chefaro Ireland DAC	PA1186/018/006	Transdermal patch	- N07BA01	- Nicotine		- Transdermal use
NiQuitin CLEAR 7 mg/24 hrs transdermal patch	Chefaro Ireland DAC	PA1186/018/004	Transdermal patch	- N07BA - N07BA01	- Nicotine		- Transdermal use
NiQuitin Fresh Mint 2mg Medicated Chewing Gum	Chefaro Ireland DAC	PA1186/019/001	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
NiQuitin Fresh Mint 4mg Medicated Chewing Gum	Chefaro Ireland DAC	PA1186/019/002	Medicated chewing-gum	- N07BA - N07BA01	- Nicotine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oromucosal use
Niquitin mini 1.5mg mint lozenges	Chefaro Ireland DAC	PA1186/018/011	Compressed lozenge	- N07BA - N07BA01	- Nicotine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oromucosal use
Niquitin Mini 2 mg citrus lozenges	Chefaro Ireland DAC	PA1186/018/018	Compressed lozenge	- N07BA01	- Nicotine resinate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oromucosal use
Niquitin Mini 2 mg Mint Lozenges	Chefaro Ireland DAC	PA1186/018/017	Compressed lozenge	- N07BA01	- Nicotine resinate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oromucosal use
Niquitin Mini 4 mg citrus lozenges	Chefaro Ireland DAC	PA1186/018/019	Compressed lozenge	- N07BA01	- Nicotine resinate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oromucosal use
Niquitin mini 4mg mint lozenges	Chefaro Ireland DAC	PA1186/018/012	Compressed lozenge	- N07BA - N07BA01	- Nicotine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oromucosal use
Nithiodote Solution for Injection	Hope Pharmaceuticals Ltd	PA22874/003/001	Solution for injection	- V03AB - V03AB06 - V03AB08	- SODIUM NITRITE - Sodium thiosulfate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Nitisinone Dipharma 10 mg hard capsules	Dipharma Arzneimittel GmbH	PA23449/001/002	Capsule, hard	- A16AX04	- Nitisinone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nitisinone Dipharma 2 mg hard capsules	Dipharma Arzneimittel GmbH	PA23449/001/003	Capsule, hard	- A16AX04	- Nitisinone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nitisinone Dipharma 20 mg hard capsules	Dipharma Arzneimittel GmbH	PA23449/001/004	Capsule, hard	- A16AX04	- Nitisinone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nitisinone Dipharma 5 mg hard capsules	Dipharma Arzneimittel GmbH	PA23449/001/001	Capsule, hard	- A16AX04	- Nitisinone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nitoman 25 mg Tablets	Bausch Health Ireland Limited	PA22698/022/001	Tablet	- N07XX - N07XX06	- Tetrabenazine		- Oral use
Nitrofurantoin 100 mg Capsules, hard	Azure Pharmaceuticals Ltd	PA22871/024/002	Capsule, hard	- J01XE01	- Nitrofurantoin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nitrofurantoin 50 mg Capsules, hard.	Azure Pharmaceuticals Ltd	PA22871/024/001	Capsule, hard	- J01XE01	- Nitrofurantoin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nitrolingual Pumpspray 400 micrograms per metered dose, sublingual spray	G Pohl-Boskamp GmbH & Co. KG	PA2243/001/001	Sublingual spray, solution	- C01DA02	- Glyceryl trinitrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Nitrous oxide Medicinal SOL, 100 % v/v, medicinal gas, liquefied	SOL S.p.A.	PA1848/004/001	Medicinal gas, liquefied	- N01AX - N01AX13	- Nitrous oxide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
Nityr	Cycle Pharmaceuticals (Europe) Ltd	EU/1/18/1290/001	Tablet	- A16AX - A16AX04	- Nitisinone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nivestim	Pfizer Europe MA EEIG	EU/1/10/631/001-3	Solution for injection/infusion	- L03AA - L03AA02	- Filgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Nivestim	Pfizer Europe MA EEIG	EU/1/10/631/004-6	Solution for injection/infusion	- L03AA - L03AA02	- Filgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Nivestim	Pfizer Europe MA EEIG	EU/1/10/631/007-9	Solution for injection/infusion	- L03AA - L03AA02	- Filgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Nizoral 20 mg/g Cream	Clonmel Healthcare Ltd	PA0126/315/003	Cream	- D01AC08	- Ketoconazole	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Cutaneous use
Nizoral 20 mg/g Cream	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/008/001	Cream	- D01AC - D01AC08	- Ketoconazole	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Cutaneous use
Nizoral 20mg/g shampoo	Clonmel Healthcare Ltd	PA0126/315/002	Shampoo	- D01AC - D01AC08	- Ketoconazole	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical
Nizoral Dandruff 20mg/g Shampoo	Clonmel Healthcare Ltd	PA0126/315/001	Shampoo	- D01AC - D01AC08	- Ketoconazole	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical
Noctura 6C tablets	A. Nelson & Company Limited	HOA1149/003/001	Tablet		- Valeriana officinalis - Potassium bromide - Passiflora incarnata - Coffea arabica	National Rules Authorisation (Article 16.2 Directive 2001/83/EC.)	- Oral use
Nolpacid 20 mg gastro-resistant tablets	KRKA, d.d., Novo mesto	PA1347/032/001	Gastro-resistant tablet	- A02BC - A02BC02	- Pantoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nolpaza 20 mg gastro-resistant tablets	KRKA, d.d., Novo mesto	PA1347/006/001 Interchangeable List Code: IC0013-003-005	Gastro-resistant tablet		- Pantoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nolpaza 40 mg gastro-resistant tablets	KRKA, d.d., Novo mesto	PA1347/006/002 Interchangeable List Code: IC0013-004-005	Gastro-resistant tablet		- Pantoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nolxado 10 mg/5 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/085/001 Interchangeable List Code: IC0102-016-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE - Naloxone hydrochloride dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nolxado 20 mg/10 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/085/002 Interchangeable List Code: IC0102-061-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE - Naloxone hydrochloride dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nolxado 40 mg/20 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/085/003 Interchangeable List Code: IC0102-160-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE - Naloxone hydrochloride dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Non-drowsy Sinutab Tablets Paracetamol 500mg Pseudoephedrine hydrochloride 30mg	JNTL Consumer Health I (Ireland) Limited	PA23490/020/001	Tablet	- N02BE - N02BE51	- PSEUDOEPHEDRINE HYDROCHLORIDE - Paracetamol		- Oral use
Non-Drowsy Sudafed Decongestant 30mg/5ml Syrup	Johnson & Johnson (Ireland) Limited	PA0330/057/001	Syrup	- R01BA - R01BA02	- PSEUDOEPHEDRINE HYDROCHLORIDE		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Non-Drowsy Sudafed Decongestant 60 mg Film-Coated Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/034/002	Film-coated tablet	- R01BA - R01BA02	- PSEUDOEPHEDRINE HYDROCHLORIDE		- Oral use
Non-Drowsy Sudaplus Tablets Paracetamol 500mg Pseudoephedrine hydrochloride 30mg	JNTL Consumer Health I (Ireland) Limited	PA23490/021/001	Tablet	- N02BE - N02BE51	- Paracetamol - PSEUDOEPHEDRINE HYDROCHLORIDE	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Non-Drowsy Sudapro Head Cold 200mg / 30mg Film-coated Tablets	Johnson & Johnson (Ireland) Limited	PA0330/056/001	Film-coated tablet	- R05X	- Ibuprofen - PSEUDOEPHEDRINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Noqturina 25 microgram oral lyophilisate	Ferring Ireland Ltd	PA1009/027/001	Oral lyophilisate	- H01BA - H01BA02	- DESMOPRESSIN ACETATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Noqturina 50 microgram oral lyophilisate	Ferring Ireland Ltd	PA1009/027/002	Oral lyophilisate	- H01BA - H01BA02	- DESMOPRESSIN ACETATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Noradrenaline (Norepinephrine) 0.08 mg/mL solution for infusion	Laboratoire AGUETTANT	PA1968/001/001	Solution for infusion	- C01CA - C01CA03	- Noradrenaline	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Noradrenaline (Norepinephrine) 1 mg/ml concentrate for solution for infusion	AS Kalceks	PA2165/009/001	Concentrate for solution for infusion	- C01CA03	- Noradrenaline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Noradrenaline (Norepinephrine) 1:1000 Concentrate For Solution For Infusion	Pfizer Healthcare Ireland	PA0822/219/001	Concentrate for solution for infusion	- C01CA - C01CA03	- Noradrenaline acid tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Noradrenaline (Norepinephrine) Kabi 1 mg/ml concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/073/001	Concentrate for solution for infusion	- C01CA03	- Sodium chloride - Noradrenaline tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Nordimet	Nordic Group B.V.	EU/1/16/1124/001	Solution for injection in pre-filled pen	- L04AX - L04AX03	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Nordimet	Nordic Group B.V.	EU/1/16/1124/002	Solution for injection in pre-filled pen	- L04AX - L04AX03	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Nordimet	Nordic Group B.V.	EU/1/16/1124/003	Solution for injection in pre-filled pen	- L04AX - L04AX03	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Nordimet	Nordic Group B.V.	EU/1/16/1124/004	Solution for injection in pre-filled pen	- L04AX - L04AX03	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Nordimet	Nordic Group B.V.	EU/1/16/1124/005	Solution for injection in pre-filled pen	- L04AX - L04AX03	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Nordimet	Nordic Group B.V.	EU/1/16/1124/006	Solution for injection in pre-filled pen	- L04AX - L04AX03	- Methotrexate		- Intramuscular use - Subcutaneous use
Nordimet	Nordic Group B.V.	EU/1/16/1124/007	Solution for injection in pre-filled pen	- L04AX - L04AX03	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Nordimet	Nordic Group B.V.	EU/1/16/1124/008	Solution for injection in pre-filled pen	- L04AX - L04AX03	- Methotrexate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Norditropin FlexPro 10 mg/1.5 ml, solution for injection in pre-filled pen	Novo Nordisk A/S	PA0218/040/012	Solution for injection in pre-filled pen	- H01AC - H01AC01	- Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Norditropin FlexPro 15 mg/1.5 ml, solution for injection in pre-filled pen	Novo Nordisk A/S	PA0218/040/013	Solution for injection in pre-filled pen	- H01AC - H01AC01	- Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Norditropin FlexPro 5 mg/1.5 ml, solution for injection in pre-filled pen	Novo Nordisk A/S	PA0218/040/011	Solution for injection in pre-filled pen	- H01AC - H01AC01	- Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Norditropin NordiFlex 10 mg/1.5 ml solution for injection in pre-filled pen	Novo Nordisk A/S	PA0218/040/009	Solution for injection in pre-filled pen	- H01AC - H01AC01	- Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Norditropin NordiFlex 15 mg/1.5 ml solution for injection in pre-filled pen	Novo Nordisk A/S	PA0218/040/010	Solution for injection in pre-filled pen	- H01AC - H01AC01	- Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Norditropin NordiFlex 5 mg/1.5 ml solution for injection in pre-filled pen	Novo Nordisk A/S	PA0218/040/008	Solution for injection in pre-filled pen	- H01AC - H01AC01	- Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Nordurine 0.1 mg Tablets	Ferring Ireland Ltd	PA1009/017/001	Tablet	- H01BA - H01BA02	- DESMOPRESSIN ACETATE		- Oral use
Nordurine 0.2 mg Tablets	Ferring Ireland Ltd	PA1009/017/002	Tablet	- H01BA - H01BA02	- DESMOPRESSIN ACETATE		- Oral use
Noriday 350 micrograms Tablets	Pfizer Healthcare Ireland	PA0822/131/001	Tablet	- G03AC - G03AC01	- Norethisterone		- Oral use
Noriday 350 micrograms tablets	PCO Manufacturing Ltd.	PPA0465/310/001	Tablet	- G03AC - G03AC01	- Norethisterone		- Oral use
NORLEVO 1.5 mg tablet	PCO Manufacturing Ltd.	PPA0465/288/001	Tablet	- G03AD - G03AD01	- Levonorgestrel		- Oral use
NORLEVO® 1.5 mg tablet	Laboratoire HRA Pharma	PA1166/002/001	Tablet	- G03AD - G03AD01	- Levonorgestrel	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Normacol 62% w/w Granules	Norgine B.V.	PA1336/007/001	Granules	- A06AC - A06AC03	- Sterculia		- Oral use
Normosang 25 mg/ml, concentrate for solution for infusion	Recordati Rare Diseases	PA0928/001/001	Concentrate for solution for infusion	- B06AB - B06AB01	- Human hemin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Nortem 10mg Tablets	Teva B.V.	PA1986/085/001	Tablet	- N05CD - N05CD07	- Temazepam		- Oral use
Nortem 20mg Tablets	Teva B.V.	PA1986/085/002	Tablet	- N05CD - N05CD07	- Temazepam		- Oral use
Nortriptyline 10 mg Film-coated Tablets	Pharmafile Limited	PA0599/005/001	Film-coated tablet	- N06AA10	- Nortriptyline	Generic application (Article 10(1) of Directive No 2001/83/EC)	
Nortriptyline 25 mg Film-coated Tablets	Pharmafile Limited	PA0599/005/002	Film-coated tablet	- N06AA - N06AA10	- Nortriptyline	Generic application (Article 10(1) of Directive No 2001/83/EC)	
Norvir	AbbVie Deutschland GmbH & Co. KG	EU/1/96/016/005-006	Film-coated tablet	- J05AE - J05AE03	- Ritonavir		- Oral use
Norvir	AbbVie Deutschland GmbH & Co. KG	EU/1/96/016/009	Powder for oral suspension	- J05AE - J05AE03	- Ritonavir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Notiabolfen XL 150 Prolonged-release Tablet	Accord Healthcare Ireland Ltd.	PA2315/066/005 Interchangeable List Code: IC0019-062-024	Prolonged-release tablet		- Quetiapine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Notiabolfen XL 200 mg prolonged-release Tablet	Accord Healthcare Ireland Ltd.	PA2315/066/001 Interchangeable List Code: IC0019-067-024	Prolonged-release tablet		- Quetiapine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Notiabolfen XL 300 mg prolonged-release Tablet	Accord Healthcare Ireland Ltd.	PA2315/066/002 Interchangeable List Code: IC0019-029-024	Prolonged-release tablet		- Quetiapine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Notiabolfen XL 400 mg prolonged-release Tablet	Accord Healthcare Ireland Ltd.	PA2315/066/003 Interchangeable List Code: IC0019-068-024	Prolonged-release tablet		- Quetiapine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Notiabolfen XL 50 mg prolonged-release tablets	Accord Healthcare Ireland Ltd.	PA2315/066/004 Interchangeable List Code: IC0019-023-024	Prolonged-release tablet		- Quetiapine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
NovaThirteen	Novo Nordisk A/S	EU/1/12/775/001	Powder and solvent for solution for injection	- B02BD11	- Rfxiii drug substance	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Novistig 0.5 mg/ml + 2.5 mg/ml solution for injection	Sintetica GmbH	PA22835/003/001	Solution for injection	- A03AB02	- Glycopyrronium bromide - Neostigmine Metilsulfate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
NovoEight	Novo Nordisk A/S	EU/1/13/888/001	Powder and solvent for solution for injection	- B02BD - B02BD02	- Turoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
NovoEight	Novo Nordisk A/S	EU/1/13/888/002	Powder and solvent for solution for injection	- B02BD - B02BD02	- Turoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
NovoEight	Novo Nordisk A/S	EU/1/13/888/003	Powder and solvent for solution for injection	- B02BD - B02BD02	- Turoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
NovoEight	Novo Nordisk A/S	EU/1/13/888/004	Powder and solvent for solution for injection	- B02BD - B02BD02	- Turoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
NovoEight	Novo Nordisk A/S	EU/1/13/888/005	Powder and solvent for solution for injection	- B02BD - B02BD02	- Turoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
NovoEight	Novo Nordisk A/S	EU/1/13/888/006	Powder and solvent for solution for injection	- B02BD - B02BD02	- Turoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Novofem film-coated tablets	Novo Nordisk A/S	PA0218/053/001	Film-coated tablet	- G03FA - G03FA01	- Estradiol - Norethisterone acetate - Estradiol		- Oral use
NovoMix 30 FlexPen	Novo Nordisk A/S	EU/1/00/142/09-010	Suspension for injection	- A10AD - A10AD06	- Insulin aspart		- Subcutaneous use
NovoMix 30 Penfill	Novo Nordisk A/S	EU/1/00/142/004-05	Suspension for injection	- A10AD - A10AD05	- Insulin aspart		- Subcutaneous use
NovoMix 50 FlexPen	Novo Nordisk A/S	EU/1/00/142/14-16	Suspension for injection	- A10AD - A10AD06	- Insulin aspart		- Subcutaneous use
NovoMix 50 PenFill	Novo Nordisk A/S	EU/1/00/142/11-13	Suspension for injection	- A10AD - A10AD06	- Insulin aspart		- Subcutaneous use
NovoMix 70 FlexPen	Novo Nordisk A/S	EU/1/00/142/020-022	Suspension for injection	- A10AD - A10AD06	- Insulin aspart		
NovoMix 70 Penfill	Novo Nordisk A/S	EU/1/00/142/017-19	Suspension for injection	- A10AD - A10AD06	- Insulin aspart		- Subcutaneous use
NOVONORM	Novo Nordisk A/S	EU/1/98/076/001	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
NovoNorm	Novo Nordisk A/S	EU/1/98/076/002	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/003	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/004	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/005	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/006	Tablet	- A10BG	- Repaglinide		

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
NovoNorm	Novo Nordisk A/S	EU/1/98/076/007	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/008	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/009	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/010	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/011	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/012	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/013	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/014	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/015	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/016	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/017	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/018	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/019	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/020	Tablet	- A10BG	- Repaglinide		
NovoNorm	Novo Nordisk A/S	EU/1/98/076/021	Tablet	- A10BG	- Repaglinide		
NovoRapid	Novo Nordisk A/S	EU/1/99/119/001	Solution for injection	- A10AB - A10AB05	- Insulin aspart		- Subcutaneous use
NovoRapid	Novo Nordisk A/S	EU/1/99/119/012	Solution for injection	- A10AB - A10AB05	- Insulin aspart		
NovoRapid FlexPen	Novo Nordisk A/S	EU/1/99/119/009-011	Solution for injection in pre-filled pen	- A10AB - A10AB05	- Insulin aspart		- Subcutaneous use
NovoRapid FlexTouch	Novo Nordisk A/S	EU/1/99/119/019	Solution for injection in pre-filled pen	- A10AB - A10AB05	- Insulin aspart		
NovoRapid InnoLet	Novo Nordisk A/S	EU/1/99/119/012-014	Solution for injection in pre-filled pen	- A10AB - A10AB05	- Insulin aspart		
NOVORAPID INNOLET	Novo Nordisk A/S	EU/1/99/119/013	Solution for injection/infusion	- A10AB - A10AB05	- Insulin aspart		
NOVORAPID NOVOLET	Novo Nordisk A/S	EU/1/99/119/005	Solution for injection	- A10AB - A10AB05	- Insulin aspart		- Subcutaneous use
NovoRapid Penfill	Novo Nordisk A/S	EU/1/99/119/003	Solution for injection in pre-filled pen	- A10AB - A10AB05	- Insulin aspart		- Subcutaneous use
NovoRapid PumpCart	Novo Nordisk A/S	EU/1/99/119/024-025	Solution for injection in cartridge	- A10AB - A10AB05	- Insulin aspart		
NovoSeven	Novo Nordisk A/S	EU/1/96/006/003	Powder and solvent for solution for injection	- B05BA - B05BA03	- Factor viia human, recombinant	Not Currently Available	- Intra-venous
NovoSeven (400 KIU)	Novo Nordisk A/S	EU/1/96/006/007	Powder and solvent for solution for injection	- B05BA - B05BA03	- Eptacog alfa (activated)		- Intravenous use
NovoSeven (100 KIU)	Novo Nordisk A/S	EU/1/96/006/005	Powder and solvent for solution for injection	- B02BD - B02BD08	- Eptacog alfa (activated)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
NovoSeven (250 KIU)	Novo Nordisk A/S	EU/1/96/006/006	Powder and solvent for solution for injection	- B02BD - B02BD08	- Eptacog alfa (activated)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
NovoSeven (50 KIU)	Novo Nordisk A/S	EU/1/96/006/004	Powder and solvent for solution for injection	- B02BD - B02BD08	- Eptacog alfa (activated)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Noxafil	Merck Sharp & Dohme BV,	EU/1/05/320/004	Concentrate for solution for infusion	- J02AC - J02AC04	- Posaconazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Noxafil	Merck Sharp & Dohme BV,	EU/1/05/320/005	Gastro-resistant powder for oral suspension	- J02AC04	- Posaconazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Noxafil 100 mg gastro-resistant tablets	Merck Sharp & Dohme BV,	EU/1/05/320/002-003 Interchangeable List Code: IC0126-024-005	Gastro-resistant tablet		- Posaconazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Noxafil 40 mg/ml oral suspension	Merck Sharp & Dohme BV,	EU/1/05/320/001 Interchangeable List Code: IC0126-132-027	Oral suspension		- Posaconazole		- Oral use
Nozinan 25 mg/ml solution for injection/infusion	Neuraxpharm Ireland Limited	PA23229/008/001	Solution for injection/infusion	- N05AA - N05AA02	- LEVOMEPROMAZINE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Nplate 250 micrograms	Amgen Europe B.V.	EU/1/08/497/1,3	Powder for solution for injection	- B02BX - B02BX04	- Romiplostim	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Nplate 250 micrograms /500 micrograms	Amgen Europe B.V.	EU/1/08/497/5-8	Powder and solvent for solution for injection	- B02BX - B02BX04	- Romiplostim		- Subcutaneous use
Nplate 500 micrograms	Amgen Europe B.V.	EU/1/08/497/2,4	Powder for solution for injection	- B02BX - B02BX04	- Romiplostim	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Nubeqa	Bayer AG	EU/1/20/1432/001	Film-coated tablet	- L02BB06	- Darolutamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Nucala	GlaxoSmithKline Trading Services Limited	EU/1/15/1043/001-002	Powder for solution for injection	- R03DX	- Mepolizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Nucala	GlaxoSmithKline Trading Services Limited	EU/1/15/1043/003-004	Solution for injection in pre-filled pen	- R03DX09	- Mepolizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Nucala	GlaxoSmithKline Trading Services Limited	EU/1/15/1043/005-006	Solution for injection in pre-filled syringe	- R03DX09	- Mepolizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	
Nucala	GlaxoSmithKline Trading Services Limited	EU/1/15/1043/009-010	Solution for injection in pre-filled syringe	- R03DX09	- Mepolizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Nuceiva	Evolus Pharma Ltd.	EU/1/19/1364/001	Powder for solution for injection	- M03AX01	- Botulinum Toxin Type A	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Nuceiva	Evolus Pharma Ltd.	EU/1/19/1364/002	Powder for solution for injection	- M03AX01	- Botulinum Toxin Type A	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Nulibry	TMC Pharma (EU) Limited	EU/1/22/1684/001	Powder for solution for injection	- A16AX - A16AX19	- Fosdenopterin hydrobromide dihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Nulojix	Bristol-Myers Squibb Pharma EEIG	EU/1/11/694/001-002	Powder for concentrate for solution for infusion	- L04AA - L04AA28	- Belatacept		- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Numeta G13%E Preterm emulsion for infusion	Baxter Holding B.V.	PA2299/030/003	Emulsion for infusion	- B05BA - B05BA10	- Alanine - Arginine - Aspartic Acid - Cysteine - Glutamic acid - Glycine - Histidine - Isoleucine - Leucine - Lysine - Methionine - Ornithine hydrochloride - Phenylalanine - Proline - Serine - Taurine - Threonine - Tryptophan - Tyrosine - Valine - Potassium acetate - Calcium chloride dihydrate - Magnesium acetate tetrahydrate - Sodium glycerophosphate, hydrated - Glucose - Refined olive oil + refined soybean oil	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Intravenous use
Numeta G16%E emulsion for infusion	Baxter Holding B.V.	PA2299/030/001	Emulsion for infusion	- B05BA - B05BA10	- Alanine - Arginine - Aspartic Acid - Cysteine - Glutamic acid - Glycine - Histidine - Isoleucine - Leucine - Lysine - Methionine - Ornithine hydrochloride - Phenylalanine - Proline - Serine - Taurine - Threonine - Tryptophan - Tyrosine - Valine - Sodium chloride ph.eur. - Potassium acetate - Calcium chloride dihydrate - Magnesium acetate tetrahydrate - Sodium glycerophosphate, hydrated - Glucose - Refined olive oil + refined soybean oil	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Numeta G19%E emulsion for infusion	Baxter Holding B.V.	PA2299/030/002	Emulsion for infusion	- B05BA - B05BA10	- Alanine - Arginine - Aspartic Acid - Cysteine - Glutamic acid - Glycine - Histidine - Isoleucine - Leucine - Lysine - Methionine - Ornithine hydrochloride - Phenylalanine - Proline - Serine - Taurine - Threonine - Tryptophan - Tyrosine - Valine - Sodium chloride - Potassium acetate - Calcium chloride dihydrate - Magnesium acetate tetrahydrate - Sodium glycerophosphate, hydrated - Glucose - Refined olive oil + refined soybean oil	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Intravenous use
Nuprin 75mg gastro-resistant tablets	Accord Healthcare Ireland Ltd.	PA2315/189/001	Gastro-resistant tablet	- B01AC - B01AC06	- Acetylsalicylic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Nurofen 200 mg coated tablets	PCO Manufacturing Ltd.	PPA0465/430/002	Coated tablet	- M01AE01	- Ibuprofen		- Oral use
Nurofen 200 mg Coated Tablets	Reckitt Benckiser Ireland Ltd	PA0979/032/006	Coated tablet	- M01AE - M01AE01	- Ibuprofen		- Oral use
Nurofen 5% w/w Gel	Reckitt Benckiser Ireland Ltd	PA0979/032/003	Gel	- M02AA - M02AA13	- Ibuprofen	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Topical use
Nurofen Advance 200mg Tablets	Reckitt Benckiser Ireland Ltd	PA0979/075/001	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen lysinate		- Oral use
Nurofen Cold & Flu film-coated tablets Ibuprofen 200mg Pseudoephedrine hydrochloride 30mg	PCO Manufacturing Ltd.	PPA0465/337/002	Film-coated tablet	- M01AE - M01AE51	- Ibuprofen - PSEUDOEPHEDRINE HYDROCHLORIDE		- Oral use
Nurofen Cold & Flu Film-coated Tablets Ibuprofen 200mg Pseudophedrine hydrochloride 30mg	Reckitt Benckiser Ireland Ltd	PA0979/033/001	Film-coated tablet	- M01AE - M01AE51	- Ibuprofen - PSEUDOEPHEDRINE HYDROCHLORIDE		- Oral use
Nurofen Durance 200 mg medicated plaster	Reckitt Benckiser Ireland Ltd	PA0979/032/018	Medicated plaster	- M02AA - M02AA13	- Ibuprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Nurofen Express 200 mg Tablets	Reckitt Benckiser Ireland Ltd	PA0979/032/010	Coated tablet	- M01AE - M01AE01	- Ibuprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Nurofen Express Maximum Strength 400 mg Tablets	Reckitt Benckiser Ireland Ltd	PA0979/032/011	Coated tablet	- M01AE - M01AE01	- Ibuprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Nurofen Express Maximum Strength 400 mg tablets	PCO Manufacturing Ltd.	PPA0465/430/001	Coated tablet	- M01AE01	- Ibuprofen		- Oral use
Nurofen Express Maximum Strength 400 mg Tablets	IMED Healthcare Ltd.	PPA1463/217/001	Coated tablet	- M01AE - M01AE01	- Ibuprofen		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Nurofen for children 100 mg chewable capsules, Soft	Reckitt Benckiser Ireland Ltd	PA0979/069/001	Capsule, soft	- M01AE - M01AE01	- Ibuprofen - Ibuprofen	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Nurofen for Children 60 mg Suppositories Age 3 months to 2 years	Reckitt Benckiser Ireland Ltd	PA0979/032/007	Suppository	- M01AE - M01AE01	- Ibuprofen		- Rectal use
Nurofen for Children Cold & Flu & Pain Orange 100mg/5ml Oral Suspension	Reckitt Benckiser Ireland Ltd	PA0979/066/001	Oral suspension	- M01AE - M01AE01	- Ibuprofen	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Nurofen for Children Cold & Flu & Pain Strawberry 100mg/5ml Oral Suspension	Reckitt Benckiser Ireland Ltd	PA0979/067/001	Oral suspension	- M01AE - M01AE01	- Ibuprofen	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Nurofen for Children Meltlets 100mg Orodispersible Tablets	Reckitt Benckiser Ireland Ltd	PA0979/032/005	Orodispersible tablet	- M01AE - M01AE01	- Ibuprofen		- Oral use
Nurofen for Children Orange 100 mg/5 ml oral suspension	Reckitt Benckiser Ireland Ltd	PA0979/032/001	Oral suspension	- M01AE - M01AE01	- Ibuprofen		- Oral use
Nurofen for Children Orange 100 mg/5 ml oral suspension	PCO Manufacturing Ltd.	PPA0465/337/001	Oral suspension	- M01AE01	- Ibuprofen		- Oral use
Nurofen for Children Sachets 100 mg/5 ml Oral Suspension	Reckitt Benckiser Ireland Ltd	PA0979/032/008	Oral suspension	- M01AE - M01AE01	- Ibuprofen	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Nurofen for Children Six Plus Orange 200 mg/5 ml oral suspension	Reckitt Benckiser Ireland Ltd	PA0979/056/001	Oral suspension	- M01AE - M01AE01	- Ibuprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Nurofen for Children Six Plus Strawberry 200 mg/5 ml oral suspension	Reckitt Benckiser Ireland Ltd	PA0979/056/002	Oral suspension	- M01AE - M01AE01	- Ibuprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Nurofen for Children Strawberry 100 mg/5 ml oral suspension	Reckitt Benckiser Ireland Ltd	PA0979/032/009	Oral suspension	- M01AE - M01AE01	- Ibuprofen		- Oral use
Nurofen Long Lasting 300 mg Prolonged Release Hard Capsules	Reckitt Benckiser Ireland Ltd	PA0979/032/015	Prolonged-release capsule, hard	- M01AE - M01AE01	- Ibuprofen		- Oral use
Nurofen Long Lasting 300 mg prolonged-release tablets	Reckitt Benckiser Ireland Ltd	PA0979/081/001	Prolonged-release tablet	- M01AE01	- Ibuprofen	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Nurofen Plus Tablets Ibuprofen 200 mg Codeine Phosphate Hemihydrate 12.8 mg	PCO Manufacturing Ltd.	PPA0465/410/001	Film-coated tablet	- N02AJ - N02AJ08	- Ibuprofen - Codeine phosphate hemihydrate		- Oral use
Nurofen Plus Tablets Ibuprofen 200mg Codeine Phosphate Hemihydrate 12.8mg	Reckitt Benckiser Ireland Ltd	PA0979/034/001	Film-coated tablet	- N02AJ - N02AJ08	- Ibuprofen - Codeine phosphate hemihydrate		- Oral use
Nurofen Rapid Relief 200mg Liquid Capsules	Reckitt Benckiser Ireland Ltd	PA0979/032/012	Capsule, soft	- M01AE - M01AE01	- Ibuprofen		- Oral use
Nurofen Rapid Relief Max 400 mg soft capsules	Reckitt Benckiser Ireland Ltd	PA0979/085/001	Capsule, soft	- M01AE01	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Nurofen Rapid Relief Maximum Strength 400 mg liquid capsules	PCO Manufacturing Ltd.	PPA0465/446/001	Capsule, soft	- M01AE01	- Ibuprofen		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Nurofen Rapid Relief Maximum Strength 400 mg Liquid Capsules	IMED Healthcare Ltd.	PPA1463/220/001	Capsule, soft	- M01AE01	- Ibuprofen	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Nurofen Rapid Relief Maximum Strength 400mg Liquid Capsules	Reckitt Benckiser Ireland Ltd	PA0979/032/013	Capsule, soft	- M01AE - M01AE01	- Ibuprofen		- Oral use
Nurofen Rapid Relief Maximum Strength 400mg Liquid Capsules	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/057/001	Capsule, soft	- M01AE - M01AE01	- Ibuprofen		- Oral use
Nurofen Rapid Relief Maximum Strength 400mg Liquid Capsules	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/050/001	Capsule, soft	- M01AE - M01AE01	- Ibuprofen		- Oral use
Nurofen Sinus and Pain Film-Coated Tablets Ibuprofen 200mg Pseudoephedrine Hydrochloride 30mg	Reckitt Benckiser Ireland Ltd	PA0979/065/001	Film-coated tablet	- M01AE - M01AE01	- Ibuprofen - PSEUDOEPHEDRINE HYDROCHLORIDE	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Nu-Seals 300 mg Gastro-resistant Tablets	Alliance Pharma (Ireland) Limited	PA2325/010/002	Gastro-resistant tablet	- N02BA - N02BA01	- Acetylsalicylic acid		- Oral use
Nu-seals 75 mg gastro-resistant tablets	Alliance Pharma (Ireland) Limited	PA2325/010/001	Gastro-resistant tablet	- B01AC - B01AC06	- Acetylsalicylic acid		- Oral use
Nustendi	Daiichi Sankyo Europe GmbH	EU/1/20/1424/001-006	Film-coated tablet	- L01XC38	- Bempedoic Acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Nutriflex basal Solution for Infusion	B. Braun Melsungen AG	PA0736/005/001	Solution for infusion	- B05BA - B05BA10	- Isoleucine - Leucine - Lysine hydrochloride - Methionine - Phenylalanine - Threonine - Tryptophan - Valine - Arginine Monoglutamate - Alanine - Aspartic Acid - Glutamic acid - Glycine - Proline - Serine - Magnesium acetate tetrahydrate - Sodium acetate trihydrate - Potassium dihydrogen phosphate - Potassium hydroxide - Sodium hydroxide - Glucose monohydrate - Calcium chloride dihydrate - Sodium chloride - Histidine hydrochloride monohydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Nutriflex peri Solution for Infusion	B. Braun Melsungen AG	PA0736/006/001	Solution for infusion	- B05BA - B05BA10	- Isoleucine - Leucine - Lysine hydrochloride - Methionine - Phenylalanine - Threonine - Tryptophan - Valine - Arginine Monoglutamate - Alanine - Aspartic Acid - Glutamic acid - Glycine - Proline - Serine - Magnesium acetate tetrahydrate - Sodium acetate trihydrate - Potassium dihydrogen phosphate - Potassium hydroxide - Sodium hydroxide - Glucose monohydrate - Calcium chloride dihydrate - Sodium chloride - Histidine hydrochloride monohydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Nutriflex plus Solution for Infusion	B. Braun Melsungen AG	PA0736/007/001	Solution for infusion	- B05BA - B05BA10	- Isoleucine - Leucine - Lysine hydrochloride - Methionine - Phenylalanine - Threonine - Tryptophan - Valine - Arginine Monoglutamate - Alanine - Aspartic Acid - Glutamic acid - Glycine - Proline - Serine - Magnesium acetate tetrahydrate - Sodium acetate trihydrate - Sodium dihydrogen phosphate dihydrate - Potassium hydroxide - Sodium hydroxide - Glucose monohydrate - Calcium chloride dihydrate - Histidine hydrochloride monohydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Nutriflex special Solution for infusion	B. Braun Melsungen AG	PA0736/008/001	Solution for infusion	- V06DE	- Isoleucine - Leucine - Lysine hydrochloride - Methionine - Phenylalanine - Threonine - Tryptophan - Valine - Arginine Monoglutamate - Alanine - Aspartic Acid - Glutamic acid - Glycine - Proline - Serine - Magnesium acetate tetrahydrate - Sodium acetate trihydrate - Potassium dihydrogen phosphate - Potassium hydroxide - Sodium hydroxide - Glucose monohydrate - Calcium chloride dihydrate - Histidine hydrochloride monohydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Nutrineal Solution for Peritoneal Dialysis 4 with 1.1% Amino Acids	Baxter Holding B.V.	PA2299/016/001	Solution for peritoneal dialysis	- B05DB	- L-tyrosine - L-tryptophan - L-phenylalanine - L-threonine - L-serine - L-proline - Glycine - L-alanine - L-valine - L-methionine - L-isoleucine - L-leucine - L-lysine hydrochloride - L-histidine - L-arginine - Calcium chloride - Magnesium chloride - Sodium (S) - lactate - Sodium chloride		- Intravenous use
NutropinAq	Ipsen Pharma	EU/1/00/164/003-004	Solution for injection	- H01AC01	- Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
NutropinAq	Ipsen Pharma	EU/1/00/164/005	Solution for injection	- H01AC01	- Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
NuvaRing 0.120 mg/0.015 mg per 24 hours, vaginal delivery system	Organon Pharma (Ireland) Limited	PA23198/020/001	Vaginal delivery system	- G03BB - G03BB01	- Etonogestrel - Ethinylestradiol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Nuvaxovid	Novavax CZ	EU/1/21/1618/001	Dispersion for injection	- J07BX03	- SARS-CoV-2 spike protein recombinant	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Nuwiq	Octapharma AB	EU/1/14/936/001	Powder and solvent for solution for injection	- B02BD - B02BD02	- Simoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Nuwiq	Octapharma AB	EU/1/14/936/002	Powder and solvent for solution for injection	- B02BD - B02BD02	- Simoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Nuwiq	Octapharma AB	EU/1/14/936/003	Powder and solvent for solution for injection	- B02BD - B02BD02	- Simoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Nuwiq	Octapharma AB	EU/1/14/936/004	Powder and solvent for solution for injection	- B02BD - B02BD02	- Simoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Nuwiq	Octapharma AB	EU/1/14/936/005	Powder and solvent for solution for injection	- B02BD - B02BD02	- Simoctocog alfa		- Intravenous use
Nuwiq	Octapharma AB	EU/1/14/936/006	Powder and solvent for solution for injection	- B02BD - B02BD02	- Simoctocog alfa		- Intravenous use
Nuwiq	Octapharma AB	EU/1/14/936/007	Powder and solvent for solution for injection	- B02BD - B02BD02	- Simoctocog alfa		- Intravenous use
Nuwiq	Octapharma AB	EU/1/14/936/008	Powder and solvent for solution for injection	- B02BD02	- Simoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Nux vom	A. Nelson & Company Limited	HOR1149/023/001	Not assigned		- Strychnos nux-vomica		- Oral use
Nytamel 10 mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/117/002 Interchangeable List Code: IC0135-002-003	Film-coated tablet		- Zolpidem tartrate		- Oral use
Nytamel 5 mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/117/001 Interchangeable List Code: IC0135-001-003	Film-coated tablet		- Zolpidem tartrate		- Oral use
Nytol One-A-Night 50 mg Tablets	Chefaro Ireland DAC	PA1186/016/001	Tablet	- R06AA - R06AA02	- Diphenhydramine hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Nyvepria	Pfizer Europe MA EEIG	EU/1/20/1486/001	Solution for injection	- L03AA13	- Pegfilgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Nyxoid	Mundipharma Corporation (Ireland) Limited	EU/1/17/1238/001	Nasal spray, solution in single-dose container	- V03AB - V03AB15	- Naloxone hydrochloride dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Nasal use
Obiltoxaximab SFL	SFL Regulatory Services GmbH	EU/1/20/1485/001	Concentrate for solution for infusion	- J06BB22	- Obiltoxaximab	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Obizur	Baxter Innovations GmbH	EU/1/15/1035/001-003	Powder and solvent for solution for injection	- B02BD - B02BD14	- Susoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ocaliva	Advanz Pharma Limited	EU/1/16/1139/001	Film-coated tablet	- A05AA - A05AA04	- Obeticholic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ocaliva	Advanz Pharma Limited	EU/1/16/1139/002	Film-coated tablet	- A05AA - A05AA04	- Obeticholic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Occlusal 26% w/w Cutaneous Solution	Alliance Pharma (Ireland) Limited	PA2325/011/001	Cutaneous solution	- D02AF	- Salicylic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Ocrevus	Roche Registration GmbH	EU/1/17/1231/001-002	Concentrate for solution for infusion	- L04AA - L04AA36	- Ocrelizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Octanate 1000 IU powder and solvent for solution for injection	Octapharma (IP) SPRL	PA2219/004/003	Powder and solvent for solution for injection	- B02BD - B02BD02	- Human coagulation factor viii	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Octanate 250 IU.Powder and solvent for solution for injection	Octapharma (IP) SPRL	PA2219/004/001	Powder and solvent for solution for injection	- B02BD - B02BD02	- Human plasmafraktion (factor viii)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Octanate 500 IU powder and solvent for solution for injection	Octapharma (IP) SPRL	PA2219/004/002	Powder and solvent for solution for injection	- B02BD - B02BD02	- Human coagulation factor viii	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Octaplex 1000 IU coagulation factor IX per vial, powder and solvent for solution for infusionHuman Prothrombin Comple	Octapharma (IP) SPRL	PA2219/005/002	Powder and solvent for solution for infusion	- B02BD - B02BD01	- Human coagulation factor ii - Human coagulation factor vii - Human coagulation factor ix - Human coagulation factor x - Protein c - Protein s	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Octaplex 500 IU coagulation factor IX per vial, powder and solvent for solution for infusionHuman Prothrombin Comple	Octapharma (IP) SPRL	PA2219/005/001	Powder and solvent for solution for infusion	- B02BD - B02BD01	- Human plasma coagulation factor ii - Human plasma coagulation factor vii - Human plasma coagulation factor ix - Human plasma coagulation factor x - Protein c - Protein s	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Octreoscan 111 MBq/mL, kit for radiopharmaceutical preparation	Curium Netherlands B.V.	PA0690/001/001	Kit for radiopharmaceutical preparation	- V09AX01	- Indium (111 in) chloride solution - Pentetreotide		- Intravenous use
Octreotide 100 micrograms/1 ml solution for injection	Pfizer Healthcare Ireland	PA0822/218/002	Solution for injection	- H01CB - H01CB02	- OCTREOTIDE ACETATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Octreotide 50 micrograms/1 ml solution for injection	Pfizer Healthcare Ireland	PA0822/218/001	Solution for injection	- H01CB - H01CB02	- OCTREOTIDE ACETATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Octreotide 500 micrograms/1 ml solution for injection	Pfizer Healthcare Ireland	PA0822/218/004	Solution for injection	- H01CB - H01CB02	- OCTREOTIDE ACETATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Odefsey	Gilead Sciences Ireland UC	EU/1/16/1112/001-002	Film-coated tablet	- J05AR - J05AR19	- Emtricitabine - Rilpivirine - Tenofovir alafenamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Odomzo	Sun Pharmaceutical Industries Europe B.V.	EU/1/15/1030/001-002	Capsule, hard	- L01XX	- Sonidegib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Odrik 1mg Hard Capsules	Mylan IRE Healthcare Limited	PA2010/005/002	Capsule, hard	- C09AA - C09AA10	- Trandolapril		- Oral use
Odrik 2mg Hard Capsules	Mylan IRE Healthcare Limited	PA2010/005/003	Capsule, hard	- C09AA - C09AA10	- Trandolapril		- Oral use
Oestrogel Pump-Pack 750 micrograms/actuation Gel	Laboratoires Besins International	PA1054/004/001	Gel	- G03CA03	- Estradiol hemihydrate		- Transdermal use
Ofev	Boehringer Ingelheim International GmbH	EU/1/14/979/001-002	Capsule, soft	- L01XE - L01XE31	- Nintedanib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ofev	Boehringer Ingelheim International GmbH	EU/1/14/979/003-004	Capsule, soft	- L01XE31	- Nintedanib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ofost 10 IU/ml concentrate for solution for infusion or solution for intramuscular injection	AS Grindeks	PA22992/001/002	Solution for injection/infusion	- H01BB02	- Oxytocin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Ofost 5 IU/ml concentrate for solution for infusion or solution for intramuscular injection	AS Grindeks	PA22992/001/001	Solution for injection/infusion	- H01BB02	- Oxytocin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Ogivri	Biosimilar Collaborations Ireland Limited	EU/1/18/1341/001	Powder for concentrate for solution for infusion	- L01XC03	- Trastuzumab		- Intravenous use
Ogivri	Biosimilar Collaborations Ireland Limited	EU/1/18/1341/002	Powder for concentrate for solution for infusion	- L01XC03	- Trastuzumab		- Intravenous use
Ogluo	Tetris Pharma B.V.	EU/1/20/1523/001-002	Solution for injection in pre-filled pen	- H04AA01	- GLUCAGON	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Ogluo	Tetris Pharma B.V.	EU/1/20/1523/003-004	Solution for injection in pre-filled syringe	- H04AA01	- GLUCAGON	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Ogluo	Tetris Pharma B.V.	EU/1/20/1523/005-006	Solution for injection in pre-filled pen	- H04AA01	- GLUCAGON	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Ogluo	Tetris Pharma B.V.	EU/1/20/1523/007-008	Solution for injection in pre-filled syringe	- H04AA01	- GLUCAGON	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Oilatum Cream	Clonmel Healthcare Ltd	PA0126/321/001	Cream	- D02AC	- Liquid paraffin light - White soft paraffin		- Topical use
Oilatum Emollient 63.4% w/w Bath Additive	Clonmel Healthcare Ltd	PA0126/322/001	Bath additive	- D02AC	- Liquid paraffin light	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Cutaneous use
Oilatum Junior Flare-Up Bath Additive Light liquid paraffin 52.5% w/w Benzalkonium chloride 6.0% w/w Triclosan	Clonmel Healthcare Ltd	PA0126/323/001	Bath additive	- D02AC	- Light liquid paraffin - Benzalkonium chloride - Triclosan		- Cutaneous use
Oilatum Plus Bath Additive Light liquid paraffin 52.5% w/w Benzalkonium chloride 6.0% w/w Triclosan 2.0% w/w	Clonmel Healthcare Ltd	PA0126/323/002	Bath additive	- D08AJ - D08AJ01	- Benzalkonium chloride - Triclosan - Light liquid paraffin		
Okedi	Laboratorios Farmacéuticos ROVI, S.A.	EU/1/21/1621/001	Powder and solvent for prolonged-release suspension for injection	- N05AX08	- Risperidone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use
Okedi	Laboratorios Farmacéuticos ROVI, S.A.	EU/1/21/1621/002	Powder and solvent for prolonged-release suspension for injection	- N05AX08	- Risperidone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use
Olanzapine 10mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/210/004 Interchangeable List Code: IC0007-002-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine 10mg Orodispersible Tablets	Accord Healthcare Ireland Ltd.	PA2315/229/002 Interchangeable List Code: IC0007-002-038	Orodispersible tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine 15mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/210/005 Interchangeable List Code: IC0007-032-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Olanzapine 15mg Orodispersible Tablets	Accord Healthcare Ireland Ltd.	PA2315/229/003 Interchangeable List Code: IC0007-032-038	Orodispersible tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine 2.5mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/210/001 Interchangeable List Code: IC0007-018-035	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine 20mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/210/006 Interchangeable List Code: IC0007-003-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine 20mg Orodispersible Tablets	Accord Healthcare Ireland Ltd.	PA2315/229/004 Interchangeable List Code: IC0007-003-038	Orodispersible tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine 5 mg Orodispersible Tablets	Accord Healthcare Ireland Ltd.	PA2315/229/001 Interchangeable List Code: IC0007-001-038	Orodispersible tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine 5mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/210/002 Interchangeable List Code: IC0007-001-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine 7.5mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/210/003 Interchangeable List Code: IC0007-041-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Accord 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/112/004 Interchangeable List Code: IC0007-002-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Accord 15 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/112/005 Interchangeable List Code: IC0007-032-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Accord 2.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/112/001 Interchangeable List Code: IC0007-018-035	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Accord 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/112/002 Interchangeable List Code: IC0007-001-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Accord 7.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/112/003 Interchangeable List Code: IC0007-041-038	Film-coated tablet		- Olanzapine form 1	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Apotex	Apotex Europe B.V.	EU/1/10/635/001 Interchangeable List Code: IC0007-018-035	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
OLANZAPINE APOTEX	Apotex Europe B.V.	EU/1/10/635/002-3 Interchangeable List Code: IC0007-001-038	Film-coated tablet		- OLANZAPINE	Article 10(1) - Generic Application	- Oral use
OLANZAPINE APOTEX	Apotex Europe B.V.	EU/1/10/635/004-5 Interchangeable List Code: IC0007-041-038	Film-coated tablet		- OLANZAPINE	Article 10(1) - Generic Application	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
OLANZAPINE APOTEX	Apotex Europe B.V.	EU/1/10/635/006-7 Interchangeable List Code: IC0007-002-038	Film-coated tablet		- OLANZAPINE	Article 10(1) - Generic Application	- Oral use
Olanzapine Apotex	Apotex Europe B.V.	EU/1/10/635/008-9 Interchangeable List Code: IC0007-001-038	Orodispersible tablet		- Olanzapine		- Oral use
Olanzapine Apotex	Apotex Europe B.V.	EU/1/10/635/010-11 Interchangeable List Code: IC0007-002-038	Orodispersible tablet		- Olanzapine		- Oral use
OLANZAPINE APOTEX	Apotex Europe B.V.	EU/1/10/635/012 Interchangeable List Code: IC0007-032-038	Orodispersible Tablet		- OLANZAPINE	Article 10(1) - Generic Application	- Oral use
OLANZAPINE APOTEX	Apotex Europe B.V.	EU/1/10/635/013-14 Interchangeable List Code: IC0007-003-038	Orodispersible Tablet		- OLANZAPINE	Article 10(1) - Generic Application	- Oral use
Olanzapine Glenmar	Glenmark Arzneimittel GmbH	EU/1/09/587/10-12 Interchangeable List Code: IC0007-002-038	Tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Glenmar	Glenmark Arzneimittel GmbH	EU/1/09/587/1-3 Interchangeable List Code: IC0007-018-035	Tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Glenmar	Glenmark Arzneimittel GmbH	EU/1/09/587/13-15 Interchangeable List Code: IC0007-032-038	Tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Glenmar	Glenmark Arzneimittel GmbH	EU/1/09/587/16-17 Interchangeable List Code: IC0007-003-038	Tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Glenmar	Glenmark Arzneimittel GmbH	EU/1/09/587/4-6 Interchangeable List Code: IC0007-001-038	Tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Glenmar	Glenmark Arzneimittel GmbH	EU/1/09/587/7-9 Interchangeable List Code: IC0007-041-038	Tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Glenmark Europe	Glenmark Arzneimittel GmbH	EU/1/09/588/10-12 Interchangeable List Code: IC0007-003-038	Orodispersible tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Glenmark Europe	Glenmark Arzneimittel GmbH	EU/1/09/588/1-3 Interchangeable List Code: IC0007-001-038	Orodispersible tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Glenmark Europe	Glenmark Arzneimittel GmbH	EU/1/09/588/4-6 Interchangeable List Code: IC0007-002-038	Orodispersible tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Glenmark Europe	Glenmark Arzneimittel GmbH	EU/1/09/588/7-9 Interchangeable List Code: IC0007-032-038	Orodispersible tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Olanzapine Mylan	Mylan Pharmaceuticals Limited	EU/1/08/475/13-17 Interchangeable List Code: IC0007-041-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Mylan	Mylan Pharmaceuticals Limited	EU/1/08/475/1-6 Interchangeable List Code: IC0007-018-035	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Mylan	Mylan Pharmaceuticals Limited	EU/1/08/475/18-24 Interchangeable List Code: IC0007-002-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Mylan	Mylan Pharmaceuticals Limited	EU/1/08/475/25-29 Interchangeable List Code: IC0007-032-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Mylan	Mylan Pharmaceuticals Limited	EU/1/08/475/30-34 Interchangeable List Code: IC0007-003-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Mylan	Mylan Pharmaceuticals Limited	EU/1/08/475/7-12 Interchangeable List Code: IC0007-001-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Teva	Teva Pharma B.V.	EU/1/07/427/004-007 Interchangeable List Code: IC0007-001-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olanzapine Teva	Teva Pharma B.V.	EU/1/07/427/008-010 Interchangeable List Code: IC0007-041-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/11-14 Interchangeable List Code: IC0007-002-038	Film-coated tablet		- OLANZAPINE	Article 10(3) - Hybrid Application	- Oral use
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/1-3 Interchangeable List Code: IC0007-018-035	Film-coated tablet		- OLANZAPINE	Article 10(1) - Generic Application	- Oral use
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/16-19 Interchangeable List Code: IC0007-032-038	Film-coated tablet		- OLANZAPINE	Article 10(3) - Hybrid Application	- Oral use
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/20-22 Interchangeable List Code: IC0007-003-038	Film-coated tablet		- OLANZAPINE	Article 10(1) - Generic Application	- Oral use
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/23-26 Interchangeable List Code: IC0007-001-038	Orodispersible Tablet		- OLANZAPINE	Article 10(1) - Generic Application	- Oral use
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/27-30 Interchangeable List Code: IC0007-002-038	Orodispersible Tablet		- OLANZAPINE	Article 10(3) - Hybrid Application	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/31-34 Interchangeable List Code: IC0007-032-038	Orodispersible Tablet		- OLANZAPINE	Article 10(3) - Hybrid Application	- Oral use
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/35-37 Interchangeable List Code: IC0007-003-038	Orodispersible Tablet		- OLANZAPINE	Article 10(3) - Hybrid Application	- Oral use
Olanzapine Teva	Teva Pharma B.V.	EU/1/07/427/8-10	Film-coated tablet	- N05AH - N05AH03	- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	
Olatuton 10 mg powder and solvent for prolonged-release suspension for injection	Teva B.V.	PA1986/076/001	Powder and solvent for prolonged-release suspension for injection	- H01CB - H01CB02	- Octreotide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Olatuton 20 mg powder and solvent for prolonged-release suspension for injection	Teva B.V.	PA1986/076/002	Powder and solvent for prolonged-release suspension for injection	- H01CB - H01CB02	- Octreotide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Olatuton 30 mg powder and solvent for prolonged-release suspension for injection	Teva B.V.	PA1986/076/003	Powder and solvent for prolonged-release suspension for injection	- H01CB - H01CB02	- Octreotide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Intramuscular use
OLAZAX	Glenmark Pharmaceuticals s.r.o.	EU/1/09/597/001 Interchangeable List Code: IC0007-001-038	Tablet		- OLANZAPINE I	Article 10(1) - Generic Application	- Oral use
OLAZAX	Glenmark Pharmaceuticals s.r.o.	EU/1/09/597/002 Interchangeable List Code: IC0007-041-038	Tablet		- OLANZAPINE I	Article 10(1) - Generic Application	- Oral use
OLAZAX	Glenmark Pharmaceuticals s.r.o.	EU/1/09/597/003 Interchangeable List Code: IC0007-002-038	Tablet		- OLANZAPINE I	Article 10(1) - Generic Application	- Oral use
OLAZAX	Glenmark Pharmaceuticals s.r.o.	EU/1/09/597/004 Interchangeable List Code: IC0007-032-038	Tablet		- OLANZAPINE I	Article 10(1) - Generic Application	- Oral use
OLAZAX	Glenmark Pharmaceuticals s.r.o.	EU/1/09/597/005 Interchangeable List Code: IC0007-003-038	Tablet		- OLANZAPINE I	Article 10(1) - Generic Application	- Oral use
Olazax Disperzi	Glenmark Pharmaceuticals s.r.o.	EU/1/09/592/001 Interchangeable List Code: IC0007-001-038	Orodispersible tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olazax Disperzi	Glenmark Pharmaceuticals s.r.o.	EU/1/09/592/002 Interchangeable List Code: IC0007-041-038	Orodispersible tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olazax Disperzi	Glenmark Pharmaceuticals s.r.o.	EU/1/09/592/003 Interchangeable List Code: IC0007-002-038	Orodispersible tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olazax Disperzi	Glenmark Pharmaceuticals s.r.o.	EU/1/09/592/004 Interchangeable List Code: IC0007-032-038	Orodispersible tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Olazax Disperzi	Glenmark Pharmaceuticals s.r.o.	EU/1/09/592/005 Interchangeable List Code: IC0007-003-038	Orodispersible tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olbas for Children Inhalation Vapour, Liquid	GR Lane Health Products Ltd	PA0257/015/004	Inhalation vapour, liquid	- R05X	- Cajuput oil - Eucalyptus oil - Methyl salicylate - Levomenthol - Mint oil, partly dementholised	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
Olbas Inhaler nasal stick	LanesHealth (Ireland) Limited	PA22702/002/003	Nasal stick	- R01AX	- Cajuput oil - Levomenthol - Eucalyptus oil - Peppermint oil		- Nasal use
Olbas Oil	LanesHealth (Ireland) Limited	PA22702/002/001	Inhalation vapour, liquid	- R05X	- Cajuput oil - Clove oil - Eucalyptus oil - Juniper oil - Levomenthol - Mint oil, partly dementholised - Methyl salicylate		- Inhalation use - Topical
Olmesartan /Amlodipine Mylan 20 mg/ 5 mg film coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/185/001	Film-coated tablet	- C09DB - C09DB02	- Olmesartan medoxomil - Amlodpine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan /Amlodipine Mylan 40 mg/ 10 mg film coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/185/003	Film-coated tablet	- C09DB - C09DB02	- Olmesartan medoxomil - Amlodpine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan /Amlodipine Mylan 40 mg/ 5 mg film coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/185/002	Film-coated tablet	- C09DB - C09DB02	- Olmesartan medoxomil - Amlodpine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/060/001 Interchangeable List Code: IC0105-002-003	Film-coated tablet		- Olmesartan medoxomil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/060/002 Interchangeable List Code: IC0105-003-003	Film-coated tablet		- Olmesartan medoxomil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan Krka 40 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/060/003 Interchangeable List Code: IC0105-004-003	Film-coated tablet		- Olmesartan medoxomil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan Medoxomil 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/113/001 Interchangeable List Code: IC0105-002-003	Film-coated tablet		- Olmesartan medoxomil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil 10 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/214/001 Interchangeable List Code: IC0105-002-003	Film-coated tablet		- Olmesartan medoxomil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil 20 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/214/002 Interchangeable List Code: IC0105-003-003	Film-coated tablet		- Olmesartan medoxomil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan Medoxomil 20 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/113/002 Interchangeable List Code: IC0105-003-003	Film-coated tablet		- Olmesartan medoxomil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan Medoxomil 40 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/113/003 Interchangeable List Code: IC0105-004-003	Film-coated tablet		- Olmesartan medoxomil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Olmesartan medoxomil 40 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/214/003 Interchangeable List Code: IC0105-004-003	Film-coated tablet		- Olmesartan medoxomil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan Medoxomil Clonmel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/273/001 Interchangeable List Code: IC0105-002-003	Film-coated tablet		- Olmesartan medoxomil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan Medoxomil Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/273/002 Interchangeable List Code: IC0105-003-003	Film-coated tablet		- Olmesartan medoxomil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan Medoxomil Clonmel 40 mg film-coated tablet	Clonmel Healthcare Ltd	PA0126/273/003 Interchangeable List Code: IC0105-004-003	Film-coated tablet		- Olmesartan medoxomil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine 20 mg/5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/074/001	Film-coated tablet	- C09DB - C09DB02	- Olmesartan medoxomil - Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine 40 mg/10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/074/003	Film-coated tablet	- C09DB - C09DB02	- Olmesartan medoxomil - Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine 40 mg/5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/074/002	Film-coated tablet	- C09DB - C09DB02	- Olmesartan medoxomil - Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide Accord 20 mg/5 mg/12.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/158/001	Film-coated tablet	- C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide Accord 40 mg/10 mg/12.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/158/003	Film-coated tablet	- C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide Accord 40 mg/10 mg/25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/158/005	Film-coated tablet	- C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide Accord 40 mg/5 mg/12.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/158/002	Film-coated tablet	- C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide Accord 40 mg/5 mg/25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/158/004	Film-coated tablet	- C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide Clonmel 20 mg/5 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/312/001	Film-coated tablet	- C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide Clonmel 40 mg/10 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/312/003	Film-coated tablet	- C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide Clonmel 40 mg/10 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/312/005	Film-coated tablet	- C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide Clonmel 40 mg/5 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/312/002	Film-coated tablet	- C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide Clonmel 40 mg/5 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/312/004	Film-coated tablet	- C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide Krka 40 mg/10 mg/25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/096/005	Film-coated tablet	- C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide Krka 40 mg/5 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/096/002	Film-coated tablet	- C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide Krka 40 mg/5 mg/25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/096/003	Film-coated tablet	- C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide Krka 20 mg/5 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/096/001	Film-coated tablet	- C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide Krka 40 mg/10 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/096/004	Film-coated tablet	- C09DX03	- Olmesartan medoxomil - Amlodipine - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan Medoxomil/Hydrochlorothiazide 20 mg/12.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/106/001 Interchangeable List Code: IC0106-162-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan Medoxomil/Hydrochlorothiazide 20 mg/25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/106/002 Interchangeable List Code: IC0106-163-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan Medoxomil/Hydrochlorothiazide 40 mg/12.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/106/003 Interchangeable List Code: IC0106-099-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan Medoxomil/Hydrochlorothiazide 40 mg/25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/106/004 Interchangeable List Code: IC0106-164-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan Rowex 10 mg film-coated tablets	Rowex Ltd	PA0711/255/001 Interchangeable List Code: IC0105-002-003	Film-coated tablet		- Olmesartan medoxomil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Olmesartan Rowex 20 mg film-coated tablets	Rowex Ltd	PA0711/255/002 Interchangeable List Code: IC0105-003-003	Film-coated tablet		- Olmesartan medoxomil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan Rowex 40 mg film-coated tablets	Rowex Ltd	PA0711/255/003 Interchangeable List Code: IC0105-004-003	Film-coated tablet		- Olmesartan medoxomil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan/Amlodipine Clonmel 20 mg/5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/293/001	Film-coated tablet	- C09DB - C09DB02	- Olmesartan medoxomil - Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan/Amlodipine Clonmel 40 mg/10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/293/003	Film-coated tablet	- C09DB - C09DB02	- Olmesartan medoxomil - Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan/Amlodipine Clonmel 40 mg/5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/293/002	Film-coated tablet	- C09DB - C09DB02	- Olmesartan medoxomil - Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan/Amlodipine Krka 20 mg/5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/075/001	Film-coated tablet	- C09DB - C09DB02	- Olmesartan medoxomil - Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan/Amlodipine Krka 40 mg/10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/075/003	Film-coated tablet	- C09DB - C09DB02	- Olmesartan medoxomil - Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan/Amlodipine Krka 40 mg/5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/075/002	Film-coated tablet	- C09DB - C09DB02	- Olmesartan medoxomil - Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan/Hydrochlorothiazide Clonmel 20 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/260/001 Interchangeable List Code: IC0106-162-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan/Hydrochlorothiazide Clonmel 20 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/260/002 Interchangeable List Code: IC0106-163-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan/Hydrochlorothiazide Clonmel 40 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/260/003 Interchangeable List Code: IC0106-099-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan/Hydrochlorothiazide Clonmel 40 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/260/004 Interchangeable List Code: IC0106-164-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan/Hydrochlorothiazide Krka 20 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/061/001 Interchangeable List Code: IC0106-162-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan/Hydrochlorothiazide Krka 20 mg/25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/061/002 Interchangeable List Code: IC0106-163-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan/Hydrochlorothiazide Krka 40 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/061/003 Interchangeable List Code: IC0106-099-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Olmesartan/Hydrochlorothiazide Krka 40 mg/25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/061/004 Interchangeable List Code: IC0106-164-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Olumiant	Eli Lilly Nederland B.V.	EU/1/16/1170/001-008	Film-coated tablet	- L04AA - L04AA37	- Baricitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Olumiant	Eli Lilly Nederland B.V.	EU/1/16/1170/009-016	Film-coated tablet	- L04AA - L04AA37	- Baricitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Olumiant	Eli Lilly Nederland B.V.	EU/1/16/1170/017-019	Film-coated tablet	- L04AA37	- Baricitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Omacor 1000 mg Soft Capsules	BASF AS	PA1099/001/001	Capsule, soft	- C10AX - C10AX06	- Omega-3-acid ethyl esters	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Omacor 1000 mg Soft Capsules	IMED Healthcare Ltd.	PPA1463/042/001	Capsule, soft	- C10AX - C10AX06	- Omega-3-acid ethyl esters		- Oral use
Omacor 1000 mg Soft Capsules	PCO Manufacturing Ltd.	PPA0465/335/001	Capsule, soft	- C10AX - C10AX06	- Omega-3-acid ethyl esters 90	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Omeflex peri emulsion for infusion	B. Braun Melsungen AG	PA0736/033/002	Emulsion for infusion	- B05BA - B05BA10	- Isoleucine - Leucine - Lysine hydrochloride - Methionine - Phenylalanine - Threonine - Tryptophan - Valine - Arginine - Histidine hydrochloride monohydrate - Alanine - Aspartic Acid - Glutamic acid - Glycine - Proline - Serine - Sodium hydroxide - Sodium chloride - Sodium acetate trihydrate - Potassium acetate - Magnesium acetate tetrahydrate - Calcium chloride dihydrate - Glucose monohydrate - Sodium dihydrogen phosphate dihydrate - Zinc acetate dihydrate - Triglycerides, medium chain - Soya bean oil, refined - Omega-3-acid triglycerides	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Omeflex plus emulsion for infusion	B. Braun Melsungen AG	PA0736/039/001	Emulsion for infusion	- B05BA - B05BA10	- Isoleucine - Leucine - Lysine hydrochloride - Methionine - Phenylalanine - Threonine - Tryptophan - Valine - Arginine - Histidine hydrochloride monohydrate - Alanine - Aspartic Acid - Glutamic acid - Glycine - Proline - Serine - Sodium hydroxide - Sodium chloride - Potassium acetate - Magnesium acetate tetrahydrate - Calcium chloride dihydrate - Glucose monohydrate - Sodium dihydrogen phosphate dihydrate - Zinc acetate dihydrate - Triglycerides, medium chain - Omega-3-acid triglycerides	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Omeflex special emulsion for infusion	B. Braun Melsungen AG	PA0736/040/001	Emulsion for infusion	- B05BA - B05BA10	- Isoleucine - Leucine - Lysine hydrochloride - Methionine - Phenylalanine - Threonine - Tryptophan - Valine - Arginine - Histidine hyprochloride monohydrate - Alanine - Aspartic Acid - Glutamic acid - Glycine - Proline - Serine - Sodium hydroxide - Sodium chloride - Sodium acetate trihydrate - Potassium acetate - Magnesium acetate tetrahydrate - Calcium chloride dihydrate - Glucose monohydrate - Sodium dihydrogen phosphate dihydrate - Zinc acetate dihydrate - Triglycerides, medium chain - Soya bean oil, refined - Omega-3-acid triglycerides	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Omeflex special without electrolytes emulsion for infusion	B. Braun Melsungen AG	PA0736/038/001	Emulsion for infusion	- B05BA - B05BA10	- Isoleucine - Leucine - Lysine monohydrate - Methionine - Phenylalanine - Threonine - Tryptophan - Valine - Arginine - Histidine - Alanine - Aspartic Acid - Glutamic acid - Glycine - Proline - Serine - Glucose monohydrate - Triglycerides medium-chain - SOYA BEAN OIL, REFINED PH. EUR. - Omega-3-acid triglycerides	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Omeprazole 10 mg Gastro-resistant Capsules, hard	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/203/001 Interchangeable List Code: IC0010-002-016	Gastro-resistant capsule, hard		- Omeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Omeprazole 10 mg gastro-resistant capsules, hard	Accord Healthcare Ireland Ltd.	PA2315/129/001 Interchangeable List Code: IC0010-002-016	Gastro-resistant capsule, hard		- Omeprazole	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Omeprazole 20 mg gastro-resistant capsules, hard	Accord Healthcare Ireland Ltd.	PA2315/129/002 Interchangeable List Code: IC0010-003-016	Gastro-resistant capsule, hard		- Omeprazole	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Omeprazole 20 mg Gastro-resistant Capsules, hard	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/203/002 Interchangeable List Code: IC0010-003-016	Gastro-resistant capsule, hard		- Omeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Omeprazole 40 mg Gastro-resistant Capsules, hard	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/203/003 Interchangeable List Code: IC0010-004-016	Gastro-resistant capsule, hard		- Omeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Omeprazole 40 mg gastro-resistant capsules, hard	Accord Healthcare Ireland Ltd.	PA2315/129/003 Interchangeable List Code: IC0010-004-016	Gastro-resistant capsule, hard		- Omeprazole	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Omeprazole Bluefish 10 mg gastro-resistant capsules	Bluefish Pharmaceuticals AB	PA1436/007/001 Interchangeable List Code: IC0010-002-016	Gastro-resistant capsule, hard		- Omeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Omeprazole Bluefish 20 mg gastro-resistant capsules	Bluefish Pharmaceuticals AB	PA1436/007/002 Interchangeable List Code: IC0010-003-016	Gastro-resistant capsule, hard		- Omeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Omeprazole Bluefish 40 mg gastro-resistant capsules	Bluefish Pharmaceuticals AB	PA1436/007/003 Interchangeable List Code: IC0010-004-016	Gastro-resistant capsule, hard		- Omeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Omeprazole Pinewood 20 mg gastro-resistant capsules, hard	Pinewood Laboratories Ltd	PA0281/152/001 Interchangeable List Code: IC0010-003-016	Gastro-resistant capsule, hard		- Omeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Omeprazole Rowa 20 mg Gastro-resistant Capsules, hard	Rowa Pharmaceuticals Limited	PA0074/075/002 Interchangeable List Code: IC0010-003-016	Gastro-resistant capsule, hard		- Omeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Omeprazole Rowa 40 mg Gastro-Resistant Capsules, hard	Rowa Pharmaceuticals Limited	PA0074/075/003 Interchangeable List Code: IC0010-004-016	Gastro-resistant capsule, hard		- Omeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Omeprazole Teva 10 mg gastro-resistant capsules, hard	Teva Pharma B.V.	PA0749/160/001 Interchangeable List Code: IC0010-002-016	Gastro-resistant capsule, hard		- Omeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Omeprazole Teva 20 mg gastro-resistant capsules, hard	Teva Pharma B.V.	PA0749/160/002 Interchangeable List Code: IC0010-003-016	Gastro-resistant capsule, hard		- Omeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Omeprazole Teva 40 mg Gastro-resistant Capsules, hard	Teva Pharma B.V.	PA0749/160/003 Interchangeable List Code: IC0010-004-016	Gastro-resistant capsule, hard		- Omeprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Omesar 10 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/011/001 Interchangeable List Code: IC0105-002-003	Film-coated tablet		- Olmesartan medoxomil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Omesar 20 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/011/002 Interchangeable List Code: IC0105-003-003	Film-coated tablet		- Olmesartan medoxomil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Omesar 40 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/011/003 Interchangeable List Code: IC0105-004-003	Film-coated tablet		- Olmesartan medoxomil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Omesar Plus 20 mg/12.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/014/001 Interchangeable List Code: IC0106-162-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Omesar Plus 20 mg/25 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/014/002 Interchangeable List Code: IC0106-163-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Omesar Plus 40 mg/12.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/014/003 Interchangeable List Code: IC0106-099-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Omesar Plus 40 mg/25 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/014/004 Interchangeable List Code: IC0106-164-003	Film-coated tablet		- Olmesartan medoxomil - Hydrochlorothiazide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Omidria 10 mg/ml + 3 mg/ml concentration for solution for intraocular irrigation	Rayner Surgical (Ireland) Limited	EU/1/15/1018/001	Concentrate for solution for intraocular irrigation	- S01	- Phenylephrine hydrochloride - Ketorolac trometamol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraocular use
Omjjara	GlaxoSmithKline Trading Services Limited	EU/1/23/1782/001	Film-coated tablet	- L01EJ04	- Momelotinib Dihydrochloride Monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Omjjara	GlaxoSmithKline Trading Services Limited	EU/1/23/1782/002	Film-coated tablet	- L01EJ04	- Momelotinib Dihydrochloride Monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Omjjara	GlaxoSmithKline Trading Services Limited	EU/1/23/1782/003	Film-coated tablet	- L01EJ04	- Momelotinib Dihydrochloride Monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Omnexel, 400 micrograms prolonged release tablets, film-coated	PCO Manufacturing Ltd.	PPA0465/171/001 Interchangeable List Code: IC0024-066-024	Prolonged-release tablet		- Tamsulosin hydrochloride		- Oral use
Omnexel®, 400 micrograms prolonged release tablets, film-coated	IMED Healthcare Ltd.	PPA1463/025/001 Interchangeable List Code: IC0024-066-024	Prolonged-release tablet		- Tamsulosin hydrochloride	ZZZ PPA	- Oral use
Omnexel®, 400 micrograms prolonged release tablets, film-coated	Astellas Pharma Co. Limited	PA1241/006/001 Interchangeable List Code: IC0024-066-024	Prolonged-release tablet		- Tamsulosin hydrochloride	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Omnipaque 140 mg I/ml Solution for Injection (Glass)	GE Healthcare AS	PA0735/006/001	Solution for injection	- V08AB - V08AB02	- Iohexol		- Intraarterial use - Intrathecal use - Intravenous use
Omnipaque 180 mg I/ml Solution for Injection (Glass)	GE Healthcare AS	PA0735/006/002	Solution for injection	- V08AB - V08AB02	- Iohexol		- Intraarterial use - Intrathecal use - Intravenous use
Omnipaque 240 mg I/ml Solution for Injection (Glass)	GE Healthcare AS	PA0735/006/004	Solution for injection	- V08AB - V08AB02	- Iohexol		- Intraarterial use - Intrathecal use - Intravenous use
Omnipaque 240 mg I/ml Solution for Injection (Polypropylene)	GE Healthcare AS	PA0735/006/023	Solution for injection	- V08AB - V08AB02	- Iohexol		- Intraarterial use - Intrathecal use - Intravenous use
Omnipaque 300 mg I/ml Solution for Injection (Glass)	GE Healthcare AS	PA0735/006/008	Solution for injection	- V08AB - V08AB02	- Iohexol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraarterial use - Intrathecal use - Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Omnipaque 300 mg I/ml Solution for Injection (Polypropylene)	GE Healthcare AS	PA0735/006/018	Solution for injection	- V08AB - V08AB02	- Iohexol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraarterial use - Intrathecal use - Intravenous use
Omnipaque 350 mg I/ml Solution for Injection (Glass)	GE Healthcare AS	PA0735/006/013	Solution for injection	- V08AB - V08AB02	- Iohexol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraarterial use - Intrathecal use - Intravenous use
Omnipaque 350 mg I/ml Solution for Injection (Polypropylene)	GE Healthcare AS	PA0735/006/020	Solution for injection	- V08AB - V08AB02	- Iohexol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraarterial use - Intrathecal use - Intravenous use
Omnitrope	Sandoz GmbH	EU/1/06/332/001	Powder and solvent for solution for injection	- H01AC - H01AC01	- Somatropin		- Subcutaneous use
Omnitrope	Sandoz GmbH	EU/1/06/332/002-003	Powder and solvent for solution for injection	- H01AC - H01AC01	- Somatropin		
Omnitrope	Sandoz GmbH	EU/1/06/332/004-006	Solution for injection in cartridge	- H01AC - H01AC01	- Somatropin		- Subcutaneous use
Omnitrope	Sandoz GmbH	EU/1/06/332/007-009	Solution for injection in cartridge	- H01AC - H01AC01	- Somatropin	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Omnitrope	Sandoz GmbH	EU/1/06/332/010-012	Solution for injection in cartridge	- H01AC - H01AC01	- Somatropin	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Omvoh	Eli Lilly Nederland B.V.	EU/1/23/1736/001	Concentrate for solution for infusion	- L04AC24	- MIRIKIZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Onbevzi	Samsung Bioepis NL B.V.	EU/1/20/1499/001-002	Concentrate for solution for infusion	- L01XC07	- Bevacizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Onbrez Breezhaler	Novartis Europharm Limited	EU/1/09/593/1-5	Inhalation powder, hard capsule	- R03AC - R03AC18	- Indacaterol maleate		- Inhalation use
Onbrez Breezhaler	Novartis Europharm Limited	EU/1/09/593/6-10	Inhalation powder, hard capsule	- R03AC - R03AC18	- Indacaterol maleate		- Inhalation use
Oncaspar	Les Laboratoires Servier	EU/1/15/1070/001	Solution for injection/infusion	- L01XX24	- Pegaspargase	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Oncaspar	Les Laboratoires Servier	EU/1/15/1070/002	Powder for solution for injection/infusion	- L01XX24	- Pegaspargase	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ondansetron 2 mg/ml Solution for Injection or Infusion	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/083/001	Solution for injection/infusion	- A04AA - A04AA01	- Ondansetron	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Ondansetron 2 mg/ml Solution for Injection or Infusion	Accord Healthcare Ireland Ltd.	PA2315/168/001	Solution for injection/infusion	- A04AA - A04AA01	- Ondansetron	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Ondansetron 2 mg/ml solution for injection/infusion	AS Kalceks	PA2165/013/001	Solution for injection/infusion	- A04AA01	- Ondansetron	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Ondansetron 2 mg/ml Solution for Injection/Infusion in Prefilled Syringe	Accord Healthcare Ireland Ltd.	PA2315/159/001	Solution for injection/infusion in pre-filled syringe	- A04AA01	- Ondansetron hydrochloride dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Ondansetron 2mg/ml Solution for Injection	Baxter Holding B.V.	PA2299/037/001	Solution for injection	- A04AA - A04AA01	- Ondansetron	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Ondansetron 2mg/ml Solution for Injection	Noridem Enterprises Limited	PA1122/004/001	Solution for injection	- A04AA - A04AA01	- Ondansetron	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ondansetron 4 mg film-coated tablets	Teva Pharma B.V.	PA0749/009/001 Interchangeable List Code: IC0114-008-061	Film-coated tablet		- Ondansetron	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ondansetron 4 mg/5 ml syrup	Syri Pharma Limited t/a Thame Laboratories	PA22697/013/001 Interchangeable List Code: IC0114-170-062	Syrup		- Ondansetron	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ondansetron 8 mg film-coated tablets	Teva Pharma B.V.	PA0749/009/002 Interchangeable List Code: IC0114-009-061	Film-coated tablet		- Ondansetron	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ondansetron Kabi 0.08 mg/ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/080/001	Solution for infusion	- A04AA01	- Ondansetron hydrochloride dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Ondansetron Kabi 0.16 mg/ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/080/002	Solution for infusion	- A04AA01	- Ondansetron hydrochloride dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Ondansetron Kabi 2 mg/ml solution for injection	Fresenius Kabi Deutschland GmbH	PA2059/048/001	Solution for injection	- A04AA - A04AA01	- Ondansetron	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Ondexxya Powder for solution for infusion	AstraZeneca AB	EU/1/18/1345/001	Powder for solution for infusion	- V03AB - V03AB38	- Andexant alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ondran 4 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/127/001 Interchangeable List Code: IC0114-008-061	Film-coated tablet		- Ondansetron	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ondran 8 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/127/002 Interchangeable List Code: IC0114-009-061	Film-coated tablet		- Ondansetron	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
One-Alpha 0.25 micrograms soft capsules	CHEPLAPHARM Arzneimittel GmbH	PA2239/017/002	Capsule, soft	- A11CC - A11CC03	- Alfacalcidol		- Oral use
One-Alpha 1 microgram soft capsules	CHEPLAPHARM Arzneimittel GmbH	PA2239/017/001	Capsule, soft	- A11CC - A11CC03	- Alfacalcidol		- Oral use
One-Alpha 1 microgram soft capsules	IMED Healthcare Ltd.	PPA1463/167/001	Capsule, soft	- A11CC - A11CC03	- Alfacalcidol		- Oral use
One-Alpha 1 microgram soft capsules	PCO Manufacturing Ltd.	PPA0465/134/002	Capsule, soft	- A11CC - A11CC03	- Alfacalcidol		- Oral use
One-Alpha 2 micrograms/ml oral drops	CHEPLAPHARM Arzneimittel GmbH	PA2239/017/003	Oral drops, solution	- A11CC - A11CC03	- Alfacalcidol		- Oral use
Ongentys	BIAL-Portela & Ca, S.A.	EU/1/15/1066/001	Capsule, hard	- N04	- Opicapone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ongentys	BIAL-Portela & Ca, S.A.	EU/1/15/1066/002-007	Capsule, hard	- N04BX	- Opicapone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Onglyza	AstraZeneca AB	EU/1/09/545/011-015	Film-coated tablet	- A10BH - A10BH03	- Saxaglitpin	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Onglyza	AstraZeneca AB	EU/1/09/545/1-10	Film-coated tablet	- A10BH - A10BH03	- Saxagliptin	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Onivyde pegylated liposomal	Les Laboratoires Servier	EU/1/16/1130/001	Concentrate for solution for infusion	- L01XX - L01XX19	- Irinotecan hydrochloride trihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Onpattro	Alnylam Netherlands B.V.	EU/1/18/1320/001	Concentrate for solution for infusion	- N07	- PATISIRAN SODIUM	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ontilyv	BIAL-Portela & Ca, S.A.	EU/1/21/1578/001-004	Capsule, hard	- N04BX - N04BX04	- Opicapone	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Ontilyv	BIAL-Portela & Ca, S.A.	EU/1/21/1578/005-010	Capsule, hard	- N04BX04	- Opicapone	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Ontozry	Angelini Pharma Italia S.P.A.	EU/1/21/1530/001	Film-coated tablet	- N03AX - N03AX25	- Cenobamate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ontozry	Angelini Pharma Italia S.P.A.	EU/1/21/1530/002-004	Film-coated tablet	- N03AX - N03AX25	- Cenobamate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ontozry	Angelini Pharma Italia S.P.A.	EU/1/21/1530/005-007	Film-coated tablet	- N03AX - N03AX25	- Cenobamate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ontozry	Angelini Pharma Italia S.P.A.	EU/1/21/1530/008-010	Film-coated tablet	- N03AX - N03AX25	- Cenobamate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ontozry	Angelini Pharma Italia S.P.A.	EU/1/21/1530/011-013	Film-coated tablet	- N03AX - N03AX25	- Cenobamate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ontruzant	Samsung Bioepis NL B.V.	EU/1/17/1241/001	Powder for concentrate for solution for infusion	- L01XC - L01XC03	- Trastuzumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Onureg	Celgene Europe B.V.	EU/1/21/1556/001-002	Film-coated tablet	- L01BC07	- Azacitidine	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Onureg	Celgene Europe B.V.	EU/1/21/1556/003-004	Film-coated tablet	- L01BC07	- Azacitidine	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Onytec 80mg/g medicated nail lacquer	Polichem S.A.	PA1005/002/001	Medicated nail lacquer	- D01AE - D01AE14	- Ciclopirox	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Opatanol	Novartis Europharm Limited	EU/1/02/217/001	Eye drops, solution	- S01GX09	- Olopatadine hydrochloride	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Opatanol	Novartis Europharm Limited	EU/1/02/217/002	Eye drops, solution	- S01GX - S01GX09	- Olopatadine hydrochloride	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Opdivo	Bristol-Myers Squibb Pharma EEIG	EU/1/15/1014/001-002	Concentrate for solution for infusion	- L01XC17	- Nivolumab - Nivolumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Opdualag	Bristol-Myers Squibb Pharma EEIG	EU/1/22/1679/001	Concentrate for solution for infusion	- L01XY - L01XY03	- RELATLIMAB - Nivolumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Opfolda	Amicus Therapeutics Europe Limited	EU/1/23/1737/001-002	Capsule, hard	- A16AX06	- Miglustat	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Oprymea	KRKA, d.d., Novo mesto	EU/1/08/469/026-029	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oprymea	KRKA, d.d., Novo mesto	EU/1/08/469/030-033	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oprymea	KRKA, d.d., Novo mesto	EU/1/08/469/034-037	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
OPRYMEA	Krka d.d., Novo mesto	EU/1/08/469/038-041	Prolonged-release tablet	- N04BC05	- PRAMIPEXOLE	Article 10(1) - Generic Application	- Oral use
Oprymea	KRKA, d.d., Novo mesto	EU/1/08/469/042-045	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
OPRYMEA	Krka d.d., Novo mesto	EU/1/08/469/046-049	Prolonged-release tablet	- N04BC05	- PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oprymea	KRKA, d.d., Novo mesto	EU/1/08/469/050-053	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oprymea 0.088 mg tablets	KRKA, d.d., Novo mesto	EU/1/08/469/1-5	Tablet	- N04BC - N04BC05	- Pramipexole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oprymea 0.18 mg tablets	KRKA, d.d., Novo mesto	EU/1/08/469/6-10	Tablet	- N04BC - N04BC05	- Pramipexole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
OPRYMEA 0.35 MG TABLETS	Krka d.d., Novo mesto	EU/1/08/469/11-15	Tablet	- N04BC05	- PRAMIPEXOLE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oprymea 0.7 mg tablets	KRKA, d.d., Novo mesto	EU/1/08/469/16-20	Tablet	- N04BC - N04BC05	- Pramipexole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
OPRYMEA 1.1 MG TABLETS	Krka d.d., Novo mesto	EU/1/08/469/21-25	Tablet	- N04BC05	- PRAMIPEXOLE	Article 10(1) - Generic Application	- Oral use
Opsumit	Janssen Pharmaceutica NV	EU/1/13/893/001-003	Film-coated tablet	- C02KX - C02KX04	- Macitentan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Opticrom 2 % w/v Eye Drops, solution	Clonmel Healthcare Ltd	PA0126/381/001	Eye drops, solution	- S01GX - S01GX01	- Sodium cromoglicate		- Ocular use
Opticrom allergy 2% w/v eye drops, solution	Clonmel Healthcare Ltd	PA0126/381/002	Eye drops, solution	- S01GX - S01GX01	- Sodium cromoglicate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Ocular use
Opticrom Allergy Single Dose 2% w/v eye drops, solution	Clonmel Healthcare Ltd	PA0126/381/003	Eye drops, solution	- S01GX - S01GX01	- Sodium cromoglicate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Optilast, 0.5 mg/ml Eye Drops, solution	Mylan IRE Healthcare Limited	PA2010/047/001	Eye drops, solution	- S01GX - S01GX07	- Azelastine hydrochloride		- Ocular use
Optiray 240 mg I/ml PFS solution for injection	Guerbet	PA0686/007/002	Solution for injection	- V08AB - V08AB07	- Ioversol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Optiray 240 mg I/ml solution for injection or infusion	Guerbet	PA0686/007/001	Solution for injection/infusion	- V08AB - V08AB07	- Ioversol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Optiray 300 mg I/ml PFS solution for injection	Guerbet	PA0686/007/004	Solution for injection	- V08AB - V08AB07	- Ioversol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Optiray 300 mg I/ml solution for injection or infusion	Guerbet	PA0686/007/003	Solution for injection/infusion	- V08AB - V08AB07	- Ioversol	Full application (Article 8(3) of Directive No 2001/83/EC)	
Optiray 320 mg I/ml solution for injection or infusion	Guerbet	PA0686/007/005	Solution for injection/infusion	- V08AB - V08AB07	- Ioversol	Full application (Article 8(3) of Directive No 2001/83/EC)	
Optiray 350 mg I/ml PFS solution for injection	Guerbet	PA0686/007/007	Solution for injection	- V08AB - V08AB07	- Ioversol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Optiray 350 mg I/ml solution for injection or infusion	Guerbet	PA0686/007/006	Solution for injection/infusion	- V08AB - V08AB07	- Ioversol	Full application (Article 8(3) of Directive No 2001/83/EC)	
Optison	GE Healthcare AS	EU/1/98/065/001	Dispersion for injection	- V08DA - V08DA01	- Perflutren - Human albumin microspheres		
Optison	GE Healthcare AS	EU/1/98/065/002	Dispersion for injection	- V08DA - V08DA01	- Perflutren - Human albumin microspheres		
OPTISULIN	Aventis Pharma Deutschland GmbH	EU/1/00/133/001	Solution for injection	- A10AE - A10AE04	- Insulin glargine		- Subcutaneous use
Optisulin	Aventis Pharma Deutschland GmbH	EU/1/00/133/002	Solution for injection	- A10AE - A10AE04	- Insulin glargine		- Subcutaneous use
Optisulin	Aventis Pharma Deutschland GmbH	EU/1/00/133/003	Solution for injection	- A10AE - A10AE04	- Insulin glargine		- Subcutaneous use
Optisulin	Aventis Pharma Deutschland GmbH	EU/1/00/133/004	Solution for injection	- A10AE - A10AE04	- Insulin glargine		- Subcutaneous use
Optisulin	Aventis Pharma Deutschland GmbH	EU/1/00/133/005	Solution for injection in cartridge	- A10AE - A10AE04	- Insulin glargine		- Subcutaneous use
Optisulin	Aventis Pharma Deutschland GmbH	EU/1/00/133/006	Solution for injection in cartridge	- A10AE - A10AE04	- Insulin glargine		- Subcutaneous use
Optisulin	Aventis Pharma Deutschland GmbH	EU/1/00/133/007	Solution for injection in cartridge	- A10AE - A10AE04	- Insulin glargine		- Subcutaneous use
Optrex Clear Eyes Eye Drops Solution Hamamelis Water 12.5% v/vNaphazoline Hydrochloride 0.01% w/v	Reckitt Benckiser Ireland Ltd	PA0979/079/001	Eye drops, solution	- S01GA - S01GA51	- Hamamelis water - Naphazoline hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Optruma	Eli Lilly Nederland B.V.	EU/1/98/074/001	Film-coated tablet	- G03X	- Raloxifene		
Optruma	Eli Lilly Nederland B.V.	EU/1/98/074/002	Film-coated tablet	- G03X	- Raloxifene		
Optruma	Eli Lilly Nederland B.V.	EU/1/98/074/003	Film-coated tablet	- G03X	- Raloxifene		
Optruma	Eli Lilly Nederland B.V.	EU/1/98/074/004	Film-coated tablet	- G03X	- Raloxifene		
Opzelura	Incyte Biosciences Distribution B.V.	EU/1/23/1726/001	Cream	- D11AH - D11AH09	- Ruxolitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Oralair 100IR & 300IR sublingual tablets	STALLERGENES	PA2113/001/001	Sublingual tablet	- V01AA - V01AA02	- Grass pollen allergen extract	Full application (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Oralair 300 IR sublingual tablets	STALLERGENES	PA2113/001/002	Sublingual tablet	- V01AA - V01AA02	- Grass pollen allergen extract	Full application (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Oraldene 0.1% w/v Gargle/Mouthwash	JNTL Consumer Health I (Ireland) Limited	PA23490/009/001	Gargle/mouthwash	- A01AB - A01AB12	- Hexetidine		- Oromucosal use
Oraldene Icemint 0.1% w/v Gargle/Mouthwash Hexetidine	Johnson & Johnson (Ireland) Limited	PA0330/024/002	Gargle/mouthwash	- A01AB - A01AB12	- Hexetidine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oromucosal use
Oramorph Concentrated oral solution 20 mg/ml	Glenwood GmbH	PA2256/004/002	Oral solution	- N02AA - N02AA01	- Morphine sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Oramorph Oral Solution 10 mg/5 ml	Glenwood GmbH	PA2256/004/001	Oral solution	- N02AA - N02AA01	- Morphine sulfate		- Oral use
Oramox 125 mg/5 ml Powder for Oral Suspension	Athlone Pharmaceuticals Limited	PA1418/013/001	Powder for oral suspension	- J01CA - J01CA04	- Amoxicillin trihydrate		- Oral use
Oramox 250 mg/5 ml Powder for Oral Suspension	Athlone Pharmaceuticals Limited	PA1418/013/002	Powder for oral suspension	- J01CA - J01CA04	- Amoxicillin		- Oral use
Oramox 250mg Hard Capsules	Athlone Pharmaceuticals Limited	PA1418/013/003	Capsule, hard	- J01CA - J01CA04	- Amoxicillin		- Oral use
Oramox 500mg Hard Capsules	Athlone Pharmaceuticals Limited	PA1418/013/004	Capsule, hard	- J01CA - J01CA04	- Amoxicillin trihydrate		- Oral use
Oraqix 25/25 mg per g Periodontal gel	DENTSPLY DeTrey GmbH	PA1045/004/001	Periodontal gel	- N01BB - N01BB20	- Lidocaine - Prilocaine		- Periodontal use
Orencia	Bristol-Myers Squibb Pharma EEIG	EU/1/07/389/004-009	Solution for injection in pre-filled syringe	- L04AA - L04AA24	- Abatacept	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Orencia	Bristol-Myers Squibb Pharma EEIG	EU/1/07/389/013	Solution for injection in pre-filled syringe	- L04AA24	- Abatacept	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Orencia	Bristol-Myers Squibb Pharma EEIG	EU/1/07/389/014	Solution for injection in pre-filled syringe	- L04AA24	- Abatacept	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Orencia	Bristol-Myers Squibb Pharma EEIG	EU/1/07/389/1-3	Powder for concentrate for solution for infusion	- L04AA - L04AA24	- Abatacept	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Orfadin	Swedish Orphan Biovitrum AB	EU/1/04/303/004	Capsule, hard	- A16AX - A16AX04	- Nitisinone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Orfadin	Swedish Orphan Biovitrum AB	EU/1/04/303/005	Oral suspension	- A16AX - A16AX04	- Nitisinone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ORFADIN	Swedish Orphan International AB	EU/1/04/303/1-3	Capsule, hard	- A16AX - A16AX04	- Nitisinone		- Powder for oral/rectal suspension
Orgalutran	N.V. Organon	EU/1/00/130/001	Solution for injection	- H01CC - H01CC01	- Ganirelix		- Subcutaneous use
Orgalutran	N.V. Organon	EU/1/00/130/002	Solution for injection	- H01CC - H01CC01	- Ganirelix		- Subcutaneous use
Orgaran 750 anti-Xa units/0.6ml Solution for injection	Mylan IRE Healthcare Limited	PA2010/068/001	Solution for injection	- B01AB - B01AB09	- Danaparoid sodium		- Intravenous use
Orgovyx	Accord Healthcare S.L.U.	EU/1/22/1642/001	Film-coated tablet	- L02BX	- Relugolix	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Orkambi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/15/1059/001	Film-coated tablet	- R07AX - R07AX30	- Lumacaftor - Ivacaftor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Orkambi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/15/1059/005	Film-coated tablet	- R07AX - R07AX30	- Lumacaftor - Ivacaftor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Orkambi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/15/1059/005-006	Granules in sachet	- R07AX30	- Ivacaftor - Lumacaftor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Orkambi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/15/1059/006	Granules in sachet	- R07AX30	- Lumacaftor - Ivacaftor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Orkambi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/15/1059/007	Granules in sachet	- R07AX30	- Ivacaftor - Lumacaftor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Orkambi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/15/1059/008	Granules	- R07AX30	- Lumacaftor - Ivacaftor	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Orladeyo	BioCryst Ireland Ltd	EU/1/21/1544/001	Capsule, hard	- B06AC06	- Berotralstat hydrochloride - Berotralstat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Orlistat Accord 120 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/263/001	Capsule, hard	- A08AB01	- Orlistat	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Orosoothe 0.15% w/v Oromucosal Spray	Phoenix Labs	PA1113/016/001	Oromucosal spray	- A01AD02	- BENZYDAMINE HYDROCHLORIDE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oromucosal use
Oroxine 100 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/004	Tablet	- H03AA - H03AA01	- Levothyroxine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oroxine 125 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/005	Tablet	- H03AA - H03AA01	- Levothyroxine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oroxine 150 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/006	Tablet	- H03AA - H03AA01	- Levothyroxine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oroxine 175 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/007	Tablet	- H03AA - H03AA01	- Levothyroxine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oroxine 200 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/008	Tablet	- H03AA - H03AA01	- Levothyroxine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oroxine 25 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/001	Tablet	- H03AA - H03AA01	- Levothyroxine sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oroxine 50 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/002	Tablet	- H03AA - H03AA01	- Levothyroxine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oroxine 75 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/003	Tablet	- H03AA - H03AA01	- Levothyroxine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Orphacol	Laboratoires CTRS	EU/1/13/870/001-003	Capsule, hard	- A05AA - A05AA03	- Cholic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Orphacol	Laboratoires CTRS	EU/1/13/870/004-006	Capsule, hard	- A05AA - A05AA03	- Cholic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Orserdu	Stemline Therapeutics B.V.	EU/1/23/1757/001	Film-coated tablet	- L02BA04	- Elacestrant Dihydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Orserdu	Stemline Therapeutics B.V.	EU/1/23/1757/002	Film-coated tablet	- L02BA - L02BA04	- Elacestrant Dihydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Oslif Breezhaler	Novartis Europharm Limited	EU/1/09/586/1-5	Inhalation powder, hard capsule	- R03AC - R03AC18	- Indacaterol maleate		- Inhalation use
Oslif Breezhaler	Novartis Europharm Limited	EU/1/09/586/6-10	Inhalation powder, hard capsule	- R03AC - R03AC18	- Indacaterol maleate		- Inhalation use
Osmohale, inhalation powder, hard capsule	Pharmaxis Europe Limited	PA22655/001/001	Inhalation powder, hard capsule	- V04CX	- Mannitol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
OSTEOCIS 3mg kit for radiopharmaceutical preparation	CIS bio International	PA0677/007/001	Kit for radiopharmaceutical preparation	- V09BA - V09BA01	- Sodium oxidronate		- Intravenous use
Osteomel Once Weekly 70 mg tablets	Clonmel Healthcare Ltd	PA0126/148/002 Interchangeable List Code: IC0051-101-002	Tablet		- Alendronic acid		- Oral use
Otezla 10 mg film-coated tablets Otezla 20 mg film-coated tablets Otezla 30 mg film-coated tablets	Amgen Europe B.V.	EU/1/14/981/001	Film-coated tablet	- L04AA32	- Apremilast - Apremilast - Apremilast	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Otezla 30 mg film-coated tablets	Amgen Europe B.V.	EU/1/14/981/002-003	Film-coated tablet	- L04AA32	- Apremilast	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Otrivine Adult 0.1% w/v Nasal Drops, Solution	Haleon Ireland Limited	PA0678/120/001	Nasal drops, solution	- R01AA - R01AA07	- Xylometazoline hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Otrivine Adult Menthol 0.1% w/v Nasal Spray, Solution	Haleon Ireland Limited	PA0678/120/004	Nasal spray, solution	- R01AA - R01AA07	- Xylometazoline hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Otrivine Congestion Relief 0.1% w/v Nasal Spray, Solution	Haleon Ireland Limited	PA0678/120/002	Nasal spray, solution	- R01AA - R01AA07	- Xylometazoline hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Otrivine Congestion Relief Menthol 0.1% w/v Nasal Spray	Haleon Ireland Limited	PA0678/120/005	Nasal spray, solution	- R01AA - R01AA07	- Xylometazoline hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Otrivine Extra Dual Relief 0.5mg/ml + 0.6mg/ml nasal spray, solution	Haleon Ireland Limited	PA0678/131/001	Nasal spray, solution	- R01AB - R01AB06	- Xylometazoline hydrochloride - Ipratropium bromide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Nasal use
Otrivine Sinusitis Relief 0.1% w/v Nasal Spray, Solution	Haleon Ireland Limited	PA0678/120/003	Nasal spray, solution	- R01AA - R01AA07	- Xylometazoline hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Otrivine-Antistin Eye Drops	Laboratoires Thea	PA1107/008/001	Eye drops, solution	- S01GA - S01GA53	- Xylometazoline hydrochloride - ANTAZOLINE SULFATE		- Ocular use
Ovaleap	Theramex Ireland Limited	EU/1/13/871/001-003	Solution for injection	- G03GA - G03GA05	- Follitropin alfa	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
OVALEAP	Teva B.V.	EU/1/13/871/002	Solution for Injection	- G03GA05	- FOLLITROPIN ALFA	Article 10(4) - Similar Biological App	- Subcutaneous
OVALEAP	Teva B.V.	EU/1/13/871/003	Solution for Injection	- G03GA05	- FOLLITROPIN ALFA	Article 10(4) - Similar Biological App	- Subcutaneous
Ovestin 1mg per gram Vaginal Cream	Aspen Pharma Trading Limited	PA1691/017/001	Vaginal cream	- G03CA - G03CA04	- Estriol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Ovitrelle	Merck Europe B.V.	EU/1/00/165/001	Powder and solvent for solution for injection	- G03GA - G03GA01	- Choriogonadotropin alfa		- Subcutaneous use
Ovitrelle	Merck Europe B.V.	EU/1/00/165/002	Powder and solvent for solution for infusion	- G03GA08	- Choriogonadotropin alfa		- Subcutaneous use
Ovitrelle	Merck Europe B.V.	EU/1/00/165/003	Powder and solvent for solution for infusion	- G03GA08	- Choriogonadotropin alfa		- Subcutaneous use
Ovitrelle	Merck Europe B.V.	EU/1/00/165/004	Powder and solvent for solution for injection	- G03GA08	- Choriogonadotropin alfa		- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ovitrelle	Merck Europe B.V.	EU/1/00/165/005	Powder and solvent for solution for injection	- G03GA08	- Choriogonadotropin alfa		- Subcutaneous use
Ovitrelle	Merck Europe B.V.	EU/1/00/165/006	Powder and solvent for solution for injection	- G03GA08	- Choriogonadotropin alfa		- Subcutaneous use
Ovitrelle	Ares-Serono (Europe) Limited	EU/1/00/165/007	Solution for injection in pre-filled syringe	- G03GA - G03GA01	- Choriogonadotropin alfa		
Ovitrelle	Merck Europe B.V.	EU/1/00/165/008	Solution for injection in pre-filled syringe	- G03GA - G03GA08	- Choriogonadotropin alfa		- Subcutaneous use
Ovranette 150 micrograms/30 micrograms coated tablets	Pfizer Healthcare Ireland	PA0822/094/001	Coated tablet	- G03AA - G03AA07	- Ethinyloestradiol - Levonorgestrel	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ovreena 30 micrograms/150 micrograms coated tablets	Gedeon Richter Plc	PA1330/015/001	Coated tablet	- G03AA - G03AA07	- Ethinylestradiol - Levonorgestrel		- Oral use
Oxaliplatin 5 mg/ml concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/049/001	Concentrate for solution for infusion	- L01XA - L01XA03	- Oxaliplatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Oxaliplatin 5mg/ml Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/114/001	Concentrate for solution for infusion	- L01XA - L01XA03	- Oxaliplatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Oxaliplatin medac 5 mg/ml powder for solution for infusion	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/008/001	Powder for solution for infusion	- L01XA - L01XA03	- Oxaliplatin		- Intravenous use
Oxbryta	Pfizer Europe MA EEIG	EU/1/21/1622/001	Film-coated tablet	- B06A - B06AX03	- Voxelotor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Oxervate	Dompe farmaceutici SpA	EU/1/17/1197/01	Eye drops, solution	- S01	- Recombinant human nerve growth factor (rhngf)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Oxis Turbohaler 12, inhalation powder	AstraZeneca AB	PA1019/015/002	Inhalation powder	- R03AC - R03AC13	- Formoterol fumatrate dihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Oxis Turbohaler 6, inhalation powder	AstraZeneca AB	PA1019/015/001	Inhalation powder	- R03AC - R03AC13	- Formoterol fumatrate dihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Oxlumo	Alnylam Netherlands B.V.	EU/1/20/1496/001	Solution for injection	- A16AX	- Lumasiran sodium	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Oxybuprocaine Agepha 4 mg/ml eye drops, solution	AGEPHA Pharma s.r.o.	PA22584/002/001	Eye drops, solution	- S01HA02	- Oxybuprocaine hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Ocular use
Oxybutynin hydrochloride 2.5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/038/001	Tablet	- G04BD - G04BD04	- Oxybutynin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oxybutynin hydrochloride 2.5 mg/5 ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/014/001	Oral solution	- G04BD - G04BD04	- Oxybutynin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oxybutynin hydrochloride 5 mg/5 ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/014/002	Oral solution	- G04BD - G04BD04	- Oxybutynin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oxybutynin Hydrochloride 5mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/038/002	Tablet	- G04BD - G04BD04	- Oxybutynin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Oxycodone Hydrochloride 10 mg/ml Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/235/001	Solution for injection/infusion	- N02AA - N02AA05	- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Oxycodone hydrochloride 10 mg/ml solution for injection/infusion	AS Kalceks	PA2165/005/001	Solution for injection/infusion	- N02AA - N02AA05	- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Oxycodone hydrochloride 10mg/ml solution for injection or infusion	hameln pharma gmbh	PA2237/001/001	Solution for injection/infusion	- N02AA05	- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Oxycodone hydrochloride 50 mg/ml solution for injection/infusion	AS Kalceks	PA2165/005/002	Solution for injection/infusion	- N02AA - N02AA05	- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Oxycodone hydrochloride 50mg/ml solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/235/002	Solution for injection/infusion	- N02AA - N02AA05	- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Oxycodone hydrochloride Rowex 10 mg Hard capsules	Rowex Ltd	PA0711/286/002 Interchangeable List Code: IC0066-002-047	Capsule, hard		- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oxycodone hydrochloride Rowex 20 mg Hard capsules	Rowex Ltd	PA0711/286/003 Interchangeable List Code: IC0066-003-047	Capsule, hard		- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oxycodone hydrochloride Rowex 5 mg Hard capsules	Rowex Ltd	PA0711/286/001 Interchangeable List Code: IC0066-001-047	Capsule, hard		- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oxycodone Lannacher SR 10 mg prolonged release tablet	Lannacher Heilmittel Ges.m.b.H	PA0947/003/002 Interchangeable List Code: IC0066-002-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oxycodone Lannacher SR 20 mg prolonged release tablets	Lannacher Heilmittel Ges.m.b.H	PA0947/003/003 Interchangeable List Code: IC0066-003-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oxycodone Lannacher SR 40 mg prolonged release tablets	Lannacher Heilmittel Ges.m.b.H	PA0947/003/004 Interchangeable List Code: IC0066-004-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oxycodone Lannacher SR 5 mg prolonged release tablet	Lannacher Heilmittel Ges.m.b.H	PA0947/003/001 Interchangeable List Code: IC0066-001-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Oxycodone Lannacher SR 80 mg prolonged release tablets	Lannacher Heilmittel Ges.m.b.H	PA0947/003/005 Interchangeable List Code: IC0066-005-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
OxyContin 10 mg prolonged release tablets	Mundipharma Pharmaceuticals Limited	PA1688/005/002 Interchangeable List Code: IC0066-002-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
OxyContin 20 mg prolonged release tablets	Mundipharma Pharmaceuticals Limited	PA1688/005/003 Interchangeable List Code: IC0066-003-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
OxyContin 40 mg prolonged release tablets	Mundipharma Pharmaceuticals Limited	PA1688/005/004 Interchangeable List Code: IC0066-004-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
OxyContin 5 mg prolonged release tablets	Mundipharma Pharmaceuticals Limited	PA1688/005/001 Interchangeable List Code: IC0066-001-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
OxyContin 80 mg prolonged release tablets	Mundipharma Pharmaceuticals Limited	PA1688/005/005 Interchangeable List Code: IC0066-005-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
OxyNorm 10 mg hard capsules	Mundipharma Pharmaceuticals Limited	PA1688/006/005 Interchangeable List Code: IC0066-002-047	Capsule, hard		- OXYCODONE HYDROCHLORIDE		- Oral use
OxyNorm 10 mg/ml, solution for injection or infusion	Mundipharma Pharmaceuticals Limited	PA1688/006/001	Solution for injection/infusion	- N02AA - N02AA05	- OXYCODONE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
OxyNorm 20 mg hard capsules	Mundipharma Pharmaceuticals Limited	PA1688/006/006 Interchangeable List Code: IC0066-003-047	Capsule, hard		- OXYCODONE HYDROCHLORIDE		- Oral use
OxyNorm 5 mg hard capsules	Mundipharma Pharmaceuticals Limited	PA1688/006/004 Interchangeable List Code: IC0066-001-047	Capsule, hard		- OXYCODONE HYDROCHLORIDE		- Oral use
OxyNorm 50 mg/ml, solution for injection or infusion	Mundipharma Pharmaceuticals Limited	PA1688/006/010	Solution for injection/infusion	- N02AA - N02AA05	- OXYCODONE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
OxyNorm concentrate 10mg/ml oral solution	Mundipharma Pharmaceuticals Limited	PA1688/006/003	Oral solution	- N02AA - N02AA05	- OXYCODONE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
OxyNorm Dispersa 10 mg Orodispersible Tablets	Mundipharma Pharmaceuticals Limited	PA1688/006/008 Interchangeable List Code: IC0066-002-047	Orodispersible tablet		- OXYCODONE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
OxyNorm Dispersa 20 mg orodispersible tablets	Mundipharma Pharmaceuticals Limited	PA1688/006/009 Interchangeable List Code: IC0066-003-047	Orodispersible tablet		- OXYCODONE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
OxyNorm Dispersa 5 mg Orodispersible Tablets	Mundipharma Pharmaceuticals Limited	PA1688/006/007 Interchangeable List Code: IC0066-001-047	Orodispersible tablet		- OXYCODONE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
OxyNorm liquid 1mg/ml oral solution	Mundipharma Pharmaceuticals Limited	PA1688/006/002	Oral solution	- N02AA - N02AA05	- OXYCODONE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Oxytocin 10 IU/ml Concentrate for Solution for Infusion	Pinewood Laboratories Ltd	PA0281/239/001	Concentrate for solution for infusion	- H01BB - H01BB02	- Oxytocin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Oyavas	Stada Arzneimittel AG	EU/1/20/1510/001-002	Concentrate for solution for infusion	- L01XC07	- Bevacizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Ozalin 2 mg/ml oral solution in single-dose container	Primex Pharmaceuticals Oy	PA1719/002/001	Oral solution in single-dose container	- N05CD08	- Midazolam	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Ozawade	Bioprojet Pharma	EU/1/21/1546/001	Film-coated tablet	- J05AP56 - QN07XX11	- Pitolisant hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ozawade	Bioprojet Pharma	EU/1/21/1546/002-003	Film-coated tablet	- J05AP56 - QN07XX11	- Pitolisant hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ozempic	Novo Nordisk A/S	EU/1/17/1251/002	Solution for injection in pre-filled pen	- A10BJ06	- Semaglutide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Ozempic	Novo Nordisk A/S	EU/1/17/1251/002-006	Solution for infusion in pre-filled syringe	- A10BJ06	- semaglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Ozempic	Novo Nordisk A/S	EU/1/17/1251/003-004	Solution for injection in pre-filled pen		- Semaglutide	New active substance (Article 8(3) of Directive No 2001/83/EC)	
Ozempic	Novo Nordisk A/S	EU/1/17/1251/005-006	Solution for injection in pre-filled pen	- A10BJ06	- Semaglutide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Ozempic®	Novo Nordisk A/S	EU/1/17/1251/010-011	Solution for injection in pre-filled pen	- A10BJ06	- Semaglutide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Ozurdex	AbbVie Deutschland GmbH & Co. KG	EU/1/10/638/001	Intravitreal implant in applicator	- S01BA - S01BA01	- Dexamethasone		- Intravitreal use
Pabal 100 micrograms/ml, solution for injection	Ferring Ireland Ltd	PA1009/021/001	Solution for injection	- H01BB - H01BB03	- Carbetocin	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Pabrinex Intravenous High Potency Concentrate for Solution for Infusion	Kyowa Kirin Holdings B.V.	PA2288/001/001	Concentrate for solution for infusion	- A11EB	- Ascorbic acid - Riboflavin - Pyridoxine hydrochloride - Nicotinamide - Thiamine hydrochloride - Glucose (as monohydrate)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intravenous use
Paclitaxel 6 mg/ml concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/050/001	Concentrate for solution for infusion	- L01CD - L01CD01	- Paclitaxel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Paclitaxel 6 mg/ml concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/180/001	Concentrate for solution for infusion	- L01CD - L01CD01	- Paclitaxel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Paclitaxel 6 mg/ml, Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/115/001	Concentrate for solution for infusion	- L01CD - L01CD01	- Paclitaxel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Padcev	Astellas Pharma Europe B.V.	EU/1/21/1615/001	Powder for concentrate for solution for infusion	- L01 - L01FX13	- Enfortumab Vedotin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Padcev	Astellas Pharma Europe B.V.	EU/1/21/1615/002	Powder for concentrate for solution for infusion	- L01 - L01FX13	- Enfortumab Vedotin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Padolieve 500mg film coated tablets	Alter Pharma	PA22983/002/001	Film-coated tablet	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Padolieve Max 1000mg film coated tablets	Alter Pharma	PA22983/002/002	Film-coated tablet	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paedisol Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/029/001	Solution for infusion	- B05BB - B05BB02	- Sodium chloride - Potassium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium acetate trihydrate - Glucose monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
PAGLITAZ	Krka d.d., Novo mesto	EU/1/11/721/001-007	Tablet	- A10BG03	- PIOGLITAZONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
PAGLITAZ	Krka d.d., Novo mesto	EU/1/11/721/008-014	Tablet	- A10BG03	- PIOGLITAZONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
PAGLITAZ	Krka d.d., Novo mesto	EU/1/11/721/015-021	Tablet	- A10BG03	- PIOGLITAZONE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Palexia 100 mg film-coated tablets	Grunenthal Pharma Ltd	PA2242/012/003	Film-coated tablet	- N02AX - N02AX06	- Tapentadol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
PALEXIA 20 mg/ml oral solution	Grunenthal Pharma Ltd	PA2242/012/011	Oral solution	- N02AX - N02AX06	- Tapentadol hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
PALEXIA 4 mg/ml oral solution	Grunenthal Pharma Ltd	PA2242/012/010	Oral solution	- N02AX - N02AX06	- Tapentadol hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Palexia 50 mg film-coated tablets	Grunenthal Pharma Ltd	PA2242/012/001	Film-coated tablet	- N02AX - N02AX06	- Tapentadol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Palexia 75 mg film-coated tablets	Grunenthal Pharma Ltd	PA2242/012/002	Film-coated tablet	- N02AX - N02AX06	- Tapentadol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Palexia SR 100 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/012/005	Prolonged-release tablet	- N02AX - N02AX06	- Tapentadol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Palexia SR 150 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/012/006	Prolonged-release tablet	- N02AX - N02AX06	- Tapentadol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Palexia SR 200 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/012/007	Prolonged-release tablet	- N02AX - N02AX06	- Tapentadol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
PALEXIA SR 25 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/012/009	Prolonged-release tablet	- N02AX - N02AX06	- Tapentadol hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Palexia SR 250 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/012/008	Prolonged-release tablet	- N02AX - N02AX06	- Tapentadol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Palexia SR 50 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/012/004	Prolonged-release tablet	- N02AX - N02AX06	- Tapentadol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Palforzia	Aimmune Therapeutics Netherlands B.V.	EU/1/20/1495/001	Oral powder in capsules for opening	- V01AA08	- Arachis Hypogaea Allergens	Full application (Article 8(3) of Directive No 2001/83/EC)	
Palforzia	Aimmune Therapeutics Netherlands B.V.	EU/1/20/1495/002-003	Oral powder in capsules for opening	- V01AA08	- Arachis Hypogaea Allergens	Full application (Article 8(3) of Directive No 2001/83/EC)	
Palforzia	Aimmune Therapeutics Netherlands B.V.	EU/1/20/1495/004	Oral powder in capsules for opening	- V01AA08	- Arachis Hypogaea Allergens	Full application (Article 8(3) of Directive No 2001/83/EC)	
Palforzia	Aimmune Therapeutics Netherlands B.V.	EU/1/20/1495/005-010	Oral powder in capsules for opening	- V01AA08	- Arachis Hypogaea Allergens	Full application (Article 8(3) of Directive No 2001/83/EC)	

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Palforzia	Aimmune Therapeutics Netherlands B.V.	EU/1/20/1495/011	Oral powder in capsules for opening	- V01AA08	- Arachis Hypogaea Allergens	Full application (Article 8(3) of Directive No 2001/83/EC)	
Palforzia	Aimmune Therapeutics Netherlands B.V.	EU/1/20/1495/012-013	Oral powder in sachet	- V01AA08	- Arachis Hypogaea Allergens	Full application (Article 8(3) of Directive No 2001/83/EC)	
Paliperidone Janssen 100 mg prolonged-release suspension for injection.	Janssen-Cilag International NV	EU/1/14/971/004 Interchangeable List Code: IC0130-024-064	Prolonged-release suspension for injection		- Paliperidone palmitate (r092670)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
Paliperidone Janssen 150 mg and Paliperidone Janssen 100 mg prolonged-release suspension for injection.	Janssen-Cilag International NV	EU/1/14/971/006 Interchangeable List Code: IC0130-179-064	Prolonged-release suspension for injection		- Paliperidone palmitate (r092670) - Paliperidone palmitate (r092670)		- Intramuscular use
Paliperidone Janssen 150 mg prolonged-release suspension for injection.	Janssen-Cilag International NV	EU/1/14/971/005 Interchangeable List Code: IC0130-062-064	Prolonged-release suspension for injection		- Paliperidone palmitate (r092670)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
Paliperidone Janssen 25 mg prolonged-release suspension for injection.	Janssen-Cilag International NV	EU/1/14/971/001 Interchangeable List Code: IC0130-022-064	Prolonged-release suspension for injection		- Paliperidone palmitate (r092670)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
Paliperidone Janssen 50 mg prolonged-release suspension for injection.	Janssen-Cilag International NV	EU/1/14/971/002 Interchangeable List Code: IC0130-023-064	Prolonged-release suspension for injection		- Paliperidone palmitate (r092670)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
Paliperidone Janssen 75 mg prolonged-release suspension for injection.	Janssen-Cilag International NV	EU/1/14/971/003 Interchangeable List Code: IC0130-028-064	Prolonged-release suspension for injection		- Paliperidone palmitate (r092670)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
Paliperidone Janssen-Cilag International 100 mg prolonged-release suspension for injection	Janssen Pharmaceutica NV	EU/1/20/1453/004 Interchangeable List Code: IC0130-024-064	Prolonged-release suspension for injection		- Paliperidone palmitate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
Paliperidone Janssen-Cilag International 150 mg and Paliperidone Janssen-Cilag International 100 mgprolonged-release suspension for injection	Janssen Pharmaceutica NV	EU/1/20/1453/006 Interchangeable List Code: IC0130-179-064	Prolonged-release suspension for injection		- Paliperidone palmitate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
Paliperidone Janssen-Cilag International 150 mg prolonged-release suspension for injection	Janssen Pharmaceutica NV	EU/1/20/1453/005 Interchangeable List Code: IC0130-062-064	Prolonged-release suspension for injection		- Paliperidone palmitate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
Paliperidone Janssen-Cilag International 25 mg prolonged-release suspension for injection	Janssen Pharmaceutica NV	EU/1/20/1453/001 Interchangeable List Code: IC0130-022-064	Prolonged-release suspension for injection		- Paliperidone palmitate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
Paliperidone Janssen-Cilag International 50 mg prolonged-release suspension for injection	Janssen Pharmaceutica NV	EU/1/20/1453/002 Interchangeable List Code: IC0130-023-064	Prolonged-release suspension for injection		- Paliperidone palmitate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Paliperidone Janssen-Cilag International 75 mg prolonged-release suspension for injection	Janssen Pharmaceutica NV	EU/1/20/1453/003 Interchangeable List Code: IC0130-028-064	Prolonged-release suspension for injection		- Paliperidone palmitate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
Paliperidone Krka 3 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/092/001 Interchangeable List Code: IC0130-045-024	Prolonged-release tablet		- Paliperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paliperidone Krka 6 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/092/002 Interchangeable List Code: IC0130-046-024	Prolonged-release tablet		- Paliperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paliperidone Krka 9 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/092/003 Interchangeable List Code: IC0130-178-024	Prolonged-release tablet		- Paliperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paliperidone Teva 100 mg prolonged-release suspension for injection	Norton Waterford	PA0436/050/004 Interchangeable List Code: IC0130-024-064	Prolonged-release suspension for injection		- Paliperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Paliperidone Teva 150 mg and Paliperidone Teva 100 mg prolonged-release suspension for injection	Norton Waterford	PA0436/050/006 Interchangeable List Code: IC0130-179-064	Prolonged-release suspension for injection		- Paliperidone - Paliperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Paliperidone Teva 150 mg prolonged-release suspension for injection	Norton Waterford	PA0436/050/005 Interchangeable List Code: IC0130-062-064	Prolonged-release suspension for injection		- Paliperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Paliperidone Teva 25 mg prolonged-release suspension for injection	Norton Waterford	PA0436/050/001 Interchangeable List Code: IC0130-022-064	Prolonged-release suspension for injection		- Paliperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Paliperidone Teva 50 mg prolonged-release suspension for injection	Norton Waterford	PA0436/050/002 Interchangeable List Code: IC0130-023-064	Prolonged-release suspension for injection		- Paliperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Paliperidone Teva 75 mg prolonged-release suspension for injection	Norton Waterford	PA0436/050/003 Interchangeable List Code: IC0130-028-064	Prolonged-release suspension for injection		- Paliperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Palladone 1.3 mg capsules	Mundipharma Pharmaceuticals Limited	PA1688/007/001	Capsule, hard	- N02AA - N02AA03	- Hydromorphone hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Palladone 2.6 mg capsules	Mundipharma Pharmaceuticals Limited	PA1688/007/002	Capsule, hard	- N02AA - N02AA03	- Hydromorphone hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Palladone SR 16 mg Prolonged-release Capsules	Mundipharma Pharmaceuticals Limited	PA1688/007/010	Prolonged-release capsule, hard	- N02AA - N02AA03	- Hydromorphone hydrochloride		- Oral use
Palladone SR 2 mg prolonged release capsules, hard	Mundipharma Pharmaceuticals Limited	PA1688/007/007	Prolonged-release capsule, hard	- N02AA - N02AA03	- Hydromorphone hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Palladone SR 4 mg Prolonged-release Capsules	Mundipharma Pharmaceuticals Limited	PA1688/007/008	Prolonged-release capsule, hard	- N02AA - N02AA03	- Hydromorphone hydrochloride		- Oral use
Palladone SR 8 mg Prolonged-release Capsules	Mundipharma Pharmaceuticals Limited	PA1688/007/009	Prolonged-release capsule, hard	- N02AA - N02AA03	- Hydromorphone hydrochloride		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Palmeux 100 mg prolonged-release suspension for injection in pre-filled syringe	Amdipharm Limited	PA1142/040/004 Interchangeable List Code: IC0130-024-064	Prolonged-release suspension for injection in pre-filled syringe		- Paliperidone palmitate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Palmeux 150 mg prolonged-release suspension for injection in pre-filled syringe	Amdipharm Limited	PA1142/040/005 Interchangeable List Code: IC0130-062-064	Prolonged-release suspension for injection in pre-filled syringe		- Paliperidone palmitate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Palmeux 25 mg prolonged-release suspension for injection in pre-filled syringe	Amdipharm Limited	PA1142/040/001 Interchangeable List Code: IC0130-022-064	Prolonged-release suspension for injection in pre-filled syringe		- Paliperidone palmitate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Palmeux 50 mg prolonged-release suspension for injection in pre-filled syringe	Amdipharm Limited	PA1142/040/002 Interchangeable List Code: IC0130-023-064	Prolonged-release suspension for injection in pre-filled syringe		- Paliperidone palmitate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Palmeux 75 mg prolonged-release suspension for injection in pre-filled syringe	Amdipharm Limited	PA1142/040/003 Interchangeable List Code: IC0130-028-064	Prolonged-release suspension for injection in pre-filled syringe		- Paliperidone palmitate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Palonosetron 250 micrograms Solution for injection	Fresenius Kabi Deutschland GmbH	PA2059/014/001	Solution for injection	- A04AA - A04AA05	- Palonosetron hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Palonosetron 250 micrograms solution for injection in pre-filled syringe	Fresenius Kabi Deutschland GmbH	PA2059/014/002	Solution for injection in pre-filled syringe	- A04AA - A04AA05	- Palonosetron hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Palonosetron Accord	Accord Healthcare S.L.U.	EU/1/16/1104/001	Solution for injection	- A04AA - A04AA05	- Palonosetron hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	
Palynziq	BioMarin International Limited	EU/1/19/1362/001	Solution for injection in pre-filled syringe	- A16A - A16AB19	- PEGVALIASE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Palynziq	BioMarin International Limited	EU/1/19/1362/002	Solution for injection in pre-filled syringe	- A16A - A16AB19	- PEGVALIASE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Palynziq	BioMarin International Limited	EU/1/19/1362/003-004	Solution for injection in pre-filled syringe	- A16A - A16AB19	- PEGVALIASE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Panadeine Extra Strength Tablets Paracetamol 500 mg Codeine Phosphate hemihydrate 12.8 mg	Haleon Ireland Limited	PA0678/026/003	Film-coated tablet	- N02AJ06	- Paracetamol - Codeine phosphate hemihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Panadol 500 mg Film Coated Tablets	Haleon Ireland Limited	PA0678/107/001	Film-coated tablet	- N02BE - N02BE01	- Paracetamol		- Oral use
Panadol ActiFast 500mg Soluble Tablets	Haleon Ireland Limited	PA0678/039/014	Soluble tablet	- N02BE - N02BE01	- Paracetamol		- Oral use
Panadol Actifast Lemon 500 mg Soluble Tablets	Haleon Ireland Limited	PA0678/039/017	Soluble tablet	- N02BE01	- Paracetamol	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Panadol Actifast Tablets 500mg	GlaxoSmithKline Consumer Healthcare (Ireland) Limited	PA0678/039/012	Film-coated tablet	- N02BE - N02BE01	- Paracetamol		- Oral use
Panadol Baby 120 mg/5 ml, Oral Suspension	Haleon Ireland Limited	PA0678/039/003	Oral suspension	- N02BE - N02BE01	- Paracetamol	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Panadol Cold & Flu Hot Blackcurrant Powder for Oral SolutionParacetamol 600mgAscorbic acid 40mg	Haleon Ireland Limited	PA0678/011/002	Powder for oral solution	- N02BE - N02BE51	- Paracetamol - Ascorbic acid	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Panadol Cold & Flu Hot Lemon Powder for Oral SolutionParacetamol 600mgAscorbic acid 40mg	Haleon Ireland Limited	PA0678/011/001	Powder for oral solution	- N02BE - N02BE51	- Paracetamol - Ascorbic acid	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Panadol Cold & Flu Hot Lemon with Honey Powder for Oral SolutionParacetamol 600mgAscorbic acid 40mg	Haleon Ireland Limited	PA0678/011/003	Powder for oral solution	- N02BE - N02BE01	- Paracetamol - Ascorbic acid	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Panadol Cold and Flu Relief 500mg/65mg Film-Coated Tablets	Haleon Ireland Limited	PA0678/105/001	Film-coated tablet	- N02BE - N02BE51	- Paracetamol - Caffeine		- Oral use
Panadol Cold and Flu Relief Orange Effervescent TabletsParacetamol 500 mgCaffeine 65 mg	Haleon Ireland Limited	PA0678/105/002	Effervescent tablet	- N02BE - N02BE51	- Paracetamol - Caffeine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Panadol Extra 500mg/65mg Soluble Effervescent Tablets	Haleon Ireland Limited	PA0678/039/010	Effervescent tablet	- N02BE - N02BE51	- Paracetamol - Caffeine		- Oral use
Panadol Extra Film-coated tablets Paracetamol 500mg Caffeine 65mg	Haleon Ireland Limited	PA0678/027/001	Film-coated tablet	- N02BE - N02BE51	- Paracetamol - Caffeine		- Oral use
Panadol Fever and Congestion Film-coated Tablets Paracetamol 500mg Pseudoephedrine Hydrochloride 30mg	Haleon Ireland Limited	PA0678/094/001	Film-coated tablet	- N02BE - N02BE51	- Paracetamol - PSEUDOEPHEDRINE HYDROCHLORIDE	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Panadol Head Cold Powder for Oral SolutionParacetamol 600 mg Ascorbic Acid 40 mg	Haleon Ireland Limited	PA0678/106/001	Powder for oral solution	- N02BE - N02BE01	- Paracetamol - Ascorbic acid		- Oral use
Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C Powder for Oral Solution Paracetamol 1000 mg Ascorbic Acid 70 mg	Haleon Ireland Limited	PA0678/011/004	Powder for oral solution	- N02BE - N02BE51	- Paracetamol - Ascorbic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Panadol Max Strength Cold and Flu Hot Lemon Powder for oral solution Paracetamol 1000mg	Haleon Ireland Limited	PA0678/039/013	Powder for oral solution	- N02BE - N02BE01	- Paracetamol	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Panadol Max Strength Fever and Congestion Hot Lemon Powder for Oral SolutionParacetamol 1000mgPhenylephrine hydrochloride 10mgAscorbic Acid 40mg	Haleon Ireland Limited	PA0678/035/001	Powder for oral solution	- N02BE - N02BE51	- Paracetamol - Phenylephrine hydrochloride - Ascorbic acid		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Panadol Night	Haleon Ireland Limited	PA0678/039/008	Film-coated tablet	- N02BE - N02BE51	- Paracetamol - Diphenhydramine hydrochloride	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Panadol Original 500 mg film-coated Tablets	Haleon Ireland Limited	PA0678/039/005	Film-coated tablet	- N02BE - N02BE01	- Paracetamol	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Panadol Sinus Relief Film Coated TabletsParacetamol 500mgCaffeine 25mgPhenylephrine Hydrochloride 5mg	Haleon Ireland Limited	PA0678/044/001	Film-coated tablet	- N02BE - N02BE51	- Paracetamol - Caffeine - Phenylephrine hydrochloride	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Panadol Soluble Max 1000mg Paracetamol Effervescent granule	Haleon Ireland Limited	PA0678/028/002	Effervescent granule	- N02BE - N02BE01	- Paracetamol		- Oral use
Panadol with Caffeine 500mg/ 65mg Film Coated Tablets	Haleon Ireland Limited	PA0678/037/001	Film-coated tablet	- N02BE - N02BE51	- Paracetamol - Caffeine		- Oral use
Panadol Woman Film-Coated TabletsParacetamol 500 mg Caffeine 65 mg	Haleon Ireland Limited	PA0678/102/001	Film-coated tablet	- N02BE - N02BE51	- Paracetamol - Caffeine	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Panagram Max 1g Film coated tablets	Haleon Ireland Limited	PA0678/039/009	Film-coated tablet	- N02BE - N02BE01	- Paracetamol		- Oral use
Pandemic influenza vaccine (H5N1) MedImmune - pandemic influenza vaccine h5n1 (live attenuated, nasal)	AstraZeneca AB	EU/1/16/1089/001	Nasal spray, suspension	- J07BB - J07BB03	- Strain. a/vietnam/1203/2004 (h5n1) strain (live attenuated)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Pantium 20 mg Gastro-resistant tablets	Clonmel Healthcare Ltd	PA0126/175/001 Interchangeable List Code: IC0013-003-005	Gastro-resistant tablet		- Pantoprazole sodium sesquihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pantium 40mg Gastro-Resistant Tablets	Clonmel Healthcare Ltd	PA0126/175/002 Interchangeable List Code: IC0013-004-005	Gastro-resistant tablet		- Pantoprazole sodium sesquihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pantoprazole 40 mg Powder for Solution for Injection	Laboratorio Reig Jofre, S.A.	PA1618/001/001	Powder for solution for injection	- A02BC - A02BC02	- Pantoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pantoprazole 40 mg powder for solution for injection	AS Kalceks	PA2165/020/001	Powder for solution for injection	- A02BC02	- Pantoprazole sodium sesquihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pantoprazole Azevedos 40 mg powder for solution for injection/infusion	Laboratórios Azevedos - Indústria Farmacêutica S.A	PA1852/001/001	Powder for solution for injection/infusion	- A02BC - A02BC02	- Pantoprazole sodium sesquihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pantoprazole Bluefish 20 mg gastro-resistant tablets	Bluefish Pharmaceuticals AB	PA1436/008/001 Interchangeable List Code: IC0013-003-005	Gastro-resistant tablet		- Pantoprazole sodium sesquihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pantoprazole Bluefish 40 mg gastro-resistant tablets	Bluefish Pharmaceuticals AB	PA1436/008/002 Interchangeable List Code: IC0013-004-005	Gastro-resistant tablet		- Pantoprazole sodium sesquihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pantoprazole Mylan 20 mg Gastro-resistant Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/146/001 Interchangeable List Code: IC0013-003-005	Gastro-resistant tablet		- Pantoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pantoprazole Mylan 40 mg Gastro-resistant Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/146/002 Interchangeable List Code: IC0013-004-005	Gastro-resistant tablet		- Pantoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pantoprazole Noridem 40 mg Powder for Solution for Injection	Noridem Enterprises Limited	PA1122/011/001	Powder for solution for injection	- A02BC - A02BC02	- Pantoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pantoprazole Teva Pharma 20 mg gastro-resistant tablets	Teva Pharma B.V.	PA0749/144/001 Interchangeable List Code: IC0013-003-005	Gastro-resistant tablet		- Pantoprazole sodium sesquihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pantoprazole Teva Pharma 40 mg gastro-resistant tablets	Teva Pharma B.V.	PA0749/144/002 Interchangeable List Code: IC0013-004-005	Gastro-resistant tablet		- Pantoprazole sodium sesquihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
PANTOZOL Control	Takeda GmbH	EU/1/09/517/001	Gastro-resistant tablet	- A02BC - A02BC02	- Pantoprazole sodium sesquihydrate		- Oral use
PANTOZOL Control	Takeda GmbH	EU/1/09/517/001-004	Gastro-resistant tablet	- A02BC - A02BC02	- Pantoprazole sodium sesquihydrate		- Oral use
Pantup 20 mg gastro-resistant tablets	Rowa Pharmaceuticals Limited	PA0074/069/001 Interchangeable List Code: IC0013-003-005	Gastro-resistant tablet		- Pantoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pantup 40 mg gastro-resistant tablets	Rowa Pharmaceuticals Limited	PA0074/069/002 Interchangeable List Code: IC0013-004-005	Gastro-resistant tablet		- Pantoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pantup Relief 20 mg Gastro-resistant tablets	Rowex Ltd	PA0711/142/003	Gastro-resistant tablet	- A02BC - A02BC02	- Pantoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Panzyga, 100 mg/ml solution for infusion	Octapharma (IP) SPRL	PA2219/010/001	Solution for infusion	- J06BA - J06BA02	- Human normal immunoglobulin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Paracetamol / Caffeine 500mg/65mg Tablets	Brillpharma (Ireland) Limited	PA22749/005/001	Tablet	- N02BE - N02BE51	- PARACETAMOL - Anhydrous caffeine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paracetamol 10 mg/ml solution for infusion	Baxter Holding B.V.	PA2299/049/001	Solution for infusion	- N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Paracetamol 10 mg/ml solution for infusion	Baxter Holding B.V.	PA2299/056/001	Solution for infusion	- N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Paracetamol 10 mg/ml solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/218/001	Solution for infusion	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Paracetamol 10 mg/ml Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/170/001	Solution for infusion	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Paracetamol 10 mg/ml Solution for Infusion	Laboratoire AGUETTANT	PA1968/021/001	Solution for infusion	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Paracetamol 10 mg/ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/015/001	Solution for infusion	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Paracetamol 10 mg/ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/015/002	Solution for infusion	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavourParacetamol 1000mg, Phenylephrine HCl 12.2mgPowder for oral solution	WICK Pharma - Zweigniederlassung der Procter & Gamble GmbH	PA2294/001/001	Powder for oral solution	- N02BE - N02BE51	- Phenylephrine hydrochloride - Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Paracetamol 10mg/ml solution for infusion	B. Braun Melsungen AG	PA0736/035/001	Solution for infusion	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
PARACETAMOL 120mg/ 5ml Infant Oral Suspension	McNeil Healthcare (Ireland) Ltd	PA0823/010/009	Oral suspension	- N02BE - N02BE01	- Paracetamol	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
PARACETAMOL 120mg/ 5ml Sugar-Free Infant Oral Suspension	McNeil Healthcare (Ireland) Ltd	PA0823/010/010	Oral suspension	- N02BE - N02BE01	- Paracetamol	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Paracetamol 125 mg suppositories	Phoenix Labs	PA1113/004/004	Suppository	- N02BE - N02BE01	- Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Rectal use
Paracetamol 250mg Suppositories	Phoenix Labs	PA1113/004/001	Suppository	- N02BE - N02BE01	- Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Rectal use
Paracetamol 500 mg Capsules, hard	Azure Pharmaceuticals Ltd	PA22871/016/001	Capsule, hard	- N02BE01	- Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Paracetamol 500 mg Film Coated Tablets	GlaxoSmithKline Consumer Healthcare (Ireland) Limited	PA0678/150/001	Film-coated tablet	- N02BE - N02BE01	- Paracetamol		- Oral use
Paracetamol 500 mg Film-Coated Tablets	Chefaro Ireland DAC	PA1186/009/001	Film-coated tablet	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paracetamol 500 mg tablets	Bluefish Pharmaceuticals AB	PA1436/040/001	Tablet	- N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine Hydrochloride 10 mg, Powder for Oral Solution	WICK Pharma - Zweigniederlassung der Procter & Gamble GmbH	PA2294/002/001	Powder for oral solution	- N02BE - N02BE51	- Paracetamol - Guaifenesin - Phenylephrine hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Paracetamol 500mg Suppositories	Phoenix Labs	PA1113/004/002	Suppository	- N02BE - N02BE01	- Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Rectal use
Paracetamol 500mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/065/003	Tablet	- N02BE - N02BE01	- Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Paracetamol 500mg/5ml Oral Solution	Pinewood Laboratories Ltd	PA0281/243/001	Oral solution	- N02BE - N02BE01	- Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard	Chefaro Ireland DAC	PA1186/025/001	Capsule, hard	- N02BE51	- Paracetamol - Guaifenesin - Phenylephrine hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Paracetamol 80 mg suppositories	Phoenix Labs	PA1113/004/003	Suppository	- N02BE - N02BE01	- Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Rectal use
Paracetamol Banner 500 mg soft capsules	Banner Pharmacaps Europe B.V.	PA1121/003/001	Capsule, soft	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paracetamol Clonmel 500 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/361/001	Film-coated tablet	- N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paracetamol Genmed 500 mg tablets	Genmed B.V.	PA1519/001/001	Tablet	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paracetamol Krka 500 mg tablets	KRKA, d.d., Novo mesto	PA1347/095/001	Tablet	- N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paracetamol Tablets 500 mg from the makers of Disprin	Reckitt Benckiser Ireland Ltd	PA0979/022/001	Tablet	- N02BE - N02BE01	- Paracetamol		- Oral use
Paracetamol Teva 500 mg film-coated tablets	Teva B.V.	PA1986/101/001	Film-coated tablet	- N02BE01	- Paracetamol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Paracetamol Zentiva 500 mg tablets	Zentiva k.s.	PA1701/007/001	Tablet	- N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paracetamol/Codeine 500 mg/30 mg, effervescent tablets	Brillpharma (Ireland) Limited	PA22749/009/001	Effervescent tablet	- N02AJ - N02AJ06	- Paracetamol - Codeine phosphate hemihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paracetamol/Codeine phosphate hemihydrate Accord 500 mg/30 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/255/001	Tablet	- N02AJ06	- Paracetamol - Codeine phosphate hemihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord 500 mg/8 mg/30 mg effervescent tablets	Accord Healthcare Ireland Ltd.	PA2315/267/001	Effervescent tablet	- N02AJ06	- Paracetamol - Codeine phosphate hemihydrate - Caffeine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paracodin 0.20% w/w Syrup	Teofarma S.R.L.	PA1235/004/002	Syrup	- N02AA - N02AA08	- Dihydrocodeine tartrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Paracodin 10 mg Tablets	Teofarma S.R.L.	PA1235/004/003	Tablet	- N02AA - N02AA08	- Dihydrocodeine Hydrogen Tartrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Paracodin 10 mg/g Oral Drops, Solution	Teofarma S.R.L.	PA1235/004/001	Oral drops, solution	- N02AA - N02AA08	- Dihydrocodeine hydrorhodanide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Paraextra Hard CapsulesParacetamol 500mgCaffeine 32mg	Haleon Ireland Limited	PA0678/152/001	Capsule, hard	- N02BE - N02BE51	- Paracetamol - Caffeine		- Oral use
Paraeze Hard Capsules Paracetamol 500mg Caffeine 32mg	Haleon Ireland Limited	PA0678/151/001	Capsule, hard	- N02BE - N02BE51	- Caffeine - Paracetamol		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Paralief 500 mg Effervescent Tablets	Clonmel Healthcare Ltd	PA0126/020/004	Effervescent tablet	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paralief 500 mg soft capsules	Clonmel Healthcare Ltd	PA0126/020/007	Capsule, soft	- N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paralief 500mg Tablets	Clonmel Healthcare Ltd	PA0126/020/001	Tablet	- N02BE - N02BE01	- Paracetamol		- Oral use
Paralief Cold & Flu hard capsules Paracetamol 300 mg Caffeine 25 mg Phenylephrine hydrochloride 5 mg	Clonmel Healthcare Ltd	PA0126/272/001	Capsule, hard	- R05X	- Paracetamol - Caffeine - Phenylephrine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paralief Extra Film-coated Tablets Paracetamol 500 mg Caffeine 65 mg	Clonmel Healthcare Ltd	PA0126/337/001	Film-coated tablet	- N02BE - N02BE51	- Paracetamol - Caffeine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paralief Hot Lemon Drink 600 mg powder for oral solution in sachet	Clonmel Healthcare Ltd	PA0126/020/006	Powder for oral solution in sachet	- N02BE - N02BE01	- Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Paralief Max 1000 mg Effervescent Tablets	Clonmel Healthcare Ltd	PA0126/020/005	Effervescent tablet	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paralief Night Film-coated Tablets Paracetamol 500 mg Diphenhydramine hydrochloride 25 mg	Clonmel Healthcare Ltd	PA0126/338/001	Film-coated tablet	- N02BE - N02BE01 - R06AA - R06AA02	- Paracetamol - Diphenhydramine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paralief Sinus Tablets Paracetamol 500 mg Pseudoephedrine hydrochloride 30 mg	Clonmel Healthcare Ltd	PA0126/339/001	Tablet	- N02BE - N02BE01 - R01BA - R01BA02	- Paracetamol - PSEUDOEPHEDRINE HYDROCHLORIDE	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Paralink 180 mg suppositories	Phoenix Healthcare Ltd	PA1721/006/002	Suppository	- N02BE - N02BE01	- Paracetamol		- Rectal use
Paralink 500 mg suppositories	Phoenix Healthcare Ltd	PA1721/006/003	Suppository	- N02BE - N02BE01	- Paracetamol		- Rectal use
Paralink Paracetamol Oral Solution 120 mg/5 ml	Phoenix Healthcare Ltd	PA1721/006/001	Oral solution	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Paralink Six Plus Paracetamol 250 mg/5 ml oral solution	Phoenix Healthcare Ltd	PA1721/006/004	Oral solution	- N02BE - N02BE01	- Paracetamol		- Oral use
Paratabs 500 mg Tablets	Pinewood Laboratories Ltd	PA0281/074/001	Tablet	- N02BE - N02BE01	- Paracetamol		- Oral use
Parecoxib 40 mg powder and solvent for solution for injection	Noridem Enterprises Limited	PA1122/028/001	Powder and solvent for solution for injection	- M01AH04	- Parecoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Parecoxib 40 mg powder for solution for injection	Noridem Enterprises Limited	PA1122/028/002	Powder for solution for injection	- M01AH04	- Parecoxib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Paricalcitol 5 micrograms/ml solution for injection	Pinewood Laboratories Ltd	PA0281/163/001	Solution for injection	- H05BX02	- Paricalcitol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
PARIET 10 mg gastro-resistant tablet	Janssen Sciences Ireland UC	PA22612/009/001 Interchangeable List Code: IC0015-002-005	Gastro-resistant tablet		- Rabeprazole sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
PARIET 20 mg gastro-resistant tablet	Janssen Sciences Ireland UC	PA22612/009/002 Interchangeable List Code: IC0015-003-005	Gastro-resistant tablet		- Rabeprazole sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Parlodel 2.5 mg Tablets	Mylan IRE Healthcare Limited	PA2010/042/001	Tablet	- G02CB - G02CB01	- BROMOCRIPTINE MESILATE		- Oral use
Parnate 10 mg coated tablets	Amdipharm Limited	PA1142/035/001	Coated tablet	- N06AF - N06AF04	- Tranylcypromine		- Oral use
Parox 10mg Film-Coated Tablets	Rowex Ltd	PA0711/052/003 Interchangeable List Code: IC0076-002-003	Film-coated tablet		- Paroxetine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Parox 20mg Film-Coated Tablets	Rowex Ltd	PA0711/052/001 Interchangeable List Code: IC0076-003-003	Film-coated tablet		- Paroxetine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Parox 30 mg Film-Coated Tablets	Rowex Ltd	PA0711/052/004 Interchangeable List Code: IC0076-033-003	Film-coated tablet		- Paroxetine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Parsabiv	Amgen Europe B.V.	EU/1/16/1142/001-004	Solution for injection	- H05BX - H05BX04	- Etelcalcetide hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Parsabiv	Amgen Europe B.V.	EU/1/16/1142/005-008	Solution for injection	- H05BX - H05BX04	- Etelcalcetide hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Parsabiv	Amgen Europe B.V.	EU/1/16/1142/009-012	Solution for injection	- H05BX - H05BX04	- Etelcalcetide hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Parvolex 200mg/ml concentrate for Solution for Infusion	Phoenix Labs	PA1113/008/001	Concentrate for solution for infusion	- V03AB - V03AB23	- Acetylcysteine		- Intravenous use
Paxlovid	Pfizer Europe MA EEIG	EU/1/22/1625/001	Film-coated tablet	- J05AE30	- PF-07321332	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pazenir	Ratiopharm GmbH	EU/1/18/1317/001	Powder for dispersion for infusion	- L01CD - L01CD01	- Paclitaxel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pazopanib Accord 200 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/265/001	Film-coated tablet	- L01	- Pazopanib hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pazopanib Accord 400 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/265/002	Film-coated tablet	- L01	- Pazopanib hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Peace & Calm Oral Liquid	Irish Botanica	TR1723/002/001	Oral solution		- VALERIAN TINCTURE 1:2 60%	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
PecFent	Kyowa Kirin Holdings B.V.	EU/1/10/644/001-002	Nasal spray, solution	- N02AB - N02AB03	- Fentanyl, as citrate salt	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Nasal use
PecFent	Kyowa Kirin Holdings B.V.	EU/1/10/644/003-004	Nasal spray, solution	- N02AB - N02AB03	- Fentanyl, as citrate salt	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Nasal use
Pedamed 100 mg/g Cream	Phoenix Healthcare Ltd	PA1721/007/001	Cream	- D01AE04	- Zinc undecylenate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Cutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pedamed 100 mg/g Cutaneous Powder	Phoenix Healthcare Ltd	PA1721/007/002	Cutaneous powder	- D01AE - D01AE04	- Zinc undecylenate		- Cutaneous use
PEDEA	Recordati Rare Diseases	EU/1/04/284/001	Solution for injection	- M01AE - M01AE01	- Ibuprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	
Pedippi 2 mg/ml powder for oral suspension	Xeolas Pharmaceuticals Limited	PA1572/002/001	Powder for oral suspension	- A02BC - A02BC01	- Omeprazole	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Pedippi 4 mg/ml powder for oral suspension	Xeolas Pharmaceuticals Limited	PA1572/002/002	Powder for oral suspension	- A02BC - A02BC01	- Omeprazole	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Peditrace concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/051/001	Concentrate for solution for infusion	- B05XA - B05XA31	- Zinc chloride - Copper chloride 2H2O - Manganese chloride 4H2O - Sodium selenite anhydrous - Sodium fluoride - Potassium iodide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Pedmarqsi	Fennec Pharmaceuticals (EU) Limited	EU/1/23/1734/001	Solution for infusion		- Sodium thiosulfate	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Pegasys	Pharmaand GmbH	EU/1/02/221/003-004	Solution for injection	- L03AB - L03AB11	- Peginterferon-alfa-2a		- Subcutaneous use
Pegasys	Pharmaand GmbH	EU/1/02/221/005-006	Solution for injection in pre-filled syringe	- L03AB - L03AB11	- Peginterferon-alfa-2a		- Subcutaneous use
Pegfilgrastim Mundipharma	Mundipharma Corporation (Ireland) Limited	EU/1/19/1409/001	Solution for injection in pre-filled syringe	- L03AA13	- Pegfilgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Peglax 10 g powder for oral solution in sachet	Casen-Recordati S.L.	PA2028/003/001	Powder for oral solution	- A06AD - A06AD15	- Macrogol 4000	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Peiotal 25 microgram/125 microgram/dose pressurised inhalation, suspension	Genetic S.p.A.	PA23010/001/002	Pressurised inhalation, suspension	- R03AK06	- Salmeterol - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Peiotal 25 microgram/250 microgram/dose pressurised inhalation, suspension	Genetic S.p.A.	PA23010/001/003	Pressurised inhalation, suspension	- R03AK06	- Salmeterol - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Peiotal 25 microgram/50 microgram/dose pressurised inhalation, suspension	Genetic S.p.A.	PA23010/001/001	Pressurised inhalation, suspension	- R03AK06	- Salmeterol - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Pelgraz	Accord Healthcare S.L.U.	EU/1/18/1313/001	Solution for injection in pre-filled syringe	- L03AA13	- Pegfilgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Pelmeg	Mundipharma Corporation (Ireland) Limited	EU/1/18/1328/001	Solution for injection in pre-filled syringe	- L03AA13	- Pegfilgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Pemazyre	Incyte Biosciences Distribution B.V.	EU/1/21/1535/001-002	Tablet	- L01EX20	- Pemigatinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pemazyre	Incyte Biosciences Distribution B.V.	EU/1/21/1535/003-004	Tablet	- L01EX20	- Pemigatinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pemazyre	Incyte Biosciences Distribution B.V.	EU/1/21/1535/005-006	Tablet	- L01EX20	- Pemigatinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pemetrexed 25 mg/ml concentrate for solution for infusion	BioOrganics BV	PA1082/004/001	Concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Accord	Accord Healthcare S.L.U.	EU/1/15/1071/001	Powder for concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed disodium - Pemetrexed		- Intravenous use
Pemetrexed Accord	Accord Healthcare S.L.U.	EU/1/15/1071/002	Powder for concentrate for solution for infusion	- L01B	- Pemetrexed disodium - Pemetrexed		- Intravenous use
Pemetrexed Accord	Accord Healthcare S.L.U.	EU/1/15/1071/003	Powder for concentrate for solution for infusion	- L01B	- Pemetrexed - Pemetrexed disodium		- Intravenous use
Pemetrexed Accord	Accord Healthcare S.L.U.	EU/1/15/1071/004-007	Concentrate for solution for infusion	- L01BA04	- Pemetrexed - Pemetrexed Disodium Hemipentahydrate	Hybrid application (Article 13(3) of Directive No 2001/82/EC)	- Intravenous use
Pemetrexed Baxter	Baxter Holding B.V.	EU/1/22/1705/001	Powder for concentrate for solution for infusion	- L01BA04	- Pemetrexed disodium heptahydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Baxter	Baxter Holding B.V.	EU/1/22/1705/002	Powder for concentrate for solution for infusion	- L01BA04	- Pemetrexed disodium heptahydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Clonmel 25 mg/ml concentrate for solution for infusion	Clonmel Healthcare Ltd	PA0126/270/001	Concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion	EVER Valinject GmbH	PA1774/005/001	Concentrate for solution for infusion	- L01BA04	- Pemetrexed	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Fresenius Kabi	Fresenius Kabi Deutschland GmbH	EU/1/16/1115/001	Concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Fresenius Kabi	Fresenius Kabi Deutschland GmbH	EU/1/16/1115/002	Concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed	Generic application (Article 10(1) of Directive No 2001/83/EC)	
Pemetrexed Fresenius Kabi	Fresenius Kabi Deutschland GmbH	EU/1/16/1115/003-005	Concentrate for solution for infusion	- L01BA04	- Pemetrexed	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Hospira	Pfizer Europe MA EEIG	EU/1/15/1057/001	Powder for concentrate for solution for infusion	- L01B	- Pemetrexed disodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Hospira	Pfizer Europe MA EEIG	EU/1/15/1057/002	Powder for concentrate for solution for infusion	- L01B	- Pemetrexed disodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Hospira	Pfizer Europe MA EEIG	EU/1/15/1057/003	Powder for concentrate for solution for infusion	- L01B	- Pemetrexed disodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Hospira	Pfizer Europe MA EEIG	EU/1/15/1057/004-006	Concentrate for solution for infusion	- L01BA04	- Pemetrexed Disodium Hemipentahydrate - Pemetrexed	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Hospira Limited	Pfizer Europe MA EEIG	EU/1/17/1183/001	Powder for concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed ditromethamine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Hospira Limited	Pfizer Europe MA EEIG	EU/1/17/1183/002	Powder for concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed ditromethamine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pemetrexed Hospira Limited	Pfizer Europe MA EEIG	EU/1/17/1183/003	Powder for concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed ditromethamine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Krka	KRKA, d.d., Novo mesto	EU/1/18/1283/001	Powder for concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed disodium heptahydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Krka	KRKA, d.d., Novo mesto	EU/1/18/1283/002	Powder for concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed disodium heptahydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Lilly	Eli Lilly Nederland B.V.	EU/1/15/1034/001	Powder for concentrate for solution for infusion	- L01BA	- Pemetrexed disodium heptahydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
PEMETREXED LILLY	Eli Lilly Nederland B.V.	EU/1/15/1034/002	Powder for concentrate for solution for infusion	- L01BA	- PEMETREXED DISODIUM HEPTAHYDRATE	Article 10(1) - Generic Application	- Intra-venous
Pemetrexed Medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/15/1038/001	Powder for concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
PEMETREXED MEDAC	Medac Gesellschaft fur Klinische Spezialpraparate mbH	EU/1/15/1038/002	Powder for concentrate for solution for infusion	- L01BA04	- PEMETREXED	Article 10(1) - Generic Application	- Intra-venous
PEMETREXED MEDAC	Medac Gesellschaft fur Klinische Spezialpraparate mbH	EU/1/15/1038/003	Powder for concentrate for solution for infusion	- L01BA04	- PEMETREXED	Article 10(3) - Hybrid Application	- Intra-venous
Pemetrexed Mylan 25 mg/ml concentrate for solution for infusion	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/229/001	Concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Sandoz	Sandoz GmbH	EU/1/15/1037/001	Powder for concentrate for solution for infusion	- L01B	- Pemetrexed	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
PEMETREXED SANDOZ	Sandoz GmbH	EU/1/15/1037/002	Powder for concentrate for solution for infusion	- L01B	- PEMETREXED	Article 10(3) - Hybrid Application	- Intra-venous
PEMETREXED SANDOZ	Sandoz GmbH	EU/1/15/1037/003	Powder for concentrate for solution for infusion	- L01B	- PEMETREXED	Article 10(3) - Hybrid Application	- Intra-venous
Pemetrexed Seacross 100 mg powder for concentrate for solution for infusion	Seacross Pharma (Europe) Limited	PA22766/002/001	Powder for concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pemetrexed Seacross 500 mg powder for concentrate for solution for infusion	Seacross Pharma (Europe) Limited	PA22766/002/002	Powder for concentrate for solution for infusion	- L01BA - L01BA04	- Pemetrexed	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pendrex 2mg tablets	Rowex Ltd	PA0711/118/001 Interchangeable List Code: IC0002-006-002	Tablet		- Perindopril tert-butylamine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pendrex 4mg tablets	Rowex Ltd	PA0711/118/002 Interchangeable List Code: IC0002-008-002	Tablet		- Perindopril tert-butylamine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pendrex 8 mg tablets	Rowex Ltd	PA0711/118/004 Interchangeable List Code: IC0002-009-002	Tablet		- Perindopril tert-butylamine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pendrex Plus 4mg/1.25mg tablets	Rowex Ltd	PA0711/171/001	Tablet	- C09BA - C09BA04	- Indapamide - Perindopril tert-butylamine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pentasa 1 g prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/450/003	Prolonged-release tablet	- A07EC - A07EC02	- Mesalazine		- Oral use
Pentasa 1 g prolonged-release tablets	IMED Healthcare Ltd.	PPA1463/110/002	Prolonged-release tablet	- A07EC - A07EC02	- Mesalazine		- Oral use
Pentasa 1 g prolonged-release tablets	Ferring Ireland Ltd	PA1009/006/007	Prolonged-release tablet	- A07EC - A07EC02	- Mesalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pentasa 1 g suppositories	Originalis B.V.	PPA2306/010/001	Suppository	- A07EC02	- Mesalazine		- Rectal use
Pentasa 10 mg/ml Rectal Suspension	Ferring Ireland Ltd	PA1009/006/003	Rectal suspension	- A07EC - A07EC02	- Mesalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Rectal use
Pentasa 1g Suppositories	Ferring Ireland Ltd	PA1009/006/002	Suppository	- A07EC - A07EC02	- Mesalazine		- Rectal use
Pentasa 1g Suppositories	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/048/001	Suppository	- A07EC - A07EC02	- Mesalazine		- Rectal use
Pentasa 500 mg prolonged-release tablets	Ferring Ireland Ltd	PA1009/006/005	Prolonged-release tablet	- A07EC - A07EC02	- Mesalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pentasa 500 mg prolonged-release tablets	IMED Healthcare Ltd.	PPA1463/110/001	Prolonged-release tablet	- A07EC - A07EC02	- Mesalazine		- Oral use
Pentasa 500 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/450/002	Prolonged-release tablet	- A07EC02	- Mesalazine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Pentasa Sachet 1g prolonged-release granules	Ferring Ireland Ltd	PA1009/006/001	Prolonged-release granules	- A07EC - A07EC02	- Mesalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pentasa Sachet 2 g prolonged-release granules	PCO Manufacturing Ltd.	PPA0465/450/001	Prolonged-release granules	- A07EC02	- Mesalazine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Pentasa Sachet 2 g prolonged-release granules	IMED Healthcare Ltd.	PPA1463/190/001	Prolonged-release granules	- A07EC02	- Mesalazine		- Oral use
Pentasa Sachet 2g prolonged-release granules	Originalis B.V.	PPA2306/010/002	Prolonged-release granules	- A07EC02	- Mesalazine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Pentasa Sachet 2g prolonged-release granules	Ferring Ireland Ltd	PA1009/006/006	Prolonged-release granules	- A07EC - A07EC02	- Mesalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pentasa Sachet 2g prolonged-release granules	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/048/002	Prolonged-release granules	- A07EC - A07EC02	- Mesalazine	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Pentasa Sachet 4 g Prolonged-release granules	Ferring Ireland Ltd	PA1009/006/008	Prolonged-release granules	- A07EC - A07EC02	- Mesalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pentasa Sachet 4 g prolonged-release granules	IMED Healthcare Ltd.	PPA1463/190/002	Prolonged-release granules	- A07EC02	- Mesalazine	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pentasa Sachet 4 g prolonged-release granules	PCO Manufacturing Ltd.	PPA0465/450/004	Prolonged-release granules	- A07EC - A07EC02	- Mesalazine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Penthrox 99.9%, 3 ml inhalation vapour, liquid	Medical Developments MD&P Limited	PA22745/001/001	Inhalation vapour, liquid	- N02BG - N02BG09	- Methoxyflurane	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Pepaxti	Oncopeptides AB	EU/1/22/1669/001	Powder for concentrate for solution for infusion	- L01AA - L01AA10	- Melphalan Flufenamide Hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Pepcid AC 10 mg Film-coated Tablets	Johnson & Johnson (Ireland) Limited	PA0330/053/001	Film-coated tablet	- A02BA - A02BA03	- Famotidine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Pepcid Duo Chewable Tablets Famotidine 10mg Magnesium Hydroxide 165mg Calcium Carbonate 800mg	JNTL Consumer Health I (Ireland) Limited	PA23490/027/001	Chewable tablet	- A02BA - A02BA53	- Famotidine - Magnesium hydroxide - Calcium carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Perdamel 0.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/169/002 Interchangeable List Code: IC0012-040-003	Film-coated tablet		- Risperidone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Perdamel 1 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/169/003 Interchangeable List Code: IC0012-039-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perdamel 2 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/169/004 Interchangeable List Code: IC0012-006-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perdamel 3 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/169/005 Interchangeable List Code: IC0012-045-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perdamel 4 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/169/006 Interchangeable List Code: IC0012-008-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pergoveris	Merck Europe B.V.	EU/1/07/396/004	Solution for injection in pre-filled pen	- G03GA - G03GA30	- Lutropin alfa - Follitropin alfa		- Subcutaneous use
Pergoveris	Merck Europe B.V.	EU/1/07/396/005	Solution for injection in pre-filled pen	- G03GA - G03GA30	- Lutropin alfa - Follitropin alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Pergoveris	Merck Europe B.V.	EU/1/07/396/006	Solution for injection in pre-filled pen	- G03GA - G03GA30	- Lutropin alfa - Follitropin alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Pergoveris	Merck Europe B.V.	EU/1/07/396/1-3	Powder and solvent for solution for injection	- G03GA30	- Lutropin alfa - Follitropin alfa		- Subcutaneous use
Perindopril Arginine Clonmel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/366/002	Film-coated tablet	- C09AA04	- Perindopril arginine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril Arginine Clonmel 2.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/366/003	Film-coated tablet	- C09AA04	- Perindopril arginine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril Arginine Clonmel 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/366/001	Film-coated tablet	- C09AA04	- Perindopril arginine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Perindopril Arginine TAD 10 mg tablets	TAD Pharma GmbH	PA0876/010/002	Tablet	- C09AA04	- Perindopril arginine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril Arginine TAD 5 mg tablets	TAD Pharma GmbH	PA0876/010/001	Tablet	- C09AA04	- Perindopril arginine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril arginine/amlodipine TAD 10 mg/10 mg tablets	TAD Pharma GmbH	PA0876/012/004	Tablet	- C09BB04	- Perindopril arginine - Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril arginine/amlodipine TAD 10 mg/5 mg tablets	TAD Pharma GmbH	PA0876/012/003	Tablet	- C09BB04	- Perindopril arginine - Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril arginine/amlodipine TAD 5 mg/10 mg tablets	TAD Pharma GmbH	PA0876/012/002	Tablet	- C09BB04	- Perindopril arginine - Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril arginine/amlodipine TAD 5 mg/5 mg tablets	TAD Pharma GmbH	PA0876/012/001	Tablet	- C09BB04	- Perindopril arginine - Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril arginine/Indapamide TAD 10 mg/2.5 mg tablets	TAD Pharma GmbH	PA0876/011/002	Tablet	- C09BA04	- Perindopril arginine - Indapamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril arginine/Indapamide TAD 5 mg/1.25 mg tablets	TAD Pharma GmbH	PA0876/011/001	Tablet	- C09BA04	- Perindopril arginine - Indapamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril arginine/Indapamide/ Amlodipine Krka 10 mg/2.5 mg/10 mg tablets	KRKA, d.d., Novo mesto	PA1347/112/003	Tablet	- C09BX01	- Perindopril arginine - Indapamide - Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril arginine/Indapamide/ Amlodipine Krka 10 mg/2.5 mg/5 mg tablets	KRKA, d.d., Novo mesto	PA1347/112/002	Tablet	- C09BX01	- Perindopril arginine - Indapamide - Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril arginine/Indapamide/ Amlodipine Krka 5 mg/1.25 mg/5 mg tablets	KRKA, d.d., Novo mesto	PA1347/112/001	Tablet	- C09BX01	- Perindopril arginine - Indapamide - Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril Krka 2 mg tablets	KRKA, d.d., Novo mesto	PA1347/041/001 Interchangeable List Code: IC0002-006-002	Tablet		- Perindopril tert-butylamine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril Krka 4 mg tablets	KRKA, d.d., Novo mesto	PA1347/041/002 Interchangeable List Code: IC0002-008-002	Tablet		- Perindopril tert-butylamine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril Krka 8 mg tablets	KRKA, d.d., Novo mesto	PA1347/041/003 Interchangeable List Code: IC0002-009-002	Tablet		- Perindopril tert-butylamine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril Tosilate Teva 10mg Film-coated Tablets	Teva Pharma B.V.	PA0749/168/003 Interchangeable List Code: IC0002-002-015	Film-coated tablet		- Perindopril tosilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril Tosilate Teva 5mg Film-coated Tablets	Teva Pharma B.V.	PA0749/168/002 Interchangeable List Code: IC0002-001-015	Film-coated tablet		- Perindopril tosilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril tosilate/Amlodipine Teva 10mg/10mg tablets	Teva Pharma B.V.	PA0749/197/004	Tablet	- C09BB - C09BB04	- Perindopril tosilate - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Perindopril tosilate/Amlodipine Teva 10mg/5mg tablets	Teva Pharma B.V.	PA0749/197/003	Tablet	- C09BB - C09BB04	- Perindopril tosilate - Amlodipine besilate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Perindopril tosilate/Amlodipine Teva 5mg/10mg tablets	Teva Pharma B.V.	PA0749/197/002	Tablet	- C09BB - C09BB04	- Perindopril tosilate - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Perindopril tosilate/Amlodipine Teva 5mg/5mg tablets	Teva Pharma B.V.	PA0749/197/001	Tablet	- C09BB - C09BB04	- Perindopril tosilate - Amlodipine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Perindopril Tosilate/Amlodipine Teva B.V. 10 mg/10 mg Tablets	Teva B.V.	PA1986/098/004	Tablet	- C09BB04	- Perindopril tosilate - Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril Tosilate/Amlodipine Teva B.V. 10 mg/5 mg Tablets	Teva B.V.	PA1986/098/003	Tablet	- C09BB04	- Perindopril tosilate - Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril Tosilate/Amlodipine Teva B.V. 5 mg/10 mg Tablets	Teva B.V.	PA1986/098/002	Tablet	- C09BB04	- Perindopril tosilate - Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril Tosilate/Amlodipine Teva B.V. 5 mg/5 mg Tablets	Teva B.V.	PA1986/098/001	Tablet	- C09BB04	- Perindopril tosilate - Amlodipine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril tosilate/Indapamide 10 mg/2.5 mg film-coated tablets	Teva B.V.	PA1986/025/001	Film-coated tablet	- C09BA - C09BA04	- Perindopril tosilate - Indapamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril tosilate/Indapamide Teva 2.5 mg/0.625 mg Film-coated tablets	Teva Pharma B.V.	PA0749/170/001 Interchangeable List Code: IC0039-019-003	Film-coated tablet		- Perindopril tosilate - Indapamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril tosilate/Indapamide Teva 5 mg/1.25 mg film-coated tablets	Teva Pharma B.V.	PA0749/170/002 Interchangeable List Code: IC0039-020-003	Film-coated tablet		- Perindopril tosilate - Indapamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril/amlodipine Krka 4 mg/10 mg tablets	KRKA, d.d., Novo mesto	PA1347/084/002	Tablet	- C09BB - C09BB04	- Perindopril tert-butylamine - Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril/amlodipine Krka 4 mg/5 mg tablets	KRKA, d.d., Novo mesto	PA1347/084/001	Tablet	- C09BB - C09BB04	- Perindopril tert-butylamine - Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril/amlodipine Krka 8 mg/10 mg tablets	KRKA, d.d., Novo mesto	PA1347/084/004	Tablet	- C09BB - C09BB04	- Perindopril tert-butylamine - Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Perindopril/amlodipine Krka 8 mg/5 mg tablets	KRKA, d.d., Novo mesto	PA1347/084/003	Tablet	- C09BB - C09BB04	- Perindopril tert-butylamine - Amlodipine besilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Periochip 2.5 mg Dental Insert	Dexcel Pharma GmbH	PA2261/005/001	Periodontal insert	- A01AB - A01AB03	- Chlorhexidine gluconate	Full application (Article 8(3) of Directive No 2001/83/EC)	
Perjeta	Roche Registration GmbH	EU/1/13/813/001	Concentrate for solution for infusion	- L01XC - L01XC13	- Pertuzumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Perrigo Cold & Flu powder for oral solution Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine hydrochloride 10 mg	Chefaro Ireland DAC	PA1186/023/001	Powder for oral solution	- N02BE - N02BE51	- Paracetamol - Guaifenesin - Phenylephrine hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Perrigo Cold & Flu Tablets Paracetamol 250 mg Guaifenesin 100 mg Phenylephrine hydrochloride 5 mg	Chefaro Ireland DAC	PA1186/021/001	Film-coated tablet	- N02BE - N02BE51	- Paracetamol - Guaifenesin - Phenylephrine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pethidine Hydrochloride 50mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/014/001	Solution for injection	- N02AB - N02AB02	- Pethidine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
Peyona	Chiesi Farmaceutici S.p.A.	EU/1/09/528/001	Solution for infusion	- N06BC - N06BC01	- Caffeine citrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use - Oral use
Pheburane	Eurocept International BV	EU/1/13/822/001	Granules	- A16AX - A16AX03	- Sodium 4-phenylbutyrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Pheburane	Eurocept International BV	EU/1/13/822/006	Oral solution	- A16AX03	- Sodium phenylbutyrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
PHELINUN	Adienne S.r.l. S.U.	EU/1/20/1487/001	Powder and solvent for concentrate for solution for infusion	- L01AA03	- MELPHALAN HYDROCHOLORIDE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
PHELINUN	Adienne S.r.l. S.U.	EU/1/20/1487/002	Powder and solvent for concentrate for solution for infusion	- L01AA03	- MELPHALAN HYDROCHOLORIDE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Phenergan 25 mg film-coated tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/011/002	Film-coated tablet	- R06AD - R06AD02	- Promethazine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Phenergan 5 mg/5 ml oral solution	Opella Healthcare France SAS T/A Sanofi	PA23180/011/001	Oral solution	- R06AD - R06AD02	- Promethazine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Phenobarbital 15 mg Tablets	Clonmel Healthcare Ltd	PA0126/019/001	Tablet	- N03AA - N03AA02	- Phenobarbital		- Oral use
Phenobarbital 30 mg Tablets	Clonmel Healthcare Ltd	PA0126/019/002	Tablet	- N03AA - N03AA02	- Phenobarbital		- Oral use
Phenoxymethylpenicillin Sugar Free 125mg/5ml Powder for Oral solution	Brown & Burk IR Limited	PA23148/002/001	Powder for oral solution	- J01CE - J01CE02	- Phenoxymethylpenicillin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Phenoxymethylpenicillin Sugar Free 250mg/5ml Powder for Oral solution	Brown & Burk IR Limited	PA23148/002/002	Powder for oral solution	- J01CE - J01CE02	- Phenoxymethylpenicillin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Phenylephrine 100 micrograms/ml solution for injection/infusion	Laboratoire AGUETTANT	PA1968/007/002	Solution for injection/infusion	- C01CA06	- Phenylephrine hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Phenylephrine 50 micrograms/ml, solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/007/001	Solution for injection in pre-filled syringe	- C01CA - C01CA06	- Phenylephrine hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Phenylephrine Hydrochloride 10 mg/ml solution for injection/infusion	Athlone Pharmaceuticals Limited	PA1418/011/001	Solution for injection/infusion	- C01CA06	- Phenylephrine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
Phesgo	Roche Registration GmbH	EU/1/20/1497/001	Solution for injection	- L01 - L01XY02	- Pertuzumab - Trastuzumab	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Subcutaneous use
Phesgo	Roche Registration GmbH	EU/1/20/1497/002	Solution for injection	- L01 - L01XY02	- Pertuzumab - Trastuzumab	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Phizamol 500 mg effervescent tablets	Accord Healthcare Ireland Ltd.	PA2315/065/001	Effervescent tablet	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Phorpain	Amdipharm Limited	PA1142/026/001	Gel	- M02AA - M02AA13	- Ibuprofen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Transdermal use
Phospho-soda 24.4g/10.8g Oral solution	Casen-Recordati S.L.	PA2028/004/001	Oral solution	- A06AD	- Sodium phosphate dibasic dodecahydrate - Sodium phosphate dibasic dihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Phoxilium 1.2 mmol/l phosphate Solution for haemodialysis/haemofiltration	Baxter Holding B.V.	PA2299/053/001	Solution for haemodialysis/haemofiltration	- B05ZB	- Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium chloride ph.eur. - Sodium hydrogen carbonate - Potassium chloride - Disodium phosphate dihydrate		
Phyllocontin Continus 225 mg Prolonged Release Tablets	Ennogen Healthcare (Europe) Limited	PA23369/001/001	Prolonged-release tablet	- R03DA - R03DA05	- Aminophylline hydrate		- Oral use
Phymet DTF 1 mg/ml Syrup	GlaxoSmithKline (Ireland) Limited	PA1077/074/001	Syrup	- N07BC - N07BC02	- Methadone hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Physioneal 35 Glucose 1.36% w/v / 13.6 mg/ml Clear-Flex,Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/010	Solution for peritoneal dialysis	- B05DB	- Glucose monohydrate - Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium (s)-lactate solution - Sodium bicarbonate		- Intraperitoneal use
Physioneal 35 Glucose 1.36% w/v / 13.6 mg/mlSolution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/007	Solution for peritoneal dialysis	- B05DB	- Glucose monohydrate - Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium bicarbonate - Sodium (s)-lactate solution		- Intraperitoneal use
Physioneal 35 Glucose 2.27% w/v / 22.7 mg/ml Clear-Flex,Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/011	Solution for peritoneal dialysis	- B05DB	- Glucose monohydrate - Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium (s)-lactate solution - Sodium bicarbonate		- Intraperitoneal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Physioneal 35 Glucose 2.27% w/v / 22.7 mg/mlSolution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/008	Solution for peritoneal dialysis	- B05DB	- Glucose monohydrate - Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium bicarbonate - Sodium (s)-lactate solution		- Intraperitoneal use
Physioneal 35 Glucose 3.86% w/v / 38.6 mg/ml Clear-Flex,Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/012	Solution for peritoneal dialysis	- B05DB	- Glucose monohydrate - Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium (s)-lactate solution - Sodium bicarbonate		- Intraperitoneal use
Physioneal 35 Glucose 3.86% w/v / 38.6 mg/mlSolution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/009	Solution for peritoneal dialysis	- B05DB	- Glucose monohydrate - Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium bicarbonate - Sodium (s)-lactate solution		- Intraperitoneal use
Physioneal 40 Glucose 1.36% w/v / 13.6 mg/ml Clear-Flex,Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/002	Solution for peritoneal dialysis	- B05DB	- Glucose monohydrate - Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium (s)-lactate solution - Sodium bicarbonate		- Intraperitoneal use
Physioneal 40 Glucose 1.36% w/v / 13.6 mg/ml Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/001	Solution for peritoneal dialysis	- B05DB	- Glucose monohydrate - Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium bicarbonate - Sodium (s)-lactate solution		- Intraperitoneal use
Physioneal 40 Glucose 2.27% w/v / 22.7 mg/ml Clear-Flex,Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/003	Solution for peritoneal dialysis	- B05DB	- Glucose monohydrate - Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium (s)-lactate solution - Sodium bicarbonate		- Intraperitoneal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Physioneal 40 Glucose 2.27% w/v / 22.7 mg/mlSolution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/005	Solution for peritoneal dialysis	- B05DB	- Glucose monohydrate - Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium bicarbonate - Sodium (s)-lactate solution	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraperitoneal use
Physioneal 40 Glucose 3.86% w/v / 38.6 mg/ml Clear-Flex,Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/004	Solution for peritoneal dialysis	- B05DB	- Glucose monohydrate - Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium (s)-lactate solution - Sodium bicarbonate		- Intraperitoneal use
Physioneal 40 Glucose 3.86% w/v / 38.6 mg/mlSolution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/006	Solution for peritoneal dialysis	- B05DB	- Glucose monohydrate - Sodium chloride - Calcium chloride dihydrate - Magnesium chloride hexahydrate - Sodium bicarbonate - Sodium (s)-lactate solution	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraperitoneal use
Picolax 10mg / 3.5g / 12 g Powder for Oral Solution	Ferring Ireland Ltd	PA1009/003/001	Powder for oral solution	- A06AB - A06AB58	- Sodium picosulfate - Magnesium oxide, light - Citric acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pifeltro	Merck Sharp & Dohme BV,	EU/1/18/1332/001-002	Film-coated tablet	- J05AG06	- Doravirine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pinacort 3 mg modified release hard capsules	Pinewood Laboratories Ltd	PA0281/251/001	Modified-release capsule, hard	- A07EA06	- Budesonide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Pinadone 1 mg/ml Oral Solution	Pinewood Laboratories Ltd	PA0281/061/001	Oral solution	- N07BC - N07BC02	- Methadone hydrochloride		- Oral use
Pinamox 125 mg/5 ml Powder for Oral Suspension	Athlone Laboratories Ltd	PA0298/010/001	Powder for oral suspension	- J01CA - J01CA04	- Amoxicillin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pinamox 250 mg/5 ml Powder for Oral Suspension	Athlone Laboratories Ltd	PA0298/010/002	Powder for oral suspension	- J01CA - J01CA04	- Amoxicillin		- Oral use
Pinamox 250mg hard capsules	Athlone Laboratories Ltd	PA0298/010/003	Capsule, hard	- J01CA - J01CA04	- Amoxicillin trihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pinamox 500mg hard Capsules	Athlone Laboratories Ltd	PA0298/010/004	Capsule, hard	- J01CA - J01CA04	- Amoxicillin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pioglitazone Accord	Accord Healthcare S.L.U.	EU/1/11/722/001-010	Tablet	- A10BG - A10BG03	- Pioglitazone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pioglitazone Accord	Accord Healthcare S.L.U.	EU/1/11/722/011-020	Tablet	- A10BG - A10BG03	- Pioglitazone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pioglitazone Accord	Accord Healthcare S.L.U.	EU/1/11/722/021-030	Tablet	- A10BG - A10BG03	- Pioglitazone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pioglitazone Actavis	Actavis Group hf	EU/1/12/755/001-009	Tablet	- A10BG - A10BG03	- Pioglitazone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pioglitazone Actavis	Actavis Group hf	EU/1/12/755/010-018	Tablet	- A10BG - A10BG03	- Pioglitazone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pioglitazone Actavis	Actavis Group hf	EU/1/12/755/019-027	Tablet	- A10BG - A10BG03	- Pioglitazone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Piperacillin Tazobactam 2 g/0.25 g powder for solution for infusion	Viatris Limited	PA23266/021/001	Powder for solution for infusion	- J01CR - J01CR05	- Piperacillin sodium - Tazobactam (as sodium salt)	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Piperacillin Tazobactam 4 g/0.5 g powder for solution for infusion	Viatris Limited	PA23266/021/002	Powder for solution for infusion	- J01CR - J01CR05	- Piperacillin sodium - Tazobactam (as sodium salt)	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Piperacillin/Tazobactam 2 g/0.25 g powder for solution for infusion	AS Kalceks	PA2165/018/001	Powder for solution for infusion	- J01CR05	- Piperacillin - Tazobactam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Piperacillin/Tazobactam 2 g/0.25g powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/016/001	Powder for solution for infusion	- J01CR - J01CR05	- Piperacillin - Tazobactam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Piperacillin/Tazobactam 2g/0.25g powder for solution for infusion	Noridem Enterprises Limited	PA1122/012/001	Powder for solution for infusion	- J01CR - J01CR05	- Piperacillin - Tazobactam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/016/002	Powder for solution for infusion	- J01CR - J01CR05	- Piperacillin - Tazobactam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion	AS Kalceks	PA2165/018/002	Powder for solution for infusion	- J01CR05	- Piperacillin - Tazobactam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Piperacillin/Tazobactam 4g/0.5g powder for solution for infusion	Stravencon Ltd	PA1947/001/001	Powder for solution for infusion	- J01CR - J01CR05	- Piperacillin sodium - Tazobactam sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Piperacillin/Tazobactam 4g/0.5g powder for solution for infusion	Noridem Enterprises Limited	PA1122/012/002	Powder for solution for infusion	- J01CR - J01CR05	- Piperacillin - Tazobactam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Piperacillin/Tazobactam Aurobindo 2 g/0.25 g powder for solution for infusion	Eugia Pharma (Malta) Limited	PA23467/001/001	Powder for solution for infusion	- J01CR - J01CR05	- Piperacillin - Tazobactam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Piperacillin/Tazobactam Aurobindo 4 g/0.5 g powder for solution for infusion	Eugia Pharma (Malta) Limited	PA23467/001/002	Powder for solution for infusion	- J01CR - J01CR05	- Piperacillin - Tazobactam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Piperacillin/Tazobactam Clonmel 4 g/0.5 g powder for solution for infusion	Clonmel Healthcare Ltd	PA0126/363/001	Powder for solution for infusion	- J01CR05	- Piperacillin - Tazobactam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Pipercin 4 g/0.5 g powder for solution for infusion	Clonmel Healthcare Ltd	PA0126/180/002	Powder for solution for infusion	- J01CR - J01CR05	- Piperacillin - Tazobactam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Piperin 4 g/0.5 g Powder for Solution for Infusion	Rowex Ltd	PA0711/113/002	Powder for solution for infusion	- J01CR - J01CR05	- Piperacillin - Tazobactam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Piqray	Novartis Europharm Limited	EU/1/20/1455/001-003	Film-coated tablet	- L01XX65	- Alpelisib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Piqray	Novartis Europharm Limited	EU/1/20/1455/004-006	Film-coated tablet	- L01XX65	- Alpelisib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Piqray	Novartis Europharm Limited	EU/1/20/1455/007-009	Film-coated tablet	- L01XX65	- Alpelisib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pirfenidone Accord 267 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/270/001 Interchangeable List Code: IC0127-173-009	Film-coated tablet		- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pirfenidone Accord 801 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/270/002 Interchangeable List Code: IC0127-175-003	Film-coated tablet		- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pirfenidone APS 267 mg Film-coated tablets	Axunio Pharma GmbH	PA23438/002/001 Interchangeable List Code: IC0127-173-009	Film-coated tablet		- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pirfenidone APS 534 mg Film-coated tablets	Axunio Pharma GmbH	PA23438/002/002 Interchangeable List Code: IC0127-174-003	Film-coated tablet		- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pirfenidone APS 801 mg film-coated tablets	Axunio Pharma GmbH	PA23438/002/003 Interchangeable List Code: IC0127-175-003	Film-coated tablet		- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pirfenidone axunio 267 mg film-coated tablets	Axunio Pharma GmbH	EU/1/22/1655/001-004 Interchangeable List Code: IC0127-173-009	Film-coated tablet		- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pirfenidone axunio 534 mg film-coated tablets	Axunio Pharma GmbH	EU/1/22/1655/005-006 Interchangeable List Code: IC0127-174-003	Film-coated tablet		- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pirfenidone Axunio 801 film-coated tablets	Axunio Pharma GmbH	EU/1/22/1655/007-010 Interchangeable List Code: IC0127-175-003	Film-coated tablet		- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pirfenidone Cipla 267 mg Film-coated Tablets	Cipla Europe NV	PA1963/016/001	Film-coated tablet	- L04AX05	- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pirfenidone Cipla 801 mg Film-coated Tablets	Cipla Europe NV	PA1963/016/002	Film-coated tablet	- L04AX05	- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pirfenidone Clonmel 267 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/350/001 Interchangeable List Code: IC0127-173-009	Film-coated tablet		- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pirfenidone Clonmel 801 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/350/002 Interchangeable List Code: IC0127-175-003	Film-coated tablet		- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pirfenidone Teva 267 mg Film-coated Tablets	Norton Waterford	PA0436/048/001 Interchangeable List Code: IC0127-173-009	Film-coated tablet		- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pirfenidone Teva 801 mg Film-coated Tablets	Norton Waterford	PA0436/048/002 Interchangeable List Code: IC0127-175-003	Film-coated tablet		- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pirfenidone Viatris 267 mg film-coated tablets	Viatris Limited	EU/1/22/1707/001-007 Interchangeable List Code: IC0127-173-009	Film-coated tablet		- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pirfenidone Viatris 534 mg film-coated tablets	Viatris Limited	EU/1/22/1707/008-010 Interchangeable List Code: IC0127-174-003	Film-coated tablet		- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pirfenidone Viatris 801 mg film-coated tablets	Viatris Limited	EU/1/22/1707/011-015 Interchangeable List Code: IC0127-175-003	Film-coated tablet		- Pirfenidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Piriton Allergy 4mg Tablets	Haleon Ireland Limited	PA0678/080/001	Tablet	- R06AB - R06AB04	- Chlorpheniramine maleate		- Oral use
Pivmecillinam hydrochloride Karo Pharma 400 mg film-coated tablets	Karo Pharma AB	PA22650/003/001	Film-coated tablet	- J01CA - J01CA08	- Pivmecillinam hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pixuvri	Les Laboratoires Servier	EU/1/12/764/001	Powder for concentrate for solution for infusion	- L01DB - L01DB11	- Pixantrone		- Intravenous use
Plaquenil 200mg Film-coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/155/001	Film-coated tablet	- P01BA - P01BA02	- Hydroxychloroquine sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Plasma-Lyte 148 & Glucose 5% w/v solution for infusion	Baxter Holding B.V.	PA2299/007/001	Solution for infusion	- B05BB - B05BB02	- Glucose monohydrate - Sodium chloride - Potassium chloride - Magnesium chloride hexahydrate - Sodium acetate trihydrate - Sodium gluconate		- Intravenous use
Plasma-Lyte® 148 (pH 7.4) solution for infusion	Baxter Holding B.V.	PA2299/032/001	Solution for infusion	- B05BB - B05BB01	- Sodium chloride - Potassium chloride - Magnesium chloride hexahydrate - Sodium acetate trihydrate - Sodium gluconate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Plavix	Sanofi Winthrop Industrie	EU/1/98/069/001-007 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- Clopidogrel hydrogensulfate		- Oral use
Plavix	Sanofi Winthrop Industrie	EU/1/98/069/008-010 Interchangeable List Code: IC0005-029-003	Film-coated tablet		- Clopidogrel hydrogensulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Plegridy	Biogen Netherlands B.V.	EU/1/14/934/001	Solution for injection in pre-filled syringe	- L03AB13	- Peginterferon beta-1a	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Plegridy	Biogen Netherlands B.V.	EU/1/14/934/002	Solution for injection in pre-filled pen	- L03AB13	- Peginterferon beta-1a	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Plegridy	Biogen Netherlands B.V.	EU/1/14/934/003-004	Solution for injection in pre-filled syringe		- Peginterferon beta-1a	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Plegridy	Biogen Netherlands B.V.	EU/1/14/934/003-006	Solution for injection	- L03AB13	- Peginterferon beta-1a	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Plegridy	Biogen Netherlands B.V.	EU/1/14/934/003-008	Solution for injection in pre-filled pen	- L03AB13	- Peginterferon beta-1a	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Plegridy	Biogen Netherlands B.V.	EU/1/14/934/005-006	Solution for injection in pre-filled pen	- L03AB13	- Peginterferon beta-1a	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Plenadren	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/11/715/001	Modified-release tablet	- H02AB - H02AB09	- Hydrocortisone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Plenadren, Hydrocortisone	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/11/715/002	Modified-release tablet	- H02AB - H02AB09	- Hydrocortisone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Plendil 10 mg prolonged-release tablets	Glenwood GmbH	PA2256/005/003	Prolonged-release tablet	- C08CA - C08CA02	- Felodipine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Plendil 10 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/405/002	Prolonged-release tablet	- C08CA - C08CA02	- Felodipine		- Oral use
Plendil 2.5 mg prolonged-release tablets	Glenwood GmbH	PA2256/005/001	Prolonged-release tablet	- C08CA - C08CA02	- Felodipine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Plendil 5 mg prolonged-release tablets	Glenwood GmbH	PA2256/005/002	Prolonged-release tablet	- C08CA - C08CA02	- Felodipine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Plendil 5 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/405/001	Prolonged-release tablet	- C08CA - C08CA02	- Felodipine		- Oral use
Plendil 5 mg prolonged-release tablets	IMED Healthcare Ltd.	PPA1463/183/001	Prolonged-release tablet	- C08CA - C08CA02	- Felodipine		- Oral use
Plenvu powder for oral solution	Norgine B.V.	PA1336/005/001	Powder for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium sulfate anhydrous - Sodium chloride - Potassium chloride - Macrogol 3350 - Sodium chloride - Potassium chloride - Sodium ascorbate - Ascorbic acid	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Plerixafor 20 mg/ml solution for injection	MSN Labs Europe Limited	PA23250/001/001	Solution for injection	- L03AX16	- Plerixafor	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Plerixafor Accord	Accord Healthcare S.L.U.	EU/1/22/1701/001	Solution for injection	- L03AX16	- Plerixafor	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Plerixafor Seacross 20 mg/ml solution for injection	Seacross Pharma (Europe) Limited	PA22766/007/001	Solution for injection	- L03AX16	- Plerixafor	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Subcutaneous use
Pliaglis 70mg/g + 70mg/g cream	Croma-Pharma GmbH	PA0846/003/001	Cream	- N01BB - N01BB52	- Lidocaine - Tetracaine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Cutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pluvicto	Advanced Accelerator Applications	EU/1/22/1703/001	Solution for injection/infusion	- V10XX - V10XX05	- Lutetium (177Lu) vipivotide tetraxetan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
PNEUMOVAX 23 solution for injection in a vial Pneumococcal Polysaccharide Vaccine	Merck Sharp & Dohme Ireland (Human Health) Limited	PA1286/055/001	Solution for injection	- J07AL - J07AL01	- Pneumococcal vaccine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
PNEUMOVAX 23 solution for injection in pre-filled syringe Pneumococcal Polysaccharide Vaccine	Merck Sharp & Dohme Ireland (Human Health) Limited	PA1286/055/002	Solution for injection in pre-filled syringe	- J07AL - J07AL01	- Pneumococcal vaccine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Polivy	Roche Registration GmbH	EU/1/19/1388/001	Powder for concentrate for solution for infusion	- L01FX14	- Polatuzumab Vedotin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Pollenna 6C tablets	A. Nelson & Company Limited	HOA1149/006/001	Tablet		- Allium cepa (ghp) - Euphrasia officinalis (ghp) - Schoenocaulon officinale (ghp)	National Rules Authorisation (Article 16.2 Directive 2001/83/EC.)	
Pollinosan Hayfever tablets	A.Vogel Ireland Limited	HOA2309/001/001	Tablet		- Ammi visnagai d1 dilution - Aralia racemose d2 trituration - Cardiospermum halicacabum d2 trituration - Thryallis glauca d3 trituration - Larrea mexicana d2 trituration - Luffa operculata d6 trituration - Okoubaka aubrevillei d2 trituration	National Rules Authorisation (Article 16.2 Directive 2001/83/EC.)	- Oral use
Pomalidomide Viatris	Viatris Limited	EU/1/23/1785/001-004	Capsule, hard	- L04AX06	- Pomalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pomalidomide Viatris	Viatris Limited	EU/1/23/1785/005-008	Capsule, hard	- L04AX06	- Pomalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pomalidomide Viatris	Viatris Limited	EU/1/23/1785/009-012	Capsule, hard	- L04AX06	- Pomalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pomalidomide Viatris	Viatris Limited	EU/1/23/1785/013-016	Capsule, hard	- L04AX06	- Pomalidomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pombiliti	Amicus Therapeutics Europe Limited	EU/1/22/1714/001-003	Powder for concentrate for solution for injection/infusion	- A16AB - A16AB23	- Cipaglucosidase alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ponstan 250 mg Capsules	Chemidex Pharma Limited	PA22643/001/001	Capsule, hard	- M01AG - M01AG01	- Mefenamic acid		- Oral use
Ponstan Forte 500 mg Film-coated Tablets	Chemidex Pharma Limited	PA22643/001/002	Film-coated tablet	- M01AG - M01AG01	- Mefenamic acid		- Oral use
Ponvory	Janssen-Cilag International NV	EU/1/21/1550/001	Film-coated tablet	- L04AA - L04AA50	- Ponesimod	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ponvory	Janssen-Cilag International NV	EU/1/21/1550/002	Film-coated tablet	- L04AA - L04AA50	- Ponesimod	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Posaconazole Accord 100 mg gastro-resistant tablets	Accord Healthcare S.L.U.	EU/1/19/1379/001-004 Interchangeable List Code: IC0126-024-005	Gastro-resistant tablet		- Posaconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Posaconazole AHCL 40 mg/ml oral suspension	Accord Healthcare S.L.U.	EU/1/19/1380/001 Interchangeable List Code: IC0126-132-027	Oral suspension		- Posaconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Posaconazole Clonmel 100 mg gastro-resistant tablets	Clonmel Healthcare Ltd	PA0126/307/001 Interchangeable List Code: IC0126-024-005	Gastro-resistant tablet		- Posaconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Posaconazole Mylan 100 mg gastro-resistant tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/188/001 Interchangeable List Code: IC0126-024-005	Gastro-resistant tablet		- Posaconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Posaconazole Teva 100 mg gastro-resistant tablets	Teva B.V.	PA1986/091/001 Interchangeable List Code: IC0126-024-005	Gastro-resistant tablet		- Posaconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
POTACTASOL	Actavis Group PTC ehf	EU/1/10/660/001	Powder for concentrate for solution for infusion	- L01XX17	- TOPOTECAN HYDROCHLORIDE	Article 10(1) - Generic Application	- Intra-venous
POTACTASOL	Actavis Group PTC ehf	EU/1/10/660/002	Powder for concentrate for solution for infusion	- L01XX17	- TOPOTECAN HYDROCHLORIDE	Article 10(1) - Generic Application	- Intra-venous
Potassium Chloride 0.15 % w/v and Glucose 5% w/v Solution for Infusion BP	Baxter Holding B.V.	PA2299/009/002	Solution for infusion	- B05XA - B05XA01	- Potassium chloride - Glucose	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Potassium Chloride 0.15% w/v & Glucose 5% w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/053/001	Solution for infusion	- B05BB - B05BB02	- Potassium chloride - Glucose	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/052/001	Solution for infusion	- B05BB - B05BB01	- Potassium chloride - Sodium chloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for Infusion - BP	Baxter Holding B.V.	PA2299/010/002	Solution for infusion	- B05BB - B05BB01	- Potassium chloride - Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Potassium Chloride 0.15% w/v, Sodium Chloride 0.18% w/v, Glucose 4% w/v Solution for Infusion	Baxter Holding B.V.	PA2299/001/002	Solution for infusion	- B05BB - B05BB02	- Potassium chloride - Sodium chloride - Glucose anhydrous	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Potassium Chloride 0.3 % w/v and Glucose 5% w/v Solution for Infusion BP	Baxter Holding B.V.	PA2299/009/001	Solution for infusion	- B05BB02	- Potassium chloride - Glucose (as monohydrate)	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Potassium Chloride 0.3% w/v & Glucose 5% w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/053/002	Solution for infusion	- B05BB - B05BB02	- Potassium chloride - Glucose	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/052/002	Solution for infusion	- B05BB - B05BB01	- Potassium chloride - Sodium chloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v Solution for Infusion BP	Baxter Holding B.V.	PA2299/010/001	Solution for infusion	- B05XA01	- Potassium chloride - Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Potassium Chloride 0.3% w/v and Sodium Chloride 0.18% w/v in Glucose 4% w/v Intravenous Infusion BP (Viaflo Container)	Baxter Holding B.V.	PA2299/001/001	Solution for infusion	- B05BB - B05BB02	- Potassium chloride - Sodium chloride - Glucose monohydrate		- Intravenous use
Potassium Chloride 15% w/v Concentrate for Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/054/001	Concentrate for solution for infusion	- B05XA - B05XA01	- Potassium chloride		- Intramuscular use - Intravenous use - Subcutaneous use
Potassium Chloride 15% w/v concentrate for solution for infusion	Noridem Enterprises Limited	PA1122/003/001	Concentrate for solution for infusion	- B05XA - B05XA01	- Potassium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Potassium Chloride 15% w/v Concentrate for Solution for Infusion	B. Braun Medical Limited	PA0179/030/002	Concentrate for solution for infusion	- B05XA - B05XA01	- Potassium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Potassium Chloride 15% w/v Concentrate for Solution for Infusion	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/106/001	Concentrate for solution for infusion	- A12BA - A12BA01	- Potassium chloride		- Intravenous use
Potassium iodide G.L. Pharma 65 mg tablets	G.L. Pharma GmbH	PA1770/001/001	Tablet	- V03AB - V03AB21	- Potassium iodide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Potassium Phosphate 1mmol/ml + 0.6mmol/ml Concentrate for Solution for Infusion	B. Braun Medical Limited	PA0179/005/001	Concentrate for solution for infusion	- B05XA - B05XA06	- Dipotassium phosphate - Potassium dihydrogen phosphate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
POTELIGEO	Kyowa Kirin Holdings B.V.	EU/1/18/1335/001	Concentrate for solution for infusion	- L01XC25	- MOGAMULIZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/0026	Coated granules	- B01AE07	- Dabigatran etexilate mesilate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/0027	Coated granules	- B01AE07	- Dabigatran etexilate mesilate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/0029	Coated granules	- B01AE07	- Dabigatran etexilate mesilate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/009-013	Capsule, hard	- B01AE - B01AE07	- Dabigatran etexilate mesilate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/025	Coated granules	- B01AE07	- Dabigatran etexilate mesilate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/028	Coated granules	- B01AE07	- Dabigatran etexilate mesilate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/030	Coated granules	- B01AE07	- Dabigatran etexilate mesilate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/1-4	Capsule, hard	- B01AE - B01AE07	- Dabigatran etexilate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/5-8	Capsule, hard	- B01AE - B01AE07	- Dabigatran etexilate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Praluent	Sanofi-Aventis Groupe	EU/1/15/1031/001-003	Solution for injection in pre-filled pen	- C10AX - C10AX14	- Alirocumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Praluent	Sanofi-Aventis Groupe	EU/1/15/1031/004-006	Solution for injection in pre-filled syringe	- C10AX - C10AX14	- Alirocumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Praluent	Sanofi-Aventis Groupe	EU/1/15/1031/007-009	Solution for injection in pre-filled pen	- C10AX - C10AX14	- Alirocumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Praluent	Sanofi-Aventis Groupe	EU/1/15/1031/010-012	Solution for injection in pre-filled syringe	- C10AX - C10AX14	- Alirocumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Praluent	Sanofi-Aventis Groupe	EU/1/15/1031/019-020	Solution for injection	- C10AX14	- Alirocumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Pramipexole Teva	Teva Pharma B.V.	EU/1/08/490/13-16	Tablet	- N04BC	- Pramipexole dihydrochloride monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pramipexole Teva	Teva Pharma B.V.	EU/1/08/490/1-4	Tablet	- N04BC	- Pramipexole dihydrochloride monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
PRAMIPEXOLE TEVA	Teva B.V.	EU/1/08/490/5-8	Tablet	- N04BC05	- PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
PRAMIPEXOLE TEVA	Teva B.V.	EU/1/08/490/9-12	Tablet	- N04BC05	- PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
PRANDIN	Novo Nordisk A/S	EU/1/00/162/001	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/002	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/003	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/004	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/005	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/006	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/007	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/008	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/009	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/010	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/011	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/012	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/013	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/014	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/015	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/016	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prandin	Novo Nordisk A/S	EU/1/00/162/017	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Prandin	Novo Nordisk A/S	EU/1/00/162/018	Tablet	- A10BX - A10BX02	- Repaglinide		- Oral use
Prasugrel Accord 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/157/002	Film-coated tablet	- B01AC - B01AC22	- Prasugrel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Prasugrel Accord 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/157/001	Film-coated tablet	- B01AC - B01AC22	- Prasugrel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Prasugrel Krka 10 mg Film-coated tablets	KRKA, d.d., Novo mesto	PA1347/080/002	Film-coated tablet	- B01AC - B01AC22	- Prasugrel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Prasugrel Krka 5 mg Film-coated tablets	KRKA, d.d., Novo mesto	PA1347/080/001	Film-coated tablet	- B01AC - B01AC22	- Prasugrel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Prasugrel Mylan	Mylan Pharmaceuticals Limited	EU/1/18/1273/001	Film-coated tablet	- B01AC - B01AC22	- Prasugrel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Prasugrel Mylan	Mylan Pharmaceuticals Limited	EU/1/18/1273/002	Film-coated tablet	- B01AC - B01AC22	- Prasugrel	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pravafenix	Laboratoires SMB S.A.	EU/1/11/679/001-006	Capsule, hard	- C10BA - C10BA03	- Fenofibrate - Pravastatin sodium	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Pravamel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/140/001 Interchangeable List Code: IC0014-002-014	Film-coated tablet		- Pravastatin sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pravamel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/140/002 Interchangeable List Code: IC0014-003-014	Film-coated tablet		- Pravastatin sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pravamel 40 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/140/003 Interchangeable List Code: IC0014-004-014	Film-coated tablet		- Pravastatin sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pravastatin Mylan 10 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/136/001 Interchangeable List Code: IC0014-002-014	Tablet		- Pravastatin sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pravastatin Mylan 20 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/136/002 Interchangeable List Code: IC0014-003-014	Tablet		- Pravastatin sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pravastatin Mylan 40 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/136/003 Interchangeable List Code: IC0014-004-014	Tablet		- Pravastatin sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pravastatin Sodium 10 mg Tablets	Norton Waterford	PA0436/046/001 Interchangeable List Code: IC0014-002-014	Tablet		- Pravastatin sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pravastatin Sodium 20 mg Tablets	Norton Waterford	PA0436/046/002 Interchangeable List Code: IC0014-003-014	Tablet		- Pravastatin sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pravastatin Sodium 40 mg Tablets	Norton Waterford	PA0436/046/003 Interchangeable List Code: IC0014-004-014	Tablet		- Pravastatin sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pravitin 10 mg Tablets	Rowex Ltd	PA0711/058/001 Interchangeable List Code: IC0014-002-014	Tablet		- Pravastatin sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pravitin 20 mg Tablets	Rowex Ltd	PA0711/058/002 Interchangeable List Code: IC0014-003-014	Tablet		- Pravastatin sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pravitin 40 mg Tablets	Rowex Ltd	PA0711/058/004 Interchangeable List Code: IC0014-004-014	Tablet		- Pravastatin sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Praxbind	Boehringer Ingelheim International GmbH	EU/1/15/1056/001	Solution for injection/infusion	- V03AB	- Idarucizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Praxilene 100 mg Capsules	Merck Serono (Ireland) Limited	PA2286/003/001	Capsule, hard	- C04AX - C04AX21	- NAFTIDROFURYL OXALATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pred Forte 1% w/v, Eye Drops Suspension	AbbVie Limited	PA1824/010/001	Eye drops, suspension	- S01BA - S01BA04	- Prednisolone acetate		- Ocular use
Pred Mild Sterile Ophthalmic Suspension, 0.12% w/v, Eye Drops, Suspension	AbbVie Limited	PA1824/009/001	Eye drops, suspension	- S01BA - S01BA04	- Prednisolone acetate		- Ocular use
Prednesol 5mg Tablets	Phoenix Labs	PA1113/001/001	Tablet	- H02AB - H02AB06	- Prednisolone		- Oral use
Prednisolone 1 mg Tablets	Clonmel Healthcare Ltd	PA0126/027/002	Tablet	- H02AB - H02AB06	- Prednisolone		- Oral use
Prednisolone 20 mg Rectal Foam	Chemidex Pharma Limited	PA22643/003/001	Rectal foam	- D07AA - D07AA03	- Prednisolone		- Rectal use
Prednisolone 5 mg soluble tablets	Amdipharm Limited	PA1142/034/001	Soluble tablet	- H02AB - H02AB06	- Prednisolone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Prednisolone 5 mg Tablets	Clonmel Healthcare Ltd	PA0126/027/001	Tablet	- H02AB - H02AB06	- Prednisolone		- Oral use
Pregabalin 100 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/004 Interchangeable List Code: IC0110-024-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin 150 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/005 Interchangeable List Code: IC0110-062-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin 20 mg/ml oral solution	Chanelle Medical Unlimited Company	PA0688/064/001 Interchangeable List Code: IC0110-128-019	Oral solution		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin 200 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/006 Interchangeable List Code: IC0110-067-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin 225 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/007 Interchangeable List Code: IC0110-064-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin 25 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/001 Interchangeable List Code: IC0110-022-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pregabalin 300 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/008 Interchangeable List Code: IC0110-029-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin 50 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/002 Interchangeable List Code: IC0110-023-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin 75 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/003 Interchangeable List Code: IC0110-028-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Accord 100 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/034-044 Interchangeable List Code: IC0110-024-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Accord 150 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/045-055 Interchangeable List Code: IC0110-062-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Accord 200 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/056-066 Interchangeable List Code: IC0110-067-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Accord 225 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/067-077 Interchangeable List Code: IC0110-064-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Accord 25 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/001-011 Interchangeable List Code: IC0110-022-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Accord 300 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/078-088 Interchangeable List Code: IC0110-029-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Accord 50 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/012-022 Interchangeable List Code: IC0110-023-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Accord 75 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/023-033 Interchangeable List Code: IC0110-028-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
PREGABALIN BASICS 20 mg/ml oral solution	Basics GmbH	PA23067/001/001 Interchangeable List Code: IC0110-128-019	Oral solution		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Clonmel 100 mg capsules, hard	Clonmel Healthcare Ltd	PA0126/290/004 Interchangeable List Code: IC0110-024-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pregabalin Clonmel 150 mg capsules, hard	Clonmel Healthcare Ltd	PA0126/290/005 Interchangeable List Code: IC0110-062-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Clonmel 200 mg capsules, hard	Clonmel Healthcare Ltd	PA0126/290/006 Interchangeable List Code: IC0110-067-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Clonmel 25 mg capsules, hard	Clonmel Healthcare Ltd	PA0126/290/001 Interchangeable List Code: IC0110-022-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Clonmel 300 mg capsules, hard	Clonmel Healthcare Ltd	PA0126/290/008 Interchangeable List Code: IC0110-029-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Clonmel 50 mg capsules, hard	Clonmel Healthcare Ltd	PA0126/290/002 Interchangeable List Code: IC0110-023-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Clonmel 75 mg capsules, hard	Clonmel Healthcare Ltd	PA0126/290/003 Interchangeable List Code: IC0110-028-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Krka 100 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/004 Interchangeable List Code: IC0110-024-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Krka 150 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/005 Interchangeable List Code: IC0110-062-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Krka 200 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/006 Interchangeable List Code: IC0110-067-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Krka 225 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/007 Interchangeable List Code: IC0110-064-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Krka 25mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/001 Interchangeable List Code: IC0110-022-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Krka 300 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/008 Interchangeable List Code: IC0110-029-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Krka 50 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/002 Interchangeable List Code: IC0110-023-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Krka 75 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/003 Interchangeable List Code: IC0110-028-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Mylan 100 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/023-027 Interchangeable List Code: IC0110-024-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pregabalin Mylan 150 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/028-034 Interchangeable List Code: IC0110-062-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Mylan 200 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/035-039 Interchangeable List Code: IC0110-067-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Mylan 225 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/040-044 Interchangeable List Code: IC0110-064-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Mylan 25 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/001-008 Interchangeable List Code: IC0110-022-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Mylan 300 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/045-050 Interchangeable List Code: IC0110-029-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Mylan 50 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/009-015 Interchangeable List Code: IC0110-023-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Mylan 75 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/016-022 Interchangeable List Code: IC0110-028-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Pfizer 100 mg hard capsules	Upjohn EESV	EU/1/14/916/020-023 Interchangeable List Code: IC0110-024-001	Capsule, hard		- Pregabalin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Pregabalin Pfizer 150 mg hard capsules	Upjohn EESV	EU/1/14/916/024-029 Interchangeable List Code: IC0110-062-001	Capsule, hard		- Pregabalin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Pregabalin Pfizer 200 mg hard capsules	Upjohn EESV	EU/1/14/916/030-033 Interchangeable List Code: IC0110-067-001	Capsule, hard		- Pregabalin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Pregabalin Pfizer 225 mg hard capsules	Upjohn EESV	EU/1/14/916/034-037 Interchangeable List Code: IC0110-064-001	Capsule, hard		- Pregabalin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Pregabalin Pfizer 25 mg hard capsules	Upjohn EESV	EU/1/14/916/001-007 Interchangeable List Code: IC0110-022-001	Capsule, hard		- Pregabalin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pregabalin Pfizer 300 mg hard capsules	Upjohn EESV	EU/1/14/916/038-043 Interchangeable List Code: IC0110-029-001	Capsule, hard		- Pregabalin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Pregabalin Pfizer 50 mg hard capsules	Upjohn EESV	EU/1/14/916/008-013 Interchangeable List Code: IC0110-023-001	Capsule, hard		- Pregabalin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Pregabalin Pfizer 75 mg hard capsules	Upjohn EESV	EU/1/14/916/014-019 Interchangeable List Code: IC0110-028-001	Capsule, hard		- Pregabalin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Pregabalin Pinewood 100 mg hard capsules	Pinewood Laboratories Ltd	PA0281/217/004 Interchangeable List Code: IC0110-024-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Pinewood 150 mg hard capsules	Pinewood Laboratories Ltd	PA0281/217/005 Interchangeable List Code: IC0110-062-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Pinewood 200 mg hard capsules	Pinewood Laboratories Ltd	PA0281/217/006 Interchangeable List Code: IC0110-067-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Pinewood 25 mg hard capsules	Pinewood Laboratories Ltd	PA0281/217/001 Interchangeable List Code: IC0110-022-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Pinewood 300 mg hard capsules	Pinewood Laboratories Ltd	PA0281/217/007 Interchangeable List Code: IC0110-029-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Pinewood 50 mg hard capsules	Pinewood Laboratories Ltd	PA0281/217/002 Interchangeable List Code: IC0110-023-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Pinewood 75 mg hard capsules	Pinewood Laboratories Ltd	PA0281/217/003 Interchangeable List Code: IC0110-028-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Sandoz 100 mg hard capsules	Sandoz GmbH	EU/1/15/1011/034-041 Interchangeable List Code: IC0110-024-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Sandoz 150 mg hard capsules	Sandoz GmbH	EU/1/15/1011/042-056 Interchangeable List Code: IC0110-062-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Sandoz 200 mg hard capsules	Sandoz GmbH	EU/1/15/1011/057-062 Interchangeable List Code: IC0110-067-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pregabalin Sandoz 225 mg hard capsules	Sandoz GmbH	EU/1/15/1011/063-068 Interchangeable List Code: IC0110-064-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Sandoz 25 mg hard capsules	Sandoz GmbH	EU/1/15/1011/001-010 Interchangeable List Code: IC0110-022-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Sandoz 300 mg hard capsules	Sandoz GmbH	EU/1/15/1011/069-083 Interchangeable List Code: IC0110-029-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Sandoz 50 mg hard capsules	Sandoz GmbH	EU/1/15/1011/011-017 Interchangeable List Code: IC0110-023-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Sandoz 75 mg hard capsules	Sandoz GmbH	EU/1/15/1011/018-033 Interchangeable List Code: IC0110-028-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Sandoz GmbH 100 mg hard capsules	Sandoz GmbH	EU/1/15/1012/034-041 Interchangeable List Code: IC0110-024-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Sandoz GmbH 150 mg hard capsules	Sandoz GmbH	EU/1/15/1012/042-056 Interchangeable List Code: IC0110-062-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Sandoz GmbH 200 mg hard capsules	Sandoz GmbH	EU/1/15/1012/057-062 Interchangeable List Code: IC0110-067-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Sandoz GmbH 225 mg hard capsules	Sandoz GmbH	EU/1/15/1012/063-068 Interchangeable List Code: IC0110-064-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Sandoz GmbH 25 mg hard capsules	Sandoz GmbH	EU/1/15/1012/001-010 Interchangeable List Code: IC0110-022-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Sandoz GmbH 300 mg hard capsules	Sandoz GmbH	EU/1/15/1012/069-083 Interchangeable List Code: IC0110-029-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Sandoz GmbH 50 mg hard capsules	Sandoz GmbH	EU/1/15/1012/011-017 Interchangeable List Code: IC0110-023-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pregabalin Sandoz GmbH 75 mg hard capsules	Sandoz GmbH	EU/1/15/1012/018-033 Interchangeable List Code: IC0110-028-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Teva 100 mg capsules, hard	Teva B.V.	PA1986/001/004 Interchangeable List Code: IC0110-024-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Teva 150 mg capsules, hard	Teva B.V.	PA1986/001/005 Interchangeable List Code: IC0110-062-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Teva 200 mg capsules, hard	Teva B.V.	PA1986/001/006 Interchangeable List Code: IC0110-067-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Teva 25 mg capsules, hard	Teva B.V.	PA1986/001/001 Interchangeable List Code: IC0110-022-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Teva 300 mg capsules, hard	Teva B.V.	PA1986/001/008 Interchangeable List Code: IC0110-029-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Teva 50 mg capsules, hard	Teva B.V.	PA1986/001/002 Interchangeable List Code: IC0110-023-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Teva 75 mg capsules, hard	Teva B.V.	PA1986/001/003 Interchangeable List Code: IC0110-028-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Zentiva 100 mg hard capsules	Zentiva k.s.	EU/1/15/1021/014-016 Interchangeable List Code: IC0110-024-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Zentiva 150 mg hard capsules	Zentiva k.s.	EU/1/15/1021/017-019 Interchangeable List Code: IC0110-062-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Zentiva 200 mg hard capsules	Zentiva k.s.	EU/1/15/1021/020-022 Interchangeable List Code: IC0110-067-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Zentiva 225 mg hard capsules	Zentiva k.s.	EU/1/15/1021/023-025 Interchangeable List Code: IC0110-064-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Zentiva 25 mg hard capsules	Zentiva k.s.	EU/1/15/1021/001-005 Interchangeable List Code: IC0110-022-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pregabalin Zentiva 300 mg hard capsules	Zentiva k.s.	EU/1/15/1021/026-028 Interchangeable List Code: IC0110-029-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Zentiva 50 mg hard capsules	Zentiva k.s.	EU/1/15/1021/006-010 Interchangeable List Code: IC0110-023-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pregabalin Zentiva 75 mg hard capsules	Zentiva k.s.	EU/1/15/1021/011-013 Interchangeable List Code: IC0110-028-001	Capsule, hard		- Pregabalin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
PreHevbri	VBI Vaccines B.V.	EU/1/22/1641	Suspension for injection	- J07BC01	- Hepatitis b surface antigen	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Premarin 0.3 mg Prolonged-release tablets	Pfizer Healthcare Ireland	PA0822/095/001	Prolonged-release tablet	- G03CA - G03CA57	- Conjugated estrogens	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Premarin 0.625 mg Prolonged-release tablets	Pfizer Healthcare Ireland	PA0822/095/002	Prolonged-release tablet	- G03CA - G03CA57	- Conjugated estrogens	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Premarin 1.25 mg Prolonged-release tablets	Pfizer Healthcare Ireland	PA0822/095/003	Prolonged-release tablet	- G03CA - G03CA57	- Conjugated estrogens	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Prenoxad 0.91 mg/ml solution for injection in a pre-filled syringe	Ethypharm	PA0549/021/001	Solution for injection in pre-filled syringe	- V03AB - V03AB15	- Naloxone hydrochloride dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intramuscular use
PREPANDEMIC INFLUENZA	GSK Vaccines S.r.l.	EU/1/10/657/001-002	Suspension for Injection	- J07BB02	- H5N1 (A/VIETNAM/1194/2004)		- Intra-Muscular
Pretomanid FGK	Mylan IRE Healthcare Limited	EU/1/20/1437/001-005	Tablet	- J04	- Pretomanid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
PREVENAR	Wyeth Lederle Vaccines S.A.	EU/1/00/167/001	Suspension for injection	- J07AL	- Pneumococcal polysaccharide type 23 (23f) - Pneumococcal type 6b - Pneumococcal polysaccharide type 19 (19f) - Pneumococcal polysaccharide type 4 (4) - Pneumococcal polysaccharide type 9v - Pneumococcal polysaccharide type 56 (18c) - Pneumococcal polysaccharide type 14 (14)		- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Prevenar	Wyeth Lederle Vaccines S.A.	EU/1/00/167/002	Suspension for injection	- J07AL	- Pneumococcal polysaccharide type 23 (23f) - Pneumococcal type 6b - Pneumococcal polysaccharide type 19 (19f) - Pneumococcal polysaccharide type 4 (4) - Pneumococcal polysaccharide type 9v - Pneumococcal polysaccharide type 56 (18c) - Pneumococcal polysaccharide type 14 (14)		- Intramuscular use
Prevenar	Wyeth Lederle Vaccines S.A.	EU/1/00/167/003	Suspension for injection in pre-filled syringe	- J07AL	- Pneumococcal polysaccharide type 23 (23f) - Pneumococcal type 6b - Pneumococcal polysaccharide type 19 (19f) - Pneumococcal polysaccharide type 4 (4) - Pneumococcal polysaccharide type 9v - Pneumococcal polysaccharide type 56 (18c) - Pneumococcal polysaccharide type 14 (14)		- Intramuscular use
Prevenar	Wyeth Lederle Vaccines S.A.	EU/1/00/167/008	Suspension for injection in pre-filled syringe	- J07AL - J07AL02	- Pneumococcal oligosaccharide serotype 18c - Pneumococcal polysaccharide serotype 9v - Pneumococcal polysaccharide serotype 6b - Pneumococcal polysaccharide serotype 19f - Crm197 carrier protein - Pneumococcal polysaccharide serotype 23f - Pneumococcal polysaccharide serotype 14 - Pneumococcal polysaccharide serotype 4		- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Prevenar	Wyeth Lederle Vaccines S.A.	EU/1/00/167/4-7	Suspension for injection	- J07AL	- Pneumococcal polysaccharide type 23 (23f) - Pneumococcal type 6b - Pneumococcal polysaccharide type 19 (19f) - Pneumococcal polysaccharide type 4 (4) - Pneumococcal polysaccharide type 9v - Pneumococcal polysaccharide type 56 (18c) - Pneumococcal polysaccharide type 14 (14)		- Intramuscular use
Prevenar 13	Pfizer Europe MA EEIG	EU/1/09/590/1-6	Suspension for injection	- J07AL - J07AL02	- Polysaccharide serotype 14 - Polysaccharide serotype 23f - Polysaccharide serotype 19f - Polysaccharide serotype 9v - Polysaccharide serotype 3 - Polysaccharide serotype 1 - Polysaccharide serotype 6a - Polysaccharide serotype 7f - Polysaccharide serotype 4 - Polysaccharide serotype 6b - Oligosaccharide serotype 18c - Polysaccharide serotype 5 - Polysaccharide serotype 19a	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Prevora 100mg/ml Dental Solution	CHX Technologies Europe Limited	PA1205/001/001	Dental solution	- A01AB - A01AB03	- CHLORHEXIDINE DIACETATE		- Dental use
Prevymis	Merck Sharp & Dohme BV,	EU/1/17/1245/001	Film-coated tablet	- J05	- LETERMOVIR	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Oral use
Prevymis	Merck Sharp & Dohme BV	EU/1/17/1245/002	Film-coated tablet	- J05	- LETERMOVIR	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Oral use
Prevymis	Merck Sharp & Dohme BV	EU/1/17/1245/003	Concentrate for solution for infusion	- J05	- LETERMOVIR	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Oral use
Prevymis	Merck Sharp & Dohme BV	EU/1/17/1245/004	Concentrate for solution for infusion	- J05	- LETERMOVIR	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Oral use
Prezista	Janssen-Cilag International NV	EU/1/06/380/001	Tablet	- J05AE - J05AE10	- Darunavir		- Oral use
Prezista	Janssen-Cilag International NV	EU/1/06/380/003	Film-coated tablet	- J05AE - J05AE10	- Darunavir		- Oral use
Prezista	Janssen-Cilag International NV	EU/1/06/380/004	Film-coated tablet	- J05AE - J05AE10	- Darunavir (as ethanolate)		- Oral use
Prezista	Janssen-Cilag International NV	EU/1/06/380/005	Film-coated tablet	- J05AE - J05AE10	- Darunavir (as ethanolate)		- Oral use
Prezista	Janssen-Cilag International NV	EU/1/06/380/006	Oral suspension	- J05AE - J05AE10			

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Prezista	Janssen-Cilag International NV	EU/1/06/380/007	Film-coated tablet	- J05AE - J05AE10	- Darunavir (as ethanolate)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
PREZISTA 600 mg film-coated tablets	Janssen-Cilag International NV	EU/1/06/380/002	Film-coated tablet	- J05AE - J05AE10	- Darunavir (as ethanolate)		- Oral use
Priadel 200mg prolonged-release tablets	Essential Pharma Limited	PA22587/001/001	Prolonged-release tablet	- N05AN - N05AN01	- Lithium carbonate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Priadel 400mg prolonged-release tablets	Essential Pharma Limited	PA22587/001/002	Prolonged-release tablet	- N05AN - N05AN01	- Lithium carbonate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
PRIALT	Esteve Pharmaceuticals GmbH	EU/1/04/302/1-3	Solution for infusion	- N02BG - N02BG08	- Ziconotide		
Priligy 30 mg film-coated tablets	A. Menarini Pharmaceuticals Ireland Ltd	PA1833/001/001	Film-coated tablet	- G04BX - G04BX14	- Dapoxetine		- Oral use
Priligy 60 mg film-coated tablets	A. Menarini Pharmaceuticals Ireland Ltd	PA1833/001/002	Film-coated tablet	- G04BX - G04BX14	- Dapoxetine		- Oral use
Primacine 125 mg/5 ml Granules for Oral Suspension	Pinewood Laboratories Ltd	PA0281/026/007	Granules for oral suspension	- J01FA - J01FA01	- Erythromycin ethylsuccinate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Primacine 250 mg/5 ml Granules for Oral Suspension	Pinewood Laboratories Ltd	PA0281/026/008	Granules for oral suspension	- J01FA - J01FA01	- Erythromycin ethylsuccinate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Primacine 500 mg/5 ml Granules for Oral Suspension	Pinewood Laboratories Ltd	PA0281/026/009	Granules for oral suspension	- J01FA - J01FA01	- Erythromycin ethylsuccinate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Primene 10% Solution for Infusion	Baxter Holding B.V.	PA2299/018/001	Solution for infusion	- B05BA - B05BA01	- L-isoleucine - L-leucine - L-valine - L-lysine - L-methionine - L-threonine - L-tryptophan - L-arginine - L-histidine - L-alanine - L-aspartic acid - Cysteine - L-glutamic acid - Glycine - L-proline - L-serine - L-tyrosine - Ornithine hydrochloride - Taurine - L-phenylalanine		- Not Currently Available
Primovist 0.25 mmol/ml, solution for injection	Bayer Limited	PA1410/021/002	Solution for injection	- V08CA - V08CA10	- Gadoxetic acid, disodium	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Primovist 0.25 mmol/ml, solution for injection, pre-filled syringe	Bayer Limited	PA1410/021/001	Solution for injection in pre-filled syringe	- V08CA - V08CA10	- Gadoxetic acid, disodium	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Priorix - Powder and solvent for solution for injection in a pre-filled syringeMeasles, Mumps and Rubella vaccine (live)	GlaxoSmithKline (Ireland) Limited	PA1077/036/001	Powder and solvent for solution for injection in pre-filled syringe	- J07BD - J07BD52	- Measles virus - schwarz strain live attenuated - Mumps vaccine rit 4385 live attenuated - Rubella virus (ra 27/3 strain)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Priorix-Tetra powder and solvent for solution for injection in pre-filled syringe Measles, mumps, rubella and varicella vaccine (live)	GlaxoSmithKline (Ireland) Limited	PA1077/117/001	Powder and solvent for solution for injection in pre-filled syringe	- J07BD - J07BD54	- Live attenuated measles virus (schwarz strain) - Live attenuated mumps virus (rit 4385 strain) - Live attenuated rubella virus (wistar ra 27/3 strain) - Live attenuated varicella virus (oka strain)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Prismasol 2 mmol/l Potassium solution for haemodialysis/haemofiltration	Baxter Holding B.V.	PA2299/052/001	Solution for haemodialysis/haemofiltration	- B05ZB	- Glucose (as monohydrate) - Magnesium chloride hexahydrate - Calcium chloride dihydrate - Lactic acid - Sodium chloride - Potassium chloride - Sodium hydrogen carbonate - Calcium - Magnesium - Sodium - Lactate - Hydrogen carbonate - Chloride - Potassium - Glucose	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Prismasol 2 mmol/l Potassium solution for haemodialysis/haemofiltration	Baxter Holding B.V.	PA2299/052/002	Solution for haemodialysis/haemofiltration	- B05ZB	- Glucose (as monohydrate) - Magnesium chloride hexahydrate - Calcium chloride dihydrate - Lactic acid - Sodium chloride - Potassium chloride - Sodium hydrogen carbonate - Calcium - Magnesium - Sodium - Chloride - Lactate - Hydrogen carbonate - Potassium - Glucose	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Prismasol 4 mmol/l Potassium solution for haemodialysis/haemofiltration	Baxter Holding B.V.	PA2299/052/003	Solution for haemodialysis/haemofiltration	- B05ZB	- Glucose (as monohydrate) - Magnesium chloride hexahydrate - Calcium chloride dihydrate - Lactic acid - Sodium chloride - Potassium chloride - Sodium hydrogen carbonate - Calcium - Magnesium - Sodium - Chloride - Lactase - Hydrogen carbonate - Potassium - Glucose	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Prismasol 4 mmol/l Potassium solution for haemodialysis/haemofiltration	Baxter Holding B.V.	PA2299/052/004	Solution for haemodialysis/haemofiltration	- B05ZB	- Glucose (as monohydrate) - Magnesium chloride hexahydrate - Calcium chloride dihydrate - Lactic acid - Sodium chloride - Potassium chloride - Sodium hydrogen carbonate - Calcium - Magnesium - Sodium - Chloride - Lactate - Hydrogen carbonate - Potassium - Glucose	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Pritor 20 mg tablets	Bayer AG	EU/1/98/089/011-014 Interchangeable List Code: IC0049-003-014	Tablet		- Telmisartan		- Oral use
Pritor 40 mg tablets	Bayer AG	EU/1/98/089/001-005 Interchangeable List Code: IC0049-004-014	Tablet		- Telmisartan		- Oral use
Pritor 80 mg tablets	Bayer AG	EU/1/98/089/006-010 Interchangeable List Code: IC0049-005-014	Tablet		- Telmisartan		- Oral use
PritorPlus 40 mg/12.5 mg tablets	Bayer AG	EU/1/02/215/1-5 Interchangeable List Code: IC0050-099-039	Tablet		- Telmisartan - Hydrochlorothiazide		- Oral use
PritorPlus 80 mg/12.5 mg tablets	Bayer AG	EU/1/02/215/006-010 Interchangeable List Code: IC0050-081-039	Tablet		- Telmisartan - Hydrochlorothiazide		- Oral use
PritorPlus 80 mg/25 mg tablets	Bayer AG	EU/1/02/215/15-21 Interchangeable List Code: IC0050-100-039	Tablet		- Hydrochlorothiazide - Telmisartan	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Privigen (Human normal immunoglobulin)	CSL Behring GmbH	EU/1/08/446/1-3	Solution for infusion	- J06BA - J06BA02	- Human normal immunoglobulin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Procoralan	Les Laboratoires Servier	EU/1/05/316/1-7	Film-coated tablet	- C01EB - C01EB17	- Ivabradine		- Oral use
Procoralan	Les Laboratoires Servier	EU/1/05/316/8-14	Film-coated tablet	- C01EB - C01EB17	- Ivabradine		- Oral use
Proctosedyl Ointment	Phoenix Labs	PA1113/029/001	Ointment	- C05AA - C05AA01	- Hydrocortisone - Cinchocaine Hydrochloride - Aesculin - Framycetin sulphate		- Topical use
Procysbi	Chiesi Farmaceutici S.p.A.	EU/1/13/861/001	Gastro-resistant capsule, hard	- A16AA - A16AA04	- Cysteamine bitartrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Procysbi	Chiesi Farmaceutici S.p.A.	EU/1/13/861/002	Gastro-resistant capsule, hard	- A16AA - A16AA04	- Cysteamine bitartrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Procysbi	Chiesi Farmaceutici S.p.A.	EU/1/13/861/003	Gastro-resistant granules	- A16AA04	- Mercaptamine bitartrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Procysbi	Chiesi Farmaceutici S.p.A.	EU/1/13/861/004	Gastro-resistant granules	- A16AA04	- Mercaptamine bitartrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Produodopa 240 mg/ml + 12 mg/ml solution for infusion	AbbVie Limited	PA1824/002/003	Solution for infusion	- N04BA	- Foslevodopa - Foscarbidopa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Pro-Epanutin 75 mg/ml concentrate for solution for infusion/solution for injection	Pfizer Healthcare Ireland	PA0822/019/001	Solution for injection/infusion	- N03AB - N03AB05	- Fosphenytoin sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Profloxin 250 mg film-coated Tablets	Clonmel Healthcare Ltd	PA0126/203/001	Film-coated tablet	- J01MA - J01MA02	- Ciprofloxacin		- Oral use
Profloxin 500 mg film-coated Tablets	Clonmel Healthcare Ltd	PA0126/203/002	Film-coated tablet	- J01MA - J01MA02	- Ciprofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Progesterone 400 mg pessaries	Gedeon Richter Plc	PA1330/027/001	Pessary	- G03DA - G03DA04	- Progesterone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Prograf 0.5 mg hard capsules	Astellas Pharma Co. Limited	PA1241/014/001	Capsule, hard	- L04AD - L04AD02	- Tacrolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Prograf 0.5 mg hard capsules	IMED Healthcare Ltd.	PPA1463/165/001	Capsule, hard	- L04AD - L04AD02	- Tacrolimus		- Oral use
Prograf 0.5 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/435/001	Capsule, hard	- L04AD02	- Tacrolimus	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Prograf 1 mg hard capsules	Astellas Pharma Co. Limited	PA1241/014/002	Capsule, hard	- L04AD - L04AD02	- Tacrolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Prograf 5 mg hard capsules	Astellas Pharma Co. Limited	PA1241/014/003	Capsule, hard	- L04AD - L04AD02	- Tacrolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Prograf 5 mg/ml concentrate for solution for infusion	Astellas Pharma Co. Limited	PA1241/014/004	Concentrate for solution for infusion	- L04AD - L04AD02	- Tacrolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
ProHance, 279.3 mg/ml, Solution for Injection, 10 ml vial	Bracco International B.V.	PA0788/001/002	Solution for injection	- V08CA - V08CA04	- Gadoteridol		- Intravenous use
ProHance, 279.3 mg/ml, Solution for Injection, 15 ml vial	Bracco International B.V.	PA0788/001/003	Solution for injection	- V08CA - V08CA04	- Gadoteridol		- Intravenous use
ProHance, 279.3 mg/ml, solution for injection, 20 ml vial	Bracco International B.V.	PA0788/001/004	Solution for injection	- V08CA - V08CA04	- Gadoteridol		- Intravenous use
Prolastin 4000 mg, powder and solvent for solution for infusion	Grifols Deutschland GmbH	PA1405/002/002	Powder and solvent for solution for infusion	- B02AB02	- Human alpha1-proteinase inhibitor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Prolastin 5000 mg, powder and solvent for solution for infusion	Grifols Deutschland GmbH	PA1405/002/003	Powder and solvent for solution for infusion	- B02AB02	- Human alpha1-proteinase inhibitor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Prolastin1000mg, powder and solvent for solution for infusion	Grifols Deutschland GmbH	PA1405/002/001	Powder and solvent for solution for infusion	- B02AB - B02AB02	- Alpha-1-proteinase inhibitor	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Prolia	Amgen Europe B.V.	EU/1/10/618/1-4	Solution for injection	- M05BX - M05BX04	- Denosumab		- Subcutaneous use
PROMETAX	Novartis Europharm Limited	EU/1/98/092/001	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Prometax	Novartis Europharm Limited	EU/1/98/092/002	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		
Prometax	Novartis Europharm Limited	EU/1/98/092/003	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		
Prometax	Novartis Europharm Limited	EU/1/98/092/004	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Prometax	Novartis Europharm Limited	EU/1/98/092/005	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Prometax	Novartis Europharm Limited	EU/1/98/092/006	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Prometax	Novartis Europharm Limited	EU/1/98/092/007	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Prometax	Novartis Europharm Limited	EU/1/98/092/008	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Prometax	Novartis Europharm Limited	EU/1/98/092/009	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Prometax	Novartis Europharm Limited	EU/1/98/092/010	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Prometax	Novartis Europharm Limited	EU/1/98/092/011	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Prometax	Novartis Europharm Limited	EU/1/98/092/012	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Prometax	Novartis Europharm Limited	EU/1/98/092/013	Oral solution	- N06DA - N06DA03	- Rivastigmine hydrogen tartrate		- Oral use
Prometax	Novartis Europharm Limited	EU/1/98/092/027-030	Transdermal patch	- N06DA - N06DA03	- Rivastigmine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Prometax	Novartis Europharm Limited	EU/1/98/092/19-22	Transdermal patch	- N06DA - N06DA03	- Rivastigmine base	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Prometax	Novartis Europharm Limited	EU/1/98/092/23-26	Transdermal patch	- N06DA - N06DA03	- Rivastigmine base	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Propafenone Hydrochloride 150mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/116/001	Film-coated tablet	- C01BC - C01BC03	- Propafenone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Propafenone Hydrochloride 300mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/116/002	Film-coated tablet	- C01BC - C01BC03	- Propafenone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Propess 10 mg vaginal delivery system	Ferring Ireland Ltd	PA1009/029/001	Vaginal delivery system	- G02AD - G02AD02	- Dinoprostone	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Vaginal use
Propinorm XL 30 mg Modified-Release Capsules	Apogepha Arzneimittel GmbH	PA0803/005/001	Modified-release capsule, hard	- G04BD - G04BD06	- Propiverine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Propofol 1 % (10 mg/1 ml) Fresenius emulsion for injection or infusion, ampoule	Fresenius Kabi Deutschland GmbH	PA2059/055/001	Emulsion for injection/infusion	- N01AX - N01AX10	- Propofol		- Intravenous use
Propofol 1 % (10 mg/1 ml) Fresenius emulsion for injection or infusion, vial	Fresenius Kabi Deutschland GmbH	PA2059/055/002	Emulsion for injection/infusion	- N01AX - N01AX10	- Propofol		- Intravenous use
Propofol 1% (10 mg/ml) emulsion for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/017/001	Emulsion for injection/infusion	- N01AX - N01AX10	- Propofol		- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Propofol 1% (10 mg/ml) emulsion for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/017/002	Emulsion for injection/infusion	- N01AX - N01AX10	- Propofol	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intravenous use
Propofol 10 mg/ml Emulsion for injection/infusion	Baxter Holding B.V.	PA2299/038/001	Emulsion for injection/infusion	- N01AX - N01AX10	- Propofol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Propofol 2 % (20 mg/1 ml) Fresenius emulsion for injection or infusion, ampoule	Fresenius Kabi Deutschland GmbH	PA2059/055/003	Emulsion for injection/infusion	- N01AX - N01AX10	- Propofol		- Intravenous use
Propofol 2 % (20 mg/1 ml) Fresenius emulsion for injection or infusion, vial	Fresenius Kabi Deutschland GmbH	PA2059/055/004	Emulsion for injection/infusion	- N01AX - N01AX10	- Propofol		- Intravenous use
Propofol 20 mg/ml Emulsion for injection/infusion	Baxter Holding B.V.	PA2299/038/002	Emulsion for injection/infusion	- N01AX - N01AX10	- Propofol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Propofol-Lipuro 1 % (10 mg/ml) emulsion for injection or infusion	B. Braun Melsungen AG	PA0736/018/001	Emulsion for injection/infusion	- N01AX - N01AX10	- Propofol		- Intravenous use
Propofol-Lipuro 1 % (10 mg/ml) emulsion for injection or infusion	B. Braun Melsungen AG	PA0736/018/002	Emulsion for injection/infusion	- N01AX - N01AX10	- Propofol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Propofol-Lipuro 2 % (20 mg/ml) emulsion for injection or infusion	B. Braun Melsungen AG	PA0736/018/003	Emulsion for injection/infusion	- N01AX - N01AX10	- Propofol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Propoven 1% emulsion for injection or infusion in pre-filled syringe (glass syringe)	Fresenius Kabi Deutschland GmbH	PA2059/017/006	Emulsion for injection/infusion in pre-filled syringe	- N01AX - N01AX10	- Propofol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Propoven 1% emulsion for injection/infusion in pre-filled syringe	Fresenius Kabi Deutschland GmbH	PA2059/017/004	Emulsion for injection/infusion in pre-filled syringe	- N01AX - N01AX10	- Propofol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Propoven 2% emulsion for injection/infusion in pre-filled syringe	Fresenius Kabi Deutschland GmbH	PA2059/017/005	Emulsion for injection/infusion in pre-filled syringe	- N01AX - N01AX10	- Propofol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Propranolol Azure 10 mg film-coated tablets	Azure Pharmaceuticals Ltd	PA22871/031/001	Film-coated tablet	- C07AA05	- Propranolol hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Propranolol Azure 40 mg film-coated tablets	Azure Pharmaceuticals Ltd	PA22871/031/002	Film-coated tablet	- C07AA05	- Propranolol hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Propylthiouracil 50 mg tablets	Halewood Chemicals (Ireland) Limited	PA22902/001/001	Tablet	- H03BA - H03BA02	- Propylthiouracil	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Proquad	Merck Sharp & Dohme BV,	EU/1/05/323/1-13	Powder and solvent for suspension for injection	- J07BD - J07BD54	- Mumps virus live attenuated jeryl lynn strain - Rubella virus (wistar ra 27/3 strain) live attenuated - Varicella virus vaccine live (oka/merck)		
Proscar 5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/098/001	Film-coated tablet	- G04CB - G04CB01	- Finasteride		- Oral use
Proscar 5 mg Film-coated tablets	IMED Healthcare Ltd.	PPA1463/127/001	Film-coated tablet	- G04CB - G04CB01	- Finasteride		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Proscar 5mg Film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/007/001	Film-coated tablet	- G04CB - G04CB01	- Finasteride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
PROSTAP 3 DCS 11.25 mg Powder and Solvent for Prolonged-release Suspension for Injection in Pre-filled Syringe	PCO Manufacturing Ltd.	PPA0465/473/001	Powder and solvent for prolonged-release suspension for injection in pre-filled syringe	- L02AE02	- Leuprorelin acetate	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Intramuscular use - Subcutaneous use
PROSTAP 3 DCS 11.25 mg Powder and Solvent for Prolonged-release Suspension for Injection in Pre-filled Syringe	Takeda Products Ireland Ltd	PA2229/009/001	Powder and solvent for prolonged-release suspension for injection in pre-filled syringe	- L02AE - L02AE02	- Leuprorelin acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
PROSTAP 6 DCS 30 mg Powder and Solvent for Prolonged-release Suspension for Injection in Pre-filled Syringe	Takeda Products Ireland Ltd	PA2229/009/002	Powder and solvent for prolonged-release suspension for injection in pre-filled syringe	- L02AE - L02AE02	- Leuprorelin acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
PROSTAP SR DCS 3.75 mg Powder and Solvent for Prolonged-release Suspension for Injection in Pre-filled Syringe	Takeda Products Ireland Ltd	PA2229/009/003	Powder and solvent for prolonged-release suspension for injection in pre-filled syringe	- L02AE - L02AE02	- Leuprorelin acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Prostasan soft capsules	A.Vogel Ireland Limited	TR2309/002/001	Capsule, soft		- Sabalis serrulatae extractum spissum	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Prostin E2 1 mg Vaginal Gel	Pfizer Healthcare Ireland	PA0822/178/001	Vaginal gel	- G02AD - G02AD02	- Dinoprostone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Prostin E2 1mg/ml Concentrate for solution for infusion	Pfizer Healthcare Ireland	PA0822/133/003	Concentrate for solution for infusion	- G02AD - G02AD02	- Dinoprostone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Prostin E2 2 mg Vaginal Gel	Pfizer Healthcare Ireland	PA0822/178/002	Vaginal gel	- G02AD - G02AD02	- Dinoprostone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Protamine sulphate LEO Pharma 1400 anti-heparin IU/ml solution for injection and infusion	LEO Pharma A/S	PA1025/002/001	Solution for injection/infusion	- V03AB - V03AB14	- Protamine sulphate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Protaphane	Novo Nordisk A/S	EU/1/02/234/016-017	Suspension for injection	- A10AC - A10AC01	- Insulin human		- Subcutaneous use
Protaphane	Novo Nordisk A/S	EU/1/02/234/1-15	Suspension for injection	- A10AB - A10AB01	- Insulin human		- Subcutaneous use
Prothiaden 25 mg Hard Capsules	Teofarma S.R.L.	PA1235/005/001	Capsule, hard	- N06AA - N06AA16	- Dothiepine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Prothiaden 75mg Coated Tablets	Teofarma S.R.L.	PA1235/005/002	Coated tablet	- N06AA - N06AA16	- Dosulepin hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Prothromplex TOTAL 500 IU powder and solvent for solution for injection	Baxalta Innovations GmbH	PA2004/005/002	Powder and solvent for solution for injection	- B02BD01	- Human coagulation factor ii - Human coagulation factor vii - Human coagulation factor ix - Human coagulation factor x - Human Protein C	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Prothromplex TOTAL 600 IU powder and solvent for solution for injection	Baxalta Innovations GmbH	PA2004/005/001	Powder and solvent for solution for injection	- B02BD - B02BD01	- Human coagulation factor ii - Human coagulation factor vii - Human coagulation factor ix - Human coagulation factor x - Protein c	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Protium 20 mg gastro-resistant tablets	Takeda Products Ireland Ltd	PA2229/010/001 Interchangeable List Code: IC0013-003-005	Gastro-resistant tablet		- Pantoprazole sodium sesquihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Protium 40 mg gastro-resistant tablets	Takeda Products Ireland Ltd	PA2229/010/002 Interchangeable List Code: IC0013-004-005	Gastro-resistant tablet		- Pantoprazole sodium sesquihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Protium i.v. 40 mg Powder for Solution for Injection	Takeda Products Ireland Ltd	PA2229/010/003	Powder for solution for injection	- A02BC - A02BC02	- Pantoprazole sodium sesquihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Protizole 20 mg gastro-resistant tablet	Accord Healthcare Ireland Ltd.	PA2315/260/001 Interchangeable List Code: IC0013-003-005	Gastro-resistant tablet		- Pantoprazole sodium sesquihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Protizole 40 mg gastro-resistant tablet	Accord Healthcare Ireland Ltd.	PA2315/260/002 Interchangeable List Code: IC0013-004-005	Gastro-resistant tablet		- Pantoprazole sodium sesquihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
PROTOPIC	LEO Pharma A/S	EU/1/02/201/001	Ointment	- D11AH - D11AH01	- Tacrolimus		- Cutaneous use
PROTOPIC	LEO Pharma A/S	EU/1/02/201/002	Ointment	- D11AH - D11AH01	- Tacrolimus		- Cutaneous use
PROTOPIC	LEO Pharma A/S	EU/1/02/201/003	Ointment	- D11AH - D11AH01	- Tacrolimus		- Cutaneous use
PROTOPIC	LEO Pharma A/S	EU/1/02/201/004	Ointment	- D11AH - D11AH01	- Tacrolimus		- Cutaneous use
PROTOPIC	LEO Pharma A/S	EU/1/02/201/005	Ointment	- D11AH - D11AH01	- Tacrolimus		- Cutaneous use
PROTOPIC	LEO Pharma A/S	EU/1/02/201/006	Ointment	- D11AH - D11AH01	- Tacrolimus		- Cutaneous use
Proursan 250mg Capsules, Hard	PRO.MED.CS Praha a.s.	PA2179/002/001	Capsule, hard	- A05AA - A05AA02	- Ursodeoxycholic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Proursan 400 mg film-coated tablets	PRO.MED.CS Praha a.s.	PA2179/001/002	Film-coated tablet	- A05AA02	- Ursodeoxycholic acid	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Proursan 500 mg film-coated tablets	PRO.MED.CS Praha a.s.	PA2179/001/001	Film-coated tablet	- A05AA - A05AA02	- Ursodeoxycholic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Provera 10 mg tablets	Pfizer Healthcare Ireland	PA0822/134/003	Tablet	- G03DA - G03DA02	- Medroxyprogesterone acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Not Currently Available
Provera 2.5 mg tablets	Pfizer Healthcare Ireland	PA0822/134/001	Tablet	- G03DA - G03DA02	- Medroxyprogesterone acetate		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Provigil 100 mg tablets	Teva Pharma B.V.	PA0749/198/001 Interchangeable List Code: IC0138-024-002	Tablet		- Modafinil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Provigil 100 mg tablets	PCO Manufacturing Ltd.	PPA0465/415/001 Interchangeable List Code: IC0138-024-002	Tablet		- Modafinil	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Provigil 200 mg tablets	Teva Pharma B.V.	PA0749/198/002 Interchangeable List Code: IC0138-067-002	Tablet		- Modafinil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
PROZAC	Clear Pharmacy	DPR1596/008/001	Capsule, hard	- N06AB03	- FLUOXETINE HYDROCHLORIDE		- Oral use
Prozamel 20 mg Capsules, Hard	Clonmel Healthcare Ltd	PA0126/110/001 Interchangeable List Code: IC0075-003-001	Capsule, hard		- FLUOXETINE HYDROCHLORIDE		- Oral use
Prucalopride 1 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/260/001 Interchangeable List Code: IC0122-039-003	Film-coated tablet		- Prucalopride Succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Prucalopride 2 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/260/002 Interchangeable List Code: IC0122-006-003	Film-coated tablet		- Prucalopride Succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Prucalopride Aristo 1 mg film-coated tablets	Aristo Pharma GmbH	PA1983/010/001 Interchangeable List Code: IC0122-039-003	Film-coated tablet		- Prucalopride Succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Prucalopride Aristo 2 mg film-coated tablets	Aristo Pharma GmbH	PA1983/010/002 Interchangeable List Code: IC0122-006-003	Film-coated tablet		- Prucalopride Succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pulmicort Respules 0.5 mg/2 ml Nebuliser Suspension	AstraZeneca AB	PA1019/017/001	Nebuliser suspension	- R03BA - R03BA02	- Budesonide		- Inhalation use
Pulmicort Respules 1 mg /2 ml Nebuliser Suspension	AstraZeneca AB	PA1019/017/002	Nebuliser suspension	- R03BA - R03BA02	- Budesonide		- Inhalation use
Pulmicort Respules 1 mg /2 ml Nebuliser Suspension	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/059/001	Nebuliser suspension	- R03BA - R03BA02	- Budesonide		- Inhalation use
Pulmicort Turbohaler 100 micrograms Inhalation Powder	AstraZeneca AB	PA1019/017/003	Inhalation powder	- R03BA - R03BA02	- Budesonide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Pulmicort Turbohaler 200 micrograms Inhalation Powder	AstraZeneca AB	PA1019/017/004	Inhalation powder	- R03BA - R03BA02	- Budesonide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Pulmicort Turbohaler 400 micrograms Inhalation Powder	AstraZeneca AB	PA1019/017/005	Inhalation powder	- R03BA - R03BA02	- Budesonide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
PULMOCIS 2 mg kit for radiopharmaceutical preparation	CIS bio International	PA0677/003/001	Kit for radiopharmaceutical preparation	- B05AA - B05AA01	- Human albumin macro aggregated	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
PULMOTEC Graphite crucible for the preparation of Technegas inhalation	Cyclomedica Ireland Ltd	PA1034/001/001	Kit for radiopharmaceutical preparation	- V09EA - V09EA02	- Graphites		- Inhalation use
Pulmozyme 2500 U/ 2.5ml, nebuliser solution	Roche Products (Ireland) Ltd	PA2307/005/001	Nebuliser solution	- R05CB - R05CB13	- Dornase alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Pulmozyme 2500 U/2.5 ml nebuliser solution	PCO Manufacturing Ltd.	PPA0465/433/001	Nebuliser solution	- R05CB - R05CB13	- Dornase alfa		- Inhalation use
Puregon	N.V. Organon	EU/1/96/008/017	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/018	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/019	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/020	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/021	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/022	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/023	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/024	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/025	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/026	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/027	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/028	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/029	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/030	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/031	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/032	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/033	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/034	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Intramuscular use - Subcutaneous use
PUREGON	N.V. Organon	EU/1/96/008/038	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/039	Solution for injection	- G03GA - G03GA06	- Follitropin beta		- Subcutaneous use
Puregon	N.V. Organon	EU/1/96/008/040	Solution for injection	- G03GA - G03GA06	- Follitropin beta		
Puregon	N.V. Organon	EU/1/96/008/041	Solution for injection	- G03GA - G03GA06	- Follitropin beta		
Puri-Nethol 50 mg Tablets	PCO Manufacturing Ltd.	PPA0465/455/001	Tablet	- L01BB02	- Mercaptopurine monohydrate		- Oral use
Puri-Nethol 50 mg Tablets	IMED Healthcare Ltd.	PPA1463/128/001	Tablet	- L01BB02	- Mercaptopurine monohydrate		- Oral use
Puri-Nethol 50 mg Tablets	Aspen Pharma Trading Limited	PA1691/009/001	Tablet	- L01BB - L01BB02	- Mercaptopurine monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pylclari	Curium Pet France	EU/1/23/1746/001	Solution for injection	- V09IX - V09IX16	- 2-(3-{1-carboxy-5-[(6-[(18)F]fluoro-pyridine-3-carbonyl)-amino]-pentyl}-ureido)-pentanedioic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Pylobactell	Torbet Laboratories Ireland Limited	EU/1/98/064/01	Soluble tablet	- V04CX	- 13c-urea		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Pyranistole 200 mg prolonged release capsules	Renata Pharmaceuticals (Ireland) Limited	PA22865/001/001	Prolonged-release capsule, hard	- B01AC - B01AC07	- Dipyridamole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Pyrukynd	Agios Netherlands B.V.	EU/1/22/1662/001-003	Film-coated tablet	- B06 - B06AX04	- Mitapivat Sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pyrukynd	Agios Netherlands B.V.	EU/1/22/1662/004-005	Film-coated tablet	- B06 - B06AX04	- Mitapivat Sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Pyrukynd	Agios Netherlands B.V.	EU/1/22/1662/006	Film-coated tablet	- B06 - B06AX04	- Mitapivat Sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Qaialdo	Nova Laboratories Ireland Limited	EU/1/23/1731/001	Oral suspension	- C03DA01	- Spironolactone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Qarziba	EUSA Pharma (Netherlands) B.V.	EU/1/17/1191/001	Concentrate for solution for infusion	- L01XC - L01XC16	- Dinutuximab beta	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Qdenga	Takeda GmbH	EU/1/22/1699/001	Powder and solvent for solution for injection	- J07B - J07BX04	- Dengue virus, serotype 2, expressing Dengue virus, serotype 1, surface proteins, live, attenuated - Dengue virus, serotype 2, live, attenuated - Dengue virus, serotype 2, expressing Dengue virus, serotype 3, surface proteins, live, attenuated - Dengue virus, serotype 2, expressing Dengue virus, serotype 4, surface proteins, live, attenuated	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Qdenga	Takeda GmbH	EU/1/22/1699/002	Powder and solvent for solution for injection	- J07B - J07BX04	- Dengue virus, serotype 2, expressing Dengue virus, serotype 1, surface proteins, live, attenuated - Dengue virus, serotype 2, live, attenuated - Dengue virus, serotype 2, expressing Dengue virus, serotype 3, surface proteins, live, attenuated - Dengue virus, serotype 2, expressing Dengue virus, serotype 4, surface proteins, live, attenuated	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Qdenga	Takeda GmbH	EU/1/22/1699/003	Powder and solvent for solution for injection	- J07B - J07BX04	- Dengue virus, serotype 2, expressing Dengue virus, serotype 1, surface proteins, live, attenuated - Dengue virus, serotype 2, live, attenuated - Dengue virus, serotype 2, expressing Dengue virus, serotype 3, surface proteins, live, attenuated - Dengue virus, serotype 2, expressing Dengue virus, serotype 4, surface proteins, live, attenuated	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Qdenga	Takeda GmbH	EU/1/22/1699/004	Powder and solvent for solution for injection	- J07B - J07BX04	- Dengue virus, serotype 2, expressing Dengue virus, serotype 1, surface proteins, live, attenuated - Dengue virus, serotype 2, live, attenuated - Dengue virus, serotype 2, expressing Dengue virus, serotype 3, surface proteins, live, attenuated - Dengue virus, serotype 2, expressing Dengue virus, serotype 4, surface proteins, live, attenuated	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Qinlock	Deciphera Pharmaceuticals (Netherlands) B.V.	EU/1/21/1569/001-002	Tablet	- L01 - L01EX19	- Ripretinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Qlaira film-coated tablets	Bayer Limited	PA1410/058/001	Film-coated tablet	- G03AA - G03AA16	- Estradiol valerate - Estradiol valerate - Dienogest - Dienogest - Estradiol valerate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Qtern	AstraZeneca AB	EU/1/16/1108/001-004	Film-coated tablet	- A10BD - A10BD21	- Dapagliflozin - Saxagliptin	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Quadramet	CIS bio International	EU/1/97/057/001	Solution for injection	- V10BX - V10BX02	- SAMARIUM (153SM) EDTMP		- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Quadrivalent Influenza Vaccine (split virion, inactivated), suspension for injection in pre-filled syringe Quadrivalent influenza vaccine (split virion, inactivated)	Sanofi Pasteur	PA2131/013/001	Suspension for injection in pre-filled syringe	- J07BB - J07BB02	- A/Victoria/4897/2022 (H1N1)pdm09-like strain (A/Victoria/4897/2022, IVR-238 - A/Darwin/9/2021 (H3N2) - like strain (A/Darwin/9/2021, IVR-228) - B/Austria/1359417/2021 - like strain (B/Michigan/01/2021, wild type) - B/PHUKET/3073/2013 -LIKE STRAIN (B/PHUKET/3073/2013, WILD TYPE)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Subcutaneous use
Quentiax SR 150mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/045/001 Interchangeable List Code: IC0019-062-024	Prolonged-release tablet		- Quetiapine hemifumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quentiax SR 200 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/045/002 Interchangeable List Code: IC0019-067-024	Prolonged-release tablet		- Quetiapine hemifumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quentiax SR 300 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/045/003 Interchangeable List Code: IC0019-029-024	Prolonged-release tablet		- Quetiapine hemifumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quentiax SR 400 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/045/005 Interchangeable List Code: IC0019-068-024	Prolonged-release tablet		- Quetiapine hemifumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quentiax SR 50mg Prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/045/004 Interchangeable List Code: IC0019-023-024	Prolonged-release tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Questran 4g/sachet, Powder for oral suspension	CHEPLAPHARM Arzneimittel GmbH	PA2239/005/001	Powder for oral suspension	- C10AC - C10AC01	- Colestyramine resin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Quetex 100 mg film-coated tablets	Rowex Ltd	PA0711/156/003 Interchangeable List Code: IC0019-024-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetex 200 mg film-coated tablets	Rowex Ltd	PA0711/156/004 Interchangeable List Code: IC0019-067-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetex 25mg film-Coated tablets	Rowex Ltd	PA0711/156/001 Interchangeable List Code: IC0019-022-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetex 300 mg film-coated tablets	Rowex Ltd	PA0711/156/005 Interchangeable List Code: IC0019-029-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetex XR 200 mg prolonged-release tablets	Rowex Ltd	PA0711/258/002 Interchangeable List Code: IC0019-067-024	Prolonged-release tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Quetex XR 300 mg prolonged-release tablets	Rowex Ltd	PA0711/258/003 Interchangeable List Code: IC0019-029-024	Prolonged-release tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetex XR 400 mg prolonged-release tablets	Rowex Ltd	PA0711/258/004 Interchangeable List Code: IC0019-068-024	Prolonged-release tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetex XR 50 mg prolonged-release tablets	Rowex Ltd	PA0711/258/001 Interchangeable List Code: IC0019-023-024	Prolonged-release tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetiapine 100 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/117/002 Interchangeable List Code: IC0019-024-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetiapine 200 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/117/003 Interchangeable List Code: IC0019-067-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetiapine 25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/117/001 Interchangeable List Code: IC0019-022-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetiapine 300 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/117/004 Interchangeable List Code: IC0019-029-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetiapine Fair-Med 100 mg film-coated tablets	Fairmed Healthcare GmbH	PA1789/002/002 Interchangeable List Code: IC0019-024-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetiapine Fair-Med 150 mg film-coated tablets	Fairmed Healthcare GmbH	PA1789/002/003	Film-coated tablet	- N05AH - N05AH04	- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetiapine Fair-Med 200 mg film-coated tablets	Fairmed Healthcare GmbH	PA1789/002/004 Interchangeable List Code: IC0019-067-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetiapine Fair-Med 25 mg film-coated tablets	Fairmed Healthcare GmbH	PA1789/002/001 Interchangeable List Code: IC0019-022-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetiapine Fair-Med 300 mg film-coated tablets	Fairmed Healthcare GmbH	PA1789/002/005 Interchangeable List Code: IC0019-029-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetiapine Fair-Med Starterpack	Fairmed Healthcare GmbH	PA1789/002/006	Film-coated tablet	- N05AH - N05AH04	- Quetiapine - Quetiapine - Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetiapine Krka 100mg Film-coated Tablets	KRKA, d.d., Novo mesto	PA1347/027/002 Interchangeable List Code: IC0019-024-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetiapine Krka 200mg Film-coated Tablets	KRKA, d.d., Novo mesto	PA1347/027/003 Interchangeable List Code: IC0019-067-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Quetiapine Krka 25mg Film-coated Tablets	KRKA, d.d., Novo mesto	PA1347/027/001 Interchangeable List Code: IC0019-022-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quetiapine Krka 300mg Film-coated Tablets	KRKA, d.d., Novo mesto	PA1347/027/004 Interchangeable List Code: IC0019-029-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Quinine Sulphate 300 mg film coated tablets	Teva B.V.	PA1986/052/001	Film-coated tablet	- P01BC - P01BC01	- Quinine sulfate		- Oral use
Quinoderm 10% w/w + 0.5% w/w Cream	Alliance Pharma (Ireland) Limited	PA2325/012/001	Cream	- D10AE - D10AE01	- Benzoyl peroxide hydrous - Potassium Hydroxyquinoline Sulphate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Quinoderm 5% w/w + 0.5% w/w Cream	Alliance Pharma (Ireland) Limited	PA2325/012/002	Cream	- D10AE - D10AE01	- Benzoyl peroxide hydrous - Potassium Hydroxyquinoline Sulphate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Quinsair	Chiesi Farmaceutici S.p.A.	EU/1/14/973/001	Nebuliser solution	- J01MA - J01MA12	- Levofloxacin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Quofenix	A. Menarini Industrie Farmaceutische Riunite S.r.l.	EU/1/19/1393/001	Powder for concentrate for solution for infusion	- J01MA - J01MA23	- DELAFLOXACIN MEGLUMINE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Quofenix	A. Menarini Industrie Farmaceutische Riunite S.r.l.	EU/1/19/1393/002-007	Tablet	- J01MA - J01MA23	- DELAFLOXACIN MEGLUMINE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Oral use
Qutenza	Grünenthal GmbH	EU/1/09/524/001-002	Cutaneous patch	- N01BX - N01BX04	- Capsaicin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Quviviq	Idorsia Pharmaceuticals Deutschland GmbH	EU/1/22/1638/001-002	Film-coated tablet	- N05	- Daridorexant hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Quviviq	Idorsia Pharmaceuticals Deutschland GmbH	EU/1/22/1638/003-004	Film-coated tablet	- N05	- Daridorexant hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rabeprazole Krka 10mg Gastro-Resistant Tablets	KRKA, d.d., Novo mesto	PA1347/030/001 Interchangeable List Code: IC0015-002-005	Gastro-resistant tablet		- Rabeprazole sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rabeprazole Krka 20mg Gastro-Resistant Tablets	KRKA, d.d., Novo mesto	PA1347/030/002 Interchangeable List Code: IC0015-003-005	Gastro-resistant tablet		- Rabeprazole sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rabies Vaccine BP > 2.5 IU/ml, Powder and solvent for suspension for injection	Sanofi Pasteur	PA2131/004/001	Powder and solvent for suspension for injection	- J07BG - J07BG01	- Inactivated Rabies Virus Strain PM/WI 38 1503 3M	Full application (Article 8(3) of Directive No 2001/83/EC)	
Raener 2 mg/0.03 mg film-coated tablets	Laboratorios Leon Farma, S.A.	PA1474/011/001	Film-coated tablet	- G03FA - G03FA15	- Dienogest micronized - Ethinylestradiol micronized	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Raloxifene Teva	Teva B.V.	EU/1/10/627/1-3	Film-coated tablet	- G03XC - G03XC01	- Raloxifene hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ramilo 1.25 mg tablets	Rowex Ltd	PA0711/063/001 Interchangeable List Code: IC0016-044-008	Tablet		- Ramipril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ramilo 10 mg Tablets	Rowex Ltd	PA0711/063/004 Interchangeable List Code: IC0016-002-008	Tablet		- Ramipril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ramilo 2.5 mg tablet	Rowex Ltd	PA0711/063/002 Interchangeable List Code: IC0016-018-008	Tablet		- Ramipril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ramilo 5 mg tablets	Rowex Ltd	PA0711/063/003 Interchangeable List Code: IC0016-001-008	Tablet		- Ramipril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ramipril Krka 1.25 mg tablets	KRKA, d.d., Novo mesto	PA1347/042/001 Interchangeable List Code: IC0016-044-008	Tablet		- Ramipril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ramipril Krka 10 mg tablets	KRKA, d.d., Novo mesto	PA1347/042/004 Interchangeable List Code: IC0016-002-008	Tablet		- Ramipril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ramipril Krka 2.5 mg tablets	KRKA, d.d., Novo mesto	PA1347/042/002 Interchangeable List Code: IC0016-018-008	Tablet		- Ramipril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ramipril Krka 5 mg tablets	KRKA, d.d., Novo mesto	PA1347/042/003 Interchangeable List Code: IC0016-001-008	Tablet		- Ramipril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ramipril Teva Pharma 1.25mg Tablets	Teva Pharma B.V.	PA0749/177/001 Interchangeable List Code: IC0016-044-008	Tablet		- Ramipril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ramipril Teva Pharma 10mg Tablets	Teva Pharma B.V.	PA0749/177/004 Interchangeable List Code: IC0016-002-008	Tablet		- Ramipril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ramipril Teva Pharma 2.5mg Tablets	Teva Pharma B.V.	PA0749/177/002 Interchangeable List Code: IC0016-018-008	Tablet		- Ramipril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ramipril Teva Pharma 5mg Tablets	Teva Pharma B.V.	PA0749/177/003 Interchangeable List Code: IC0016-001-008	Tablet		- Ramipril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ramitace 10mg Tablets	Clonmel Healthcare Ltd	PA0126/163/003 Interchangeable List Code: IC0016-002-008	Tablet		- Ramipril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ramitace 2.5mg Tablets	Clonmel Healthcare Ltd	PA0126/163/001 Interchangeable List Code: IC0016-018-008	Tablet		- Ramipril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ramitace 5 mg tablets	Clonmel Healthcare Ltd	PA0126/163/002 Interchangeable List Code: IC0016-001-008	Tablet		- Ramipril	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ramonna 1500 microgram Tablet	Gedeon Richter Plc	PA1330/021/001	Tablet	- G03AD - G03AD01	- Levonorgestrel	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ranexa	Menarini International Operations Luxembourg S.A.	EU/1/08/462/1,2,7,8	Prolonged-release tablet	- C01EB - C01EB18	- Ranolazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ranexa 500 mg prolonged-release tablets	Menarini International Operations Luxembourg S.A.	EU/1/08/462/3,4,9,10	Prolonged-release tablet	- C01EB	- Ranolazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ranexa 750 mg prolonged-release tablets	Menarini International Operations Luxembourg S.A.	EU/1/08/462/5,6,11, 12	Prolonged-release tablet	- C01EB	- Ranolazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Raniviso	Midas Pharma GmbH	EU/1/22/1673/001	Solution for injection	- S01LA04	- Ranibizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravitreal use
Ranolazine 375 mg Prolonged-release tablet	Elc Group s.r.o.	PA23245/003/001	Prolonged-release tablet	- C01EB18	- Ranolazine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ranolazine 500 mg Prolonged-release tablet	Elc Group s.r.o.	PA23245/003/002	Prolonged-release tablet	- C01EB18	- Ranolazine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ranolazine 750 mg Prolonged-release tablet	Elc Group s.r.o.	PA23245/003/003	Prolonged-release tablet	- C01EB18	- Ranolazine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ranolazine Clonmel 375 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/356/001	Prolonged-release tablet	- C01EB18	- Ranolazine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ranolazine Clonmel 500 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/356/002	Prolonged-release tablet	- C01EB18	- Ranolazine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ranolazine Clonmel 750 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/356/003	Prolonged-release tablet	- C01EB18	- Ranolazine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ranolazine Krka 375 mg prolonged release tablets	KRKA, d.d., Novo mesto	PA1347/109/001	Prolonged-release tablet	- C01EB18	- Ranolazine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ranolazine Krka 500 mg prolonged release tablets	KRKA, d.d., Novo mesto	PA1347/109/002	Prolonged-release tablet	- C01EB18	- Ranolazine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ranolazine Krka 750 mg prolonged release tablets	KRKA, d.d., Novo mesto	PA1347/109/003	Prolonged-release tablet	- C01EB18	- Ranolazine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/001	Oral solution	- L04AA - L04AA10	- Sirolimus		- Oral use
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/002	Oral solution	- L04AA	- Sirolimus		- Oral use
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/005	Oral solution	- L04AA	- Sirolimus		- Oral use
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/007	Coated tablet	- L04AA - L04AA10	- Sirolimus		- Oral use
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/008	Coated tablet	- L04AA - L04AA10	- Sirolimus		- Oral use
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/009-010	Coated tablet	- L04AA - L04AA10	- Sirolimus		- Oral use
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/013-014	Coated tablet	- L04AA - L04AA10	- Sirolimus	Not Currently Available	- Oral use
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/14	Coated tablet	- L04AA - L04AA10	- Sirolimus	Not Currently Available	- Oral use
Rapibloc 300 mg powder for solution for infusion	Orpha-Devel Handels und Vertriebs GmbH	PA1353/007/001	Powder for solution for infusion	- C07AB	- Landiolol hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Rapifen 500 micrograms/ml solution for injection or infusion	Piramal Critical Care B.V.	PA22583/001/001	Solution for injection/infusion	- N01AH - N01AH02	- ALFENTANIL HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Rapilysin	Actavis Group hf	EU/1/96/018/001	Powder and solvent for solution for injection	- B01AD - B01AD07	- Reteplase		
Rapiscan	GE Healthcare AS	EU/1/10/643/001	Solution for injection	- C01EB - C01EB21	- Regadenoson		- Intravenous use
Raporsin 4 mg prolonged-release tablets	Accord Healthcare Ireland Ltd.	PA2315/005/002 Interchangeable List Code: IC0021-008-024	Prolonged-release tablet		- Doxazosin mesilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Raporsin 8mg prolonged release tablets	Accord Healthcare Ireland Ltd.	PA2315/005/001 Interchangeable List Code: IC0021-009-024	Prolonged-release tablet		- Doxazosin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rapydan 70 mg/70 mg medicated plaster	Eurocept International BV	PA1591/001/001	Medicated plaster	- N01BB - N01BB52	- Lidocaine - Tetracaine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Cutaneous use
Rasagiline Accord 1 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/174/001 Interchangeable List Code: IC0112-039-002	Tablet		- Rasagiline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rasagiline Bluefish 1 mg tablets	Bluefish Pharmaceuticals AB	PA1436/028/001 Interchangeable List Code: IC0112-039-002	Tablet		- Rasagiline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rasagiline Clonmel 1 mg tablets	Clonmel Healthcare Ltd	PA0126/276/001 Interchangeable List Code: IC0112-039-002	Tablet		- Rasagiline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rasagiline Krka 1 mg tablets	KRKA, d.d., Novo mesto	PA1347/088/001 Interchangeable List Code: IC0112-039-002	Tablet		- Rasagiline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rasagiline Mylan 1 mg tablets	Mylan Pharmaceuticals Limited	EU/1/16/1090/001-012 Interchangeable List Code: IC0112-039-002	Tablet		- Rasagiline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rasagiline Ratiopharm 1 mg tablets	Teva B.V.	EU/1/14/977/001-007 Interchangeable List Code: IC0112-039-002	Tablet		- Rasagiline	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Rasagiline Rowex 1 mg tablets	Rowex Ltd	PA0711/264/001 Interchangeable List Code: IC0112-039-002	Tablet		- Rasagiline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rasagiline Teva 1 mg tablets	Teva B.V.	PA1986/017/001 Interchangeable List Code: IC0112-039-002	Tablet		- Rasagiline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rasilez	Noden Pharma DAC	EU/1/07/405/11-20,31-40	Film-coated tablet	- C09XA - C09XA02	- Aliskiren hemifumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ratiograstim 30 MIU/0.5 ml solution for injection	Ratiopharm GmbH	EU/1/08/444/1-4	Solution for injection/infusion	- L03AA - L03AA02	- Filgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ratiograstim 48 MIU/0.8 ml solution for injection	Ratiopharm GmbH	EU/1/08/444/5-8	Solution for injection/infusion	- L03AA - L03AA02	- Filgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Ravicti	Immedica Pharma AB	EU/1/15/1062/001-004	Oral liquid	- A16AX09	- Glycerol phenylbutyrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Raxone	Chiesi Farmaceutici S.p.A.	EU/1/15/1020/001	Film-coated tablet	- N06BX - N06BX13	- Idebenone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Rayvow	Eli Lilly Nederland B.V.	EU/1/21/1587/001-010	Film-coated tablet	- N02CC - N02CC08	- Lasmiditan Succinate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rayvow	Eli Lilly Nederland B.V.	EU/1/21/1587/011-020	Film-coated tablet	- N02CC - N02CC08	- Lasmiditan Succinate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rayvow	Eli Lilly Nederland B.V.	EU/1/21/1587/021-030	Film-coated tablet	- N02CC - N02CC08	- Lasmiditan Succinate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Razolager 15 mg hard gastro-resistant capsules	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/065/001 Interchangeable List Code: IC0008-032-033	Gastro-resistant capsule, hard		- Lansoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Razolager 30 mg hard gastro-resistant capsules	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/065/002 Interchangeable List Code: IC0008-033-033	Gastro-resistant capsule, hard		- Lansoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Razole 10 mg Gastro-resistant tablets	Rowa Pharmaceuticals Limited	PA0074/073/001 Interchangeable List Code: IC0015-002-005	Gastro-resistant tablet		- Rabeprazole sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Razole 20 mg Gastro-resistant tablets	Rowa Pharmaceuticals Limited	PA0074/073/002 Interchangeable List Code: IC0015-003-005	Gastro-resistant tablet		- Rabeprazole sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Reagila	Gedeon Richter Plc	EU/1/17/1209/001-010	Capsule, hard	- N05AX - N05AX15	- Cariprazine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Reagila	Gedeon Richter Plc	EU/1/17/1209/011-020	Capsule, hard	- N05AX - N05AX15	- Cariprazine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Reagila	Gedeon Richter Plc	EU/1/17/1209/021-028	Capsule, hard	- N05AX - N05AX15	- Cariprazine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Reagila	Gedeon Richter Plc	EU/1/17/1209/029-036	Capsule, hard	- N05AX - N05AX15	- Cariprazine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rebif	Merck Europe B.V.	EU/1/98/063/008,18	Solution for injection in cartridge	- L03AB - L03AB07	- Interferon beta-1-a		- Subcutaneous use
Rebif	Merck Europe B.V.	EU/1/98/063/009,019	Solution for injection in cartridge	- L03AB - L03AB07	- Interferon beta-1-a		- Subcutaneous use
Rebif	Merck Europe B.V.	EU/1/98/063/010	Solution for injection in cartridge	- L03AB - L03AB07	- Interferon beta-1-a		- Subcutaneous use
REBIF	Merck Europe B.V.	EU/1/98/063/017	Solution for injection in pre-filled pen	- L03AB - L03AB07	- Interferon beta - 1a		- Subcutaneous use
REBIF	Merck Europe B.V.	EU/1/98/063/001,11-13	Solution for injection in pre-filled pen	- L03AB - L03AB07	- Interferon beta - 1a		- Subcutaneous use
Rebif	Merck Europe B.V.	EU/1/98/063/002	Solution for injection in pre-filled syringe	- L03AB - L03AB07	- Interferon beta - 1a		- Subcutaneous use
Rebif	Merck Europe B.V.	EU/1/98/063/003	Solution for injection in pre-filled syringe	- L03AB - L03AB07	- Interferon beta - 1a		- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Rebif	Merck Europe B.V.	EU/1/98/063/004	Solution for injection in pre-filled syringe	- L03AB - L03AB07	- Interferon beta - 1a		- Subcutaneous use
Rebif	Merck Europe B.V.	EU/1/98/063/005	Solution for injection in pre-filled syringe	- L03AB - L03AB07	- Interferon beta - 1a		- Subcutaneous use
Rebif	Merck Europe B.V.	EU/1/98/063/006	Solution for injection in pre-filled syringe	- L03AB - L03AB07	- Interferon beta - 1a		- Subcutaneous use
Rebif Starter Pack	Merck Europe B.V.	EU/1/98/063/007	Solution for injection in pre-filled syringe	- L03AB	- Interferon beta - 1a		
Reblozyl	Bristol-Myers Squibb Pharma EEIG	EU/1/20/1452/001	Powder for solution for injection	- B03XA06	- Luspatercept	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Reblozyl	Bristol-Myers Squibb Pharma EEIG	EU/1/20/1452/002	Powder for solution for injection	- B03XA06	- Luspatercept	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Recarbrio	Merck Sharp & Dohme BV,	EU/1/19/1420/001	Powder for solution for infusion	- J01DH56	- Imipenem - Cilastatin - Relebactam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Rectogesic 4 mg/g Rectal Ointment	Kyowa Kirin Holdings B.V.	PA2288/001/003	Rectal ointment	- C05AE - C05AE01	- Glyceryl trinitrate		- Rectal use
Redoxon Double Action 1000 mg/10 mg Effervescent Tablets	Bayer Limited	PA1410/050/001	Effervescent tablet	- A11GB	- Ascorbic acid - Zinc citrate trihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
ReFacto	Pfizer Europe MA EEIG	EU/1/99/103/004	Powder and solvent for solution for injection	- B02BD - B02BD02	- Recombinant antihemophilic factor		- Intravenous use
ReFacto	Pfizer Europe MA EEIG	EU/1/99/103/002	Powder and solvent for solution for injection	- B02BD - B02BD02	- Recombinant antihemophilic factor		- Intravenous use
REFACTO AF	Pfizer Europe MA EEIG	EU/1/99/103/003	Powder and solvent for solution for injection	- B02BD - B02BD02	- Recombinant antihemophilic factor		- Intravenous use
ReFacto AF	Pfizer Europe MA EEIG	EU/1/99/103/005	Powder and solvent for solution for injection in pre-filled syringe	- B02BD - B02BD02	- Moroctocog alfa		- Intravenous use
ReFacto AF	Pfizer Europe MA EEIG	EU/1/99/103/006	Powder and solvent for solution for injection in pre-filled syringe	- B02BD - B02BD02	- Moroctocog alfa		- Intravenous use
ReFacto AF	Pfizer Europe MA EEIG	EU/1/99/103/007	Powder and solvent for solution for injection in pre-filled syringe	- B02BD - B02BD02	- Moroctocog alfa		- Intravenous use
ReFacto AF	Pfizer Europe MA EEIG	EU/1/99/103/008	Powder and solvent for solution for injection in pre-filled syringe	- B02BD - B02BD02	- Moroctocog alfa		- Intravenous use
REFACTO AF	Pfizer Europe MA EEIG	EU/1/99/103/001	Powder and solvent for solution for injection	- B02BD - B02BD02	- Recombinant antihemophilic factor		- Intravenous use
Refixia	Novo Nordisk A/S	EU/1/17/1193/001	Powder and solvent for solution for injection	- B02BD - B02BD04	- Nonacog beta pegol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Refixia	Novo Nordisk A/S	EU/1/17/1193/002	Powder and solvent for solution for injection	- B02BD - B02BD04	- Nonacog beta pegol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Refixia	Novo Nordisk A/S	EU/1/17/1193/003	Powder and solvent for solution for injection	- B02BD - B02BD04	- Nonacog beta pegol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Refixia	Novo Nordisk A/S	EU/1/17/1193/004	Powder and solvent for solution for injection	- B02BD04	- Nonacog beta pegol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
REFLAD 50 mg film-coated tablets	PRO.MED.CS Praha a.s.	PA2179/003/001	Film-coated tablet	- A03FA07	- Itopride hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Refresh Ophthalmic 1.4%w/v + 0.6%w/v Eye Drops Solution	AbbVie Limited	PA1824/013/001	Eye drops, solution	- S01XA20	- Povidone - Polyvinyl Alcohol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Regaine Extra Strength 5% w/v Cutaneous Solution	JNTL Consumer Health I (Ireland) Limited	PA23490/038/002	Cutaneous solution	- D11AX - D11AX01	- Minoxidil		- Topical use
Regaine for Men Extra Strength Scalp Foam 5% w/w Cutaneous Foam	JNTL Consumer Health I (Ireland) Limited	PA23490/018/001	Cutaneous foam	- D11AX - D11AX01	- Minoxidil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical
Regaine for Women Extra Strength Scalp Foam 5% w/w Cutaneous Foam	JNTL Consumer Health I (Ireland) Limited	PA23490/018/002	Cutaneous foam	- D11AX - D11AX01	- Minoxidil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical
Regaine for Women Regular Strength 2% w/v Cutaneous Solution	JNTL Consumer Health I (Ireland) Limited	PA23490/038/001	Cutaneous solution	- D11AX - D11AX01	- Minoxidil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Regiocit Solution for haemofiltration	Baxter Holding B.V.	PA2299/054/001	Solution for haemofiltration	- B05ZB	- Sodium citrate - Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Regkirona	Celltrion Healthcare Hungary Kft.	EU/1/21/1597/001	Concentrate for solution for infusion	- J06BD06	- Regdanvimab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Regurin 20 mg coated tablets	Viatris Healthcare Limited	PA23355/005/001	Coated tablet	- G04BD - G04BD09	- Trospium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Regurin 20 mg coated tablets	IMED Healthcare Ltd.	PPA1463/143/001	Coated tablet	- G04BD - G04BD09	- Trospium chloride	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Regurin 20 mg coated tablets	PCO Manufacturing Ltd.	PPA0465/281/001	Coated tablet	- G04BD09	- Trospium chloride		- Oral use
REKAMBYS	Janssen-Cilag International NV	EU/1/20/1482/001	Prolonged-release suspension for injection	- J05AG05	- Rilpivirine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
REKAMBYS	Janssen-Cilag International NV	EU/1/20/1482/002	Prolonged-release suspension for injection	- J05AG - J05AG05	- Rilpivirine	Full application (Article 8(3) of Directive No 2001/83/EC)	
Rekovelle	Ferring Pharmaceuticals A/S	EU/1/16/1150/004	Solution for injection	- G03GA - G03GA10	- Follitropin delta	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Rekovelle	Ferring Pharmaceuticals A/S	EU/1/16/1150/005	Solution for injection	- G03GA - G03GA10	- Follitropin delta	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Rekovelle	Ferring Pharmaceuticals A/S	EU/1/16/1150/006	Solution for injection	- G03GA - G03GA10	- Follitropin delta	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Relenza 5mg/dose, inhalation powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/011/001	Inhalation powder, pre-dispensed	- J05AH01	- Zanamivir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Relestat, 0.5 mg/ml, eye drops, solution	AbbVie Limited	PA1824/018/001	Eye drops, solution	- S01GX - S01GX10	- Epinastine hydrochloride		- Ocular use
Reletrans 10 micrograms/hour Transdermal Patches	Rowex Ltd	PA0711/236/002	Transdermal patch	- N02AE - N02AE01	- Buprenorphine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Transdermal use
Reletrans 15 micrograms/hour Transdermal Patches	Rowex Ltd	PA0711/236/003	Transdermal patch	- N02AE - N02AE01	- Buprenorphine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Transdermal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Reletrans 20 micrograms/hour Transdermal Patches	Rowex Ltd	PA0711/236/004	Transdermal patch	- N02AE - N02AE01	- Buprenorphine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Transdermal use
Reletrans 5 micrograms/hour Transdermal Patches	Rowex Ltd	PA0711/236/001	Transdermal patch	- N02AE - N02AE01	- Buprenorphine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Transdermal use
Relifex 1g film-coated tablets	Mylan IRE Healthcare Limited	PA2010/036/002	Film-coated tablet	- M01AX - M01AX01	- Nabumetone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Relifex 500 mg film-coated Tablets	Mylan IRE Healthcare Limited	PA2010/036/001	Film-coated tablet	- M01AX - M01AX01	- Nabumetone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Relistor	Bausch Health Ireland Limited	EU/1/08/463/004-008	Solution for injection in pre-filled syringe	- A06AH - A06AH01	- Methylnaltrexone bromide		
RELISTOR	Bausch Health Ireland Limited	EU/1/08/463/1-3	Solution for injection	- A06AH - A06AH01	- Methylnaltrexone bromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Relistor	Bausch Health Ireland Limited	EU/1/08/463/8-11	Solution for injection in pre-filled syringe	- A06AH - A06AH01	- Methylnaltrexone bromide		
Relpax 40 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/491/001	Film-coated tablet	- N02CC06	- ELETRIPTAN		- Oral use
RELPAX 40 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/009/001	Film-coated tablet	- N02CC - N02CC06	- ELETRIPTAN		- Oral use
RELPAX 40mg film-coated tablets	Upjohn EESV	PA23055/002/002	Film-coated tablet	- N02CC - N02CC06	- ELETRIPTAN	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Relvar Ellipta	GlaxoSmithKline (Ireland) Limited	EU/1/13/886/001-003	Inhalation powder, pre-dispensed	- R03AK10	- Fluticasone furoate micronised - Vilanterol trifenatate micronised	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Relvar Ellipta	GlaxoSmithKline (Ireland) Limited	EU/1/13/886/004-006	Inhalation powder, pre-dispensed	- R03AK10	- Fluticasone furoate micronised - Vilanterol trifenatate micronised	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Remegel 800 mg Chewable Tablets	Reckitt Benckiser Ireland Ltd	PA0979/077/001	Chewable tablet	- A02AC - A02AC01	- Calcium carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Remicade	Janssen Biologics B.V.	EU/1/99/116/001-5	Powder for concentrate for solution for infusion	- L04AB - L04AB02	- Infliximab		- Intravenous use
Remifentanil 1 mg powder for concentrate for solution for injection or infusion	Fresenius Kabi Deutschland GmbH	PA2059/056/001	Powder for concentrate for solution for injection/infusion	- N01AH - N01AH06	- Remifentanil	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Remifentanil 2 mg powder for concentrate for solution for injection or infusion	Fresenius Kabi Deutschland GmbH	PA2059/056/002	Powder for concentrate for solution for injection/infusion	- N01AH - N01AH06	- Remifentanil	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Remifentanil 5 mg powder for concentrate for solution for injection or infusion	Fresenius Kabi Deutschland GmbH	PA2059/056/003	Powder for concentrate for solution for injection/infusion	- N01AH - N01AH06	- Remifentanil	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Remifentanil Noridem 1 mg powder for concentrate for solution for injection or infusion	Noridem Enterprises Limited	PA1122/014/001	Powder for concentrate for solution for injection/infusion	- N01AH - N01AH06	- Remifentanil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Remifentanil Noridem 2 mg powder for concentrate for solution for injection or infusion	Noridem Enterprises Limited	PA1122/014/002	Powder for concentrate for solution for injection/infusion	- N01AH - N01AH06	- Remifentanil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Remifentanil Noridem 5 mg powder for concentrate for solution for injection or infusion	Noridem Enterprises Limited	PA1122/014/003	Powder for concentrate for solution for injection/infusion	- N01AH - N01AH06	- Remifentanil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
REMINYL 4 mg/ml oral solution	Originalis B.V.	PPA2306/012/001	Oral solution	- N06DA04	- Galantamine		- Oral use
REMINYL 4 mg/ml oral solution	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/003/001	Oral solution	- N06DA - N06DA04	- Galantamine hydrobromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
REMINYL XL 16 mg prolonged-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/003/003	Prolonged-release capsule, hard	- N06DA - N06DA04	- Galantamine hydrobromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Reminyl XL 16 mg prolonged-release capsules, hard	Originalis B.V.	PPA2306/008/001	Prolonged-release capsule, hard	- N06DA04	- Galantamine		- Oral use
Reminyl XL 16 mg prolonged-release capsules, hard	PCO Manufacturing Ltd.	PPA0465/166/004	Prolonged-release capsule, hard	- N06DA - N06DA04	- GALANTAMINE HYDROBROMIDE		- Oral use
Reminyl XL 24 mg prolonged-release capsules, hard	PCO Manufacturing Ltd.	PPA0465/166/003	Prolonged-release capsule, hard	- N06DA - N06DA04	- Galantamine		- Oral use
Reminyl XL 24 mg prolonged-release capsules, hard	Originalis B.V.	PPA2306/009/001	Prolonged-release capsule, hard	- N06DA - N06DA04	- Galantamine		- Oral use
REMINYL XL 24 mg prolonged-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/003/004	Prolonged-release capsule, hard	- N06DA - N06DA04	- Galantamine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
REMINYL XL 8 mg prolonged-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/003/002	Prolonged-release capsule, hard	- N06DA - N06DA04	- Galantamine hydrobromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Reminyl XL 8 mg prolonged-release capsules, hard	PCO Manufacturing Ltd.	PPA0465/166/002	Prolonged-release capsule, hard	- N06DA - N06DA04	- Galantamine		- Oral use
Remsima	Celltrion Healthcare Hungary Kft.	EU/1/13/853/001	Powder for concentrate for solution for infusion	- L04AB - L04AB02	- Infliximab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Remsima	Celltrion Healthcare Hungary Kft.	EU/1/13/853/006-011	Solution for injection in pre-filled syringe	- L04AB02	- Infliximab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Remsima	Celltrion Healthcare Hungary Kft.	EU/1/13/853/012-014	Solution for injection in pre-filled pen	- L04AB02	- Infliximab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Renagel	Genzyme Europe B.V.	EU/1/99/123/005	Film-coated tablet	- V03AE	- Sevelamer		- Oral use
Renagel	Genzyme Europe B.V.	EU/1/99/123/006	Film-coated tablet	- V03AE02	- Sevelamer		- Oral use
Renagel	Genzyme Europe B.V.	EU/1/99/123/007	Film-coated tablet	- V03AE02	- Sevelamer		- Oral use
Renagel	Genzyme Europe B.V.	EU/1/99/123/008	Film-coated tablet	- V03AE	- Sevelamer		- Oral use
Renagel	Genzyme Europe B.V.	EU/1/99/123/009	Film-coated tablet	- V03AE02	- Sevelamer		- Oral use
Renagel	Genzyme Europe B.V.	EU/1/99/123/010	Film-coated tablet	- V03AE02	- Sevelamer		- Oral use
RENAGEL	Genzyme Europe B.V.	EU/1/99/123/011	Tablets	- V03AE02	- SEVELAMER		
Renagel	Genzyme Europe B.V.	EU/1/99/123/011-013	Film-coated tablet		- Sevelamer		

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Rennie 750 mg Medicated Chewing Gum	Bayer Limited	PA1410/089/001	Medicated chewing-gum	- A02AC01	- Calcium carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Rennie Deflatine Chewable Tablets Calcium Carbonate 680mg Magnesium Carbonate 80mg Simeticone 25mg	Bayer Limited	PA1410/051/001	Chewable tablet	- A02AA01 - A02AC01 - A02AX - A03AX13	- Calcium carbonate - Magnesium carbonate - Simeticone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rennie Dual Action Chewable Tablets Calcium carbonate 625mg Magnesium carbonate 73.5mg Alginic acid 150mg	Bayer Limited	PA1410/052/003	Chewable tablet	- A02AD	- Alginic acid - Calcium carbonate - Magnesium carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Rennie ICE 680 mg/ 80 mg Chewable Tablets	Bayer Limited	PA1410/053/004	Chewable tablet	- A01AC01 - A02AA01 - A02AX	- Calcium carbonate - Heavy magnesium carbonate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rennie Orange 500mg Chewable Tablets	Bayer Limited	PA1410/054/001	Chewable tablet	- A02AC01	- Calcium carbonate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rennie Peppermint 680mg/80mg Chewable Tablets	Bayer Limited	PA1410/053/001	Chewable tablet	- A02AA01 - A02AC01 - A02AX	- Calcium carbonate - Magnesium carbonate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rennie Spearmint 680mg / 80mg Chewable tablets	Bayer Limited	PA1410/053/002	Chewable tablet	- A02AA01 - A02AC01 - A02AX	- Calcium carbonate - Magnesium carbonate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rennie Sugar Free 680mg / 80mg Chewable tablets	Bayer Limited	PA1410/053/003	Chewable tablet	- A02AD - A02AD01	- Magnesium carbonate - Calcium carbonate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
RENOCIS 1 mg kit for radiopharmaceutical preparation	CIS bio International	PA0677/005/001	Kit for radiopharmaceutical preparation	- V09CA - V09CA02	- Dimercaptosuccinic acid		
Renvela	Genzyme Europe B.V.	EU/1/09/521/008	Powder for oral suspension	- V03AB02	- Sevelamer carbonate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Renvela	Genzyme Europe B.V.	EU/1/09/521/1-3	Film-coated tablet	- V03AE - V03AE02	- Sevelamer carbonate		- Oral use
Renvela	Genzyme Europe B.V.	EU/1/09/521/4-5	Powder for oral suspension	- V03AE - V03AE02	- Sevelamer carbonate		- Oral use
Renvela	Genzyme Europe B.V.	EU/1/09/521/6-7	Powder for oral suspension	- V03AE - V03AE02	- Sevelamer carbonate		- Oral use
Repaglinide Accord	Accord Healthcare S.L.U.	EU/1/11/743/001-005	Tablet	- A10BX - A10BX02	- Repaglinide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Repaglinide Accord	Accord Healthcare S.L.U.	EU/1/11/743/006-010	Tablet	- A10BX - A10BX02	- Repaglinide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Repaglinide Accord	Accord Healthcare S.L.U.	EU/1/11/743/011-015	Tablet	- A10BX - A10BX02	- Repaglinide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
REPAGLINIDE KRKA	Krka d.d., Novo mesto	EU/1/09/579/13-18	Tablet	- A10BX02	- REPAGLINIDE	Article 10(1) - Generic Application	- Oral use
REPAGLINIDE KRKA	Krka d.d., Novo mesto	EU/1/09/579/1-6	Tablet	- A10BX02	- REPAGLINIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
REPAGLINIDE KRKA	Krka d.d., Novo mesto	EU/1/09/579/7-12	Tablet	- A10BX02	- REPAGLINIDE	Article 10(1) - Generic Application	- Oral use
REPAGLINIDE TEVA	Teva B.V.	EU/1/09/530/11-15	Tablet	- A10BX02	- REPAGLINIDE	Article 10(1) - Generic Application	- Oral use
REPAGLINIDE TEVA	Teva B.V.	EU/1/09/530/1-5	Tablet	- A10BX02	- REPAGLINIDE	Article 10(1) - Generic Application	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
REPAGLINIDE TEVA	Teva Pharma B.V.	EU/1/09/530/6-10	Tablet	- A10BX02	- REPAGLINIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Repatha	Amgen Europe B.V.	EU/1/15/1016/001-005	Solution for injection	- C10A	- Evolocumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Repatha	Amgen Europe B.V.	EU/1/15/1016/006-007	Solution for injection	- C10AX - C10AX13	- Evolocumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
REPEVAX, suspension for injection, in pre-filled syringe Diphtheria, Tetanus, Pertussis (acellular, component) and Poliomyelitis (inactivated) Vaccine (adsorbed, reduced antigen(s) content)	Sanofi Pasteur	PA2131/006/001	Suspension for injection in pre-filled syringe	- J07CA - J07CA02	- Tetanus toxoid - Diphtheria toxoid - Pertussis toxoid - Filamentous haemagglutinin - Pertactin - Polio virus type 1 inactivated - Polio virus type 2 inactivated - Polio virus type 3 inactivated - Adsorbed aluminium phosphate - Adsorbed fimbriae types 2 + 3	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
REPLAGAL 1MG/ML	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/01/189/001	Concentrate for solution for infusion	- A16AB - A16AB03	- Agalsidase alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
REPSO	Teva B.V.	EU/1/11/674/006-010	Film-coated tablet	- L04AA13	- LEFLUNOMIDE	Article 10(1) - Generic Application	- Oral use
Requip 0.25 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/037/001	Film-coated tablet	- N04BC - N04BC04	- Ropinirole hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Requip 1 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/037/003	Film-coated tablet	- N04BC - N04BC04	- Ropinirole hydrochloride		- Oral use
Requip 2 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/037/004	Film-coated tablet	- N04BC - N04BC04	- Ropinirole hydrochloride		- Oral use
Requip 5 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/037/005	Film-coated tablet	- N04BC - N04BC04	- Ropinirole hydrochloride		- Oral use
Requip-Modutab 2 mg Prolonged-Release Tablets	GlaxoSmithKline (Ireland) Limited	PA1077/037/006	Prolonged-release tablet	- N04BC - N04BC04	- Ropinirole hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Requip-Modutab 2 mg Prolonged-Release Tablets	PCO Manufacturing Ltd.	PPA0465/279/002	Prolonged-release tablet	- N04BC - N04BC04	- Ropinirole hydrochloride		- Oral use
Requip-Modutab 2 mg Prolonged-Release Tablets	IMED Healthcare Ltd.	PPA1463/163/001	Prolonged-release tablet	- N04BC04	- Ropinirole		- Oral use
Requip-Modutab 4 mg Prolonged-Release Tablets	IMED Healthcare Ltd.	PPA1463/163/002	Prolonged-release tablet	- N04BC04	- Ropinirole		- Oral use
Requip-Modutab 4 mg prolonged-release tablets	Originalis B.V.	PPA2306/002/002	Prolonged-release tablet	- N04BC04	- Ropinirole		- Oral use
Requip-Modutab 4 mg Prolonged-Release Tablets	PCO Manufacturing Ltd.	PPA0465/279/003	Prolonged-release tablet	- N04BC - N04BC04	- Ropinirole hydrochloride		- Oral use
Requip-Modutab 4 mg Prolonged-Release Tablets	GlaxoSmithKline (Ireland) Limited	PA1077/037/008	Prolonged-release tablet	- N04BC - N04BC04	- Ropinirole hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Requip-Modutab 8 mg Prolonged-Release Tablets	GlaxoSmithKline (Ireland) Limited	PA1077/037/009	Prolonged-release tablet	- N04BC - N04BC04	- Ropinirole hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Requip-Modutab 8 mg prolonged-release tablets	Originalis B.V.	PPA2306/002/001	Prolonged-release tablet	- N04BC04	- Ropinirole		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Requip-Modutab 8 mg Prolonged-Release Tablets	IMED Healthcare Ltd.	PPA1463/163/003	Prolonged-release tablet	- N04BC04	- Ropinirole		- Oral use
Requip-Modutab 8mg Prolonged-Release Tablets	PCO Manufacturing Ltd.	PPA0465/279/001	Prolonged-release tablet	- N04BC - N04BC04	- Ropinirole hydrochloride		- Oral use
Resolor 1 mg film-coated tablets	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/09/581/001 Interchangeable List Code: IC0122-039-003	Film-coated tablet		- Prucalopride Succinate		- Oral use
Resolor 2 mg film-coated tablets	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/09/581/002 Interchangeable List Code: IC0122-006-003	Film-coated tablet		- Prucalopride Succinate		- Oral use
Respreeza	CSL Behring GmbH	EU/1/15/1006/001	Powder and solvent for solution for injection	- B02AB - B02AB02	- Human alpha1-proteinase inhibitor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Retacrit	Pfizer Europe MA EEIG	EU/1/07/431/1-6	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Epoetin zeta	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Retacrit	Pfizer Europe MA EEIG	EU/1/07/431/17-19	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Epoetin zeta	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Retacrit	Pfizer Europe MA EEIG	EU/1/07/431/7-16	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Epoetin zeta	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Retrovir 10 mg/ml IV concentrate for solution for infusion	ViiV Healthcare BV	PA22575/001/003	Concentrate for solution for infusion	- J05AF - J05AF01	- Zidovudine		- Intravenous use
Retrovir 100 mg capsules, hard	ViiV Healthcare BV	PA22575/001/001	Capsule, hard	- J05AF - J05AF01	- Zidovudine		- Oral use
Retrovir 100 mg/10 ml oral solution	ViiV Healthcare BV	PA22575/001/002	Oral solution	- J05AF - J05AF01	- Zidovudine		- Oral use
Retsevmo	Eli Lilly Nederland B.V.	EU/1/20/1527/001	Capsule, hard	- L01 - L01EX22	- Selpercatinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Retsevmo	Eli Lilly Nederland B.V.	EU/1/20/1527/002-003	Capsule, hard	- L01EX22	- Selpercatinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Revatio	Upjohn EESV	EU/1/05/318/001 Interchangeable List Code: IC0063-003-003	Film-coated tablet		- Sildenafil		- Oral use
Revatio	Upjohn EESV	EU/1/05/318/002	Solution for injection	- G04BE - G04BE03	- Sildenafil citrate for parenteral use		- Intravenous use
Revatio	Upjohn EESV	EU/1/05/318/003	Powder for oral suspension	- G04BE - G04BE03	- Sildenafil citrate		- Oral use
REVAXIS Suspension for injection in pre-filled syringe Diphtheria, tetanus and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content)	Sanofi Pasteur	PA2131/007/001	Suspension for injection in pre-filled syringe	- J07CA - J07CA01	- Diphtheria toxoid - Tetanus toxoid - POLIOVIRUS, TYPE 1 - Poliovirus, type 2 - Poliovirus, type 3	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Revestive	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/12/787/001	Powder and solvent for solution for injection	- A16AX - A16AX08	- Teduglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Revestive	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/12/787/003	Powder and solvent for solution for injection	- A16AX - A16AX08	- Teduglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Revinty Ellipta	GlaxoSmithKline (Ireland) Limited	EU/1/14/929/001-003	Inhalation powder, pre-dispensed	- R03AK10	- Fluticasone furoate micronised - Vilanterol	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Inhalation use
Revinty Ellipta	GlaxoSmithKline (Ireland) Limited	EU/1/14/929/004-006	Inhalation powder, pre-dispensed	- R03AK - R03AK10	- Fluticasone furoate micronised - Vilanterol	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Inhalation use
Revlimid 10 mg hard capsules	Bristol-Myers Squibb Pharma EEIG	EU/1/07/391/002 Interchangeable List Code: IC0125-002-001	Capsule, hard		- Lenalidomide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Revlimid 15 mg hard capsules	Bristol-Myers Squibb Pharma EEIG	EU/1/07/391/003 Interchangeable List Code: IC0125-032-001	Capsule, hard		- Lenalidomide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Revlimid 2.5 mg hard capsules	Bristol-Myers Squibb Pharma EEIG	EU/1/07/391/005 Interchangeable List Code: IC0125-018-001	Capsule, hard		- Lenalidomide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Revlimid 20 mg hard capsules	Bristol-Myers Squibb Pharma EEIG	EU/1/07/391/009 Interchangeable List Code: IC0125-003-001	Capsule, hard		- Lenalidomide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Revlimid 25 mg hard capsules	Bristol-Myers Squibb Pharma EEIG	EU/1/07/391/004 Interchangeable List Code: IC0125-022-001	Capsule, hard		- Lenalidomide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Revlimid 5 mg hard capsules	Bristol-Myers Squibb Pharma EEIG	EU/1/07/391/001 Interchangeable List Code: IC0125-001-001	Capsule, hard		- Lenalidomide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Revlimid 7.5 mg hard capsules	Bristol-Myers Squibb Pharma EEIG	EU/1/07/391/006 Interchangeable List Code: IC0125-041-001	Capsule, hard		- Lenalidomide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Revolade	Novartis Europharm Limited	EU/1/10/612/007-009	Film-coated tablet	- B02BX - B02BX05	- Eltrombopag (sb-497115)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Revolade	Novartis Europharm Limited	EU/1/10/612/013	Powder for oral suspension	- B02BX - B02BX05	- Eltrombopag olamine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Revolade	Novartis Europharm Limited	EU/1/10/612/1-3	Film-coated tablet	- B02BX - B02BX05	- Eltrombopag olamine		- Oral use
Revolade	Novartis Europharm Limited	EU/1/10/612/4-6	Film-coated tablet	- B02BX - B02BX05	- Eltrombopag olamine		- Oral use
Reyataz	Bristol-Myers Squibb Pharma EEIG	EU/1/03/267/012	Oral powder	- J05AE - J05AE08	- Atazanavir sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Reyataz	Bristol-Myers Squibb Pharma EEIG	EU/1/03/267/01-7	Capsule, hard	- J05AE - J05AE08	- Atazanavir		- Oral use
Reyataz	Bristol-Myers Squibb Pharma EEIG	EU/1/03/267/8-9	Capsule, hard	- J05AE - J05AE08	- Atazanavir sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
REZOLSTA	Janssen-Cilag International NV	EU/1/14/967/001	Film-coated tablet	- J05AR - J05AR14	- Darunavir - Cobicistat	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Rezzayo	Mundipharma GmbH	EU/1/23/1775/001	Powder for concentrate for solution for infusion	- J02AX08	- Rezafungin acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Rhinaspray 21 micrograms per metered dose, Nasal Spray Solution	Opella Healthcare France SAS T/A Sanofi	PA23180/021/001	Nasal spray, solution	- R01AX - R01AX03	- Ipratropium bromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Rhinex Relief 50 micrograms/actuation Nasal spray, suspension	Rowex Ltd	PA0711/279/001	Nasal spray, suspension	- R01AD - R01AD09	- Mometasone furoate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Nasal use
Rhinolast 140 micrograms per Spray, Nasal Spray	Mylan IRE Healthcare Limited	PA2010/037/001	Nasal spray, solution	- R01AC - R01AC03	- Azelastine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intranasal use
Rhinolast Hayfever 140 micrograms per spray, nasal spray solution	Mylan IRE Healthcare Limited	PA2010/037/002	Nasal spray, solution	- R01AC - R01AC03	- Azelastine hydrochloride		- Intranasal use
Rhinolast S nasal spray, solution	Mylan IRE Healthcare Limited	PA2010/037/003	Nasal spray, solution	- R01AC - R01AC03	- Azelastine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Rhokiinsa	Santen OY	EU/1/19/1400/001	Eye drops, solution	- S01EX05	- NETARSUDIL MESILATE - NETARSUDIL	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Rhophylac 300 micrograms / 2 ml, solution for injection in pre-filled syringe	CSL Behring GmbH	PA0800/006/002	Solution for injection in pre-filled syringe	- J06BB - J06BB01	- Human anti-D immunoglobulin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Rhus tox	A. Nelson & Company Limited	HOR1149/025/001	Not assigned		- Rhus toxicodendron		- Oral use
Riarify	Chiesi Farmaceutici S.p.A.	EU/1/18/1275/001-005	Pressurised inhalation, solution	- R03AL - R03AL09	- Beclometasone dipropionate - Formoterol fumarate dihydrate - GLYCLOPYRAMIDUM	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Inhalation use
Riastap 1 g Powder for Solution for Injection / Infusion	CSL Behring GmbH	PA0800/007/001	Powder for solution for injection/infusion	- B02BB - B02BB01	- Human fibrinogen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ridate Once a Week 35mg film-coated tablets	Rowex Ltd	PA0711/189/001 Interchangeable List Code: IC0068-124-003	Film-coated tablet		- Risedronate sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ridate Plus Ca & D 35 mg Film-Coated Tablets + 1000 mg/880 IU Effervescent Tablets	Rowex Ltd	PA0711/191/001	Effervescent tablet + film-coated tablet	- M05BB - M05BB04	- Calcium carbonate - Cholecalciferol - Risedronate sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ridonex 10 mg orodispersible tablets	Clonmel Healthcare Ltd	PA0126/291/001	Orodispersible tablet	- A03FA - A03FA03	- Domperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rifadin 100 mg/5 ml Oral Suspension	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/066/004	Oral suspension	- J04AB - J04AB02	- Rifampicin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rifadin 150mg Capsules	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/066/001	Capsule, hard	- J04AB - J04AB02	- Rifampicin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rifadin 300mg Capsules	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/066/002	Capsule, hard	- J04AB - J04AB02	- Rifampicin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rifadin Intravenous 600mg Powder and Solvent for Concentrate for Solution for Infusion	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/066/003	Powder and solvent for concentrate for solution for infusion	- J04AB - J04AB02	- Rifampicin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Rifater 50 mg/300 mg/120 mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/067/001	Tablet	- J04AM - J04AM05	- Isoniazid - Pyrazinamide - Rifampicin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rifaximin Alfasigma 550 mg film-coated tablets	Alfasigma S.p.A	PA2206/001/001	Film-coated tablet	- A07AA - A07AA11	- Rifaximin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rifinah 150/100 mg Film- Coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/068/001	Film-coated tablet	- J04AM - J04AM02	- Rifampicin - Isoniazid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rifinah 300 / 150 mg Film Coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/068/002	Film-coated tablet	- J04AM - J04AM02	- Rifampicin - Isoniazid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Riltrava Aerosphere	AstraZeneca AB	EU/1/21/1604/001-002	Pressurised inhalation, suspension	- R03AL11	- Formoterol fumarate dihydrate - Glycopyrronium bromide - Budesonide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Inhalation use
Rilutek	Sanofi Winthrop Industrie	EU/1/96/010/001	Tablet	- N07XX - N07XX02	- Riluzole	Full application (Article 8(3) of Directive No 2001/83/EC)	
Riluzole Zentiva	Aventis Pharma S.A.	EU/1/12/768/001	Film-coated tablet	- N07XX - N07XX02	- Riluzole	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Rimicorim 300mg Capsules	Brown & Burk IR Limited	PA23148/001/001	Capsule, hard	- J01AA - J01AA04	- Lymecycline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ringer's Solution for Infusion, Viaflo container	Baxter Holding B.V.	PA2299/011/001	Solution for infusion	- B05BB - B05BB01	- Sodium chloride - Potassium chloride - Calcium chloride dihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Rinozal 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/179/001 Interchangeable List Code: IC0095-001-003	Film-coated tablet		- Levocetirizine dihydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Rinvoq	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1404/001-005	Prolonged-release tablet	- L04AA - L04AA44	- UPADACITINIB - Upadacitinib Hemihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
RINVOQ	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1404/006-009	Prolonged-release tablet	- L04AA - L04AA44	- Upadacitinib Hemihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
RINVOQ	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1404/010-011	Prolonged-release tablet	- L04AA - L04AA44	- Upadacitinib Hemihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Risedronate Bluefish Once a Week 35 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/017/001 Interchangeable List Code: IC0068-124-003	Film-coated tablet		- Risedronate sodium hemipentahydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Risedronate Sodium Accord Once A Week 35 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/140/003 Interchangeable List Code: IC0068-124-003	Film-coated tablet		- Risedronate sodium		- Oral use
Risedronate Sodium Accord Once a Week 35 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/165/001 Interchangeable List Code: IC0068-124-003	Film-coated tablet		- Risedronate sodium	ZZZ PPA	- Oral use
Risonate Once Weekly 35 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/064/001 Interchangeable List Code: IC0068-124-003	Film-coated tablet		- Risedronate sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Risontel Once a week 35mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/197/001 Interchangeable List Code: IC0068-124-003	Film-coated tablet		- Risedronate sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
RISPERDAL 0.5 mg film-coated tablets	Janssen Sciences Ireland UC	PA22612/010/009 Interchangeable List Code: IC0012-040-003	Film-coated tablet		- Risperidone		- Oral use
RISPERDAL 1 mg film-coated tablets	Janssen Sciences Ireland UC	PA22612/010/004 Interchangeable List Code: IC0012-039-003	Film-coated tablet		- Risperidone		- Oral use
RISPERDAL 1 mg/ml oral solution	Janssen Sciences Ireland UC	PA22612/010/001 Interchangeable List Code: IC0012-047-019	Oral solution		- Risperidone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
RISPERDAL 1 mg/ml oral solution	Originalis B.V.	PPA2306/007/001 Interchangeable List Code: IC0012-047-019	Oral solution		- Risperidone		- Oral use
RISPERDAL 2 mg film-coated tablets	Janssen Sciences Ireland UC	PA22612/010/005 Interchangeable List Code: IC0012-006-003	Film-coated tablet		- Risperidone		- Oral use
RISPERDAL 3 mg film-coated tablets	Janssen Sciences Ireland UC	PA22612/010/006 Interchangeable List Code: IC0012-045-003	Film-coated tablet		- Risperidone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
RISPERDAL 4 mg film-coated tablets	Janssen Sciences Ireland UC	PA22612/010/007 Interchangeable List Code: IC0012-008-003	Film-coated tablet		- Risperidone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
RISPERDAL 6 mg film-coated tablets	Janssen Sciences Ireland UC	PA22612/010/002 Interchangeable List Code: IC0012-046-003	Film-coated tablet		- Risperidone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
RISPERDAL CONSTA 25 mg powder and solvent for prolonged-release suspension for injection	Janssen Sciences Ireland UC	PA22612/010/010 Interchangeable List Code: IC0012-022-065	Powder and solvent for prolonged-release suspension for injection		- Risperidone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
RISPERDAL CONSTA 37.5 mg powder and solvent for prolonged-release suspension for injection	Janssen Sciences Ireland UC	PA22612/010/011 Interchangeable List Code: IC0012-063-065	Powder and solvent for prolonged-release suspension for injection		- Risperidone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
RISPERDAL CONSTA 50 mg powder and solvent for prolonged-release suspension for injection	Janssen Sciences Ireland UC	PA22612/010/012 Interchangeable List Code: IC0012-023-065	Powder and solvent for prolonged-release suspension for injection		- Risperidone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Risperidone 0.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/175/001 Interchangeable List Code: IC0012-040-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Risperidone 1 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/175/002 Interchangeable List Code: IC0012-039-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Risperidone 1mg/ml Oral Solution	Pinewood Laboratories Ltd	PA0281/248/001 Interchangeable List Code: IC0012-047-019	Oral solution		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Risperidone 1mg/ml Oral Solution	Chanelle Medical Unlimited Company	PA0688/006/008 Interchangeable List Code: IC0012-047-019	Oral solution		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Risperidone 2 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/175/003 Interchangeable List Code: IC0012-006-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Risperidone 3 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/175/004 Interchangeable List Code: IC0012-045-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Risperidone 4 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/175/005 Interchangeable List Code: IC0012-008-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Risperidone 6 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/175/006 Interchangeable List Code: IC0012-046-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Risperidone Grindeks 0.5 mg film-coated tablets	AS Grindeks	PA22992/021/001 Interchangeable List Code: IC0012-040-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Risperidone Grindeks 1 mg film-coated tablets	AS Grindeks	PA22992/021/002 Interchangeable List Code: IC0012-039-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Risperidone Grindeks 2 mg film-coated tablets	AS Grindeks	PA22992/021/003 Interchangeable List Code: IC0012-006-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Risperidone Grindeks 3 mg film-coated tablets	AS Grindeks	PA22992/021/004 Interchangeable List Code: IC0012-045-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Risperidone Grindeks 4 mg film-coated tablets	AS Grindeks	PA22992/021/005 Interchangeable List Code: IC0012-008-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Risperidone Grindeks 6 mg film-coated tablets	AS Grindeks	PA22992/021/006 Interchangeable List Code: IC0012-046-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rispeva 0.5 mg film-coated tablets	Teva B.V.	PA1986/021/001 Interchangeable List Code: IC0012-040-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rispeva 1 mg film-coated tablets	Teva Pharma B.V.	PA0749/049/007 Interchangeable List Code: IC0012-039-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rispeva 2 mg film-coated tablets	Teva Pharma B.V.	PA0749/049/008 Interchangeable List Code: IC0012-006-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Rispeva 3 mg film-coated tablets	Teva Pharma B.V.	PA0749/049/009 Interchangeable List Code: IC0012-045-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rispeva 4 mg film-coated tablets	Teva Pharma B.V.	PA0749/049/010 Interchangeable List Code: IC0012-008-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rispone 0.5 mg film-coated tablets	Rowex Ltd	PA0711/106/002 Interchangeable List Code: IC0012-040-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rispone 1 mg film-coated tablets	Rowex Ltd	PA0711/106/006 Interchangeable List Code: IC0012-039-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rispone 1 mg/ml oral solution	Rowex Ltd	PA0711/106/001 Interchangeable List Code: IC0012-047-019	Oral solution		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rispone 2 mg film-coated tablets	Rowex Ltd	PA0711/106/007 Interchangeable List Code: IC0012-006-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rispone 3 mg film-coated tablets	Rowex Ltd	PA0711/106/008 Interchangeable List Code: IC0012-045-003	Film-coated tablet		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ristaben 100 mg film-coated tablets	Merck Sharp & Dohme BV,	EU/1/10/621/13-18 Interchangeable List Code: IC0131-024-003	Film-coated tablet		- Sitagliptin as monohydrate phosphate salt	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Ristaben 25 mg film-coated tablets	Merck Sharp & Dohme BV	EU/1/10/621/1-6 Interchangeable List Code: IC0131-022-003	Film-coated tablet		- Sitagliptin as monohydrate phosphate salt	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Ristaben 50 mg film-coated tablets	Merck Sharp & Dohme BV,	EU/1/10/621/7-12 Interchangeable List Code: IC0131-023-003	Film-coated tablet		- Sitagliptin as monohydrate phosphate salt	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Ristfor	Merck Sharp & Dohme BV,	EU/1/10/620/009-016 Interchangeable List Code: IC0070-122-003	Film-coated tablet		- Metformin Hydrochloride - Sitagliptin phosphate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Ristfor	Merck Sharp & Dohme BV	EU/1/10/620/1-8 Interchangeable List Code: IC0070-121-003	Film-coated tablet		- Metformin Hydrochloride - Sitagliptin phosphate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Ristfor	Merck Sharp & Dohme BV,	EU/1/10/620/9-16 Interchangeable List Code: IC0070-122-003	Film-coated tablet		- Metformin Hydrochloride - Sitagliptin phosphate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Ritalin 10mg Tablets	InfectoPharm Arzneimittel und Consilium GmbH	PA1972/002/001	Tablet	- N06BA - N06BA04	- Methylphenidate hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	
Ritalin LA 20mg prolonged-release capsules	InfectoPharm Arzneimittel und Consilium GmbH	PA1972/002/002	Prolonged-release capsule, hard	- N06BA - N06BA04	- Methylphenidate hydrochloride		- Oral use
Ritalin LA 30mg prolonged-release capsules	InfectoPharm Arzneimittel und Consilium GmbH	PA1972/002/003	Prolonged-release capsule, hard	- N06BA - N06BA04	- Methylphenidate hydrochloride		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ritalin LA 40mg prolonged-release capsules	InfectoPharm Arzneimittel und Consilium GmbH	PA1972/002/004	Prolonged-release capsule, hard	- N06BA - N06BA04	- Methylphenidate hydrochloride		- Oral use
Ritonavir 100 mg film-coated tablet	Accord Healthcare Ireland Ltd.	PA2315/176/001	Film-coated tablet	- J05AE - J05AE03	- Ritonavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ritonavir Mylan (Previously Ritonavir JensonR+))	Mylan S.A.S.	EU/1/17/1242/001-003	Film-coated tablet	- J05AE - J05AE03	- Ritonavir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban 10 mg film-coated tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/010/001	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban 10 mg film-coated tablets	Flynn Pharma Limited	PA1226/016/002	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban 15 mg film-coated tablets	Flynn Pharma Limited	PA1226/016/003	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban 15 mg film-coated tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/010/002	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban 2.5 mg film-coated tablets	Flynn Pharma Limited	PA1226/016/001	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban 20 mg film-coated tablets	Flynn Pharma Limited	PA1226/016/004	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban 20 mg film-coated tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/010/003	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Accord	Accord Healthcare S.L.U.	EU/1/20/1488/001-011	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Accord	Accord Healthcare S.L.U.	EU/1/20/1488/012-023	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Accord	Accord Healthcare S.L.U.	EU/1/20/1488/024-039	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Accord	Accord Healthcare S.L.U.	EU/1/20/1488/040-053	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Clonmel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/035/002	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Clonmel 15 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/035/003	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Clonmel 15 mg film-coated tablets Rivaroxaban Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/035/005	Film-coated tablet	- B01AF01	- Rivaroxaban - Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Clonmel 15 mg hard capsules	Clonmel Healthcare Ltd	PA0126/353/001	Capsule, hard	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Rivaroxaban Clonmel 15 mg hard capsules Rivaroxaban Clonmel 20 mg hard capsules	Clonmel Healthcare Ltd	PA0126/353/003	Capsule, hard	- B01AF01	- Rivaroxaban - Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Clonmel 2.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/035/001	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/035/004	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Clonmel 20 mg hard capsules	Clonmel Healthcare Ltd	PA0126/353/002	Capsule, hard	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/098/002	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Krka 15 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/098/003	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Krka 2.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/098/001	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/098/004	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Rowex 10 mg Film-coated tablets	Rowex Ltd	PA0711/275/001	Film-coated tablet	- B01AF - B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Rowex 15 mg Film-coated tablets	Rowex Ltd	PA0711/275/002	Film-coated tablet	- B01AF - B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Rowex 20 mg Film-coated tablets	Rowex Ltd	PA0711/275/003	Film-coated tablet	- B01AF - B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Teva 10 mg film-coated tablets	TEVA GmbH	PA22579/002/001	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Teva 15 mg film-coated tablets	TEVA GmbH	PA22579/002/002	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Teva 20 mg film-coated tablets	TEVA GmbH	PA22579/002/003	Film-coated tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Viatris	Viatris Limited	EU/1/21/1588/001-014	Tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Viatris	Viatris Limited	EU/1/21/1588/015-025	Tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Viatris	Viatris Limited	EU/1/21/1588/026-040	Tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivaroxaban Viatris	Viatris Limited	EU/1/21/1588/041-055	Tablet	- B01AF01	- Rivaroxaban	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Rivastigmine - 1 A Pharma	1 A Pharma GmbH	EU/1/09/585/001-4	Capsule, hard	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Rivastigmine - 1 A Pharma	1 A Pharma GmbH	EU/1/09/585/005-8	Capsule, hard	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Rivastigmine - 1 A Pharma	1 A Pharma GmbH	EU/1/09/585/009-12	Capsule, hard	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Rivastigmine - 1 A Pharma	1 A Pharma GmbH	EU/1/09/585/013-16	Capsule, hard	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Rivastigmine 1 A Pharma (120ml)	1 A Pharma GmbH	EU/1/09/585/018	Oral solution	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)		- Oral use
Rivastigmine 1 A Pharma (50ml)	1 A Pharma GmbH	EU/1/09/585/017	Oral solution	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)		- Oral use
Rivastigmine Actavis	Actavis Group hf	EU/1/11/693/001-004	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogentartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivastigmine Actavis	Actavis Group hf	EU/1/11/693/005-008	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogentartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivastigmine Actavis	Actavis Group hf	EU/1/11/693/009-012	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogentartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rivastigmine Actavis	Actavis Group hf	EU/1/11/693/013-016	Capsule, hard	- N06DA - N06DA03	- Rivastigmine hydrogentartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
RIVASTIGMINE ACTAVIS	Actavis Group PTC ehf	EU/1/11/693/017-20	Transdermal Patch	- N06DA03	- RIVASTIGMINE	Article 10(1) - Generic Application	- Transdermal
RIVASTIGMINE ACTAVIS	Actavis Group PTC ehf	EU/1/11/693/021-24	Transdermal Patch	- N06DA03	- RIVASTIGMINE	Article 10(1) - Generic Application	- Transdermal
Rivastigmine Hexal	Hexal AG	EU/1/09/589/13-16	Capsule, hard	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Rivastigmine Hexal	Hexal AG	EU/1/09/589/1-4	Capsule, hard	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Rivastigmine Hexal	Hexal AG	EU/1/09/589/5-8	Capsule, hard	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Rivastigmine Hexal	Hexal AG	EU/1/09/589/9-12	Capsule, hard	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Rivastigmine Hexal (120 ml)	Hexal AG	EU/1/09/589/018	Oral solution	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)		- Oral use
Rivastigmine Hexal (50 ml)	Hexal AG	EU/1/09/589/017	Oral solution	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)		- Oral use
Rivastigmine Sandoz	Sandoz Pharmaceuticals GmbH	EU/1/09/599/13-16	Capsule, hard	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Rivastigmine Sandoz	Sandoz Pharmaceuticals GmbH	EU/1/09/599/1-4	Capsule, hard	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Rivastigmine Sandoz	Sandoz Pharmaceuticals GmbH	EU/1/09/599/5-8	Capsule, hard	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Rivastigmine Sandoz	Sandoz Pharmaceuticals GmbH	EU/1/09/599/9-12	Capsule, hard	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Rivastigmine Sandoz (120 ml)	Sandoz Pharmaceuticals GmbH	EU/1/09/599/018	Oral solution	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)		- Oral use
Rivastigmine Sandoz (50 ml)	Sandoz Pharmaceuticals GmbH	EU/1/09/599/017	Oral solution	- N06DA - N06DA03	- Sdz ena 713 hta (rivastigmine hydrogen tartrate)		- Oral use
Rivotril 0.5 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/020/001	Tablet	- N03AE - N03AE01	- Clonazepam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rixathon	Sandoz GmbH	EU/1/17/1185/001-002	Concentrate for solution for infusion	- L01XC - L01XC02	- Rituximab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Rixathon	Sandoz GmbH	EU/1/17/1185/003-004	Concentrate for solution for infusion	- L01XC - L01XC02	- Rituximab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Riximyo	Sandoz GmbH	EU/1/17/1184/001-002	Concentrate for solution for infusion	- L01XC - L01XC02	- Rituximab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Riximyo	Sandoz GmbH	EU/1/17/1184/003-004	Concentrate for solution for infusion	- L01XC - L01XC02	- Rituximab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Rixubis	Baxter Innovations GmbH	EU/1/14/970/001	Powder and solvent for solution for injection	- B02BD - B02BD04	- Nonacog gamma	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Rixubis	Baxter Innovations GmbH	EU/1/14/970/002	Powder and solvent for solution for injection	- B02BD - B02BD04	- Nonacog gamma	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Rixubis	Baxter Innovations GmbH	EU/1/14/970/003	Powder and solvent for solution for injection	- B02BD - B02BD04	- Nonacog gamma	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Rixubis	Baxter Innovations GmbH	EU/1/14/970/004	Powder and solvent for solution for injection	- B02BD - B02BD04	- Nonacog gamma	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Rixubis	Baxter Innovations GmbH	EU/1/14/970/005	Powder and solvent for solution for injection	- B02BD - B02BD04	- Nonacog gamma	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Rizadia 5 mg oral lyophilisate	Diapharm GmbH & Co. KG	PA1958/009/001	Orodispersible tablet	- N02CC04	- Rizatriptan benzoate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Rizadia 5 mg Tablets	Diapharm GmbH & Co. KG	PA1958/009/002	Tablet	- N02CC04	- Rizatriptan benzoate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
RIZATRIPTAN MSD 10 mg oral lyophilisates	Organon Pharma (Ireland) Limited	PA23198/013/004	Oral lyophilisate	- N02CC - N02CC04	- Rizatriptan benzoate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
RIZATRIPTAN MSD 10 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/013/002	Tablet	- N02CC - N02CC04	- Rizatriptan benzoate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
RIZATRIPTAN MSD 5 mg oral lyophilisates	Organon Pharma (Ireland) Limited	PA23198/013/003	Oral lyophilisate	- N02CC - N02CC04	- Rizatriptan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
RIZATRIPTAN MSD 5 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/013/001	Tablet	- N02CC - N02CC04	- Rizatriptan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rizmoic	Shionogi B.V.	EU/1/18/1291/001-003	Film-coated tablet	- A06AH05	- Naldemedine tosilate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Roaccutane 10 mg soft capsules	Roche Products (Ireland) Ltd	PA2307/007/001	Capsule, soft	- D10BA - D10BA01	- Isotretinoin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Roaccutane 20 mg soft capsules	Roche Products (Ireland) Ltd	PA2307/007/002	Capsule, soft	- D10BA - D10BA01	- Isotretinoin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
RoActemra	Roche Registration GmbH	EU/1/08/492/001-006	Concentrate for solution for infusion	- L04AC - L04AC07	- Tocilizumab		- Intravenous use
RoActemra	Roche Registration GmbH	EU/1/08/492/007	Solution for injection in pre-filled syringe	- L04AC07	- Tocilizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Robitussin Chesty Cough 100mg/5ml Oral Solution	Haleon Ireland Limited	PA0678/153/001	Oral solution	- R05CA - R05CA03	- Guaifenesin		- Oral use
Robitussin Dry Cough 7.5mg/5ml Oral Solution	Haleon Ireland Limited	PA0678/155/001	Oral solution	- R05DA - R05DA09	- Dextromethorphan hydrobromide		- Oral use
Robitussin Plus Oral Solution Guaifenesin 100 mg/5ml Pseudoephedrine HCl 30 mg/5ml	Haleon Ireland Limited	PA0678/154/001	Oral solution	- R01BA - R01BA52	- Guaiphenesin - PSEUDOEPHEDRINE HYDROCHLORIDE	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Rocephin 1 g powder and solvent for IM injection only	Roche Products (Ireland) Ltd	PA2307/008/002	Powder and solvent for solution for injection	- J01DD04	- Ceftriaxone sodium - Lidocaine Hydrochloride Monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Rocephin 1 g powder for solution for injection/infusion	Roche Products (Ireland) Ltd	PA2307/008/003	Powder for solution for injection/infusion	- J01DD04	- Ceftriaxone sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Roclanda	Santen OY	EU/1/20/1502/001	Eye drops, solution	- S01EE51	- NETARSUDIL MESILATE - NETARSUDIL - Latanoprost	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Ocular use
Roctavian	BioMarin International Limited	EU/1/22/1668/001	Solution for infusion	- B02	- Valoctocogene Roxaparvovec	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Rocuronium 10 mg/ml solution for injection / infusion	Fresenius Kabi Deutschland GmbH	PA2059/018/001	Solution for injection/infusion	- M03AC - M03AC09	- Rocuronium bromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Rocuronium 10 mg/ml solution for injection/infusion	B. Braun Melsungen AG	PA0736/029/001	Solution for injection/infusion	- M03AC - M03AC09	- Rocuronium bromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Rocuronium bromide 10 mg / mL solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/015/001	Solution for injection in pre-filled syringe	- M03AC09	- Rocuronium bromide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Rocuronium bromide 10 mg/mL Solution for injection/infusion	Noridem Enterprises Limited	PA1122/022/001	Solution for injection/infusion	- M03AC09	- Rocuronium bromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Rocuronium bromide 10 mg/ml solution for injection/infusion	AS Kalceks	PA2165/004/001	Solution for injection/infusion	- M03AC09	- Rocuronium bromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Rocuronium Bromide 10mg/ml solution for Injection/Infusion	Ibigen Srl	PA1862/001/001	Solution for injection/infusion	- M03AC - M03AC09	- Rocuronium bromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Rolpryna SR 2 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/012/001	Prolonged-release tablet	- N04BC - N04BC04	- Ropinirole hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rolpryna SR 4 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/012/002	Prolonged-release tablet	- N04BC - N04BC04	- Ropinirole hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rolpryna SR 8 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/012/003	Prolonged-release tablet	- N04BC - N04BC04	- Ropinirole hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rolufta Ellipta	GlaxoSmithKline Trading Services Limited	EU/1/17/1174/001-003	Inhalation powder, pre-dispensed	- R03BB07	- Umeclidinium bromide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Inhalation use
Rolyprexa 10 mg film-coated tablets	Rowex Ltd	PA0711/124/004 Interchangeable List Code: IC0007-002-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rolyprexa 2.5 mg film-coated tablets	Rowex Ltd	PA0711/124/001 Interchangeable List Code: IC0007-018-035	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rolyprexa 5 mg film-coated tablets	Rowex Ltd	PA0711/124/002 Interchangeable List Code: IC0007-001-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rolyprexa 7.5 mg film-coated tablets	Rowex Ltd	PA0711/124/003 Interchangeable List Code: IC0007-041-038	Film-coated tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Romax Once Weekly 70mg Tablets	Aurobindo Pharma (Malta) Limited	PA1445/017/001 Interchangeable List Code: IC0051-101-002	Tablet		- Alendronic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
RONAPREVE	Roche Registration GmbH	EU/1/21/1601/001	Solution for injection/infusion	- J06BD07	- casirivimab - imdevimab	Full application (Article 8(3) of Directive No 2001/83/EC)	
RONAPREVE	Roche Registration GmbH	EU/1/21/1601/002	Solution for injection/infusion	- J06BD07	- casirivimab - imdevimab	Full application (Article 8(3) of Directive No 2001/83/EC)	
Ropivacaine 2 mg/ml solution for injection	Fresenius Kabi Deutschland GmbH	PA2059/021/001	Solution for injection	- N01BB - N01BB09	- Ropivacaine Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use - Perineural use
Ropivacaine 7.5 mg/ml solution for injection	Fresenius Kabi Deutschland GmbH	PA2059/021/002	Solution for injection	- N01BB - N01BB09	- Ropivacaine Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Epidural use - Perineural use
Ropivacaine Readyfusor 10 mg/h solution for infusion in administration syste	BioQ Pharma B.V.	PA2284/001/001	Solution for infusion in administration system	- N01BB - N01BB09	- Ropivacaine hydrochloride monohydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Perineural use
Rosuva 10 mg film-coated tablets	Rowex Ltd	PA0711/176/002 Interchangeable List Code: IC0006-002-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuva 20 mg film-coated tablets	Rowex Ltd	PA0711/176/003 Interchangeable List Code: IC0006-003-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Rosuva 40 mg film-coated tablets	Rowex Ltd	PA0711/176/004 Interchangeable List Code: IC0006-004-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuva 5 mg film-coated tablets	Rowex Ltd	PA0711/176/001 Interchangeable List Code: IC0006-001-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin 10 mg Film-coated Tablets	Brillpharma (Ireland) Limited	PA22749/017/002 Interchangeable List Code: IC0006-002-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/068/002 Interchangeable List Code: IC0006-002-003	Film-coated tablet		- Rosuvastatin calcium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin 20 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/068/003 Interchangeable List Code: IC0006-003-003	Film-coated tablet		- Rosuvastatin calcium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin 20 mg Film-coated Tablets	Brillpharma (Ireland) Limited	PA22749/017/003 Interchangeable List Code: IC0006-003-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin 40 mg Film-coated Tablets	Brillpharma (Ireland) Limited	PA22749/017/004 Interchangeable List Code: IC0006-004-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin 40 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/068/004 Interchangeable List Code: IC0006-004-003	Film-coated tablet		- Rosuvastatin calcium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/068/001 Interchangeable List Code: IC0006-001-003	Film-coated tablet		- Rosuvastatin calcium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin 5 mg Film-coated Tablets	Brillpharma (Ireland) Limited	PA22749/017/001 Interchangeable List Code: IC0006-001-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Clonmel 10mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/261/002 Interchangeable List Code: IC0006-002-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Clonmel 20mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/261/003 Interchangeable List Code: IC0006-003-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Clonmel 40mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/261/004 Interchangeable List Code: IC0006-004-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Clonmel 5mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/261/001 Interchangeable List Code: IC0006-001-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/016/002 Interchangeable List Code: IC0006-002-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Rosuvastatin Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/016/003 Interchangeable List Code: IC0006-003-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Krka 40 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/016/004 Interchangeable List Code: IC0006-004-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Krka 5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/016/001 Interchangeable List Code: IC0006-001-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Pinewood 10 mg Film-coated Tablets	Pinewood Laboratories Ltd	PA0281/157/002 Interchangeable List Code: IC0006-002-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Pinewood 20 mg Film-coated Tablets	Pinewood Laboratories Ltd	PA0281/157/003 Interchangeable List Code: IC0006-003-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Pinewood 40 mg Film-coated Tablets	Pinewood Laboratories Ltd	PA0281/157/004 Interchangeable List Code: IC0006-004-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Pinewood 5 mg Film-coated Tablets	Pinewood Laboratories Ltd	PA0281/157/001 Interchangeable List Code: IC0006-001-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Rowa 10 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/093/002 Interchangeable List Code: IC0006-002-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Rowa 20 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/093/003 Interchangeable List Code: IC0006-003-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Rowa 40 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/093/004 Interchangeable List Code: IC0006-004-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Rowa 5 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/093/001 Interchangeable List Code: IC0006-001-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Teva Pharma 10 mg Film-coated Tablets	Teva B.V.	PA1986/024/002 Interchangeable List Code: IC0006-002-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Teva Pharma 20 mg Film-coated Tablets	Teva B.V.	PA1986/024/003 Interchangeable List Code: IC0006-003-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Teva Pharma 40 mg Film-coated Tablets	Teva B.V.	PA1986/024/004 Interchangeable List Code: IC0006-004-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Teva Pharma 5 mg Film-coated Tablets	Teva B.V.	PA1986/024/001 Interchangeable List Code: IC0006-001-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Rosuvastatin Viatris 10 mg film-coated tablets	Viatris Limited	PA23266/003/002 Interchangeable List Code: IC0006-002-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Viatris 20 mg film-coated tablets	Viatris Limited	PA23266/003/003 Interchangeable List Code: IC0006-003-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Viatris 40 mg film-coated tablets	Viatris Limited	PA23266/003/004 Interchangeable List Code: IC0006-004-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Viatris 5 mg film-coated tablets	Viatris Limited	PA23266/003/001 Interchangeable List Code: IC0006-001-003	Film-coated tablet		- Rosuvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Zentiva 10 mg film-coated tablets	Zentiva k.s.	PA1701/005/002 Interchangeable List Code: IC0006-002-003	Film-coated tablet		- Rosuvastatin calcium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Zentiva 20 mg film-coated tablets	Zentiva k.s.	PA1701/005/003 Interchangeable List Code: IC0006-003-003	Film-coated tablet		- Rosuvastatin calcium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Zentiva 40 mg film-coated tablets	Zentiva k.s.	PA1701/005/004 Interchangeable List Code: IC0006-004-003	Film-coated tablet		- Rosuvastatin calcium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin Zentiva 5 mg film-coated tablets	Zentiva k.s.	PA1701/005/001 Interchangeable List Code: IC0006-001-003	Film-coated tablet		- Rosuvastatin calcium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rosuvastatin/Ezetimibe KRKA 10 mg/10 mg Film-Coated Tablets	KRKA, d.d., Novo mesto	PA1347/108/001 Interchangeable List Code: IC0111-017-009	Film-coated tablet		- Rosuvastatin calcium - Ezetimibe	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Rosuvastatin/Ezetimibe KRKA 20 mg/10 mg Film-Coated Tablets	KRKA, d.d., Novo mesto	PA1347/108/002 Interchangeable List Code: IC0111-061-009	Film-coated tablet		- Rosuvastatin calcium - Ezetimibe	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Rotarix	GlaxoSmithKline Biologicals S.A.	EU/1/05/330/1-4	Powder and solvent for oral suspension	- J07BH - J07BH01	- Rotavirus live attenuated, rix4414 strain, human		- Oral use
Rotarix	GlaxoSmithKline Biologicals S.A.	EU/1/05/330/5-11	Powder and solvent for oral suspension	- J07BH - J07BH01	- Human rotavirus, live attenuated	Full application (Article 8(3) of Directive No 2001/83/EC)	
RotaTeq	Merck Sharp & Dohme BV,	EU/1/06/348/01	Oral solution	- J07BH - J07BH02	- Rotavirus vaccine, live, pentavalent gi - Rotavirus vaccine, live, pentavalent g2 - Rotavirus vaccine, live, pentavalent g3 - Rotavirus vaccine, live, pentavalent g4 - Rotavirus vaccine, live, pentavalent p1		- Oral use
Roteas	Berlin-Chemie AG	EU/1/16/1152/001-002	Film-coated tablet	- B01AF - B01AF03	- Edoxaban tosilate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Roteas	Berlin-Chemie AG	EU/1/16/1152/003-015	Film-coated tablet	- B01AF - B01AF03	- Edoxaban tosilate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Roteas	Berlin-Chemie AG	EU/1/16/1152/016-028	Film-coated tablet	- B01AF - B01AF03	- Edoxaban tosilate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Rowachol Gastro-resistant Capsules, Soft	Rowa Pharmaceuticals Limited	PA0074/008/001	Gastro-resistant capsule, soft		- Menthol - Menthone - Alpha pinene - Borneol - Cineole - Camphene - Beta pinene	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rowachol Oral Drops, Solution	Rowa Pharmaceuticals Limited	PA0074/008/002	Oral drops, solution		- Alpha pinene - Borneol - Menthol - Beta pinene - Menthone - Camphene - Cineole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rowalief 500 mg Film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/065/001	Film-coated tablet	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rowalief Max 1000 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/065/002	Film-coated tablet	- N02BE - N02BE01	- Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Rowarolan Cutaneous Powder	Rowa Pharmaceuticals Limited	PA0074/046/001	Cutaneous powder		- Calcium carbonate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical
Rowatanal Cream	Rowa Pharmaceuticals Limited	PA0074/016/001	Cream	- C05AX - C05AX04	- Levomenthol - Bismuth subgallate - Zinc oxide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Rectal use
Rowatinex Gastro-resistant Capsules, Soft	Rowa Pharmaceuticals Limited	PA0074/009/001	Gastro-resistant capsule, soft		- Beta pinene - Cineole - Camphene - Alpha pinene - Fenchone - Anethole - Borneol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rowatinex Oral Drops, Solution	Rowa Pharmaceuticals Limited	PA0074/009/002	Oral drops, solution		- Anethol - Alpha pinene - Borneol - Fenchone - Camphene - Cineole - Beta pinene	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rozex 7.5 mg/g Cream	Galderma International	PA22743/013/002	Cream	- D06BX - D06BX01	- Metronidazole	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical
Rozex 7.5 mg/g Gel	Galderma International	PA22743/013/001	Gel	- D06BX - D06BX01	- Metronidazole	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Topical use
Rozex 7.5 mg/g Gel	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/011/001	Gel	- D06BX - D06BX01	- Metronidazole		- Topical use
Rozex 7.5 mg/g Gel	IMED Healthcare Ltd.	PPA1463/184/001	Gel	- D06BX - D06BX01	- Metronidazole		- Cutaneous use
Rozex 7.5 mg/g Gel	PCO Manufacturing Ltd.	PPA0465/222/001	Gel	- D06BX01	- Metronidazol	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Topical use
Rozlytrek	Roche Registration GmbH	EU/1/20/1460/001	Capsule, hard	- L01EX14	- Entrectinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rozlytrek	Roche Registration GmbH	EU/1/20/1460/002	Capsule, hard	- L01EX14	- Entrectinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Rubraca	zr pharma& GmbH	EU/1/17/1250/001	Film-coated tablet	- L01XX - L01XX55	- Rucaparib camsylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rubraca	zr pharma& GmbH	EU/1/17/1250/002	Film-coated tablet	- L01XX - L01XX55	- Rucaparib camsylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rubraca	zr pharma& GmbH	EU/1/17/1250/003	Film-coated tablet	- L01XX - L01XX55	- Rucaparib camsylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ruconest	Pharming Group N.V.	EU/1/10/641/001	Powder for solution for injection	- B06AC - B06AC04	- Conestat alfa		- Intravenous use
Ruconest	Pharming Group N.V.	EU/1/10/641/002	Powder and solvent for solution for injection	- B06AC - B06AC04	- Conestat alfa		- Intravenous use
Rukobia	ViiV Healthcare BV	EU/1/20/1518/001	Prolonged-release tablet	- J05AX29	- Fostemsavir Tromethamine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rupafin 1 mg/ml oral solution	J. Uriach y Compania S.A.	PA1129/001/002	Oral solution	- R06AX - R06AX28	- Rupatadine (as fumarate)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rupafin 10mg tablets	J. Uriach y Compania S.A.	PA1129/001/001	Tablet	- R06AX - R06AX28	- Rupatadine (as fumarate)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ruta grav	A. Nelson & Company Limited	HOR1149/026/001	Pillules		- Ruta graveolens		- Oral use
Ruxience	Pfizer Europe MA EEIG	EU/1/20/1431/001	Concentrate for solution for infusion	- L01XC02	- Rituximab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Ruxience	Pfizer Europe MA EEIG	EU/1/20/1431/002	Concentrate for solution for infusion	- L01XC02	- Rituximab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
RXULTI	Otsuka Pharmaceutical Netherlands B.V.	EU/1/18/1294/001	Film-coated tablet	- N05AX16	- Brexpiprazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
RXULTI	Otsuka Pharmaceutical Netherlands B.V.	EU/1/18/1294/002	Film-coated tablet	- N05AX16	- Brexpiprazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
RXULTI	Otsuka Pharmaceutical Netherlands B.V.	EU/1/18/1294/003-004	Film-coated tablet	- N05AX16	- Brexpiprazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
RXULTI	Otsuka Pharmaceutical Netherlands B.V.	EU/1/18/1294/005	Film-coated tablet	- N05AX16	- Brexpiprazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
RXULTI	Otsuka Pharmaceutical Netherlands B.V.	EU/1/18/1294/006	Film-coated tablet	- N05AX16	- Brexpiprazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
RXULTI	Otsuka Pharmaceutical Netherlands B.V.	EU/1/18/1294/007	Film-coated tablet	- N05AX16	- Brexpiprazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ryaltris 25 microgram/actuation + 600 microgram/actuation nasal spray, suspension	Glenmark Pharmaceuticals s.r.o.	PA1543/002/001	Nasal spray, suspension	- R01AD59	- Mometasone furoate - Olopatadine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Nasal use
Rybelsus	Novo Nordisk A/S	EU/1/20/1430/001-004	Tablet	- A10BJ06	- Semaglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Rybelsus	Novo Nordisk A/S	EU/1/20/1430/005-007	Tablet	- A10BJ06	- Semaglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rybelsus	Novo Nordisk A/S	EU/1/20/1430/008-010	Tablet	- A10BJ06	- Semaglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Rybrevant	Janssen-Cilag International NV	EU/1/21/1594/001	Concentrate for solution for infusion	- L01FX18	- Amivantamab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Rybrila 160 micrograms/ml Oral Solution	Clinigen Healthcare B.V.	PA22701/001/001	Oral solution	- A03AB02	- Glycopyrronium bromide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Rydapt	Novartis Europharm Limited	EU/1/17/1218/001	Capsule, soft	- L01XE - L01XE39	- Midostaurin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ryeqo	Gedeon Richter Plc	EU/1/21/1565/001-002	Film-coated tablet	- H01C - H01CC54	- Relugolix - Estradiol hemihydrate - Norethisterone acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ryzodeg	Novo Nordisk A/S	EU/1/12/806/1,4,5,7,8	Solution for injection	- A10AD - A10AD06	- Insulin degludec (ideg) - Insulin aspart (iasp)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Sabril 500 mg film-coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/023/001	Film-coated tablet	- N03AG - N03AG04	- Vigabatrin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sabril 500 mg Granules for Oral Solution	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/023/002	Granules for oral solution	- N03AG - N03AG04	- Vigabatrin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Saflutan 15 micrograms/ml eye drops, solution	Santen OY	PA0879/008/001	Eye drops, solution	- S01EE05	- Tafluprost	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Saflutan 15 micrograms/ml, eye drops, solution in single-dose container	Santen OY	PA0879/006/001	Eye drops, solution in single-dose container	- S01EE - S01EE05	- Tafluprost	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Saflutan 15 micrograms/ml, eye drops, solution in single-dose container	PCO Manufacturing Ltd.	PPA0465/324/001	Eye drops, solution in single-dose container	- S01EE - S01EE05	- Tafluprost		- Ocular use
Saizen 5.83 mg/ml solution for injection in cartridge	Merck Serono (Ireland) Limited	PA2286/006/001	Solution for injection in cartridge	- H01AC - H01AC01	- Somatropin	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Saizen 8 mg/ml solution for injection in cartridge	Merck Serono (Ireland) Limited	PA2286/006/002	Solution for injection in cartridge	- H01AC - H01AC01	- Somatropin	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Salactol Collodion	Dermal Laboratories (Ireland) Limited	PA23128/003/001	Collodion	- D11AF	- Salicylic acid - Lactic acid		- Topical
Salamol CFC-Free Inhaler 100 micrograms pressurised inhalation, suspension	Norton Waterford	PA0436/032/001 Interchangeable List Code: IC0078-138-053	Pressurised inhalation, suspension		- SALBUTAMOL SULFATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Salamol Easi-Breathe CFC-Free Inhaler 100 micrograms Pressurised Inhalation, Suspension	Norton Waterford	PA0436/032/002	Pressurised inhalation, suspension	- R03AC - R03AC02	- SALBUTAMOL SULFATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Salamol Steri-Neb 2.5 mg/2.5 ml nebuliser solution	Teva B.V.	PA1986/086/001 Interchangeable List Code: IC0078-137-052	Nebuliser solution		- SALBUTAMOL SULFATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Inhalation use
Salamol Steri-Neb 5 mg/2.5 ml Nebuliser Solution	Teva B.V.	PA1986/086/002 Interchangeable List Code: IC0078-139-052	Nebuliser solution		- Salbutamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Inhalation use
Salatac Gel Salicylic Acid 12.0% w/w Lactic Acid 4.0% w/w	Dermal Laboratories (Ireland) Limited	PA23128/007/001	Gel	- D11AF	- Salicylic acid - Lactic acid		- Cutaneous use - Transdermal use
Salazopyrin EN Tabs 500 mg Gastro-resistant tablets	PCO Manufacturing Ltd.	PPA0465/160/001	Gastro-resistant tablet	- A07EC - A07EC01	- Sulfasalazine	ZZZ PPA	- Oral use
Salazopyrin EN Tabs 500 mg gastro-resistant tablets	IMED Healthcare Ltd.	PPA1463/059/001	Gastro-resistant tablet	- A07EC - A07EC01	- Sulfasalazine		- Oral use
Salazopyrin® 500 mg Tablets	Pfizer Healthcare Ireland	PA0822/196/002	Tablet	- A07EC - A07EC01	- Sulfasalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Salazopyrin® EN Tabs 500 mg Gastro-resistant tablets	Pfizer Healthcare Ireland	PA0822/196/001	Gastro-resistant tablet	- A07EC - A07EC01	- Sulfasalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Salbutamol CFC-Free Inhaler 100 micrograms per metered dose, pressurised inhalation, suspension	Valeas SPA Industria Chimica e Farmaceutica	PA1987/001/001 Interchangeable List Code: IC0078-138-053	Pressurised inhalation, suspension		- Salbutamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Inhalation use
Salbutamol Neutec 2.5 mg/2.5 ml nebuliser solution	Neutec Inhaler Ireland Limited	PA23030/002/001 Interchangeable List Code: IC0078-137-052	Nebuliser solution		- SALBUTAMOL SULFATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Saline Steri-Neb 0.9% w/v Nebuliser Solution	Teva B.V.	PA1986/087/001	Nebuliser solution		- Sodium chloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Inhalation use
Salofalk 1.5g prolonged-release granules	Dr. Falk Pharma GmbH	PA0573/003/007	Prolonged-release granules	- A07EC - A07EC02	- Mesalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Salofalk 1000mg prolonged-release granules	Dr. Falk Pharma GmbH	PA0573/003/002	Prolonged-release granules	- A07EC - A07EC02	- Mesalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Salofalk 1g Suppositories	Dr. Falk Pharma GmbH	PA0573/004/004	Suppository	- A07EC - A07EC02	- Mesalazine		- Rectal use
Salofalk 1g Suppositories	IMED Healthcare Ltd.	PPA1463/212/001	Suppository	- A07EC - A07EC02	- Mesalazine		- Rectal use
Salofalk 1g/Actuation Rectal Foam	Dr. Falk Pharma GmbH	PA0573/004/005	Rectal foam	- A07EC - A07EC02	- Mesalazine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Rectal use
Salofalk 250 mg Suppositories	Dr. Falk Pharma GmbH	PA0573/004/002	Suppository	- A07EC - A07EC02	- Mesalazine		- Rectal use
Salofalk 250mg Gastro-Resistant Tablets	Dr. Falk Pharma GmbH	PA0573/004/003	Gastro-resistant tablet	- A07EC - A07EC02	- Mesalazine		- Oral use
Salofalk 3g prolonged-release granules	Dr. Falk Pharma GmbH	PA0573/003/006	Prolonged-release granules	- A07EC - A07EC02	- Mesalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Salofalk 4g/60ml Enema	Dr. Falk Pharma GmbH	PA0573/004/001	Rectal suspension	- A07EC - A07EC02	- Mesalazine		- Rectal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Salofalk 500 mg prolonged-release granules	Dr. Falk Pharma GmbH	PA0573/003/001	Prolonged-release granules	- A07EC - A07EC02	- Mesalazine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Salvacyl, 11.25 mg powder and solvent for prolonged-release suspension for injection	Ipsen Pharmaceuticals Limited	PA0869/008/001	Powder and solvent for prolonged-release suspension for injection	- L02AE - L02AE04	- Triptorelin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Sametec Airmaster 50 microgram/ 100 microgram/ dose, inhalation powder, pre-dispensed	Clonmel Healthcare Ltd	PA0126/342/001	Inhalation powder, pre-dispensed	- R03AK06	- SALMETEROL XINAFOATE - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Sametec Airmaster 50 microgram/ 250 microgram/ dose, inhalation powder, pre-dispensed	Clonmel Healthcare Ltd	PA0126/342/002	Inhalation powder, pre-dispensed	- R03AK06	- SALMETEROL XINAFOATE - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Sametec Airmaster 50 microgram/ 500 microgram/ dose, inhalation powder, pre-dispensed	Clonmel Healthcare Ltd	PA0126/342/003	Inhalation powder, pre-dispensed	- R03AK06	- SALMETEROL XINAFOATE - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Samsca	Otsuka Pharmaceutical Netherlands B.V.	EU/1/09/539/005-006	Tablet	- C03XA - C03XA01	- Tolvaptan (opc-41061)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Samsca	Otsuka Pharmaceutical Netherlands B.V.	EU/1/09/539/1-2	Tablet	- C03XA - C03XA01	- Tolvaptan		- Oral use
Samsca	Otsuka Pharmaceutical Netherlands B.V.	EU/1/09/539/3-4	Tablet	- C03XA - C03XA01	- Tolvaptan		- Oral use
Sancuso	Kyowa Kirin Holdings B.V.	EU/1/12/766/001	Transdermal patch	- A04AA - A04AA02	- Granisetron	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Transdermal use
Sandimmun 100 mg/ml concentrate for oral solution	Novartis Ireland Limited	PA0896/027/001	Concentrate for oral solution	- L04AD - L04AD01	- Ciclosporin		- Oral use
Sandimmun 100mg Soft Capsules	Novartis Ireland Limited	PA0896/027/004	Capsule, soft	- L04AD - L04AD01	- Ciclosporin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sandimmun 25mg Soft Capsules	Novartis Ireland Limited	PA0896/027/003	Capsule, soft	- L04AD - L04AD01	- Ciclosporin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sandimmun 50 mg/ml Concentrate for Solution for Infusion	Novartis Ireland Limited	PA0896/027/002	Concentrate for solution for infusion	- L04AD - L04AD01	- Ciclosporin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Sandimmun 50mg Soft Capsules	Novartis Ireland Limited	PA0896/027/005	Capsule, soft	- L04AD - L04AD01	- Ciclosporin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
SANDOSTATIN 100 microgram/1ml, solution for injection/infusion	Novartis Ireland Limited	PA0896/028/002	Solution for injection/infusion	- H01CB - H01CB02	- Octreotide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
SANDOSTATIN 50 microgram/1 ml, solution for injection/infusion	Novartis Ireland Limited	PA0896/028/001	Solution for injection/infusion	- H01CB - H01CB02	- Octreotide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
SANDOSTATIN 500 microgram/1 ml, solution for injection/infusion	Novartis Ireland Limited	PA0896/028/003	Solution for injection/infusion	- H01CB - H01CB02	- Octreotide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Sandostatin LAR 10 mg powder and solvent for suspension for injection	Novartis Ireland Limited	PA0896/028/004	Powder and solvent for suspension for injection	- H01CB - H01CB02	- Octreotide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Sandostatin LAR 20 mg powder and solvent for suspension for injection	Novartis Ireland Limited	PA0896/028/005	Powder and solvent for suspension for injection	- H01CB - H01CB02	- Octreotide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Sandostatin LAR 30 mg powder and solvent for suspension for injection	Novartis Ireland Limited	PA0896/028/006	Powder and solvent for suspension for injection	- H01CB - H01CB02	- Octreotide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Sanomigran 1.5mg Tablets	Phoenix Labs	PA1113/012/002	Coated tablet	- N02CX - N02CX01	- Pizotifen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sanomigran 500 microgram Tablets	Phoenix Labs	PA1113/012/001	Coated tablet	- N02CX - N02CX01	- Pizotifen	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Saphnelo	AstraZeneca AB	EU/1/21/1623/001	Concentrate for solution for infusion	- L04AA - L04AA51	- Anifrolumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Sapropterin Dipharma	Dipharma Arzneimittel GmbH	EU/1/21/1620/001-003	Powder for oral solution	- A16AX07	- Sapropterin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sapropterin Dipharma	Dipharma Arzneimittel GmbH	EU/1/21/1620/004	Powder for oral solution	- A16AX07	- Sapropterin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sapvit-D3 400 IU/drop oral drops, solution	Fresenius Kabi Austria GmbH	PA0773/006/001	Oral drops, solution	- A11CC - A11CC05	- Cholecalciferol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sarclisa	Sanofi Winthrop Industrie	EU/1/20/1435/001-003	Concentrate for solution for infusion	- L01XC38	- Isatuximab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Sastravi 100mg/25mg/200mg Film-coated Tablets	Teva B.V.	PA1986/120/003	Film-coated tablet	- N04BA - N04BA03	- Levodopa - Carbidopa - Entacapone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sastravi 125mg/31.25mg/200 mg Film-coated Tablets	Teva B.V.	PA1986/120/004	Film-coated tablet	- N04BA - N04BA03	- Levodopa - Carbidopa - Entacapone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sastravi 150mg/37.5mg/200 mg Film-coated Tablets	Teva B.V.	PA1986/120/005	Film-coated tablet	- N04BA - N04BA03	- Levodopa - Carbidopa - Entacapone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sastravi 175mg/43.75mg/200 mg Film-coated Tablets	Teva B.V.	PA1986/120/006	Film-coated tablet	- N04BA - N04BA03	- Levodopa - Carbidopa - Entacapone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sastravi 200mg/50mg/200mg Film-coated Tablets	Teva B.V.	PA1986/120/007	Film-coated tablet	- N04BA - N04BA03	- Levodopa - Carbidopa - Entacapone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sastravi 50mg/12.5mg/200mg Film-coated Tablets	Teva B.V.	PA1986/120/001	Film-coated tablet	- N04BA - N04BA03	- Levodopa - Carbidopa - Entacapone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sastravi 75mg/18.75mg/200 mg Film-coated Tablets	Teva B.V.	PA1986/120/002	Film-coated tablet	- N04BA - N04BA03	- Levodopa - Carbidopa - Entacapone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sativex Oromucosal Spray	Jazz Pharmaceuticals Ireland Limited	PA23494/001/001	Oromucosal spray, solution	- N02B - N02BG10	- Delta-9-tetrahydrocannabinol botanical drug substance (thc bds) - Cannabidiol botanical drug substance (cbd bds)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oromucosal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Savene	Clinigen Healthcare B.V.	EU/1/06/350/001	Powder and solvent for concentrate for solution for infusion	- V03AF - V03AF02	- Dexrazoxane		- Intravenous use
Savlon Antiseptic Cream Cetrimide 0.5% w/w Chlorhexidine Digluconate 0.1% w/w	Clonmel Healthcare Ltd	PA0126/324/002	Cream	- D08AJ - D08AJ04	- Cetrimide - Chlorhexidine gluconate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Topical
Savlon Antiseptic Liquid	Haleon Ireland Limited	PA0678/139/001	Concentrate for cutaneous solution	- D08AJ - D08AJ04	- Chlorhexidine gluconate - Cetrimide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Cutaneous use
Saxenda	Novo Nordisk A/S	EU/1/15/992/001-003	Solution for injection in pre-filled pen	- A10BX - A10BX07	- Liraglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Scandonest 3% w/v Solution for Injection	Septodont	PA0196/015/001	Solution for injection	- N01BB - N01BB03	- Mepivacaine hydrochloride		- Intravenous use
Scemblix	Novartis Europharm Limited	EU/1/22/1670/001-002	Film-coated tablet	- L01 - L01EA06	- Asciminib hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Scemblix	Novartis Europharm Limited	EU/1/22/1670/003-004	Film-coated tablet	- L01EA06	- Asciminib hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Scenesse	Clinuvel Europe Limited	EU/1/14/969/001	Implant	- D02BB - D02BB02	- Afamelanotide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Scheriproct 1.5mg/g + 5mg/g rectal ointment	KARO PHARMA AB	PA22650/005/001	Rectal ointment	- C05AA - C05AA04	- PREDNISOLONE CAPROATE - Cinchocaine hydrochloride		- Oral use
Scheriproct 1mg + 1mg suppositories	KARO PHARMA AB	PA22650/005/002	Suppository	- C05AA - C05AA04	- Prednisolone - Cinchocaine Hydrochloride		
Scintimun	CIS bio International	EU/1/09/602/1-2	Kit for radiopharmaceutical preparation	- V09HA - V09HA03	- Besilesomab		- Intravenous use
Sedaconda 100% V/V inhalation vapour, liquid	Sedana Medical AB	PA23141/001/001	Inhalation vapour, liquid	- N01AB06	- Isoflurane	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Seebri Breezhaler	Novartis Europharm Limited	EU/1/12/788/001-006	Inhalation powder, hard capsule	- R03BB - R03BB06	- Glycopyrronium bromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Seffalair Spiromax	Teva B.V.	EU/1/21/1533/001-002	Inhalation powder	- R03AK06	- SALMETEROL XINAFOATE - Fluticasone propionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Seffalair Spiromax	Teva B.V.	EU/1/21/1533/003-004	Inhalation powder	- R03AK06	- SALMETEROL XINAFOATE - Fluticasone propionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Segluromet	Merck Sharp & Dohme BV	EU/1/18/1265/001-007	Film-coated tablet	- A10BD - A10BD23	- Metformin Hydrochloride - Ertugliflozin l-pyroglutamic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Segluromet	Merck Sharp & Dohme BV	EU/1/18/1265/008-014	Film-coated tablet	- A10BD - A10BD23	- Ertugliflozin l-pyroglutamic acid - Metformin Hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Segluromet	Merck Sharp & Dohme BV	EU/1/18/1265/015-021	Film-coated tablet	- A10BD - A10BD23	- Ertugliflozin l-pyroglutamic acid - Metformin Hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Segluromet	Merck Sharp & Dohme BV	EU/1/18/1265/022-028	Film-coated tablet	- A10BD - A10BD23	- Ertugliflozin l-pyroglutamic acid - Metformin Hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
SeHCAT 370kBq capsules	GE Healthcare Buchler GmbH & Co KG	PA22661/001/001	Capsule, hard	- V09DX - V09DX01	- Tauroselcholic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Selesyn 100 micrograms/2 ml, oral solution (50 micrograms/ml)	biosyn Arzneimittel GmbH	PA1131/001/001	Oral solution	- A12CE - A12CE02	- Selenium		- Oral use
Selesyn 100 micrograms/2 ml, solution for injection (50 micrograms/ml)	biosyn Arzneimittel GmbH	PA1131/001/003	Solution for injection	- A12CE - A12CE02	- Selenium		- Intramuscular use - Intravenous use
Selesyn 500 micrograms/10 ml, oral solution (50 micrograms/ml)	biosyn Arzneimittel GmbH	PA1131/001/002	Oral solution	- A12CE - A12CE02	- Selenium		- Oral use
Selesyn 500 micrograms/10 ml, solution for injection (50 micrograms/ml)	biosyn Arzneimittel GmbH	PA1131/001/004	Solution for injection	- A12CE - A12CE02	- Selenium		- Intramuscular use - Intravenous use
Selincro	H. Lundbeck A/S	EU/1/12/815/001-005	Film-coated tablet	- N07BB - N07BB05	- Nalmefene	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Selsun Shampoo 2.5% w/v	Opella Healthcare France SAS T/A Sanofi	PA23180/013/001	Shampoo	- D11AC - D11AC03	- Selenium disulfide		- Topical use
Semglee	Biosimilar Collaborations Ireland Limited	EU/1/18/1270/001-004	Solution for injection in pre-filled pen	- A10AE - A10AE04	- Insulin glargine	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Senokot 7.5 mg/5 ml Syrup	Reckitt Benckiser Ireland Ltd	PA0979/016/003	Syrup	- A06AB - A06AB06	- Sennoside b		- Oral use
Senokot 7.5mg Tablets	Reckitt Benckiser Ireland Ltd	PA0979/016/002	Tablet	- A06AB - A06AB06	- Senna pods powdered		- Oral use
Senshio	Shionogi B.V.	EU/1/14/978/001-002	Film-coated tablet	- G03XC05	- Ospemifene	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Septabene 1.5 mg/ml + 5.0 mg/ml oromucosal spray, solution	KRKA, d.d., Novo mesto	PA1347/049/001	Oromucosal spray, solution	- R02AA - R02AA20	- BENZYDAMINE HYDROCHLORIDE - Cetylpyridinium chloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Septabene eucalyptus 3 mg/1 mg lozenges	KRKA, d.d., Novo mesto	PA1347/063/001	Lozenge	- R02AA - R02AA20	- BENZYDAMINE HYDROCHLORIDE - Cetylpyridinium chloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oromucosal use
Septabene lemon and elderflower 3 mg /1 mg lozenges	KRKA, d.d., Novo mesto	PA1347/063/003	Lozenge	- R02AA20	- BENZYDAMINE HYDROCHLORIDE - Cetylpyridinium chloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Septabene Lemon and Honey 3 mg/1 mg lozenges	KRKA, d.d., Novo mesto	PA1347/063/002	Lozenge	- R02AA20	- BENZYDAMINE HYDROCHLORIDE - Cetylpyridinium chloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Septanazal 1 mg/ 50 mg in 1 ml nasal spray solution	KRKA, d.d., Novo mesto	PA1347/058/002	Nasal spray, solution	- R01AB - R01AB06	- Xylometazoline hydrochloride - Dexpanthenol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Nasal use
Septanazal for children 0.5 mg/ 50 mg in 1 ml nasal spray solution	KRKA, d.d., Novo mesto	PA1347/058/001	Nasal spray, solution	- R01AB - R01AB06	- Xylometazoline hydrochloride - Dexpanthenol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Nasal use
Septanest 40 mg/ml + 10 micrograms/ml, solution for injection	Septodont	PA0196/017/002	Solution for injection	- N01BB58	- Articaine hydrochloride - Adrenaline tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Dental use - Infiltration - Perineural use
Septrin 80 mg/400 mg per ampoule, concentrate for solution for infusion	Aspen Pharma Trading Limited	PA1691/010/005	Concentrate for solution for infusion	- J01EE01	- Sulfamethoxazole - Trimethoprim	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Intravenous use
Septrin 80 mg/400 mg Tablets	Aspen Pharma Trading Limited	PA1691/010/001	Tablet	- J01EE - J01EE01	- Sulfamethoxazole - Trimethoprim	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Septrin Adult 80 mg/400 mg per 5 ml Oral Suspension	Aspen Pharma Trading Limited	PA1691/010/004	Oral suspension	- J01EE - J01EE01	- Sulphamethoxazole - Trimethoprim	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Septrin Forte 160 mg/800 mg Tablets	Aspen Pharma Trading Limited	PA1691/010/002	Tablet	- J01EE - J01EE01	- Sulphamethoxazole - Trimethoprim	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Septrin Paediatric 40 mg/200 mg per 5 ml Oral Suspension	Aspen Pharma Trading Limited	PA1691/010/003	Oral suspension	- J01EE - J01EE01	- Sulphamethoxazole - Trimethoprim	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Serc 16 mg tablets	PCO Manufacturing Ltd.	PPA0465/482/001 Interchangeable List Code: IC0084-038-002	Tablet		- Betahistine dihydrochloride		- Oral use
Serc 16mg Tablets	Viatris Healthcare Limited	PA23355/014/002 Interchangeable List Code: IC0084-038-002	Tablet		- BETAHISTINE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Serc 8mg Tablets	Viatris Healthcare Limited	PA23355/014/001 Interchangeable List Code: IC0084-009-002	Tablet		- BETAHISTINE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sereflo 25 microgram/125 microgram per actuation pressurised inhalation, suspension	Cipla Europe NV	PA1963/013/001 Interchangeable List Code: IC0128-176-053	Pressurised inhalation, suspension		- SALMETEROL XINAFOATE - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Sereflo 25 microgram/250 microgram per actuation pressurised inhalation, suspension	Cipla Europe NV	PA1963/013/002 Interchangeable List Code: IC0128-177-053	Pressurised inhalation, suspension		- Fluticasone propionate - SALMETEROL XINAFOATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Seretide 100 Diskus 50 microgram/100 microgram / dose inhalation powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/046/001	Inhalation powder, pre-dispensed	- R03AK - R03AK06	- SALMETEROL XINAFOATE - Fluticasone propionate		- Inhalation use
Seretide 100 Diskus 50 microgram/100 microgram/dose inhalation powder, pre-dispensed	PCO Manufacturing Ltd.	PPA0465/091/001	Inhalation powder, pre-dispensed	- R03AK - R03AK06	- Fluticasone propionate - Salmeterol	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Inhalation use
Seretide 100 Diskus 50 microgram/100 microgram/dose inhalation powder, pre-dispensed	IMED Healthcare Ltd.	PPA1463/006/003	Inhalation powder, pre-dispensed	- R03AK - R03AK06	- Salmeterol - Fluticasone propionate		- Inhalation use
Seretide 125 Evohaler 25 microgram/125 microgram/dose pressurised inhalation, suspension	PCO Manufacturing Ltd.	PPA0465/091/005 Interchangeable List Code: IC0128-176-053	Pressurised inhalation, suspension		- Fluticasone propionate - SALMETEROL XINAFOATE	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Inhalation use
Seretide 125 Evohaler 25 microgram/125 microgram/dose pressurised inhalation, suspension	GlaxoSmithKline (Ireland) Limited	PA1077/046/005 Interchangeable List Code: IC0128-176-053	Pressurised inhalation, suspension		- SALMETEROL XINAFOATE - Fluticasone propionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Seretide 250 Diskus 50 microgram/250 microgram/dose inhalation powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/046/002	Inhalation powder, pre-dispensed	- R03AK - R03AK06	- SALMETEROL XINAFOATE - Fluticasone propionate		- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Seretide 250 Diskus 50 microgram/250 microgram/dose inhalation powder, pre-dispensed	IMED Healthcare Ltd.	PPA1463/006/002	Inhalation powder, pre-dispensed	- R03AK - R03AK06	- Fluticasone propionate - Salmeterol		- Inhalation use
Seretide 250 Diskus 50 microgram/250 microgram/dose inhalation powder, pre-dispensed	Merit Pharmaceuticals Limited	PPA23080/028/001	Inhalation powder, pre-dispensed	- R03AK06	- Salmeterol - Fluticasone propionate		- Inhalation use
Seretide 250 Diskus, 50 microgram/250 microgram/dose inhalation powder, pre-dispensed	PCO Manufacturing Ltd.	PPA0465/091/002	Inhalation powder, pre-dispensed	- R03AK - R03AK06	- Salmeterol - Fluticasone propionate	ZZZ PPA	- Inhalation use
Seretide 250 Evohaler 25 microgram/250 microgram/dose pressurised inhalation, suspension	PCO Manufacturing Ltd.	PPA0465/091/006 Interchangeable List Code: IC0128-177-053	Pressurised inhalation, suspension		- SALMETEROL XINAFOATE - Fluticasone propionate	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Inhalation use
Seretide 250 Evohaler 25 microgram/250 microgram/dose pressurised inhalation, suspension	GlaxoSmithKline (Ireland) Limited	PA1077/046/006 Interchangeable List Code: IC0128-177-053	Pressurised inhalation, suspension		- SALMETEROL XINAFOATE - Fluticasone propionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Seretide 50 Evohaler 25 microgram/50 microgram/dose pressurised inhalation, suspension	GlaxoSmithKline (Ireland) Limited	PA1077/046/004	Pressurised inhalation, suspension	- R03AK06	- SALMETEROL XINAFOATE - Fluticasone propionate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Seretide 500 Diskus 50 microgram/500 microgram/dose inhalation powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/046/003	Inhalation powder, pre-dispensed	- R03AK - R03AK06	- SALMETEROL XINAFOATE - Fluticasone propionate		- Inhalation use
Seretide 500 Diskus 50 microgram/500 microgram/dose inhalation powder, pre-dispensed	Merit Pharmaceuticals Limited	PPA23080/028/002	Inhalation powder, pre-dispensed	- R03AK06	- Salmeterol - Fluticasone propionate		- Inhalation use
Seretide 500 Diskus 50 microgram/500 microgram/dose inhalation powder, pre-dispensed	IMED Healthcare Ltd.	PPA1463/006/001	Inhalation powder, pre-dispensed	- R03AK - R03AK06	- Fluticasone propionate - Salmeterol		- Inhalation use
Seretide 500 Diskus, 50 microgram/500 microgram/dose inhalation powder, pre-dispensed	PCO Manufacturing Ltd.	PPA0465/091/003	Inhalation powder, pre-dispensed	- R03AK - R03AK06	- Salmeterol - Fluticasone propionate	ZZZ PPA	- Inhalation use
Seretral 100 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/023/002 Interchangeable List Code: IC0064-024-003	Film-coated tablet		- Sertraline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Seretral 50 mg film-coated tablets	Teva Pharma B.V.	PA0749/023/001 Interchangeable List Code: IC0064-023-003	Film-coated tablet		- Sertraline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Serevent Diskus, 50 micrograms per metered dose, inhalation powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/047/003	Inhalation powder, pre-dispensed	- R03AC - R03AC12	- Salmeterol		- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Serevent Evohaler 25 micrograms per actuation pressurised inhalation suspension	GlaxoSmithKline (Ireland) Limited	PA1077/047/005	Pressurised inhalation, suspension	- R03AC - R03AC12	- Salmeterol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Serevent Evohaler 25 micrograms per actuation pressurised inhalation suspension	PCO Manufacturing Ltd.	PPA0465/503/001	Pressurised inhalation, suspension	- R03AC12	- Salmeterol	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Inhalation use
Serevent Evohaler 25 micrograms per actuation pressurised inhalation suspension	IMED Healthcare Ltd.	PPA1463/204/001	Pressurised inhalation, suspension	- R03AC - R03AC12	- Salmeterol		- Inhalation use
Serimel 100 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/135/002 Interchangeable List Code: IC0064-024-003	Film-coated tablet		- Sertraline		- Oral use
Serimel 50 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/135/001 Interchangeable List Code: IC0064-023-003	Film-coated tablet		- Sertraline		- Oral use
Serlan 100 mg Film-Coated Tablet	Rowex Ltd	PA0711/065/002 Interchangeable List Code: IC0064-024-003	Film-coated tablet		- Sertraline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Serlan 50 mg film-coated tablets	Rowex Ltd	PA0711/065/001 Interchangeable List Code: IC0064-023-003	Film-coated tablet		- Sertraline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Seropia 100 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/185/002 Interchangeable List Code: IC0019-024-003	Film-coated tablet		- Quetiapine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Seropia 200 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/185/003 Interchangeable List Code: IC0019-067-003	Film-coated tablet		- Quetiapine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Seropia 25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/185/001 Interchangeable List Code: IC0019-022-003	Film-coated tablet		- Quetiapine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Seropia 300 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/185/004 Interchangeable List Code: IC0019-029-003	Film-coated tablet		- Quetiapine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Seropia XR 150 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/275/002 Interchangeable List Code: IC0019-062-024	Prolonged-release tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Seropia XR 200 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/275/003 Interchangeable List Code: IC0019-067-024	Prolonged-release tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Seropia XR 300 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/275/004 Interchangeable List Code: IC0019-029-024	Prolonged-release tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Seropia XR 400 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/275/005 Interchangeable List Code: IC0019-068-024	Prolonged-release tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Seropia XR 50 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/275/001 Interchangeable List Code: IC0019-023-024	Prolonged-release tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Seroquel 100 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/182/002 Interchangeable List Code: IC0019-024-003	Film-coated tablet		- Quetiapine		- Oral use
Seroquel 100 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/438/006 Interchangeable List Code: IC0019-024-003	Film-coated tablet		- Quetiapine		- Oral use
Seroquel 100 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/002 Interchangeable List Code: IC0019-024-003	Film-coated tablet		- Quetiapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Seroquel 200 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/003 Interchangeable List Code: IC0019-067-003	Film-coated tablet		- Quetiapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Seroquel 25 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/001 Interchangeable List Code: IC0019-022-003	Film-coated tablet		- Quetiapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Seroquel 25 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/438/005 Interchangeable List Code: IC0019-022-003	Film-coated tablet		- Quetiapine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Seroquel 25 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/182/001 Interchangeable List Code: IC0019-022-003	Film-coated tablet		- Quetiapine		- Oral use
Seroquel 300 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/004 Interchangeable List Code: IC0019-029-003	Film-coated tablet		- Quetiapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Seroquel XR 150 mg prolonged-release tablets	Originalis B.V.	PPA2306/011/002 Interchangeable List Code: IC0019-062-024	Prolonged-release tablet		- Quetiapine		- Oral use
Seroquel XR 150 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/438/002 Interchangeable List Code: IC0019-062-024	Prolonged-release tablet		- Quetiapine		- Oral use
Seroquel XR 150mg prolonged-release tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/006 Interchangeable List Code: IC0019-062-024	Prolonged-release tablet		- Quetiapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Seroquel XR 200 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/438/003 Interchangeable List Code: IC0019-067-024	Prolonged-release tablet		- Quetiapine		- Oral use
Seroquel XR 200mg prolonged-release tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/007 Interchangeable List Code: IC0019-067-024	Prolonged-release tablet		- Quetiapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Seroquel XR 300 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/438/004 Interchangeable List Code: IC0019-029-024	Prolonged-release tablet		- Quetiapine		- Oral use
Seroquel XR 300mg prolonged-release tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/008 Interchangeable List Code: IC0019-029-024	Prolonged-release tablet		- Quetiapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Seroquel XR 400 mg prolonged-release tablets	Originalis B.V.	PPA2306/011/001 Interchangeable List Code: IC0019-068-024	Prolonged-release tablet		- Quetiapine		- Oral use
Seroquel XR 400mg prolonged-release tablets.	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/009 Interchangeable List Code: IC0019-068-024	Prolonged-release tablet		- Quetiapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Seroquel XR 50 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/438/001 Interchangeable List Code: IC0019-023-024	Prolonged-release tablet		- Quetiapine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Seroquel XR 50mg prolonged-release tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/005 Interchangeable List Code: IC0019-023-024	Prolonged-release tablet		- Quetiapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Seroxat 10 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/097/004 Interchangeable List Code: IC0076-002-003	Film-coated tablet		- Paroxetine hydrochloride hemihydrate		- Oral use
Seroxat 20 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/097/002 Interchangeable List Code: IC0076-003-003	Film-coated tablet		- Paroxetine hydrochloride hemihydrate		- Oral use
Seroxat 20 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/483/001 Interchangeable List Code: IC0076-003-003	Film-coated tablet		- Paroxetine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Seroxat 30 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/097/003 Interchangeable List Code: IC0076-033-003	Film-coated tablet		- Paroxetine hydrochloride hemihydrate		- Oral use
Sertraline 100 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/177/002 Interchangeable List Code: IC0064-024-003	Film-coated tablet		- Sertraline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sertraline 50 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/177/001 Interchangeable List Code: IC0064-023-003	Film-coated tablet		- Sertraline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sertraline Bluefish 100 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/021/002 Interchangeable List Code: IC0064-024-003	Film-coated tablet		- Sertraline hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sertraline Bluefish 50 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/021/001 Interchangeable List Code: IC0064-023-003	Film-coated tablet		- Sertraline hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Sertraline Krka 100 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/019/002 Interchangeable List Code: IC0064-024-003	Film-coated tablet		- Sertraline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sertraline Krka 50 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/019/001 Interchangeable List Code: IC0064-023-003	Film-coated tablet		- Sertraline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sevelamer Carbonate 800 mg film coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/205/001	Film-coated tablet	- V03AE - V03AE02	- Sevelamer carbonate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Sevelamer carbonate Genthon 800 mg, film-coated tablets	Genthon B.V.	PA0740/014/001	Film-coated tablet	- V03AE - V03AE02	- Sevelamer carbonate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Sevelamer carbonate Zentiva	Genzyme Europe B.V.	EU/1/14/952/001	Film-coated tablet	- V03AE - V03AE02	- Sevelamer carbonate - Sevelamer carbonate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Sevelamer carbonate Zentiva	Genzyme Europe B.V.	EU/1/14/952/002-003	Powder for oral suspension	- V03AE - V03AE02	- Sevelamer carbonate		
Sevelamer carbonate Zentiva	Genzyme Europe B.V.	EU/1/14/952/005	Powder for oral suspension	- V03AE02	- Sevelamer carbonate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Sevelamer Hydrochloride Waymade 800 mg film-coated tablets	Waymade B.V.	PA22879/001/002	Film-coated tablet	- V03AE - V03AE02	- Sevelamer hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
SEVELAMER HYDROCHLORIDE ZENTIVA	Genzyme Europe B.V.	EU/1/14/953/001	Film-coated tablet	- V03AE02	- SEVELAMER HYDROCHLORIDE	Article 10c -Informed Consent	- Oral use
Sevoflurane 100% inhalation vapour, liquid	Chanelle Medical Unlimited Company	PA0688/036/001	Inhalation vapour, liquid	- N01AB - N01AB08	- Sevoflurane	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Inhalation use
Sevoflurane 100% Inhalation Vapour, liquid	Piramal Critical Care B.V.	PA22583/003/001	Inhalation vapour, liquid	- N01AB - N01AB08	- Sevoflurane	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Inhalation use
Sevoflurane Baxter, 100%, inhalation vapour, liquid	Baxter Holding B.V.	PA2299/031/001	Inhalation vapour, liquid	- N01AB - N01AB08	- Sevoflurane	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Inhalation use
Sevorane 100% v/v Inhalation Gas	AbbVie Limited	PA1824/004/001	Inhalation vapour, liquid	- N01AB - N01AB08	- Sevoflurane	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Sevredol 10mg Film-Coated Tablets	Mundipharma Pharmaceuticals Limited	PA1688/009/001	Film-coated tablet	- N02AA - N02AA01	- Morphine sulfate		- Oral use
Sevredol 20 mg Film-Coated Tablets	Mundipharma Pharmaceuticals Limited	PA1688/009/002	Film-coated tablet	- N02AA - N02AA01	- Morphine sulfate		- Oral use
Shingrix	GlaxoSmithKline Biologicals S.A.	EU/1/18/1272/001-002	Powder and suspension for suspension for injection	- J07BK - J07BK03	- Recombinant varicella zoster virus surface glycoprotein e	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Sialanar 320 micrograms/ml oral solution	Proveca Pharma Limited	EU/1/16/1135/001	Oral solution	- A03AB - A03AB02	- Glycopyrronium bromide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Sibnayal	Advicenne Pharma SA	EU/1/20/1517/001-006	Prolonged-release granules	- A12BA30	- Potassium citrate - Potassium hydrogen carbonate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Sibnayal	Advicenne Pharma SA	EU/1/20/1517/007-012	Prolonged-release granules	- A12BA30	- Potassium citrate - Potassium hydrogen carbonate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Sidena 100 mg tablets	Rowex Ltd	PA0711/170/003 Interchangeable List Code: IC0063-024-014	Tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sidena 25 mg tablets	Rowex Ltd	PA0711/170/001 Interchangeable List Code: IC0063-022-014	Tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sidena 50 mg Tablets	Rowex Ltd	PA0711/170/002	Tablet	- G04BE - G04BE03	- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/001	Tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/003	Tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/005	Tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/011	Tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/028-30	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate, milled		- Oral use
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/031-33	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate, milled		- Oral use
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/13-15	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate, milled		- Oral use
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/16-18	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate, milled		- Oral use
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/19-21	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate, milled		- Oral use
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/22-24	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate, milled		- Oral use
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/25-27	Prolonged-release tablet	- N04BC - N04BC05	- Pramipexole dihydrochloride monohydrate, milled		- Oral use
Signifor	Recordati Rare Diseases	EU/1/12/753/001-004	Solution for injection	- H01CB - H01CB05	- Pasireotide disapartate		- Subcutaneous use
Signifor	Recordati Rare Diseases	EU/1/12/753/005-008	Solution for injection	- H01CB - H01CB05	- Pasireotide disapartate		- Subcutaneous use
Signifor	Recordati Rare Diseases	EU/1/12/753/009-012	Solution for injection	- H01CB - H01CB05	- Pasireotide disapartate		- Subcutaneous use
Signifor	Recordati Rare Diseases	EU/1/12/753/013	Powder and solvent for suspension for injection	- H01CB - H01CB05	- Pasireotide pamoate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Signifor	Recordati Rare Diseases	EU/1/12/753/014-015	Powder and solvent for suspension for injection	- H01CB - H01CB05	- Pasireotide pamoate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Signifor	Recordati Rare Diseases	EU/1/12/753/016-017	Powder and solvent for suspension for injection	- H01CB - H01CB05	- Pasireotide pamoate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Signifor	Recordati Rare Diseases	EU/1/12/753/018	Powder and solvent for suspension for injection	- H01CB - H01CB05	- Pasireotide pamoate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Signifor	Recordati Rare Diseases	EU/1/12/753/019	Powder and solvent for suspension for injection	- H01CB - H01CB05	- Pasireotide pamoate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Siklos	Addmedica	EU/1/07/397/001	Film-coated tablet	- L01XX - L01XX05	- Hydroxycarbamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Siklos	Addmedica	EU/1/07/397/002-004	Film-coated tablet	- L01XX - L01XX05	- Hydroxycarbamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Silapo	Stada Arzneimittel AG	EU/1/07/432/1-6	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Epoetin zeta		- Intravenous use - Subcutaneous use
Silapo	Stada Arzneimittel AG	EU/1/07/432/17-19	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Epoetin zeta		- Intravenous use - Subcutaneous use
Silapo	Stada Arzneimittel AG	EU/1/07/432/7-16	Solution for injection in pre-filled syringe	- B03XA - B03XA01	- Epoetin zeta		- Intravenous use - Subcutaneous use
Silcarfil 20 mg film-coated tablets	Rowex Ltd	PA0711/266/001 Interchangeable List Code: IC0063-003-003	Film-coated tablet		- Sildenafil citrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Silcock's Base CreamWhite Soft Paraffin 20%w/w, Emulsifying Wax 15% w/w	Ovelle Limited	PA0206/020/001	Cream	- D02AC	- Emulsifying wax - White soft paraffin		- Topical
Sildenafil Accord 100 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/069/003 Interchangeable List Code: IC0063-024-014	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Accord 25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/069/001 Interchangeable List Code: IC0063-022-014	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Accord 50 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/069/002 Interchangeable List Code: IC0063-023-003	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Actavis 100 mg film-coated tablets	Actavis Group hf	EU/1/09/595/11-15 Interchangeable List Code: IC0063-024-014	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Actavis 25 mg film-coated tablets	Actavis Group hf	EU/1/09/595/1-5 Interchangeable List Code: IC0063-022-014	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Actavis 50 mg film-coated tablets	Actavis Group hf	EU/1/09/595/6-10 Interchangeable List Code: IC0063-023-003	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Clonmel 100 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/199/003 Interchangeable List Code: IC0063-024-014	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/199/004 Interchangeable List Code: IC0063-003-003	Film-coated tablet		- Sildenafil citrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Clonmel 25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/199/001 Interchangeable List Code: IC0063-022-014	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Sildenafil Clonmel 25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/382/001 Interchangeable List Code: IC0063-022-014	Film-coated tablet		- Sildenafil citrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Clonmel 50 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/382/002 Interchangeable List Code: IC0063-023-003	Film-coated tablet		- Sildenafil citrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Clonmel 50 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/199/002 Interchangeable List Code: IC0063-023-003	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Mylan 100 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/141/003 Interchangeable List Code: IC0063-024-014	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Mylan 25 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/141/001 Interchangeable List Code: IC0063-022-014	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Mylan 50 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/141/002 Interchangeable List Code: IC0063-023-003	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil ratiopharm 100 mg film-coated tablets	Ratiopharm GmbH	EU/1/09/603/9-12 Interchangeable List Code: IC0063-024-014	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil ratiopharm 25 mg film-coated tablets	Ratiopharm GmbH	EU/1/09/603/1-4 Interchangeable List Code: IC0063-022-014	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil ratiopharm 50 mg film-coated tablets	Ratiopharm GmbH	EU/1/09/603/5-8 Interchangeable List Code: IC0063-023-003	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Teva 100 mg film-coated tablets	Teva B.V.	EU/1/09/584/13-18 Interchangeable List Code: IC0063-024-014	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Teva 20 mg Film-coated Tablets	Teva B.V.	PA1986/031/001 Interchangeable List Code: IC0063-003-003	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Teva 25 mg film-coated tablets	Teva B.V.	EU/1/09/584/1-6 Interchangeable List Code: IC0063-022-014	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenafil Teva 50 mg film-coated tablets	Teva B.V.	EU/1/09/584/7-12 Interchangeable List Code: IC0063-023-003	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sildenvia 50 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/261/001	Film-coated tablet	- G04BE03	- Sildenafil	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Silkis 3 micrograms per g ointment	Galderma International	PA22743/014/001	Ointment	- D05AX - D05AX03	- Calcitriol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Silodosin Recordati	Recordati Ireland Limited	EU/1/18/1343/001-006	Capsule, hard	- G04CA04	- Silodosin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Silodosin Recordati	Recordati Ireland Limited	EU/1/18/1343/007-012	Capsule, hard	- G04CA04	- Silodosin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Silodyx	Recordati Ireland Limited	EU/1/09/607/1-7	Capsule, hard	- G04CA - G04CA04	- Silodosin		- Oral use
Silodyx	Recordati Ireland Limited	EU/1/09/607/8-14	Capsule, hard	- G04CA - G04CA04	- Silodosin		- Oral use
SimAlvia 60mg/300mg, soft capsules	Laboratoires Galeniques Vernin	PA1927/001/001	Capsule, soft	- A03AX - A03AX58	- ALVERINE CITRATE - Simeticone	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Simbrinza	Novartis Europharm Limited	EU/1/14/933/001-002	Eye drops, suspension	- S01EC54	- Brinzolamide - Brimonidine tartrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Ocular use
Simponi	Janssen Biologics B.V.	EU/1/09/546/005-008	Solution for injection	- L04AB - L04AB06	- Golimumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Simponi	Janssen Biologics B.V.	EU/1/09/546/009	Solution for injection in pre-filled pen	- L04AB06	- Golimumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Simponi	Janssen Biologics B.V.	EU/1/09/546/1-4	Solution for injection	- L04AB - L04AB06	- Golimumab (cnto 148)		- Subcutaneous use
Simtan 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/125/002 Interchangeable List Code: IC0018-002-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simtan 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/125/003 Interchangeable List Code: IC0018-003-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simtan 40 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/125/004 Interchangeable List Code: IC0018-004-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simtan 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/125/001	Film-coated tablet	- C10AA - C10AA01	- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simulect	Novartis Europharm Limited	EU/1/98/084/001	Powder and solvent for solution for injection/infusion	- L04AC - L04AC02	- Basiliximab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Simulect	Novartis Europharm Limited	EU/1/98/084/002	Powder and solvent for solution for injection/infusion	- L04AC - L04AC02	- Basiliximab		- Intravenous use
Simvastatin 10 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/054/001 Interchangeable List Code: IC0018-002-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simvastatin 20 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/054/002 Interchangeable List Code: IC0018-003-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simvastatin 20 mg film-coated tablets	Genthon B.V.	PA0740/003/003 Interchangeable List Code: IC0018-003-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Simvastatin 40 mg film-coated tablets	Genthon B.V.	PA0740/003/004 Interchangeable List Code: IC0018-004-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simvastatin 40 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/054/003 Interchangeable List Code: IC0018-004-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simvastatin 80 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/054/004	Film-coated tablet	- C10AA - C10AA01	- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simvastatin Bluefish 10 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/003/001 Interchangeable List Code: IC0018-002-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simvastatin Bluefish 20mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/003/002 Interchangeable List Code: IC0018-003-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simvastatin Bluefish 40mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/003/003 Interchangeable List Code: IC0018-004-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simvastatin Krka 10 mg Film-Coated Tablets	KRKA, d.d., Novo mesto	PA1347/028/001 Interchangeable List Code: IC0018-002-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simvastatin Krka 20 mg Film Coated Tablets	KRKA, d.d., Novo mesto	PA1347/028/002 Interchangeable List Code: IC0018-003-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simvastatin Krka 40 mg Film Coated Tablets	KRKA, d.d., Novo mesto	PA1347/028/003 Interchangeable List Code: IC0018-004-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simvastatin Teva 10 mg film-coated tablets	Teva Pharma B.V.	PA0749/052/002 Interchangeable List Code: IC0018-002-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simvastatin Teva 20 mg film-coated tablets	Teva Pharma B.V.	PA0749/052/003 Interchangeable List Code: IC0018-003-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Simvastatin Teva 40 mg film-coated tablets	Teva Pharma B.V.	PA0749/052/004 Interchangeable List Code: IC0018-004-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sinemet 10 mg/100 mg tablets	Organon Pharma (Ireland) Limited	PA23198/004/002	Tablet	- N04BA - N04BA02	- Carbidopa - Levodopa		- Oral use
Sinemet 12.5 mg/50 mg tablets	Organon Pharma (Ireland) Limited	PA23198/004/001	Tablet	- N04BA - N04BA02	- Carbidopa - Levodopa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sinemet 25 mg/250 mg tablets	Organon Pharma (Ireland) Limited	PA23198/004/004	Tablet	- N04BA - N04BA02	- Levodopa - Carbidopa		- Oral use
Sinemet CR 50 mg/200 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/468/002	Prolonged-release tablet	- N04BA02	- Carbidopa - Levodopa		- Oral use
Sinemet CR 50mg/200 mg Prolonged-release Tablets	Organon Pharma (Ireland) Limited	PA23198/004/005	Prolonged-release tablet	- N04BA - N04BA02	- Levodopa - Carbidopa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Sinemet Plus 25 mg/100 mg tablets	Organon Pharma (Ireland) Limited	PA23198/004/003	Tablet	- N04BA - N04BA02	- Levodopa - Carbidopa		- Oral use
Sinemet Plus 25 mg/100 mg tablets	PCO Manufacturing Ltd.	PPA0465/468/001	Film-coated tablet	- N04BA - N04BA02	- Carbidopa - Levodopa		- Oral use
Singulair 10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/111/001 Interchangeable List Code: IC0023-002-003	Film-coated tablet		- Montelukast		- Oral use
Singulair 10 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/064/003 Interchangeable List Code: IC0023-002-003	Film-coated tablet		- Montelukast		- Oral use
Singulair 10 mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/014/004 Interchangeable List Code: IC0023-002-003	Film-coated tablet		- Montelukast sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Singulair Paediatric 4 mg chewable tablets	Organon Pharma (Ireland) Limited	PA23198/014/001 Interchangeable List Code: IC0023-008-007	Chewable tablet		- Montelukast	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Singulair Paediatric 4 mg granules	Organon Pharma (Ireland) Limited	PA23198/014/002 Interchangeable List Code: IC0023-008-041	Granules		- Montelukast sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Singulair Paediatric 5 mg chewable tablets	Organon Pharma (Ireland) Limited	PA23198/014/003 Interchangeable List Code: IC0023-001-007	Chewable tablet		- Montelukast sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Singulair Paediatric 5 mg Chewable Tablet	IMED Healthcare Ltd.	PPA1463/064/002 Interchangeable List Code: IC0023-001-007	Chewable tablet		- Montelukast		- Oral use
Singulair Paediatric 5 mg chewable tablets	PCO Manufacturing Ltd.	PPA0465/111/002 Interchangeable List Code: IC0023-001-007	Chewable tablet		- Montelukast sodium	ZZZ PPA	- Oral use
Sinora 0.08 mg/ml solution for infusion	Sintetica GmbH	PA22835/001/001	Solution for infusion	- C01CA - C01CA03	- NOREPINEPHRINE BITARTRATE	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sinora 0.1 mg/ml solution for infusion	Sintetica GmbH	PA22835/004/002	Solution for infusion	- C01CA - C01CA03	- Noradrenaline tartrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sinora 0.16 mg/ml solution for infusion	Sintetica GmbH	PA22835/001/002	Solution for infusion	- C01CA - C01CA03	- NOREPINEPHRINE BITARTRATE	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sinora 0.2 mg/ml solution for infusion	Sintetica GmbH	PA22835/004/003	Solution for infusion	- C01CA - C01CA03	- Noradrenaline tartrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sinora 1 mg/ml concentrate for solution for infusion	Sintetica GmbH	PA22835/004/001	Concentrate for solution for infusion	- C01CA - C01CA03	- Noradrenaline tartrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sirdupla 25 microgram/125 microgram per metered dose pressurised inhalation, suspension	Viatris Limited	PA23266/020/001 Interchangeable List Code: IC0128-176-053	Pressurised inhalation, suspension		- SALMETEROL XINAFOATE - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Sirdupla 25 microgram/250 microgram per metered dose pressurised inhalation, suspension	Viatris Limited	PA23266/020/002 Interchangeable List Code: IC0128-177-053	Pressurised inhalation, suspension		- SALMETEROL XINAFOATE - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Sirturo	Janssen-Cilag International NV	EU/1/13/901/001	Tablet	- J04AK - J04AK05	- Bedaquiline fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sirturo	Janssen-Cilag International NV	EU/1/13/901/003	Tablet	- J04AK05	- Bedaquiline fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Grindeks 100 mg film-coated tablets	AS Grindeks	PA22992/005/003 Interchangeable List Code: IC0131-024-003	Film-coated tablet		- Sitagliptin Hydrochloride Monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Grindeks 25 mg film-coated tablets	AS Grindeks	PA22992/005/001 Interchangeable List Code: IC0131-022-003	Film-coated tablet		- Sitagliptin Hydrochloride Monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Grindeks 50 mg film-coated tablets	AS Grindeks	PA22992/005/002 Interchangeable List Code: IC0131-023-003	Film-coated tablet		- Sitagliptin Hydrochloride Monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Krka 100 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/094/003 Interchangeable List Code: IC0131-024-003	Film-coated tablet		- Sitagliptin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Krka 25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/094/001 Interchangeable List Code: IC0131-022-003	Film-coated tablet		- Sitagliptin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Krka 50 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/094/002 Interchangeable List Code: IC0131-023-003	Film-coated tablet		- Sitagliptin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Metformin Hydrochloride Mylan	Mylan Ireland Limited	EU/1/21/1619/001-008 Interchangeable List Code: IC0070-121-003	Film-coated tablet		- Sitagliptin - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Metformin Hydrochloride Mylan	Mylan Ireland Limited	EU/1/21/1619/009-020 Interchangeable List Code: IC0070-122-003	Film-coated tablet		- Metformin Hydrochloride - Sitagliptin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Mylan 100 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/232/003 Interchangeable List Code: IC0131-024-003	Film-coated tablet		- Sitagliptin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Mylan 25 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/232/001 Interchangeable List Code: IC0131-022-003	Film-coated tablet		- Sitagliptin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Mylan 50 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/232/002 Interchangeable List Code: IC0131-023-003	Film-coated tablet		- Sitagliptin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Sitagliptin Pinewood 100 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/219/003 Interchangeable List Code: IC0131-024-003	Film-coated tablet		- Sitagliptin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Pinewood 25 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/219/001 Interchangeable List Code: IC0131-022-003	Film-coated tablet		- Sitagliptin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Pinewood 50 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/219/002 Interchangeable List Code: IC0131-023-003	Film-coated tablet		- Sitagliptin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Rowa 100 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/089/003 Interchangeable List Code: IC0131-024-003	Film-coated tablet		- Sitagliptin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Rowa 25 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/089/001 Interchangeable List Code: IC0131-022-003	Film-coated tablet		- Sitagliptin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Rowa 50 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/089/002 Interchangeable List Code: IC0131-023-003	Film-coated tablet		- Sitagliptin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin SUN 100 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	EU/1/21/1598/009-012 Interchangeable List Code: IC0131-024-003	Film-coated tablet		- Sitagliptin Fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin SUN 25 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	EU/1/21/1598/001-004 Interchangeable List Code: IC0131-022-003	Film-coated tablet		- Sitagliptin Fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin SUN 50 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	EU/1/21/1598/005-008 Interchangeable List Code: IC0131-023-003	Film-coated tablet		- Sitagliptin Fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin Teva 100 mg film-coated tablets	Teva B.V.	PA1986/020/001 Interchangeable List Code: IC0131-024-003	Film-coated tablet		- Sitagliptin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin/Metformin Clonmel 50 mg/1000 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/327/002 Interchangeable List Code: IC0070-122-003	Film-coated tablet		- Sitagliptin - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin/Metformin Clonmel 50 mg/850 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/327/001 Interchangeable List Code: IC0070-121-003	Film-coated tablet		- Sitagliptin - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin/Metformin Hydrochloride Accord	Accord Healthcare S.L.U.	EU/1/22/1661/001-016 Interchangeable List Code: IC0070-121-003	Film-coated tablet		- Sitagliptin Hydrochloride Monohydrate - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin/Metformin Hydrochloride Accord	Accord Healthcare S.L.U.	EU/1/22/1661/017-032 Interchangeable List Code: IC0070-122-003	Film-coated tablet		- Sitagliptin Hydrochloride Monohydrate - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Sitagliptin/Metformin hydrochloride Grindeks 50 mg/1000 mg film-coated tablets	AS Grindeks	PA22992/006/002 Interchangeable List Code: IC0070-122-003	Film-coated tablet		- Sitagliptin Hydrochloride Monohydrate - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin/Metformin hydrochloride Grindeks 50 mg/850 mg film-coated tablets	AS Grindeks	PA22992/006/001 Interchangeable List Code: IC0070-121-003	Film-coated tablet		- Metformin Hydrochloride - Sitagliptin Hydrochloride Monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin/Metformin hydrochloride Krka 50 mg/1000 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/100/002 Interchangeable List Code: IC0070-122-003	Film-coated tablet		- Sitagliptin - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin/Metformin hydrochloride Krka 50 mg/850 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/100/001 Interchangeable List Code: IC0070-121-003	Film-coated tablet		- Sitagliptin - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin/Metformin Hydrochloride Pinewood 50 mg/1000 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/220/002 Interchangeable List Code: IC0070-122-003	Film-coated tablet		- Sitagliptin hydrochloride - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin/Metformin Hydrochloride Pinewood 50 mg/850 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/220/001 Interchangeable List Code: IC0070-121-003	Film-coated tablet		- Sitagliptin hydrochloride - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin/Metformin hydrochloride Rowa 50 mg/1000 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/090/002 Interchangeable List Code: IC0070-122-003	Film-coated tablet		- Sitagliptin Hydrochloride Monohydrate - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin/Metformin hydrochloride Rowa 50 mg/850 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/090/001 Interchangeable List Code: IC0070-121-003	Film-coated tablet		- Sitagliptin Hydrochloride Monohydrate - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin/Metformin hydrochloride SUN	Sun Pharmaceutical Industries Europe B.V.	EU/1/23/1720/001-003	Film-coated tablet	- A10BD07	- Sitagliptin Fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin/Metformin hydrochloride SUN	Sun Pharmaceutical Industries Europe B.V.	EU/1/23/1720/004-006	Film-coated tablet	- A10BD07	- Sitagliptin Fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin/Metformin hydrochloride Teva 50 mg/1000 mg film-coated tablets	Norton Waterford	PA0436/051/002 Interchangeable List Code: IC0070-122-003	Film-coated tablet		- Sitagliptin Hydrochloride Monohydrate - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sitagliptin/Metformin hydrochloride Teva 50 mg/850 mg film-coated tablets	Norton Waterford	PA0436/051/001 Interchangeable List Code: IC0070-121-003	Film-coated tablet		- Sitagliptin Hydrochloride Monohydrate - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sivatin 10 mg film-coated tablets	Rowex Ltd	PA0711/050/001 Interchangeable List Code: IC0018-002-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sivatin 20 mg film-coated tablets	Rowex Ltd	PA0711/050/002 Interchangeable List Code: IC0018-003-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sivatin 40 mg film-coated tablets	Rowex Ltd	PA0711/050/003 Interchangeable List Code: IC0018-004-003	Film-coated tablet		- Simvastatin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Sivextro	Merck Sharp & Dohme BV	EU/1/15/991/001	Film-coated tablet	- J01XX	- Tedizolid phosphate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sivextro	Merck Sharp & Dohme BV	EU/1/15/991/002-003	Powder for concentrate for solution for infusion	- J01XX	- Tedizolid phosphate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Six Plus Parapaed Paracetamol Oral Suspension 250 mg/5 ml	Pinewood Laboratories Ltd	PA0281/002/003	Oral suspension	- N02BE - N02BE01	- Paracetamol		- Oral use
Sixmo 74.2 mg implant	FGK Representative Service GmbH	EU/1/19/1369/001	Implant	- N07BC01	- Buprenorphine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Skilarence	Almirall, S.A.	EU/1/17/1201/001	Gastro-resistant tablet		- Dimethyl Fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Skilarence	Almirall, S.A.	EU/1/17/1201/002-011	Gastro-resistant tablet		- Dimethyl Fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Skinoren 15% Gel	LEO Pharma A/S	PA1025/009/001	Gel	- D10AX - D10AX03	- Azelaic acid		- Topical
Skudexa 75 mg/25 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/020/001 Interchangeable List Code: IC0103-161-058	Film-coated tablet		- Dexketoprofen - Tramadol hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Skudexa 75 mg/25 mg granules for oral solution in sachet	Menarini International Operations Luxembourg S.A.	PA0865/020/003 Interchangeable List Code: IC0103-161-058	Granules for oral solution in sachet		- Tramadol hydrochloride - Dexketoprofen	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Skyrizi	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1361/001	Solution for injection in pre-filled syringe	- L04AC	- RISANKIZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Skyrizi	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1361/002	Solution for injection in pre-filled pen	- L04AC18	- RISANKIZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Skyrizi	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1361/003	Solution for injection in pre-filled syringe	- L04AC18	- RISANKIZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Skyrizi	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1361/004	Concentrate for solution for infusion	- L04AC18	- RISANKIZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Skyrizi	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1361/005	Solution for injection in cartridge	- L04AC18	- RISANKIZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Skyrizi	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1361/006	Solution for injection in pre-filled syringe	- L04AC18	- RISANKIZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/001	Powder and solvent for solution for injection	- H01AC09	- Lonapegsomatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/002	Powder and solvent for solution for injection	- H01AC09	- Lonapegsomatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/003	Powder and solvent for solution for injection	- H01AC - H01AC09	- Lonapegsomatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/004	Powder and solvent for solution for injection	- H01AC09	- Lonapegsomatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/005	Powder and solvent for solution for injection	- H01AC09	- Lonapegsomatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/006	Powder and solvent for solution for injection	- H01AC09	- Lonapegsomatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/007	Powder and solvent for solution for injection	- H01AC09	- Lonapegsomatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/008	Powder and solvent for solution for injection	- H01AC09	- Lonapegsomatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/009	Powder and solvent for solution for injection	- H01AC09	- Lonapegsomatropin - Somatropin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Slenyto	RAD Neurim Pharmaceuticals EEC SARL	EU/1/18/1318/001-002	Prolonged-release tablet	- N05CM01	- Melatonin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Slenyto	RAD Neurim Pharmaceuticals EEC SARL	EU/1/18/1318/003-004	Prolonged-release tablet	- N05CM01	- Melatonin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Slow K 600mg Prolonged-release Coated Tablets	Essential Pharma (M) Limited	PA22644/002/001	Prolonged-release tablet	- A12BA - A12BA01	- Potassium chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Slyndy 4 mg film-coated tablets	Exeltis healthcare S.L.	PA22998/002/001	Film-coated tablet	- QG03AC10	- Drospirenone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
SmofKabiven Central emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/058/002	Emulsion for infusion	- B05BA - B05BA10	- Soya bean oil, refined - Medium chain triglycerides - Refined soyabean oil - Fish oil, rich in omega-3 acids - L-alanine - L-arginine - Glycine (aminoacetic acid) - L-histidine - L-isoleucine - L-leucine - L-lysine - L-methionine - L-phenylalanine - L-proline - L-serine - Taurine - L-threonine - L-tryptophan - L-tyrosine - L-valine - Calcium chloride - Sodium glycerophosphate - Magnesium sulfate - Potassium chloride - Sodium acetate - Zinc sulfate - Glucose	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
SmofKabiven Central emulsion for infusion, Excel bags	Fresenius Kabi Deutschland GmbH	PA2059/058/001	Emulsion for infusion	- B05BA - B05BA10	- L-alanine - L-arginine - Glycine - L-histidine - L-isoleucine - L-leucine - L-lysine - L-methionine - L-phenylalanine - L-proline - L-serine - Taurine - L-threonine - L-tryptophan - L-tyrosine - L-valine - Calcium chloride - Sodium glycerophophate hydrate - Magnesium sulphate heptahydrate - Potassium chloride - Sodium acetate trihydrate - Zinc sulphate heptahydrate - Glucose monohydrate - Soya bean oil, refined - Triglycerides, medium chain - Olive oil, refined - Fish oil, rich in omega-3 acids	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
SmofKabiven Electrolyte Free Central emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/059/002	Emulsion for infusion	- B05BA - B05BA10	- L-alanine - L-arginine - Glycine - L-histidine - L-isoleucine - L-leucine - L-lysine acetate - L-methionine - L-phenylalanine - L-proline - L-serine - Taurine - L-threonine - L-tryptophan - L-tyrosine - L-valine - Glucose monohydrate - Soya bean oil, refined - Triglycerides, medium chain - Olive oil, refined - Fish oil, rich in omega-3 acids	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
SmofKabiven extra Nitrogen Electrolyte free, emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/060/002	Emulsion for infusion	- B05BA - B05BA10	- Alanine - Arginine - Glycine - Histidine - Isoleucine - Leucine - Lysine acetate - Methionine - Phenylalanine - Proline - Serine - Taurine - Tryptophan - Tyrosine - Valine - Glucose monohydrate - Soya bean oil, refined - Triglycerides, medium chain - Olive oil, refined - Fish oil, rich in omega-3 acids	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
SmofKabiven extra Nitrogen, emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/060/001	Emulsion for infusion	- B05BA - B05BA10	- Alanine - Arginine - Glycine - Histidine - Isoleucine - Leucine - Lysine acetate - Methionine - Phenylalanine - Proline - Serine - Taurine - Tryptophan - Tyrosine - Valine - Calcium chloride dihydrate - Sodium glycerophophate hydrate - Magnesium sulfate heptahydrate - Potassium chloride - Sodium acetate trihydrate - Zinc sulphate heptahydrate - Glucose monohydrate - Soya bean oil, refined - Triglycerides, medium chain - Olive oil, refined - Fish oil, rich in omega-3 acids	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
SmofKabiven Low Osmo Peripheral emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/022/001	Emulsion for infusion	- B05BA - B05BA10	- Alanine - Arginine - Glycine - Histidine - Isoleucine - Leucine - Lysine acetate - Methionine - Phenylalanine - Proline - Serine - Taurine - Threonine - Tryptophan - Tyrosine - Valine - Calcium chloride dihydrate - Sodium glycerophophate hydrate - Magnesium sulphate heptahydrate - Potassium chloride - Sodium acetate trihydrate - Zinc sulphate heptahydrate - Glucose monohydrate - Soya bean oil, refined - Triglycerides, medium chain - Olive oil, refined - Fish oil, rich in omega-3 acids	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
SmofKabiven Nutribase emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/058/003	Emulsion for infusion	- B05BA10	- Alanine - Arginine - Glycine - Histidine - Isoleucine - Leucine - Lysine acetate - Methionine - Phenylalanine - Proline - Serine - Taurine - Threonine - Tryptophan - Tyrosine - Valine - Calcium chloride dihydrate - Sodium glycerophosphate - Magnesium sulfate - Potassium chloride - Sodium acetate trihydrate - Zinc sulphate heptahydrate - Glucose monohydrate - Soya-bean oil refined - Triglycerides medium-chain - Olive oil, refined - Fish oil, rich in omega-3 acids	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
SmofKabiven Peripheral, emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/061/002	Emulsion for infusion	- B05BA - B05BA10	- SOYA BEAN OIL, REFINED PH. EUR. - Medium chain triglycerides - Refined olive oil - Fish oil, rich in omega-3 acids - Isoleucine - Leucine - Methionine - Lysine acetate - Phenylalanine - Threonine - Tryptophan - Valine - Arginine - Histidine - Alanine - Glycine - Proline - Serine - Tyrosine - Taurine - Calcium chloride dihydrate - Sodium glycerophophate hydrate - Magnesium sulphate heptahydrate - Potassium chloride - Sodium acetate trihydrate - Zinc sulphate heptahydrate - Glucose monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
SMOFlipid 200 mg/ml emulsion for infusion, excel bag	Fresenius Kabi Deutschland GmbH	PA2059/062/002	Emulsion for infusion	- B05BA - B05BA02	- Soya bean oil - Medium chain triglycerides - Refined olive oil - Purified fish oil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
SMOFlipid 200 mg/ml emulsion for infusion, glass bottle	Fresenius Kabi Deutschland GmbH	PA2059/062/001	Emulsion for infusion	- B05BA - B05BA02	- Soybean oil - Triglycerides, medium chain - Refined olive oil - Purified fish oil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Sodium Chloride 0.3 % w/v and Glucose 3.3% w/v Solution for Infusion BP	Baxter Holding B.V.	PA2299/008/004	Solution for infusion	- B05CB - B05CB01	- Sodium chloride - Glucose	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sodium Chloride 0.45 % w/v and Glucose 2.5% w/v Solution for Infusion BP	Baxter Holding B.V.	PA2299/008/003	Solution for infusion	- B05CB - B05CB01	- Sodium chloride - Glucose		- Intravenous use
Sodium Chloride 0.45 % w/v and Glucose 5.0 % w/v Solution for Infusion BP	Baxter Holding B.V.	PA2299/008/001	Solution for infusion	- B05BB - B05BB02	- Sodium chloride - Glucose	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sodium Chloride 0.45% w/v Solution for Infusion	Baxter Holding B.V.	PA2299/002/002	Solution for infusion	- B05XA - B05XA03	- Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sodium Chloride 0.9 % w/v and Glucose 5% w/v Solution for Infusion BP (Viaflo container)	Baxter Holding B.V.	PA2299/008/002	Solution for infusion	- B05CB - B05CB01	- Sodium chloride - Glucose		- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Sodium Chloride 0.9 % w/v solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/063/003	Solution for infusion	- B05XA - B05XA03	- Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sodium Chloride 0.9% w/v Injection B	Noridem Enterprises Limited	PA1122/002/001	Solvent for parenteral use	- V07AB	- Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sodium Chloride 0.9% w/v Intravenous Infusion BP	Baxter Holding B.V.	PA2299/002/001	Solution for infusion	- B05BB - B05BB01	- Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sodium Chloride 0.9% w/v Intravenous Infusion BP Solution for Infusion	B. Braun Melsungen AG	PA0736/003/001	Solution for infusion	- B05BB - B05BB01	- Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sodium Chloride 0.9% w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/063/004	Solution for infusion	- B05XA03	- Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sodium Chloride 0.9% w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/063/002	Solution for infusion	- B05XA03	- Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sodium Chloride 0.9% w/v Solution for Infusion, polyethylene bottle	Fresenius Kabi Deutschland GmbH	PA2059/063/005	Solution for infusion	- B05XA - B05XA03	- Sodium chloride		- Intravenous use
Sodium chloride 0.9% w/v solvent for parenteral use	Fresenius Kabi Deutschland GmbH	PA2059/063/006	Solvent for parenteral use	- B05XA - B05XA03	- Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
Sodium Chloride 0.9%w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/063/001	Solution for infusion	- B05XA03	- Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sodium chloride 5 mmol/ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/015/001	Oral solution	- A12CA01	- Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Sodium Chloride Intravenous Infusion BP 0.9% w/v (viaflex container)	Baxter Holding B.V.	PA2299/002/003	Solution for infusion	- B05XA - B05XA03	- Sodium chloride		- Intravenous use
Sodium Chloride Intravenous Infusion BP 0.9% w/v Solution for Infusion	B. Braun Medical Limited	PA0179/002/007	Solution for infusion	- B05BB - B05BB01	- Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sodium Chloride Intravenous Infusion BP 0.9% w/v Solution for Infusion, Ecobag	B. Braun Medical Limited	PA0179/002/031	Solution for infusion	- B05BB - B05BB01	- Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sodium Iodide (I131) Capsule T 37-7400 MBq hard capsule	Curium Netherlands B.V.	PA0690/006/002	Capsule, hard	- V10XA - V10XA01	- Sodium iodide (131 i)	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Sodium Nitrite Hope Pharmaceuticals 30 mg/mL Solution for Injection	Hope Pharmaceuticals Ltd	PA22874/001/001	Solution for injection	- V03AB08	- SODIUM NITRITE	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Sodium oxybate 500 mg/ml oral solution	AS Kalceks	PA2165/007/001	Oral solution	- N07XX04	- Sodium Oxybate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sodium Thiosulfate Hope Pharmaceuticals 250 mg/mL Solution for Injection	Hope Pharmaceuticals Ltd	PA22874/002/001	Solution for injection	- V03AB - V03AB06	- Sodium thiosulfate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Sogroya	Novo Nordisk A/S	EU/1/20/1501/001-002	Solution for injection in pre-filled pen	- H01AC - H01AC07	- Somapacitan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Sogroya	Novo Nordisk A/S	EU/1/20/1501/003-004	Solution for injection in pre-filled pen	- H01AC07	- Somapacitan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Sogroya	Novo Nordisk A/S	EU/1/20/1501/005-006	Solution for injection in pre-filled pen	- H01AC07	- Somapacitan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Solaraze 3% gel	PCO Manufacturing Ltd.	PPA0465/488/001 Interchangeable List Code: IC0056-123-043	Gel		- Diclofenac sodium		- Cutaneous use
Solaraze 3% gel	IMED Healthcare Ltd.	PPA1463/205/001 Interchangeable List Code: IC0056-123-043	Gel		- Diclofenac sodium		- Cutaneous use
Solaraze 3% gel	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/021/001 Interchangeable List Code: IC0056-123-043	Gel		- Diclofenac sodium		- Cutaneous use
Solaraze 3% gel	Almirall, S.A.	PA0968/004/001 Interchangeable List Code: IC0056-123-043	Gel		- Diclofenac sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Solferol 1,000 IU Soft Capsules	Windzor Pharma Ireland Limited	PA23126/001/003	Capsule, soft	- A11CC - A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Solferol 10,000 IU Soft Capsules	Windzor Pharma Ireland Limited	PA23126/001/004	Capsule, soft	- A11CC - A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Solferol 20,000 IU Soft Capsules	Windzor Pharma Ireland Limited	PA23126/002/001	Capsule, soft	- A11CC - A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Solferol 400 IU Soft Capsules	Windzor Pharma Ireland Limited	PA23126/001/001	Capsule, soft	- A11CC - A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Solferol 800 IU Soft Capsules	Windzor Pharma Ireland Limited	PA23126/001/002	Capsule, soft	- A11CC - A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Solian 100mg Tablet	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/158/002	Tablet	- N05AL - N05AL05	- Amisulpride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Solian 200mg Tablet	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/158/003	Tablet	- N05AL - N05AL05	- Amisulpride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Solian 400 mg film-coated tablets	Originalis B.V.	PPA2306/019/001	Film-coated tablet	- N05AL05	- Amisulpride		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Solian 400mg Film-coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/158/004	Film-coated tablet	- N05AL - N05AL05	- Amisulpride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Solian 50mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/158/001	Tablet	- N05AL - N05AL05	- Amisulpride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Solifenacin Clonmel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/288/002 Interchangeable List Code: IC0116-002-003	Film-coated tablet		- Solifenacin succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Solifenacin Clonmel 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/288/001 Interchangeable List Code: IC0116-001-003	Film-coated tablet		- Solifenacin succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Solifenacin succinate 10 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/206/002 Interchangeable List Code: IC0116-002-003	Film-coated tablet		- Solifenacin succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Solifenacin succinate 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/118/002 Interchangeable List Code: IC0116-002-003	Film-coated tablet		- Solifenacin succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Solifenacin succinate 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/118/001 Interchangeable List Code: IC0116-001-003	Film-coated tablet		- Solifenacin succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Solifenacin succinate 5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/206/001 Interchangeable List Code: IC0116-001-003	Film-coated tablet		- Solifenacin succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Solifenacin succinate Aristo 10 mg film-coated tablets	Aristo Pharma GmbH	PA1983/006/002 Interchangeable List Code: IC0116-002-003	Film-coated tablet		- Solifenacin succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Solifenacin succinate Aristo 5 mg film-coated tablets	Aristo Pharma GmbH	PA1983/006/001 Interchangeable List Code: IC0116-001-003	Film-coated tablet		- Solifenacin succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Solifenacin succinate Rowex 10 mg film-coated tablets	Rowex Ltd	PA0711/280/002 Interchangeable List Code: IC0116-002-003	Film-coated tablet		- Solifenacin succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Solifenacin succinate Rowex 5 mg film-coated tablets	Rowex Ltd	PA0711/280/001 Interchangeable List Code: IC0116-001-003	Film-coated tablet		- Solifenacin succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Solifenacin succinate Vivanta 10 mg film-coated tablets	Vivanta Generics s.r.o.	PA2265/001/002 Interchangeable List Code: IC0116-002-003	Film-coated tablet		- Solifenacin succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Solifenacin succinate Vivanta 5 mg film-coated tablets	Vivanta Generics s.r.o.	PA2265/001/001 Interchangeable List Code: IC0116-001-003	Film-coated tablet		- Solifenacin succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Solifenacin succinate/Tamsulosin hydrochloride Clonmel 6 mg/0.4 mg modified-release tablets	Clonmel Healthcare Ltd	PA0126/351/001 Interchangeable List Code: IC0101-154-021	Modified-release tablet		- Solifenacin succinate - Tamsulosin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Solifenacin succinate/Tamsulosin hydrochloride Rowex 6 mg/0.4 mg modified-release tablets	Rowex Ltd	PA0711/317/001 Interchangeable List Code: IC0101-154-021	Modified-release tablet		- Solifenacin succinate - Tamsulosin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Solifenacin TAD 10 mg film-coated tablets	TAD Pharma GmbH	PA0876/008/002 Interchangeable List Code: IC0116-002-003	Film-coated tablet		- Solifenacin succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Solifenacin TAD 5 mg film-coated tablets	TAD Pharma GmbH	PA0876/008/001 Interchangeable List Code: IC0116-001-003	Film-coated tablet		- Solifenacin succinate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Soliris	Alexion Europe SAS	EU/1/07/393/001	Concentrate for solution for infusion	- L04AA - L04AA25	- Eculizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Solivito N powder for concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/064/001	Powder for concentrate for solution for infusion	- B05XC	- Thiamine nitrate - Riboflavin sodium phosphate - Nicotinamide - Pyridoxine hydrochloride - Sodium pantothenate - Sodium ascorbate - Biotin - Folic acid - Cyanocobalamin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Solpa Cold & Flu Multi-Relief Capsules Paracetamol 500mg,Guaifenesin 100mg,Phenylephrine hydrochloride 6.1mg	Chefaro Ireland DAC	PA1186/021/002	Capsule, hard	- N02BE - N02BE51	- Paracetamol - Guaifenesin - Phenylephrine hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Solpa Cold & Flu Multi-Relief Max Powder for Oral Solution Paracetamol 1000 mg, Guaifenesin 200 mg, Phenylephrine hydrochloride 12.2 mg	Chefaro Ireland DAC	PA1186/021/003	Powder for oral solution	- N02BE - N02BE51	- Paracetamol - Guaifenesin - Phenylephrine hydrochloride		- Oral use
Solpadeine Capsules, Paracetamol 500mg, Codeine Phosphate Hemihydrate 8mg, Caffeine 30mg	Chefaro Ireland DAC	PA1186/011/002	Capsule, hard	- N02AJ - N02AJ06	- Paracetamol - Codeine phosphate hemihydrate - Caffeine		- Oral use
Solpadeine Soluble Tablets Paracetamol 500mg Codeine Phosphate Hemihydrate 8mg Caffeine 30mg	Chefaro Ireland DAC	PA1186/011/001	Effervescent tablet	- N02AJ - N02AJ06	- Paracetamol - Codeine phosphate hemihydrate - Caffeine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Solpadeine TabletsParacetamol 500mg, Codeine Phosphate Hemihydrate 8mg, Caffeine 30mg	Chefaro Ireland DAC	PA1186/011/003	Tablet	- N02AJ - N02AJ06	- Paracetamol - Codeine phosphate hemihydrate - Caffeine		- Oral use
Solpadol 500 mg/30 mg Effervescent Tablets	Phoenix Labs	PA1113/027/002	Effervescent tablet	- N02AJ - N02AJ06	- Paracetamol - Codeine phosphate hemihydrate		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Solpadol Caplets 500 mg/30 mg Tablets	Phoenix Labs	PA1113/027/001	Tablet	- N02AJ - N02AJ06	- Paracetamol - Codeine phosphate hemihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Solpa-Extra 500 mg/65 mg Soluble Tablets	Chefaro Ireland DAC	PA1186/017/001	Soluble tablet	- N02BE - N02BE51	- Caffeine - Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Solpa-Extra Tablets Paracetamol 500 mg Caffeine 65 mg	Chefaro Ireland DAC	PA1186/026/001	Tablet	- N02BE - N02BE51	- Paracetamol - Caffeine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Solpa-Plus Tablets Paracetamol 500 mg Codeine Phosphate Hemihydrate 12.8 mg	Chefaro Ireland DAC	PA1186/011/005	Film-coated tablet	- N02AJ - N02AJ06	- Paracetamol - Codeine phosphate hemihydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Solpa-Plus with Caffeine Soluble Tablets Paracetamol 500 mg Codeine Phosphate Hemihydrate 12.8 mg Caffeine 30 mg	Chefaro Ireland DAC	PA1186/011/004	Effervescent tablet	- N02AJ - N02AJ06	- Paracetamol - Codeine phosphate hemihydrate - Caffeine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Solpa-Sinus Film-coated Tablets Paracetamol 500mg Pseudoephedrine Hydrochloride 30mg	Chefaro Ireland DAC	PA1186/012/001	Film-coated tablet	- N02BE - N02BE51	- Paracetamol - PSEUDOEPHEDRINE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Solu-Cortef Powder for Solution for Injection or Infusion 100mg	Pfizer Healthcare Ireland	PA0822/137/001	Powder and solvent for solution for injection/infusion	- H02AB - H02AB09	- HYDROCORTISONE PH. EUR.	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Solu-Medrone powder and solvent for solution for injection or concentrate for solution for infusion 1000 mg/vial	Pfizer Healthcare Ireland	PA0822/136/004	Powder and solvent for solution for injection/infusion	- H02AB - H02AB04	- Methylprednisolone hydrogen succinate ph. eur.	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Solu-Medrone powder and solvent for solution for injection or concentrate for solution for infusion 125 mg/vial	Pfizer Healthcare Ireland	PA0822/136/002	Powder and solvent for solution for injection/infusion	- H02AB - H02AB04	- Methylprednisolone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Solu-Medrone powder and solvent for solution for injection or concentrate for solution for infusion 40 mg/vial	Pfizer Healthcare Ireland	PA0822/136/001	Powder and solvent for solution for injection/infusion	- H02AB - H02AB04	- Methylprednisolone hydrogen succinate ph. eur.	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Solu-Medrone powder and solvent for solution for injection or concentrate for solution for infusion 500 mg/vial	Pfizer Healthcare Ireland	PA0822/136/003	Powder and solvent for solution for injection/infusion	- H02AB - H02AB04	- Methylprednisolone hydrogen succinate ph. eur.	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
SoluPrep 2% w/v / 70% v/v cutaneous solution	3M Deutschland GmbH	PA1762/002/001	Cutaneous solution	- D08AC - D08AC52	- Chlorhexidine gluconate - Isopropyl alcohol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
SoluPrep with tint 2%w/v/70%v/v cutaneous solution	3M Deutschland GmbH	PA1762/002/002	Cutaneous solution	- D08AC - D08AC52	- Chlorhexidine gluconate - Isopropyl alcohol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Soluprick Negative control, Solution for skin prick test	ALK-Abello A/S	PA1255/003/002	Solution for skin-prick test	- V04CL		Well-established use application (Article 10a of Directive No 2001/83/EC)	
Soluprick Positive control, 10 mg/ml, Solution for skin-prick test	ALK-Abello A/S	PA1255/003/001	Solution for skin-prick test	- V04CL	- Histamine dihydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	
Soluprick SQ Timothy Grass (Phleum pratense) pollen 10 HEP Solution for skin-prick testing	ALK-Abello A/S	PA1255/005/001	Solution for skin-prick test	- V04CL	- Phleum pratense	Full application (Article 8(3) of Directive No 2001/83/EC)	
Somac Control	Takeda GmbH	EU/1/09/516/001	Gastro-resistant tablet	- A02BC - A02BC02	- Pantoprazole sodium sesquihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Somac Control	Takeda GmbH	EU/1/09/516/001-004	Gastro-resistant tablet	- A02BC - A02BC02	- Pantoprazole sodium sesquihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
SomaKit TOC	Advanced Accelerator Applications	EU/1/16/1141/001	Kit for radiopharmaceutical preparation	- V09IX - V09IX09	- Edoteotide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Somatuline Autogel 120 mg, solution for injection in a pre-filled syringe	PCO Manufacturing Ltd.	PPA0465/478/001	Solution for injection in pre-filled syringe	- H01CB - H01CB03	- Lanreotide acetate		- Subcutaneous use
Somatuline Autogel 120mg, solution for injection in a pre-filled syringe	Originalis B.V.	PPA2306/026/002	Solution for injection in pre-filled syringe	- H01CB - H01CB03	- Lanreotide		- Intramuscular use
Somatuline Autogel 120mg, solution for injection in a pre-filled syringe	Ipsen Pharmaceuticals Limited	PA0869/004/004	Solution for injection in pre-filled syringe	- H01CB - H01CB03	- Lanreotide acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Somatuline Autogel 60 mg, solution for injection in a prefilled syringe	Ipsen Pharmaceuticals Limited	PA0869/004/002	Solution for injection in pre-filled syringe	- H01CB - H01CB03	- Lanreotide acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Somatuline Autogel 60 mg, solution for injection in a prefilled syringe	Originalis B.V.	PPA2306/026/001	Solution for injection in pre-filled syringe	- H01CB - H01CB03	- Lanreotide		- Intramuscular use
Somatuline Autogel 90mg, solution for injection in a pre-filled syringe	Ipsen Pharmaceuticals Limited	PA0869/004/003	Solution for injection in pre-filled syringe	- H01CB - H01CB03	- Lanreotide acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Somavert	Pfizer Europe MA EEIG	EU/1/02/240/009-010	Powder and solvent for solution for injection	- H01AX01	- Pegvisomant	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Somavert	Pfizer Europe MA EEIG	EU/1/02/240/011-012	Powder and solvent for solution for injection	- H01AX01	- Pegvisomant	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Somavert	Pfizer Europe MA EEIG	EU/1/02/240/1-3	Powder and solvent for solution for injection	- H01AX01	- Pegvisomant		- Subcutaneous use
Sondelbay	Accord Healthcare S.L.U.	EU/1/22/1628/001-002	Solution for injection in pre-filled pen	- H05AA02	- Teriparatide	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
SonoVue	Bracco International B.V.	EU/1/01/177/002	Powder and solvent for solution for infusion	- V08DA - V08DA05	- Sulphur hexafluoride		- Intravenous use
Soolantra 10 mg/g Cream	PCO Manufacturing Ltd.	PPA0465/498/001	Cream	- D11AX - D11AX22	- Ivermectin		- Cutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Soolantra 10mg/g Cream	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/014/001	Cream	- D11AX - D11AX22	- Ivermectin		- Cutaneous use
Soolantra 10mg/g Cream	Galderma International	PA22743/015/001	Cream	- D11AX - D11AX22	- Ivermectin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Sorafenib Accord	Accord Healthcare S.L.U.	EU/1/22/1696/001	Film-coated tablet	- L01 - L01EX02	- Sorafenib Tosilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sorafenib Bluefish 200 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/038/001	Film-coated tablet	- L01XE05	- Sorafenib Tosilate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sormon 60 mg Prolonged-release Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/202/001	Prolonged-release tablet	- C01DA - C01DA14	- Isosorbide-5-mononitrate		- Oral use
Sotoger 80mg Tablets	Viatris Limited	PA23266/014/001	Tablet	- C07AA - C07AA07	- SOTALOL HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
SOTYKTU	Bristol-Myers Squibb Pharma EEIG	EU/1/23/1718/001-008	Film-coated tablet	- L04AA - L04AA56	- Deucravacitinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sovaldi	Gilead Sciences Ireland UC	EU/1/13/894/001-002	Film-coated tablet	- J05AX - J05AX15	- Sofosbuvir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sovaldi	Gilead Sciences Ireland UC	EU/1/13/894/003	Film-coated tablet	- J05AP08	- Sofosbuvir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sovaldi	Gilead Sciences Ireland UC	EU/1/13/894/004	Granules	- J05AP08	- Sofosbuvir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sovaldi	Gilead Sciences Ireland UC	EU/1/13/894/005	Granules	- J05AP08	- Sofosbuvir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Spasmalvex 60 mg/300 mg, soft capsules	Laboratoires Galeniques Vernin	PA1927/002/001	Capsule, soft	- A03AX58	- ALVERINE CITRATE - Simeticone	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Spasmonal 60mg hard Capsules	Mylan IRE Healthcare Limited	PA2010/043/001	Capsule, hard	- A03AX - A03AX08	- ALVERINE CITRATE		- Oral use
Spasmonal Forte 120mg Hard Capsules	Mylan IRE Healthcare Limited	PA2010/043/002	Capsule, hard	- A03AX - A03AX08	- ALVERINE CITRATE		- Oral use
Spectrila	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/15/1072/001-002	Powder for concentrate for solution for infusion	- L01XX - L01XX02	- Recombinant l-asparaginase	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Spedra	Menarini International Operations Luxembourg S.A.	EU/1/13/841/001-003	Tablet	- G04BE - G04BE10	- Avanafil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Spedra	Menarini International Operations Luxembourg S.A.	EU/1/13/841/004-007	Tablet	- G04BE - G04BE10	- Avanafil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Spedra	Menarini International Operations Luxembourg S.A.	EU/1/13/841/008-010	Tablet	- G04BE - G04BE10	- Avanafil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sperizak 25 mg powder and solvent for prolonged-release suspension for injection	Accord Healthcare Ireland Ltd.	PA2315/248/001 Interchangeable List Code: IC0012-022-065	Powder and solvent for prolonged-release suspension for injection		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Sperizak 37.5 mg powder and solvent for prolonged-release suspension for injection	Accord Healthcare Ireland Ltd.	PA2315/248/002 Interchangeable List Code: IC0012-063-065	Powder and solvent for prolonged-release suspension for injection		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Sperizak 50 mg powder and solvent for prolonged-release suspension for injection	Accord Healthcare Ireland Ltd.	PA2315/248/003 Interchangeable List Code: IC0012-023-065	Powder and solvent for prolonged-release suspension for injection		- Risperidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Spevigo	Boehringer Ingelheim International GmbH	EU/1/22/1688/001	Concentrate and solvent for solution for infusion	- L04AC - L04AC22	- Spesolimab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Spexotras	Novartis Europharm Limited	EU/1/23/1781/001	Powder for oral solution	- L01EE01	- Dabrafenib Mesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Spherox 10-70 spheroids/ cm2 implantation suspension	Rejuvenate GmbH	EU/1/17/1181/001-002	Implantation suspension	- M09AX02	- Spheroids of human autologous matrix-associated chondrocytes	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraarticular use
Spikevax	MODERNA BIOTECH SPAIN, S.L	EU/1/20/1507/001	Dispersion for injection	- J07BX03	- mRNA-1273	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Spikevax	Moderna Biotech Spain S.L.	EU/1/20/1507/002	Dispersion for injection	- J07BX03	- Elasomeran	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Spikevax	Moderna Biotech Spain S.L.	EU/1/20/1507/003	Dispersion for injection	- J07BX03	- Elasomeran	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Spikevax bivalent Original/Omicron BA.1	Moderna Biotech Spain S.L.	EU/1/20/1507/004-005	Dispersion for injection	- J07BX03	- Elasomeran	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Spikevax bivalent Original/Omicron BA.1	Moderna Biotech Spain S.L.	EU/1/20/1507/007-008	Dispersion for injection	- J07BX03	- Elasomeran	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Spikevax bivalent Original/Omicron BA4-5	Moderna Biotech Spain S.L.	EU/1/20/1507/006	Dispersion for injection	- J07BX03	- Elasomeran	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Spinraza	Biogen Netherlands B.V.	EU/1/17/1188/001	Solution for injection	- N07	- Nusinersen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intrathecal use
Spiolto Respimat 2.5 microgram/2.5 microgram, inhalation solution	Boehringer Ingelheim International GmbH	PA0775/009/001	Inhalation solution	- R03BB - R03BB54	- Tiotropium - Olodaterol	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Spiolto Respimat 2.5 microgram/2.5 microgram, inhalation solution	IMED Healthcare Ltd.	PPA1463/185/001	Inhalation solution	- R03BB - R03BB54	- Olodaterol - Tiotropium		- Inhalation use
Spiolto Respimat 2.5 microgram/2.5 microgram, inhalation solution	PCO Manufacturing Ltd.	PPA0465/463/001	Inhalation solution	- R03BB - R03BB54	- Tiotropium - Olodaterol		- Inhalation use
Spiriva 18 microgram inhalation powder, hard capsule	Merit Pharmaceuticals Limited	PPA23080/007/001	Inhalation powder, hard capsule	- R03BB - R03BB04	- Tiotropium bromide		- Oral use
SPIRIVA 18 microgram, inhalation powder, hard capsule	Boehringer Ingelheim International GmbH	PA0775/002/001	Inhalation powder, hard capsule	- R03BB - R03BB04	- Tiotropium		- Oral use
Spiriva Respimat 2.5 microgram inhalation solution	Boehringer Ingelheim International GmbH	PA0775/002/002	Inhalation solution	- R03BB - R03BB04	- Tiotropium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Spiriva Respimat 2.5 microgram inhalation solution	IMED Healthcare Ltd.	PPA1463/142/002	Inhalation solution	- R03BB04	- Tiotropium		- Inhalation use
Spiriva Respimat 2.5 microgram, inhalation solution	PCO Manufacturing Ltd.	PPA0465/286/001	Inhalation solution	- R03BB - R03BB04	- Tiotropium		- Inhalation use
Spironolactone 100 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/119/003	Film-coated tablet	- C03DA - C03DA01	- Spironolactone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Spironolactone 25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/119/001	Film-coated tablet	- C03DA - C03DA01	- Spironolactone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Spironolactone 50 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/119/002	Film-coated tablet	- C03DA - C03DA01	- Spironolactone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sporanox 10 mg/mL oral solution	Janssen Sciences Ireland UC	PA22612/012/001	Oral solution	- J02AC - J02AC02	- Itraconazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sporanox 100 mg Capsules	PCO Manufacturing Ltd.	PPA0465/400/001	Capsule, hard	- J02AC - J02AC02	- Itraconazole		- Oral use
Sporanox 100 mg Capsules	IMED Healthcare Ltd.	PPA1463/188/001	Capsule	- J02AC - J02AC02	- Itraconazole		- Oral use
Sporanox 100mg Capsules	Janssen Sciences Ireland UC	PA22612/012/002	Capsule, hard	- J02AC - J02AC02	- Itraconazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Spravato	Janssen-Cilag International NV	EU/1/19/1410/001-004	Nasal spray, solution	- N06AX27	- ESKETAMINE HYDROCHLORIDE - Esketamine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Sprilon 12.5 % Zinc Oxide and 1.04 % Dimeticone Cutaneous Spray, Suspension	Ayrton Saunders (Ireland) Limited	PA22906/001/001	Cutaneous spray, suspension	- D02AB	- Dimeticone 350 - Zinc oxide		- Cutaneous use
Sprycel	Bristol-Myers Squibb Pharma EEIG	EU/1/06/363/010-11	Film-coated tablet	- L01XE - L01XE06	- Dasatinib		- Oral use
Sprycel	Bristol-Myers Squibb Pharma EEIG	EU/1/06/363/012-013	Film-coated tablet	- L01XE - L01XE06	- Dasatinib		- Oral use
Sprycel	Bristol-Myers Squibb Pharma EEIG	EU/1/06/363/014-015	Film-coated tablet	- L01XE - L01XE06	- Dasatinib		- Oral use
Sprycel	Bristol-Myers Squibb Pharma EEIG	EU/1/06/363/016	Powder for oral suspension	- L01XE - L01XE06	- Dasatinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sprycel	Bristol-Myers Squibb Pharma EEIG	EU/1/06/363/1-4-7	Film-coated tablet	- L01XE - L01XE06	- Dasatinib		- Oral use
Sprycel	Bristol-Myers Squibb Pharma EEIG	EU/1/06/363/2-5-8	Film-coated tablet	- L01XE - L01XE06	- Dasatinib		- Oral use
Sprycel	Bristol-Myers Squibb Pharma EEIG	EU/1/06/363/3-6-9	Film-coated tablet	- L01XE - L01XE06	- Dasatinib		- Oral use
Stagliptin Accord 100 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/22/1633/011-015 Interchangeable List Code: IC0131-024-003	Film-coated tablet		- Sitagliptin Hydrochloride Monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Stagliptin Accord 25 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/22/1633/001-005 Interchangeable List Code: IC0131-022-003	Film-coated tablet		- Sitagliptin Hydrochloride Monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Stagliptin Accord 50 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/22/1633/006-010 Interchangeable List Code: IC0131-023-003	Film-coated tablet		- Sitagliptin Hydrochloride Monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Stalevo	Orion Corporation	EU/1/03/260/001-004,13,16	Film-coated tablet	- N04BA - N04BA03	- Carbidopa - Entacapone - Levodopa		
Stalevo	Orion Corporation	EU/1/03/260/005-008,14,17	Not assigned	- N04BA - N04BA03			
Stalevo	Orion Corporation	EU/1/03/260/009-012,15,18	Not assigned	- N04BA - N04BA03			
Stalevo	Orion Corporation	EU/1/03/260/034-038	Film-coated tablet	- N04BA - N04BA03	- Carbidopa - Entacapone - Levodopa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Stalevo	Orion Corporation	EU/1/03/260/19-23	Film-coated tablet	- N04BA - N04BA03	- Carbidopa - Entacapone - Levodopa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Stalevo	Orion Corporation	EU/1/03/260/24-28	Film-coated tablet	- N04BA - N04BA03	- Carbidopa monohydrate - Levodopa - Entacapone		- Oral use
Stalevo	Orion Corporation	EU/1/03/260/29-33	Film-coated tablet	- N04BA - N04BA03	- Carbidopa monohydrate - Entacapone - Levodopa		- Oral use
Stalpex 50 microgram/500 microgram/dose inhalation powder, pre-dispensed	Glenmark Pharmaceuticals Nordic AB	PA22815/001/001	Inhalation powder, pre-dispensed	- R03AK06	- Salmeterol - Fluticasone propionate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
STAMARIL, powder and solvent for suspension for injection in pre-filled syringe.Yellow fever vaccine (Live)	Sanofi Pasteur	PA2131/008/001	Powder and solvent for suspension for injection in pre-filled syringe	- J07BL - J07BL01	- Yellow fever virus 17 d-204 strain	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
STAMICIS 1mg kit for radiopharmaceutical preparation	CIS bio International	PA0677/018/001	Kit for radiopharmaceutical preparation	- V09GA - V09GA01	- Tetrakis (2-methoxy isobutyl isonitrile) copper (i) tetrafluorolborate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Stayveer	Janssen Pharmaceutica NV	EU/1/13/832/001	Film-coated tablet	- C02KX - C02KX01	- Bosentan monohydrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Stayveer	Janssen Pharmaceutica NV	EU/1/13/832/002	Film-coated tablet	- C02KX - C02KX01	- Bosentan monohydrate	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Steglatro	Merck Sharp & Dohme BV	EU/1/18/1267/001-006	Film-coated tablet	- A10BK - A10BK04	- Ertugliflozin l-pyroglutamic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Steglatro	Merck Sharp & Dohme BV	EU/1/18/1267/007-012	Film-coated tablet	- A10BK - A10BK04	- Ertugliflozin l-pyroglutamic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Steglujan	Merck Sharp & Dohme BV	EU/1/18/1266/001-006	Film-coated tablet	- A10BD - A10BD24	- Ertugliflozin l-pyroglutamic acid - Sitagliptin phosphate monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Steglujan	Merck Sharp & Dohme BV	EU/1/18/1266/007-012	Film-coated tablet	- A10BD - A10BD24	- Ertugliflozin l-pyroglutamic acid - Sitagliptin phosphate monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
STELARA	Janssen-Cilag International NV	EU/1/08/494/001	Solution for injection	- L04AC05	- Ustekinumab	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
STELARA	Janssen-Cilag International NV	EU/1/08/494/002	Solution for injection	- L04AC05	- Ustekinumab	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
STELARA	Janssen-Cilag International NV	EU/1/08/494/003	Solution for injection in pre-filled syringe	- L04AC05	- Ustekinumab	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
STELARA	Janssen-Cilag International NV	EU/1/08/494/004	Solution for injection in pre-filled syringe	- L04AC05	- Ustekinumab	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
STELARA	Janssen-Cilag International NV	EU/1/08/494/005	Concentrate for solution for infusion	- L04AC05	- Ustekinumab	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Stelazine 1mg Film-coated Tablets	Amdipharm Limited	PA1142/037/001	Film-coated tablet	- N05AB - N05AB06	- Trifluoperazine		- Oral use
Stelazine 5 mg film-coated tablets	Amdipharm Limited	PA1142/037/002	Film-coated tablet	- N05AB - N05AB06	- Trifluoperazine		- Oral use
Stemetil 12.5 mg/ml solution for injection - 1 ml Ampoule	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/127/002	Solution for injection	- N05AB - N05AB04	- PROCHLORPERAZINE MESILATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Stemetil 5mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/127/005	Tablet	- N05AB - N05AB04	- Prochlorperazine maleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Sterile Dopamine Concentrate BP 160mg/ml, 5ml	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/108/002	Concentrate for solution for infusion	- C01CA04	- DOPAMINE HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Sterile Dopamine Concentrate BP 40mg/ml	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/108/001	Concentrate for solution for infusion	- C01CA - C01CA04	- DOPAMINE HYDROCHLORIDE		- Intravenous use
Stesolid rectal solution 10mg	Accord Healthcare Ireland Ltd.	PA2315/137/002	Rectal solution	- N05BA - N05BA01	- Diazepam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Rectal use
Stesolid rectal solution 5mg	Accord Healthcare Ireland Ltd.	PA2315/137/001	Rectal solution	- N05BA - N05BA01	- Diazepam	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Rectal use
Stieprox 15 mg/g Shampoo	GlaxoSmithKline (Ireland) Limited	PA1077/130/001	Shampoo	- D01AE - D01AE14	- CICLOPIROX OLAMINE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Stieprox 15 mg/g Shampoo	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/055/001	Shampoo	- D01AE - D01AE14	- CICLOPIROX OLAMINE		- Cutaneous use
Stilnoct 10 mg Film-coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/160/002 Interchangeable List Code: IC0135-002-003	Film-coated tablet		- Zolpidem tartrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Stilnoct 5 mg Film Coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/160/001 Interchangeable List Code: IC0135-001-003	Film-coated tablet		- Zolpidem tartrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Stimufend	Fresenius Kabi Deutschland GmbH	EU/1/22/1632/001	Solution for injection in pre-filled syringe	- L03AA13	- Pegfilgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Stirlescent 250mg Effervescent Tablets	Stirling Anglian Pharmaceuticals Ireland Limited	PA23138/002/001	Effervescent tablet	- M01AE - M01AE02	- Naproxen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Stivarga	Bayer Pharma AG	EU/1/13/858/001-002	Film-coated tablet	- L01XE - L01XE21	- Regorafenib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
STOCRIN	Merck Sharp & Dohme BV,	EU/1/99/111/001	Capsule	- J05AG - J05AG03	- Efavirenz		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
STOCRIN	Merck Sharp & Dohme BV,	EU/1/99/111/002	Capsule	- J05AG - J05AG03	- Efavirenz		- Oral use
Stocrin	Merck Sharp & Dohme BV,	EU/1/99/111/003	Capsule	- J05AG - J05AG03	- Efavirenz		- Oral use
Stocrin	Merck Sharp & Dohme BV,	EU/1/99/111/004	Capsule	- J05AG - J05AG03	- Efavirenz		- Oral use
Stocrin	Merck Sharp & Dohme BV,	EU/1/99/111/005	Oral solution	- J05AG - J05AG03	- Efavirenz		- Oral use
Stocrin	Merck Sharp & Dohme BV,	EU/1/99/111/010	Film-coated tablet	- J05AG - J05AG03	- Efavirenz		
Stocrin	Merck Sharp & Dohme BV,	EU/1/99/111/011	Film-coated tablet	- J05AG - J05AG03	- Efavirenz		
Stocrin Film-Coated	Merck Sharp & Dohme BV,	EU/1/99/111/6-7	Film-coated tablet	- J05AG - J05AG03	- Efavirenz		- Oral use
Stocrin Film-Coated	Merck Sharp & Dohme BV,	EU/1/99/111/8-9	Film-coated tablet	- J05AG - J05AG03	- Efavirenz		- Oral use
Strattera 4 mg/mL oral solution	Eli Lilly Nederland B.V.	PA2276/007/008	Oral solution	- N06BA - N06BA09	- ATOMOXETINE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Strensiq	Alexion Europe SAS	EU/1/15/1015/001-002	Solution for injection	- A16AB	- Asfotase alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Strensiq	Alexion Europe SAS	EU/1/15/1015/003-004	Solution for injection	- A16AB	- Asfotase alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Strepsils +Plus Anaesthetic Lozenges Amylmetacresol 0.6mg 2,4-Dichlorobenzyl Alcohol 1.2mg Lidocaine Hydrochloride 10mg	Reckitt Benckiser Ireland Ltd	PA0979/040/001	Lozenge	- R02AA - R02AA03	- Amylmetacresol - 2, 4-dichlorobenzyl alcohol - Lidocaine Hydrochloride Ph. Eur.		- Oral use
Strepsils +Plus Anaesthetic Throat Spray Amylmetacresol 0.29mg/spray 2,4-Dichlorobenzyl Alcohol 0.58mg/spray Lidocaine 0.78mg/spray	Reckitt Benckiser Ireland Ltd	PA0979/040/002	Oromucosal spray	- R02AA - R02AA03	- Amylmetacresol - 2,4-Dichlorobenzyl alcohol - Lidocaine		- Oromucosal use
Strepsils Extra Blackcurrant Lozenges	Reckitt Benckiser Ireland Ltd	PA0979/042/001	Lozenge	- R02AA12	- Hexylresorcinol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Strepsils Honey & Lemon Lozenges Amylmetacresol 0.6mg 2,4-Dichlorobenzyl alcohol 1.2mg	Reckitt Benckiser Ireland Ltd	PA0979/038/002	Lozenge	- R02AA - R02AA03	- Amylmetacresol - 2,4-Dichlorobenzyl alcohol		- Oromucosal use
Strepsils Intensive 8.75 mg Lozenges	Reckitt Benckiser Ireland Ltd	PA0979/041/001	Lozenge	- R02AX - R02AX01	- Flurbiprofen		- Oral use
Strepsils Intensive Cherry & Mint 8.75mg/dose Oromucosal Spray	Reckitt Benckiser Ireland Ltd	PA0979/041/005	Oromucosal spray, solution	- R02AX - R02AX01	- Flurbiprofen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oromucosal use
Strepsils Intensive Honey & Eucalyptus Sugar Free 8.75 mg lozenges	Reckitt Benckiser Ireland Ltd	PA0979/080/001	Lozenge	- R02AX01	- Flurbiprofen	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oromucosal use
Strepsils Intensive Honey and Lemon 8.75mg/dose Oromucosal Spray	Reckitt Benckiser Ireland Ltd	PA0979/072/001	Oromucosal spray, solution	- R02AX - R02AX01	- Flurbiprofen	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oromucosal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Strepsils Intensive Orange Sugar Free 8.75mg Lozenges	Reckitt Benckiser Ireland Ltd	PA0979/041/004	Lozenge	- R02AX - R02AX01	- Flurbiprofen	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Strepsils Intensive Sugar-Free 8.75 mg Lozenges	Reckitt Benckiser Ireland Ltd	PA0979/041/006	Lozenge	- R02AX01	- Flurbiprofen	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Strepsils Orange with Vitamin C Lozenges Amylmetacresol 0.6mg 2,4-Dichlorobenzyl Alcohol 1.2mg Vitamin C 100mg	Reckitt Benckiser Ireland Ltd	PA0979/039/001	Lozenge	- R02AA - R02AA03	- Amylmetacresol - 2, 4-dichlorobenzyl alcohol - Vitamin c		- Oromucosal use
Strepsils Sore Throat & Blocked Nose Lozenges Amylmetacresol 0.6mg 2,4-Dichlorobenzyl Alcohol 1.2mg Levomenthol 8.0mg	Reckitt Benckiser Ireland Ltd	PA0979/060/001	Lozenge	- R02AA - R02AA03	- Amylmetacresol - Levomenthol - 2,4-Dichlorobenzyl alcohol		- Oromucosal use
Strepsils Strawberry Sugar Free Lozenges Amylmetacresol 600 micrograms 2, 4-Dichlorobenzyl Alcohol 1.2 mg	Reckitt Benckiser Ireland Ltd	PA0979/038/003	Lozenge	- R02AA - R02AA03	- Amylmetacresol - 2, 4-dichlorobenzyl alcohol		- Oral use
STRIASCAN	CIS bio International	EU/1/19/1372/001-002	Solution for injection	- V09AB - V09AB03	- IOFLUPANE (1231)	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Stribild	Gilead Sciences Ireland UC	EU/1/13/830/001	Film-coated tablet	- J05AR - J05AR09	- Emtricitabine - Tenofovir disoproxil - Cobicistat - Elvitegravir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Strimvelis	Orchard Therapeutics (Netherlands) B.V.	EU/1/16/1097/001	Dispersion for infusion	- L03	- Autologous cd34+ enriched cell fraction	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Striverdi Respimat 2.5 microgram inhalation solution	Boehringer Ingelheim International GmbH	PA0775/006/001	Inhalation solution	- R03AC19	- Olodaterol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Stugeron 15 mg Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/024/001	Tablet	- N07CA - N07CA02	- Cinnarizine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Sublimaze 50 micrograms/ml solution for injection	Piramal Critical Care B.V.	PA22583/002/001	Solution for injection	- N01AH - N01AH01	- FENTANYL CITRATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Suboxone	Indivior Europe Limited	EU/1/06/359/005-006	Sublingual tablet	- N07BC - N07BC51	- Buprenorphine hydrochloride - Naloxone hydrochloride dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Sublingual use
Suboxone	Indivior Europe Limited	EU/1/06/359/007-009	Sublingual film	- N07BC51	- Buprenorphine hydrochloride - Naloxone hydrochloride dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Buccal use - Sublingual use
Suboxone	Indivior Europe Limited	EU/1/06/359/010-012	Sublingual film	- N07BC51	- Buprenorphine hydrochloride - Naloxone hydrochloride dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Buccal use - Sublingual use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Suboxone	Indivior Europe Limited	EU/1/06/359/01-02	Sublingual tablet	- N07BC - N07BC51	- Naloxone - Buprenorphine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Sublingual use
Suboxone	Indivior Europe Limited	EU/1/06/359/013-015	Sublingual film	- N07BC51	- Buprenorphine hydrochloride - Naloxone hydrochloride dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Buccal use - Sublingual use
Suboxone	Indivior Europe Limited	EU/1/06/359/016-018	Sublingual film	- N07BC51	- Buprenorphine hydrochloride - Naloxone hydrochloride dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Buccal use - Sublingual use
Suboxone	Indivior Europe Limited	EU/1/06/359/03-04	Sublingual tablet	- N07BC - N07BC51	- Buprenorphine hydrochloride - NALOXONE HYDROCHLORIDE		- Oral use
Subutex 0.4 mg sublingual tablets	Indivior Europe Limited	PA22617/001/001	Sublingual tablet	- N02AE - N02AE01	- Buprenorphine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oromucosal use
Subutex 2 mg sublingual tablets	Indivior Europe Limited	PA22617/001/002	Sublingual tablet	- N02AE - N02AE01	- Buprenorphine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Subutex 8 mg sublingual Tablets	Indivior Europe Limited	PA22617/001/003	Sublingual tablet	- N02AE - N02AE01	- Buprenorphine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oromucosal use
Sudafed 0.1% w/v Nasal spray solution	Johnson & Johnson (Ireland) Limited	PA0330/027/001	Nasal spray, solution	- R01AA - R01AA07	- Xylometazoline hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Nasal use
Sudocrem Antiseptic Healing Cream	Norton Waterford	PA0436/054/001	Cream	- D02AB	- Benzyl alcohol - Benzyl cinnamate - Benzyl benzoate - Wool fat - Zinc oxide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical
Sugammadex	Juta Pharma GmbH	PA22716/002/001	Solution for injection	- V03AB35	- Sugammadex sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex – Amomed®	AOP Orphan Pharmaceuticals AG	EU/1/22/1708/001	Solution for injection	- V03AB35	- Sugammadex sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex 10 mg/ml solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/016/001	Solution for injection in pre-filled syringe	- V03AB35	- Sugammadex sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex 100 mg/ml Solution for injection	Noridem Enterprises Limited	PA1122/032/001	Solution for injection	- V03AB35	- Sugammadex sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex 100 mg/ml solution for injection	Flynn Pharma Limited	PA1226/015/001	Solution for injection	- V03AB35	- Sugammadex sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex 100 mg/ml solution for injection	AS Kalceks	PA2165/022/001	Solution for injection	- V03AB35	- Sugammadex sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex 100 mg/ml Solution for Injection	Baxter Holding B.V.	PA2299/058/001	Solution for injection	- V03AB35	- Sugammadex sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex 100 mg/ml solution for injection	Reddy Holding GmbH	PA23092/006/001	Solution for injection	- V03AB35	- Sugammadex	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex 100 mg/mL solution for injection	MSN Labs Europe Limited	PA23250/012/001	Solution for injection	- V03AB35	- Sugammadex sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Sugammadex 50 mg/ml solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/016/002	Solution for injection in pre-filled syringe	- V03AB35	- Sugammadex sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex Adroiq	Extrovis EU Kft.	EU/1/23/1733/001-002	Solution for injection	- V03AB35	- Sugammadex sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex Aspen 100 mg/mL solution for injection	Aspen Pharma Trading Limited	PA1691/036/001	Solution for injection	- V03AB35	- Sugammadex sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex Clonmel 100 mg/ml solution for injection	Clonmel Healthcare Ltd	PA0126/352/001	Solution for injection	- V03AB35	- Sugammadex sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex Fresenius Kabi	Fresenius Kabi Deutschland GmbH	EU/1/22/1663/001-003	Solution for injection	- V03AB35	- Sugammadex	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex Mylan	Mylan IRE Healthcare Limited	EU/1/21/1583/001-004	Solution for injection	- V03AB35	- Sugammadex sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex Orion 100 mg/ml solution for injection	Orion Corporation	PA1327/020/001	Solution for injection	- V03AB35	- Sugammadex sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex Piramal	Piramal Critical Care B.V.	EU/1/23/1739/001-002	Solution for injection	- V03AB35	- Sugammadex sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Sugammadex Teva 100 mg/ml solution for injection	Teva B.V.	PA1986/102/001	Solution for injection	- V03AB35	- Sugammadex sodium	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
SULFUR	A. Nelson & Company Limited	HOR1149/029/001	Not assigned		- Sulfur		- Oral use
Suliqua	Sanofi-Aventis Groupe	EU/1/16/1157/001-002	Solution for injection in pre-filled pen	- A10AE - A10AE04	- Insulin glargine - Lixisenatide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Subcutaneous use
Suliqua	Sanofi-Aventis Groupe	EU/1/16/1157/003-004	Solution for injection in pre-filled pen	- A10AE - A10AE04	- Lixisenatide - Insulin glargine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Subcutaneous use
Sulpiride Grindeks 100 mg tablets	AS Grindeks	PA22992/009/002	Tablet	- N05AL01	- Sulpiride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Sulpiride Grindeks 200 mg tablets	AS Grindeks	PA22992/009/003	Tablet	- N05AL01	- Sulpiride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Sulpiride Grindeks 50 mg tablets	AS Grindeks	PA22992/009/001	Tablet	- N05AL01	- Sulpiride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
SUMATRAN 100 mg tablets	Rowex Ltd	PA0711/081/002 Interchangeable List Code: IC0143-024-014	Tablet		- Sumatriptan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
SUMATRAN 50 mg tablets	Rowex Ltd	PA0711/081/001 Interchangeable List Code: IC0143-023-014	Tablet		- Sumatriptan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sumatran Relief 50mg tablets	Rowex Ltd	PA0711/272/001	Tablet	- N02CC - N02CC01	- Sumatriptan	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Sumatriptan 100 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/070/002 Interchangeable List Code: IC0143-024-014	Film-coated tablet		- Sumatriptan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sumatriptan 50 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/070/001 Interchangeable List Code: IC0143-023-014	Film-coated tablet		- Sumatriptan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sunitinib Accord	Accord Healthcare S.L.U.	EU/1/20/1511/001-003	Capsule, hard	- L01XE04	- Sunitinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sunitinib Accord	Accord Healthcare S.L.U.	EU/1/20/1511/004-006	Capsule, hard	- L01XE04	- Sunitinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sunitinib Accord	Accord Healthcare S.L.U.	EU/1/20/1511/007-009	Capsule, hard	- L01XE04	- Sunitinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sunitinib Accord	Accord Healthcare S.L.U.	EU/1/20/1511/010-012	Capsule, hard	- L01XE04	- Sunitinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sunitinib Bluefish 12.5 mg hard capsules	Bluefish Pharmaceuticals AB	PA1436/041/001	Capsule, hard	- L01EX01	- Sunitinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sunitinib Bluefish 25 mg hard capsules	Bluefish Pharmaceuticals AB	PA1436/041/002	Capsule, hard	- L01EX01	- Sunitinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sunitinib Bluefish 50 mg hard capsules	Bluefish Pharmaceuticals AB	PA1436/041/003	Capsule, hard	- L01EX01	- Sunitinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sunitinib Krka 12.5 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/104/001	Capsule, hard	- L01XE04	- Sunitinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sunitinib Krka 25 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/104/002	Capsule, hard	- L01XE04	- Sunitinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sunitinib Krka 50 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/104/003	Capsule, hard	- L01XE04	- Sunitinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sunitinib Rowex 12.5 mg hard capsules	Rowex Ltd	PA0711/289/001	Capsule, hard	- L01XE - L01XE04	- Sunitinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sunitinib Rowex 25 mg hard capsules	Rowex Ltd	PA0711/289/002	Capsule, hard	- L01XE - L01XE04	- Sunitinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sunitinib Rowex 50 mg hard capsules	Rowex Ltd	PA0711/289/003	Capsule, hard	- L01XE - L01XE04	- Sunitinib	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Sunlenca	Gilead Sciences Ireland UC	EU/1/22/1671/01	Film-coated tablet	- J05AX - J05AX31	- Lenacapavir sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use - Subcutaneous use
Sunlenca	Gilead Sciences Ireland UC	EU/1/22/1671/02	Solution for injection	- J05AX31	- Lenacapavir sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use - Subcutaneous use
Sunosi	Atnahs Pharma Netherlands B.V.	EU/1/19/1408/001-005	Film-coated tablet	- N06BA14	- Solriamfetol Hydrochloride	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Sunosi	Atnahs Pharma Netherlands B.V.	EU/1/19/1408/006-010	Film-coated tablet	- N06BA14 - N07	- Solriamfetol Hydrochloride	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Supemtek	Sanofi Pasteur	EU/1/20/1484/001-006	Solution for injection in pre-filled syringe	- J07BB - J07BB02	- A/(H1N1)-LIKE VIRUS ANTIGEN	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Suprane Inhalation vapour, solution	Baxter Holding B.V.	PA2299/023/001	Inhalation vapour, solution	- N01AB - N01AB07	- Desflurane	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Suprax 200 mg Film-coated Tablets	Amdipharm Limited	PA1142/042/001	Film-coated tablet	- J01DD - J01DD08	- CEFIXIME TRIHYDRATE		- Oral use
Surmontil 25mg film-coated Tablets	Neuraxpharm Ireland Limited	PA23229/009/002	Film-coated tablet	- N06AA - N06AA06	- Trimipramine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Surmontil 50mg hard Capsules	Neuraxpharm Ireland Limited	PA23229/009/001	Capsule, hard	- N06AA - N06AA06	- Trimipramine maleate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
SUSTIVA	Bristol-Myers Squibb Pharma EEIG	EU/1/99/110/001	Capsule, hard	- J05AG - J05AG03	- Efavirenz		- Oral use
Sustiva	Bristol-Myers Squibb Pharma EEIG	EU/1/99/110/002	Capsule, hard	- J05A	- Efavirenz		- Oral use
Sustiva	Bristol-Myers Squibb Pharma EEIG	EU/1/99/110/003	Capsule, hard	- J05A	- Efavirenz		- Oral use
Sustiva	Bristol-Myers Squibb Pharma EEIG	EU/1/99/110/004	Capsule, hard	- J05A	- Efavirenz		- Oral use
Sustiva	Bristol-Myers Squibb Pharma EEIG	EU/1/99/110/005	Oral solution	- J05AG03	- Efavirenz		- Oral use
Sustiva	Bristol-Myers Squibb Pharma EEIG	EU/1/99/110/006	Film-coated tablet	- J05A	- Efavirenz		
Sustiva	Bristol-Myers Squibb Pharma	EU/1/99/110/007	Film-coated tablet	- J05A	- Efavirenz		
Sustiva	Bristol-Myers Squibb Pharma EEIG	EU/1/99/110/008	Film-coated tablet	- J05A	- Efavirenz		
Sustiva	Bristol-Myers Squibb Pharma	EU/1/99/110/009	Film-coated tablet	- J05A	- Efavirenz		
Sutent	Pfizer Europe MA EEIG	EU/1/06/347/001	Capsule, hard	- L01XE - L01XE04	- Sunitinib malate		- Oral use
Sutent	Pfizer Europe MA EEIG	EU/1/06/347/002	Capsule, hard	- L01XE - L01XE04	- Sunitinib malate		- Oral use
Sutent	Pfizer Europe MA EEIG	EU/1/06/347/003	Capsule, hard	- L01XE - L01XE04	- Sunitinib malate		- Oral use
Sutent	Pfizer Europe MA EEIG	EU/1/06/347/7-8	Capsule, hard	- L01XE - L01XE04	- Sunitinib malate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Suvezen 10 mg/10 mg film-coated tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/193/001 Interchangeable List Code: IC0111-017-009	Film-coated tablet		- Rosuvastatin - Ezetimibe	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Suvezen 20 mg/10 mg film-coated tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/193/002 Interchangeable List Code: IC0111-061-009	Film-coated tablet		- Rosuvastatin - Ezetimibe	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Suvezen 40 mg/10 mg film-coated tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/193/003 Interchangeable List Code: IC0111-093-009	Film-coated tablet		- Rosuvastatin - Ezetimibe	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Suxamethonium Chloride 50 mg/ml solution for injection/infusion	Ethypharm	PA0549/014/001	Solution for injection	- M03AB01	- Suxamethonium chloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Suxamethonium Chloride 50mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/110/001	Solution for injection	- M03AB - M03AB01	- Suxamethonium chloride		- Intramuscular use - Intravenous use
Sycrest	NV Organon	EU/1/10/640/001-003	Sublingual tablet	- N05AH - N05AH05	- Asenapine maleate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Sycrest	NV Organon	EU/1/10/640/004-006	Sublingual tablet	- N05AH - N05AH05	- Asenapine maleate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Sublingual use
Sylvant	EUSA Pharma (Netherlands) B.V.	EU/1/14/928/001	Powder for concentrate for solution for infusion	- L04AC - L04AC11	- Siltuximab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Sylvant	EUSA Pharma (Netherlands) B.V.	EU/1/14/928/002	Powder for concentrate for solution for infusion	- L04AC - L04AC11	- Siltuximab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Symbicort Turbohaler 100 micrograms/6 micrograms/inhalation inhalation powder	IMED Healthcare Ltd.	PPA1463/051/002	Inhalation powder	- R03AK - R03AK07	- Budesonide - Formoterol fumatrate dihydrate		- Inhalation use
Symbicort Turbohaler 200 micrograms/6 micrograms/inhalation inhalation powder	IMED Healthcare Ltd.	PPA1463/051/001	Inhalation powder	- R03AK - R03AK07	- Formoterol fumatrate dihydrate - Budesonide	ZZZ PPA	- Inhalation use
Symbicort Turbohaler 200 micrograms/6 micrograms/inhalation, inhalation powder	Merit Pharmaceuticals Limited	PPA23080/021/001	Inhalation powder	- R03AK07	- Budesonide - Formoterol fumarate dihydrate		- Inhalation use
Symbicort Turbohaler 400 micrograms/12 micrograms/inhalation inhalation powder	IMED Healthcare Ltd.	PPA1463/051/003	Inhalation powder	- R03AK - R03AK07	- Formoterol fumarate dihydrate - Budesonide		- Inhalation use
Symbicort Turbohaler, 100 micrograms /6 micrograms/inhalation, inhalation powder	AstraZeneca AB	PA1019/020/001	Inhalation powder	- R03AK	- Budesonide - Formoterol fumarate dihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Symbicort Turbohaler, 200 micrograms/6 micrograms/inhalation, inhalation powder	PCO Manufacturing Ltd.	PPA0465/225/001	Inhalation powder	- R03AK - R03AK07	- Budesonide - Formoterol fumatrate dihydrate		- Inhalation use
Symbicort Turbohaler, 400 micrograms/12 micrograms/inhalation, inhalation powder	PCO Manufacturing Ltd.	PPA0465/225/002	Inhalation powder	- R03AK - R03AK07	- Formoterol fumatrate dihydrate - Budesonide		- Inhalation use
Symbicort Turbohaler, 400 micrograms/12 micrograms/inhalation, inhalation powder	Merit Pharmaceuticals Limited	PPA23080/021/002	Inhalation powder	- R03AK07	- Budesonide dihydrate - Formoterol fumarate dihydrate		- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Symbicort Turbohaler, 400 micrograms/12 micrograms/inhalation, inhalation powder	AstraZeneca AB	PA1019/020/003	Inhalation powder	- R03AK07	- Budesonide - Formoterol fumatrate dihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Symbicort, 200 micrograms/6 micrograms per inhalation, pressurised inhalation, suspension	AstraZeneca AB	PA1019/020/004	Pressurised inhalation, suspension	- R03AK - R03AK07	- Budesonide micronised - Formoterol fumarate dihydrate (micronised)	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Symbicort® Turbohaler; 200 micrograms/6 micrograms/inhalation, inhalation powder	AstraZeneca AB	PA1019/020/002	Inhalation powder	- R03AK	- Budesonide - Formoterol fumatrate dihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Symkevi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/18/1036/001	Film-coated tablet	- R07AX31	- TEZACAFTOR - Ivacaftor		- Oral use
Symkevi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/18/1306/001	Film-coated tablet	- R07AX31	- TEZACAFTOR - Ivacaftor		- Oral use
Symkevi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/18/1306/002	Film-coated tablet	- R07AX31	- TEZACAFTOR - Ivacaftor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Symtuza	Janssen-Cilag International NV	EU/1/17/1225/001	Film-coated tablet	- J05A	- Tenofovir alafenamide - Darunavir ethanolate - Emtricitabine - Cobicistat	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Synacthen 250 micrograms/ml solution for injection	Alfasigma S.p.A	PA2206/002/001	Solution for injection	- H01AA - H01AA02	- Tetracosactide acetate		- Intravenous use
Synagis	AstraZeneca AB	EU/1/99/117/003-004	Solution for injection	- J06BB - J06BB16	- Palivizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Synarel 200 micrograms/dose Nasal Spray Solution	Pfizer Healthcare Ireland	PA0822/138/001	Nasal spray, solution	- H01CA - H01CA02	- Nafarelin		- Nasal use
Synflorix	GlaxoSmithKline Biologicals S.A.	EU/1/09/508/1-13	Suspension for injection	- J07AL - J07AL52	- Pneumococcal polysaccharide serotype 1 - Pneumococcal polysaccharide serotype 4 - Pneumococcal polysaccharide serotype 5 - Pneumococcal polysaccharide serotype 6b - Pneumococcal polysaccharide serotype 7f - Pneumococcal polysaccharide serotype 9v - Pneumococcal polysaccharide serotype 14 - Pneumococcal polysaccharide serotype 19f - Pneumococcal polysaccharide serotype 23f - Pneumococcal polysaccharide serotype 18c		- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Synflorix	GlaxoSmithKline Biologicals S.A.	EU/1/09/508/1-9	Suspension for injection	- J07AL - J07AL52	- Pneumococcal polysaccharide serotype 1 - Pneumococcal polysaccharide serotype 4 - Pneumococcal polysaccharide serotype 5 - Pneumococcal polysaccharide serotype 6b - Pneumococcal polysaccharide serotype 7f - Pneumococcal polysaccharide serotype 9v - Pneumococcal polysaccharide serotype 14 - Pneumococcal polysaccharide serotype 19f - Pneumococcal polysaccharide serotype 23f - Pneumococcal polysaccharide serotype 18c		- Intramuscular use
Synjardy	Boehringer Ingelheim International GmbH	EU/1/15/1003/001-009	Film-coated tablet	- A10BX	- Empagliflozin - Metformin Hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Synjardy	Boehringer Ingelheim International GmbH	EU/1/15/1003/010-018	Film-coated tablet	- A10BX	- Empagliflozin - Metformin Hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Synjardy	Boehringer Ingelheim International GmbH	EU/1/15/1003/019-027	Film-coated tablet	- A10BX	- Empagliflozin - Metformin Hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Synjardy	Boehringer Ingelheim International GmbH	EU/1/15/1003/028-036	Film-coated tablet	- A10BX	- Empagliflozin - Metformin Hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Syntocinon Ampoules 10 IU/ml Concentrate for solution for Infusion or solution for intramuscular Injection	Alfasigma S.p.A	PA2206/003/002	Solution for injection/infusion	- H01BB - H01BB02	- Oxytocin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Syntocinon Ampoules 5 IU/ml Concentrate for solution for infusion or Solution for intramuscular injection	Alfasigma S.p.A	PA2206/003/001	Solution for injection/infusion	- H01BB - H01BB02	- Oxytocin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Syntometrine 500 micrograms/5 IU solution for injection	Alliance Pharma (Ireland) Limited	PA2325/014/001	Solution for injection	- G02AC - G02AC01	- ERGOMETRINE MALEATE - Oxytocin		- Intramuscular use
Syrisal 1mmol/ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/016/001	Oral solution	- A12CA - A12CA01	- Sodium chloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Tabrecta	Novartis Europharm Limited	EU/1/22/1650/001-002	Film-coated tablet	- L01 - L01EX17	- Capmatinib dihydrochloride monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tabrecta	Novartis Europharm Limited	EU/1/22/1650/003-004	Film-coated tablet	- L01 - L01EX17	- Capmatinib dihydrochloride monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Tacforius	Teva B.V.	EU/1/17/1244/001-006	Prolonged-release capsule, hard	- L04AD - L04AD02	- Tacrolimus monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tacforius	Teva B.V.	EU/1/17/1244/007-014	Prolonged-release capsule, hard	- L04AD - L04AD02	- Tacrolimus monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tacforius	Teva B.V.	EU/1/17/1244/015-020	Prolonged-release capsule, hard	- L04AD - L04AD02	- Tacrolimus monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tacforius	Teva B.V.	EU/1/17/1244/021-026	Prolonged-release capsule, hard	- L04AD - L04AD02	- Tacrolimus monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
TACHOSIL	Corza Medical GmbH	EU/1/04/277/1-4	Sealant matrix	- B02BC - B02BC30	- Fibrinogen		- Epilesional use
Tacrolimus 0.03% ointment	Accord Healthcare Ireland Ltd.	PA2315/269/001	Ointment	- D11A - D11AH01	- Tacrolimus	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Tacrolimus 0.1% Ointment	Accord Healthcare Ireland Ltd.	PA2315/120/001	Ointment	- D11A	- Tacrolimus	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Tadalafil 10mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/020/003	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil 10mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/071/002	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil 2.5mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/020/001	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil 20 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/071/003	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil 20mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/020/004	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil 5mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/020/002	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil 5mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/071/001	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil Clonmel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/311/001	Film-coated tablet	- G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/311/002	Film-coated tablet	- G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil Generics ((previously known Tadalafil Mylan Pharma))	Viatris Limited	EU/1/16/1153/001-004	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/071/003	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil Krka 2.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/071/001	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Tadalafil Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/071/004	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil Krka 5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/071/002	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil Lilly	Eli Lilly Nederland B.V.	EU/1/17/1177/001	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Tadalafil Lilly	Eli Lilly Nederland B.V.	EU/1/17/1177/002-004	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Tadalafil Lilly	Eli Lilly Nederland B.V.	EU/1/17/1177/005	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Tadalafil Lilly	Eli Lilly Nederland B.V.	EU/1/17/1177/006-009	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Tadalafil Mylan	Mylan Pharmaceuticals Limited	EU/1/14/961/001	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil Mylan	Mylan Pharmaceuticals Limited	EU/1/14/961/003-006	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil Mylan	Mylan Pharmaceuticals Limited	EU/1/14/961/008-009	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tadalafil Mylan	Mylan Pharmaceuticals Limited	EU/1/14/961/012-016	Film-coated tablet	- G04BE - G04BE08	- Tadalafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tafinlar 50 mg hard capsules	Novartis Europharm Limited	EU/1/13/865/001-002	Capsule, hard	- L01XE23	- Dabrafenib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tafinlar 75 mg hard capsules	Novartis Europharm Limited	EU/1/13/865/003-004	Capsule, hard	- L01XE23	- Dabrafenib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tagrisso	AstraZeneca AB	EU/1/16/1086/001	Film-coated tablet	- L01XE - L01XE35	- Osimertinib mesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tagrisso	AstraZeneca AB	EU/1/16/1086/002	Film-coated tablet	- L01XE - L01XE35	- Osimertinib mesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
TAKHZYRO	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/18/1340/001	Solution for injection	- B06AC05	- LANADELUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Takhzyro	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/18/1340/007-009	Solution for injection	- B06AC05	- LANADELUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Taltz	Eli Lilly and Company (Ireland) Limited	EU/1/15/1085/001-003	Solution for injection in pre-filled pen	- L04AC - L04AC13	- Ixekizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Taltz	Eli Lilly and Company (Ireland) Limited	EU/1/15/1085/004-006	Solution for injection in pre-filled syringe	- L04AC - L04AC13	- Ixekizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Talvey	Janssen-Cilag International NV	EU/1/23/1748/001	Solution for injection	- L01 - L01FX29	- Talquetamab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Talvey	Janssen-Cilag International NV	EU/1/23/1748/002	Solution for injection	- L01 - L01FX29	- Talquetamab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Talzenna	Pfizer Europe MA EEIG	EU/1/19/1377/001-004	Capsule, hard	- L01XX60	- TALAZOPARIB TOSYLATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Talzenna	Pfizer Europe MA EEIG	EU/1/19/1377/005-006	Capsule, hard	- L01XX60	- TALAZOPARIB TOSYLATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Talzenna	Pfizer Europe MA EEIG	EU/1/19/1377/007	Capsule, hard	- L01XK04	- TALAZOPARIB TOSYLATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tambocor 10 mg/ml Solution for Injection or Infusion	Mylan IRE Healthcare Limited	PA2010/026/001	Solution for injection/infusion	- C01BC - C01BC04	- Flecainide acetate		- Intravenous use
Tambocor 100 mg Tablets	Mylan IRE Healthcare Limited	PA2010/026/003	Tablet	- C01BC - C01BC04	- Flecainide acetate		- Not Currently Available
Tambocor 50 mg Tablets	Mylan IRE Healthcare Limited	PA2010/026/002	Tablet	- C01BC - C01BC04	- Flecainide acetate		- Oral use
Tamiflu	Roche Registration GmbH	EU/1/02/222/001	Capsule, hard	- J05AH02	- Oseltamivir phosphate		- Oral use
Tamiflu	Roche Registration GmbH	EU/1/02/222/003	Capsule, hard	- J05AH02	- Oseltamivir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tamiflu	Roche Registration GmbH	EU/1/02/222/004	Capsule, hard	- J05AH02	- Oseltamivir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tamiflu	Roche Registration GmbH	EU/1/02/222/005	Powder for oral suspension	- J05AH02	- Oseltamivir phosphate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tamnexyl XL 400 micrograms prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/224/001 Interchangeable List Code: IC0024-066-024	Prolonged-release tablet		- Tamsulosin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tamnic 400 micrograms Modified-release Capsules, hard	Clonmel Healthcare Ltd	PA0126/151/001 Interchangeable List Code: IC0024-066-044	Modified-release capsule, hard		- Tamsulosin hydrochloride		- Oral use
Tamox 10 mg Film-coated tablets	Rowex Ltd	PA0711/022/001	Film-coated tablet	- L02BA - L02BA01	- Tamoxifen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tamox 20 mg Film-coated tablets	Rowex Ltd	PA0711/022/002	Film-coated tablet	- L02BA - L02BA01	- Tamoxifen	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tamoxifen 20 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/207/001	Tablet	- L02BA - L02BA01	- Tamoxifen citrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Not Currently Available
TAMSU 400 micrograms modified-release capsules, hard	Rowex Ltd	PA0711/079/001 Interchangeable List Code: IC0024-066-044	Modified-release capsule, hard		- Tamsulosin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tamsulosin 400 micrograms Modified-release Capsules, Hard	Viatris Limited	PA23266/016/001 Interchangeable List Code: IC0024-066-044	Modified-release capsule, hard		- Tamsulosin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Tamsulosin Hydrochloride 400 micrograms Modified-release Capsules, hard	Synthon BV	PA0840/013/001 Interchangeable List Code: IC0024-066-044	Modified-release capsule, hard		- Tamsulosin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tamzeltos 400 micrograms prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/087/001 Interchangeable List Code: IC0024-066-024	Prolonged-release tablet		- Tamsulosin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tandemact	CHEPLAPHARM Arzneimittel GmbH	EU/1/06/366/005-16	Tablet	- A10BD06	- Glimepiride - Pioglitazone		- Oral use
Tandemact	CHEPLAPHARM Arzneimittel GmbH	EU/1/06/366/1-2	Tablet	- A10BD	- Pioglitazone - Glimepiride		- Oral use
Tandemact	CHEPLAPHARM Arzneimittel GmbH	EU/1/06/366/17-22	Tablet	- A10BD06	- Glimepiride - Pioglitazone hydrochloride		- Oral use
TANYZ 400 micrograms hard modified-release capsules	KRKA, d.d., Novo mesto	PA1347/086/001 Interchangeable List Code: IC0024-066-044	Modified-release capsule, hard		- Tamsulosin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tapentadol Liconsa 100 mg prolonged-release tablets	Laboratorios LICONSA, S.A.	PA1239/029/003	Prolonged-release tablet	- N02AX06	- Tapentadol Tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tapentadol Liconsa 150 mg prolonged-release tablets	Laboratorios LICONSA, S.A.	PA1239/029/004	Prolonged-release tablet	- N02AX06	- Tapentadol Tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tapentadol Liconsa 200 mg prolonged-release tablets	Laboratorios LICONSA, S.A.	PA1239/029/005	Prolonged-release tablet	- N02AX06	- Tapentadol Tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tapentadol Liconsa 25 mg prolonged-release tablets	Laboratorios LICONSA, S.A.	PA1239/029/001	Prolonged-release tablet	- N02AX06	- Tapentadol Tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tapentadol Liconsa 250 mg prolonged-release tablets	Laboratorios LICONSA, S.A.	PA1239/029/006	Prolonged-release tablet	- N02AX06	- Tapentadol Tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tapentadol Liconsa 50 mg prolonged-release tablets	Laboratorios LICONSA, S.A.	PA1239/029/002	Prolonged-release tablet	- N02AX06	- Tapentadol Tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tapimio 100 mg prolonged-release tablets	Neuraxpharm Ireland Limited	PA23229/005/003	Prolonged-release tablet	- N02AX06	- Tapentadol Phosphate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tapimio 150 mg prolonged-release tablets	Neuraxpharm Ireland Limited	PA23229/005/004	Prolonged-release tablet	- N02AX06	- Tapentadol Phosphate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tapimio 200 mg prolonged-release tablets	Neuraxpharm Ireland Limited	PA23229/005/005	Prolonged-release tablet	- N02AX06	- Tapentadol Phosphate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tapimio 25 mg prolonged-release tablets	Neuraxpharm Ireland Limited	PA23229/005/001	Prolonged-release tablet	- N02AX06	- Tapentadol Phosphate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tapimio 250 mg prolonged-release tablets	Neuraxpharm Ireland Limited	PA23229/005/006	Prolonged-release tablet	- N02AX06	- Tapentadol Phosphate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tapimio 50 mg prolonged-release tablets	Neuraxpharm Ireland Limited	PA23229/005/002	Prolonged-release tablet	- N02AX06	- Tapentadol Phosphate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Taptiqom 15 micrograms/ml + 5 mg/ml eye drops, solution in single-dose container	PCO Manufacturing Ltd.	PPA0465/475/001	Eye drops, solution in single-dose container	- S01ED - S01ED51	- Tafluprost - Timolol		- Ocular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Taptiqom 15 micrograms/ml + 5 mg/ml eye drops, solution in single-dose container	Santen OY	PA0879/003/001	Eye drops, solution in single-dose container	- S01ED - S01ED51	- Tafluprost - Timolol	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Ocular use
Tarceva	Roche Registration GmbH	EU/1/05/311/01-3	Film-coated tablet	- L01EB02	- ERLOTINIB HYDROCHLORIDE		- Oral use
Targaxan 550 mg film-coated tablets	Norgine B.V.	PA1336/009/001	Film-coated tablet	- A07AA - A07AA11	- Rifaximin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Targin 10mg/5mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/002 Interchangeable List Code: IC0102-016-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE - Naloxone hydrochloride dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Targin 15 mg/7.5 mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/006	Prolonged-release tablet	- N02AA - N02AA55	- OXYCODONE HYDROCHLORIDE - NALOXONE HYDROCHLORIDE	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Targin 20mg/10mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/003 Interchangeable List Code: IC0102-061-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE - Naloxone hydrochloride dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Targin 30 mg/15 mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/007	Prolonged-release tablet	- N02AA - N02AA55	- OXYCODONE HYDROCHLORIDE - NALOXONE HYDROCHLORIDE	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Targin 40 mg/20 mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/004 Interchangeable List Code: IC0102-160-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE - Naloxone hydrochloride dihydrate	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Targin 5 mg/2.5 mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/001 Interchangeable List Code: IC0102-159-024	Prolonged-release tablet		- OXYCODONE HYDROCHLORIDE - Naloxone hydrochloride dihydrate	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Targin 60 mg/30 mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/008	Prolonged-release tablet	- N02AA - N02AA55	- OXYCODONE HYDROCHLORIDE - NALOXONE HYDROCHLORIDE	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Targin 80 mg/40 mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/009	Prolonged-release tablet	- N02AA - N02AA55	- OXYCODONE HYDROCHLORIDE - NALOXONE HYDROCHLORIDE	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Targocid 200mg Powder and Solvent for Solution for Injection/infusion or oral solution	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/021/001	Powder and solvent for solution for injection/infusion	- J01XA - J01XA02	- Teicoplanin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Targocid 400mg Powder and Solvent for Solution for Injection/infusion or oral solution	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/021/002	Powder and solvent for solution for injection/infusion	- J01XA - J01XA02	- Teicoplanin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Oral use
Targretin	Eisai GmbH	EU/1/01/178/001	Capsule, soft	- L01XX - L01XX25	- Bexarotene		- Oral use
Tasigna	Novartis Europharm Limited	EU/1/07/422/001-004	Capsule, hard	- L01XE - L01XE08	- Nilotinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tasigna	Novartis Europharm Limited	EU/1/07/422/005-006	Capsule, hard	- L01XE - L01XE08	- Nilotinib (as hydrochloride monohydrate)		- Oral use
Tasigna	Novartis Europharm Limited	EU/1/07/422/015	Capsule, hard	- L01XE - L01XE08	- Nilotinib (as hydrochloride monohydrate)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tasmar	Viatris Healthcare Limited	EU/1/97/044/001	Film-coated tablet	- N04BX - N04BX01	- Tolcapone		- Oral use
Tasmar	Viatris Healthcare Limited	EU/1/97/044/002	Film-coated tablet	- M03BX - M03BX04	- Tolcapone		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Tasmar	Viatris Healthcare Limited	EU/1/97/044/003	Film-coated tablet	- M03BX - M03BX04	- Tolcapone		- Oral use
Tasmar	Viatris Healthcare Limited	EU/1/97/044/004	Film-coated tablet	- M03BX - M03BX04	- Tolcapone		- Oral use
Tasmar	Viatris Healthcare Limited	EU/1/97/044/005	Film-coated tablet	- M03BX - M03BX04	- Tolcapone		- Oral use
Tasmar	Viatris Healthcare Limited	EU/1/97/044/006	Film-coated tablet	- M03BX - M03BX04	- Tolcapone		- Oral use
Taurolin 2% w/v solution for intraperitoneal lavage after dilution or solution for instillation	Elara Pharmaservices Europe Limited	PA22637/005/001	Intraperitoneal solution	- B05CA - B05CA05	- Taurolidine		- Intraperitoneal use
Tavager 500 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/104/002	Film-coated tablet	- J01MA - J01MA12	- Levofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tavanic 5 mg/ml solution for infusion	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/077/001	Solution for infusion	- J01MA - J01MA12	- Levofloxacin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Tavanic 500 mg film-coated tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/077/003	Film-coated tablet	- J01MA - J01MA12	- Levofloxacin		- Oral use
Tavanic 500 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/302/001	Film-coated tablet	- J01MA - J01MA12	- Levofloxacin		- Oral use
Tavlesse	Instituto Grifols S.A.	EU/1/19/1405/002	Film-coated tablet	- B02BX09	- FOSTAMATINIB	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tavlesse	Rigel Pharmaceuticals B.V.	EU/1/19/1408/001	Film-coated tablet	- B02BX09	- FOSTAMATINIB	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tavneos	Vifor Fresenius Medical Care Renal Pharma France	EU/1/21/1605/001-002	Capsule, hard	- L04	- Avacopan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
TAXOTERE	Sanofi Winthrop Industrie	EU/1/95/002/001	Concentrate for solution for infusion	- L01CD - L01CD02	- Docetaxel trihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	
Taxotere	Sanofi Winthrop Industrie	EU/1/95/002/002	Concentrate and solvent for solution for infusion	- L01CD - L01CD02	- Docetaxel trihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	
Taxotere	Sanofi Winthrop Industrie	EU/1/95/002/003	Concentrate and solvent for solution for infusion	- L01CD - L01CD02	- Docetaxel trihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Taxotere	Sanofi Winthrop Industrie	EU/1/95/002/004	Concentrate and solvent for solution for infusion	- L01CD - L01CD02	- Docetaxel trihydrate	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
TdaPBooster, suspension for injection in pre-filled syringe.Diphtheria, tetanus and pertussis (acellular component) vaccine (adsorbed, reduced antigen content)	AJ Vaccines A/S	PA2160/002/001	Suspension for injection in pre-filled syringe	- J07AJ - J07AJ52	- Diphtheria toxoid, purified - Tetanus toxoid, purified - Pertussis toxoid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Tecartus	Kite Pharma EU B.V.	EU/1/20/1492/001	Dispersion for infusion	- L01XL06	- Autologous Peripheral Blood T Cells CD4 and CD8 selected and CD3 and CD28 Activated Transduced with Retroviral	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Tecentriq	Roche Registration GmbH	EU/1/17/1220/001	Concentrate for solution for infusion	- L01FF05	- Atezolizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Tecentriq	Roche Registration GmbH	EU/1/17/1220/002	Concentrate for solution for infusion	- L01FF05	- Atezolizumab	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Tecentriq	Roche Registration GmbH	EU/1/17/1220/003	Solution for injection	- L01FF05	- Atezolizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Tecfidera	Biogen Netherlands B.V.	EU/1/13/837/001	Gastro-resistant capsule, hard	- L04AX07	- Dimethyl Fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tecfidera	Biogen Netherlands B.V.	EU/1/13/837/002	Gastro-resistant capsule, hard	- L04AX07	- Dimethyl Fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Technescan DMSA 1.2 mg kit for radiopharmaceutical preparation	Curium Netherlands B.V.	PA0690/011/001	Kit for radiopharmaceutical preparation	- V09CA - V09CA02	- Succimer	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
TechneScan DTPA 20.8 mg kit for radiopharmaceutical preparation	Curium Netherlands B.V.	PA0690/015/001	Kit for radiopharmaceutical preparation	- V09CA01 - V09EA01	- PENTETIC ACID	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use - Intravenous use - Oral use
TechneScan HDP 3mg, kit for radiopharmaceutical preparation	Curium Netherlands B.V.	PA0690/004/001	Kit for radiopharmaceutical preparation	- V09BA - V09BA01	- Oxidronate disodium	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
TechneScan MAG3, powder for solution for injection	Curium Netherlands B.V.	PA0690/018/001	Powder for solution for injection	- V09CA - V09CA03	- Betiatide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Technescan MIBI 1mg kit for radiopharmaceutical preparation	Curium Netherlands B.V.	PA0690/020/001	Kit for radiopharmaceutical preparation	- V09GA01	- Tetrakis (2-methylopropyl-isocyanide) copper (i) tetrafluoroborate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Technescan PYP 20 mg kit for radiopharmaceutical preparation	Curium Netherlands B.V.	PA0690/010/001	Kit for radiopharmaceutical preparation	- V09GA - V09GA06	- Sodium pyrophosphate decahydrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Tecovirimat SIGA 200 mg hard capsules	SIGA Technologies Netherlands B.V.	EU/1/21/1600/001	Capsule, hard	- J05AX24	- Tecovirimat Monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tecvayli	Janssen-Cilag International NV	EU/1/22/1675/001	Solution for injection	- L01	- Teclistamab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Tecvayli	Janssen-Cilag International NV	EU/1/22/1675/002	Solution for injection		- Teclistamab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Teedex Oral Solution Paracetamol 120 mg/5 ml Diphenhydramine Hydrochloride 12.5 mg/5 ml	Phoenix Healthcare Ltd	PA1721/004/001	Oral solution	- N02BE - N02BE51	- Diphenhydramine hydrochloride - Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Teetha Chamomilla Teething Gel	Pharmaceutical Business Consultants Limited	HOA23352/002/001	Gel		- Chamomilla 12c hab	National Rules Authorisation (Article 16.2 Directive 2001/83/EC.)	- Oral use
Teetha Teething Granules	Pharmaceutical Business Consultants Limited	HOA23352/001/001	Granules		- Chamomilla recutita	National Rules Authorisation (Article 16.2 Directive 2001/83/EC.)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Tefin 150 mg Suppositories	Clonmel Healthcare Ltd	PA0126/330/002	Suppository	- M01AE - M01AE01	- Ibuprofen	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Rectal use
Tefin 75 mg Suppositories	Clonmel Healthcare Ltd	PA0126/330/001	Suppository	- M01AE - M01AE01	- Ibuprofen	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Rectal use
Tegretol 100mg Tablets	Novartis Ireland Limited	PA0896/030/002	Tablet	- N03AF - N03AF01	- Carbamazepine		- Oral use
Tegretol 100mg/5ml Oral Suspension	Novartis Ireland Limited	PA0896/030/001	Oral suspension	- N03AF - N03AF01	- Carbamazepine		- Oral use
Tegretol 200mg Tablets	Novartis Ireland Limited	PA0896/030/003	Tablet	- N03AF - N03AF01	- Carbamazepine		- Oral use
Tegretol 400mg Tablets	Novartis Ireland Limited	PA0896/030/004	Tablet	- N03AF - N03AF01	- Carbamazepine		- Oral use
Tegretol SR 200mg prolonged release tablets	Novartis Ireland Limited	PA0896/030/005	Prolonged-release tablet	- N03AF - N03AF01	- Carbamazepine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tegretol SR 400mg prolonged release tablets	Novartis Ireland Limited	PA0896/030/006	Prolonged-release tablet	- N03AF - N03AF01	- Carbamazepine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tegsedi (Inotersen-Ionis)	Akcea Therapeutics Ireland Ltd	EU/1/18/1296/001-002	Solution for injection in pre-filled syringe	- N07	- INOTERSEN	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Teicoplanin 200 mg Powder and Solvent for Solution for injection/infusion or oral solution	Noridem Enterprises Limited	PA1122/009/001	Powder and solvent for solution for injection/infusion	- J01XA - J01XA02	- Teicoplanin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Oral use
Teicoplanin 400 mg Powder and Solvent for Solution for injection/infusion or oral solution	Noridem Enterprises Limited	PA1122/009/002	Powder and solvent for solution for injection/infusion	- J01XA - J01XA02	- Teicoplanin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Oral use
Teicoplanin Hikma 200mg Powder for solution for injection/infusion or oral solution	Hikma Farmacêutica (Portugal) S.A.	PA1217/010/001	Powder for solution for injection/infusion	- J01XA - J01XA02	- Teicoplanin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Teicoplanin Hikma 400mg Powder for solution for injection/infusion or oral solution	Hikma Farmacêutica (Portugal) S.A.	PA1217/010/002	Powder for solution for injection/infusion	- J01XA - J01XA02	- Teicoplanin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Tekcis 2-50 GBq radionuclide generator	CIS bio International	PA0677/020/001	Radionuclide generator	- V09FX - V09FX01	- Sodium pertechnetate (99m tc)	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intraocular use - Intravenous use
Telfast 120 mg film-coated tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/003/002	Film-coated tablet	- R06AX - R06AX26	- Fexofenadine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Telfast 180 mg film-coated tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/003/003	Film-coated tablet	- R06AX - R06AX26	- Fexofenadine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Telfast 30 mg film-coated tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/003/001	Film-coated tablet	- R06A	- Fexofenadine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Telfast Allergy 120 mg film-coated tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/014/001	Film-coated tablet	- R06AX - R06AX26	- Fexofenadine hydrochloride	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Telfast Allergy 120 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/500/001	Film-coated tablet	- R06AX - R06AX26	- Fexofenadine hydrochloride		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Telmisartan 20 mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/014/001 Interchangeable List Code: IC0049-003-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan 20 mg tablets	Brillpharma (Ireland) Limited	PA22749/012/001 Interchangeable List Code: IC0049-003-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan 40 mg tablets	Brillpharma (Ireland) Limited	PA22749/012/002 Interchangeable List Code: IC0049-004-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan 40 mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/014/002 Interchangeable List Code: IC0049-004-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan 80 mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/014/003 Interchangeable List Code: IC0049-005-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan 80 mg tablets	Brillpharma (Ireland) Limited	PA22749/012/003 Interchangeable List Code: IC0049-005-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Actavis 20 mg tablets	Actavis Group hf	EU/1/10/639/001-010 Interchangeable List Code: IC0049-003-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Actavis 40 mg tablets	Actavis Group hf	EU/1/10/639/011-020 Interchangeable List Code: IC0049-004-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Actavis 80 mg tablets	Actavis Group hf	EU/1/10/639/021-030 Interchangeable List Code: IC0049-005-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/228/001 Interchangeable List Code: IC0049-003-014	Film-coated tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Clonmel 40 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/228/002 Interchangeable List Code: IC0049-004-014	Film-coated tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Clonmel 80 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/228/003 Interchangeable List Code: IC0049-005-014	Film-coated tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Fair-Med 20 mg Tablets	Fair-Med Healthcare GmbH	PA1789/008/001 Interchangeable List Code: IC0049-003-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Fair-Med 40 mg Tablets	Fairmed Healthcare GmbH	PA1789/008/002 Interchangeable List Code: IC0049-004-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Telmisartan Fair-Med 80 mg Tablets	Fairmed Healthcare GmbH	PA1789/008/003 Interchangeable List Code: IC0049-005-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Mylan 20 mg tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/135/001 Interchangeable List Code: IC0049-003-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Mylan 40 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/135/002 Interchangeable List Code: IC0049-004-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Mylan 80 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/135/003 Interchangeable List Code: IC0049-005-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Rowa 20 mg tablets	Rowa Pharmaceuticals Limited	PA0074/078/001 Interchangeable List Code: IC0049-003-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Rowa 40 mg tablets	Rowa Pharmaceuticals Limited	PA0074/078/002 Interchangeable List Code: IC0049-004-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Rowa 80 mg tablets	Rowa Pharmaceuticals Limited	PA0074/078/003 Interchangeable List Code: IC0049-005-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Teva Pharma 20 mg tablets	Teva B.V.	EU/1/11/719/001-020 Interchangeable List Code: IC0049-003-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Teva Pharma 40 mg tablets	Teva B.V.	EU/1/11/719/021-040 Interchangeable List Code: IC0049-004-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan Teva Pharma 80 mg tablets	Teva B.V.	EU/1/11/719/041-060 Interchangeable List Code: IC0049-005-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan/Hydrochlorothiazide 40 mg/12.5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/107/001 Interchangeable List Code: IC0050-099-039	Tablet		- Telmisartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan/Hydrochlorothiazide 80 mg/12.5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/107/002 Interchangeable List Code: IC0050-081-039	Tablet		- Telmisartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan/Hydrochlorothiazide 80 mg/25 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/107/003 Interchangeable List Code: IC0050-100-039	Tablet		- Telmisartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan/Hydrochlorothiazide Clonmel 40 mg/12.5 mg tablets	Clonmel Healthcare Ltd	PA0126/259/001 Interchangeable List Code: IC0050-099-039	Tablet		- Telmisartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Telmisartan/Hydrochlorothiazide Clonmel 80 mg/12.5 mg tablets	Clonmel Healthcare Ltd	PA0126/259/002 Interchangeable List Code: IC0050-081-039	Tablet		- Telmisartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan/Hydrochlorothiazide Clonmel 80 mg/25 mg tablets	Clonmel Healthcare Ltd	PA0126/259/003 Interchangeable List Code: IC0050-100-039	Tablet		- Telmisartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan/Hydrochlorothiazide Liconsa 40 mg/12.5 mg tablets	Laboratorios LICONSA, S.A.	PA1239/025/001 Interchangeable List Code: IC0050-099-039	Tablet		- Telmisartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan/Hydrochlorothiazide Liconsa 80 mg/12.5 mg tablets	Laboratorios LICONSA, S.A.	PA1239/025/002 Interchangeable List Code: IC0050-081-039	Tablet		- Telmisartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan/Hydrochlorothiazide Liconsa 80 mg/25 mg tablets	Laboratorios LICONSA, S.A.	PA1239/025/003 Interchangeable List Code: IC0050-100-039	Tablet		- Telmisartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan/Hydrochlorothiazide Rowa 40 mg/12.5 mg tablets	Rowa Pharmaceuticals Limited	PA0074/081/001 Interchangeable List Code: IC0050-099-039	Tablet		- Telmisartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan/Hydrochlorothiazide Rowa 80 mg/12.5 mg tablets	Rowa Pharmaceuticals Limited	PA0074/081/002 Interchangeable List Code: IC0050-081-039	Tablet		- Telmisartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Telmisartan/Hydrochlorothiazide Rowa 80 mg/25 mg tablets	Rowa Pharmaceuticals Limited	PA0074/081/003 Interchangeable List Code: IC0050-100-039	Tablet		- Hydrochlorothiazide - Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
TELZIR	ViiV Healthcare BV	EU/1/04/282/1-2	Film-coated tablet	- J05AE - J05AE07	- Fosamprevanir calcium	Not Currently Available	- Unknown
Temgesic 200 microgram Sublingual Tablets	Eumedica Pharmaceuticals GmbH	PA23460/001/001	Sublingual tablet	- N02AE - N02AE01	- Buprenorphine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	
Temgesic 300 micrograms/ml, solution for injection	Eumedica Pharmaceuticals GmbH	PA23460/001/002	Solution for injection	- N02AE - N02AE01	- Buprenorphine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Temodal	Merck Sharp & Dohme BV	EU/1/98/096/001-002 Interchangeable List Code: IC0080-001-001	Capsule, hard		- Temozolomide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Temodal	Merck Sharp & Dohme BV	EU/1/98/096/003-004 Interchangeable List Code: IC0080-003-001	Capsule, hard		- Temozolomide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Temodal	Merck Sharp & Dohme BV,	EU/1/98/096/005-006 Interchangeable List Code: IC0080-024-001	Capsule, hard		- Temozolomide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Temodal	Merck Sharp & Dohme BV,	EU/1/98/096/007-008 Interchangeable List Code: IC0080-130-001	Capsule, hard		- Temozolomide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Temodal	Merck Sharp & Dohme BV	EU/1/98/096/009-010 Interchangeable List Code: IC0080-134-001	Capsule, hard		- Temozolomide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Temodal	Merck Sharp & Dohme BV	EU/1/98/096/011-012 Interchangeable List Code: IC0080-135-001	Capsule, hard		- Temozolomide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Temodal	Merck Sharp & Dohme BV	EU/1/98/096/023	Powder for solution for infusion	- L01AX - L01AX03	- Temozolomide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
TEMOMEDAC	Medac Gesellschaft fur Klinische Spezialpraparate mbH	EU/1/09/605/11-12 Interchangeable List Code: IC0080-130-001	Capsule, hard		- TEMOZOLOMIDE	Article 10(1) - Generic Application	- Oral use
TEMOMEDAC	Medac Gesellschaft fur Klinische Spezialpraparate mbH	EU/1/09/605/1-2 Interchangeable List Code: IC0080-001-001	Capsule, hard		- TEMOZOLOMIDE	Article 10(1) - Generic Application	- Oral use
TEMOMEDAC	Medac Gesellschaft fur Klinische Spezialpraparate mbH	EU/1/09/605/3-4 Interchangeable List Code: IC0080-003-001	Capsule, hard		- TEMOZOLOMIDE	Article 10(1) - Generic Application	- Oral use
TEMOMEDAC	Medac Gesellschaft fur Klinische Spezialpraparate mbH	EU/1/09/605/5-6 Interchangeable List Code: IC0080-024-001	Capsule, hard		- TEMOZOLOMIDE	Article 10(1) - Generic Application	- Oral use
TEMOMEDAC	Medac Gesellschaft fur Klinische Spezialpraparate mbH	EU/1/09/605/7-8 Interchangeable List Code: IC0080-134-001	Capsule, hard		- TEMOZOLOMIDE	Article 10(1) - Generic Application	- Oral use
TEMOMEDAC	Medac Gesellschaft fur Klinische Spezialpraparate mbH	EU/1/09/605/9-10 Interchangeable List Code: IC0080-135-001	Capsule, hard		- TEMOZOLOMIDE	Article 10(1) - Generic Application	- Oral use
Temozolomide Accord	Accord Healthcare S.L.U.	EU/1/10/615/001-002 Interchangeable List Code: IC0080-001-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide Accord	Accord Healthcare S.L.U.	EU/1/10/615/005-006 Interchangeable List Code: IC0080-003-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide Accord	Accord Healthcare S.L.U.	EU/1/10/615/009-010 Interchangeable List Code: IC0080-024-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide Accord	Accord Healthcare S.L.U.	EU/1/10/615/013-014 Interchangeable List Code: IC0080-134-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide Accord	Accord Healthcare S.L.U.	EU/1/10/615/017-018 Interchangeable List Code: IC0080-135-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Temozolomide Accord	Accord Healthcare S.L.U.	EU/1/10/615/021-022 Interchangeable List Code: IC0080-130-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide Clonmel 100mg hard capsules	Clonmel Healthcare Ltd	PA0126/188/003 Interchangeable List Code: IC0080-024-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide Clonmel 140mg hard capsules	Clonmel Healthcare Ltd	PA0126/188/004 Interchangeable List Code: IC0080-134-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide Clonmel 180 mg hard capsules	Clonmel Healthcare Ltd	PA0126/188/005 Interchangeable List Code: IC0080-135-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide Clonmel 20 mg hard capsules	Clonmel Healthcare Ltd	PA0126/188/002 Interchangeable List Code: IC0080-003-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide Clonmel 250 mg hard capsules	Clonmel Healthcare Ltd	PA0126/188/006 Interchangeable List Code: IC0080-130-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide Clonmel 5mg hard capsules	Clonmel Healthcare Ltd	PA0126/188/001 Interchangeable List Code: IC0080-001-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide FAIR-MED 100 mg hard capsules	Fairmed Healthcare GmbH	PA1789/005/003 Interchangeable List Code: IC0080-024-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide FAIR-MED 140 mg hard capsules	Fairmed Healthcare GmbH	PA1789/005/004 Interchangeable List Code: IC0080-134-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide FAIR-MED 180 mg hard capsules	Fairmed Healthcare GmbH	PA1789/005/005 Interchangeable List Code: IC0080-135-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide FAIR-MED 20 mg hard capsules	Fairmed Healthcare GmbH	PA1789/005/002 Interchangeable List Code: IC0080-003-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide FAIR-MED 250 mg hard capsules	Fairmed Healthcare GmbH	PA1789/005/006 Interchangeable List Code: IC0080-130-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide FAIR-MED 5 mg hard capsules	Fairmed Healthcare GmbH	PA1789/005/001 Interchangeable List Code: IC0080-001-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
TEMOZOLOMIDE SUN	Sun Phamaceutical Industries Europe B.V.	EU/1/11/697/001-002 Interchangeable List Code: IC0080-001-001	Capsule, hard		- TEMOZOLOMIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
TEMOZOLOMIDE SUN	Sun Phamaceutical Industries Europe B.V.	EU/1/11/697/003-004 Interchangeable List Code: IC0080-003-001	Capsule, hard		- TEMOZOLOMIDE	Article 10(1) - Generic Application	- Oral use
TEMOZOLOMIDE SUN	Sun Phamaceutical Industries Europe B.V.	EU/1/11/697/005-006 Interchangeable List Code: IC0080-024-001	Capsule, hard		- TEMOZOLOMIDE	Article 10(1) - Generic Application	- Oral use
TEMOZOLOMIDE SUN	Sun Phamaceutical Industries Europe B.V.	EU/1/11/697/007-008 Interchangeable List Code: IC0080-134-001	Capsule, hard		- TEMOZOLOMIDE	Article 10(1) - Generic Application	- Oral use
TEMOZOLOMIDE SUN	Sun Phamaceutical Industries Europe B.V.	EU/1/11/697/009-010 Interchangeable List Code: IC0080-135-001	Capsule, hard		- TEMOZOLOMIDE		- Oral use
TEMOZOLOMIDE SUN	Sun Phamaceutical Industries Europe B.V.	EU/1/11/697/011-012 Interchangeable List Code: IC0080-130-001	Capsule, hard		- TEMOZOLOMIDE	Article 10(1) - Generic Application	- Oral use
Temozolomide Teva	Teva B.V.	EU/1/09/606/001-002 Interchangeable List Code: IC0080-001-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide Teva	Teva B.V.	EU/1/09/606/003-004 Interchangeable List Code: IC0080-003-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide Teva	Teva B.V.	EU/1/09/606/005-006 Interchangeable List Code: IC0080-024-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide Teva	Teva B.V.	EU/1/09/606/007-008 Interchangeable List Code: IC0080-134-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide Teva	Teva B.V.	EU/1/09/606/009-010 Interchangeable List Code: IC0080-135-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Temozolomide Teva	Teva B.V.	EU/1/09/606/011-012 Interchangeable List Code: IC0080-130-001	Capsule, hard		- Temozolomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tendrotil SR 2 mg Prolonged-Release Capsules, Hard	Accord Healthcare Ireland Ltd.	PA2315/134/001 Interchangeable List Code: IC0025-006-032	Prolonged-release capsule, hard		- Tolterodine tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tendrotil SR 4 mg Prolonged-Release Capsules, Hard	Accord Healthcare Ireland Ltd.	PA2315/134/002 Interchangeable List Code: IC0025-008-032	Prolonged-release capsule, hard		- Tolterodine tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Tenkasi	Menarini International Operations Luxembourg S.A.	EU/1/15/989/001	Powder for concentrate for solution for infusion	- J01XA - J01XA05	- Oritavancin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Tenkasi	Menarini International Operations Luxembourg S.A.	EU/1/15/989/002	Powder for concentrate for solution for infusion	- J01XA05	- Oritavancin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Tenofovir disoproxil Accordpharma 245 mg Film-coated Tablets.	Accord Healthcare Ireland Ltd.	PA2315/022/001	Film-coated tablet	- J05AF07	- Tenofovir disoproxil fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tenofovir disoproxil Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1129/001	Film-coated tablet	- J05AF - J05AF07	- Tenofovir disoproxil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tenofovir Disoproxil Teva 245 mg Film-coated Tablets	Teva B.V.	PA1986/003/001	Film-coated tablet	- J05AF - J05AF07	- Tenofovir disoproxil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tenofovir disoproxil Zentiva	Zentiva k.s.	EU/1/16/1127/001-002	Film-coated tablet	- J05AF - J05AF07	- Tenofovir disoproxil phosphate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tepadina	Adienne S.r.l.	EU/1/10/622/001	Powder for concentrate for solution for infusion	- L01AC - L01AC01	- Thiotepa		- Intravenous use
Tepadina	Adienne S.r.l.	EU/1/10/622/002	Powder for concentrate for solution for infusion	- L01AC - L01AC01	- Thiotepa		- Intravenous use
Tepadina	Adienne S.r.l. S.U.	EU/1/10/622/003	Powder and solvent for solution for infusion	- L01AC01	- Thiotepa	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Tepkinly	AbbVie Deutschland GmbH & Co. KG	EU/1/23/1759/001	Concentrate for solution for injection	- L01FX18	- Epcoritamab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Tepkinly	AbbVie Deutschland GmbH & Co. KG	EU/1/23/1759/002	Solution for injection	- L01FX18	- Epcoritamab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Tepmetko	Merck Europe B.V.	EU/1/21/1596/001	Film-coated tablet	- L01 - L01EX21	- Tepotinib hydrochloride monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Terbasil 250mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/099/001	Tablet	- D01BA - D01BA02	- Terbinafine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Terbinafine Rowa 250 mg Tablets	Rowa Pharmaceuticals Limited	PA0074/084/001	Tablet	- D01BA - D01BA02	- Terbinafine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Terbza 98 mg/ml cutaneous solution	Moberg Pharma AB (publ)	PA23368/001/001	Cutaneous solution	- D01AE15	- Terbinafine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Teriflunomide Accord	Accord Healthcare S.L.U.	EU/1/22/1693/001-004	Film-coated tablet	- L04AA31	- Teriflunomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Teriflunomide Clonmel 14 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/375/001	Film-coated tablet	- L04AA31	- Teriflunomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Teriflunomide Mylan	Mylan Pharmaceuticals Limited	EU/1/22/1698/001-007	Film-coated tablet	- L04AA31	- Teriflunomide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Teriparatide SUN	Sun Phamaceutical Industries Europe B.V.	EU/1/22/1697/001-002	Solution for injection in pre-filled pen	- H05AA02	- Teriparatide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Terlipressin acetate EVER Pharma 0.2 mg/ml solution for injection	EVER Valinject GmbH	PA1774/007/001	Solution for injection	- H01BA04	- Terlipressin acetate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Terrosa	Gedeon Richter Plc	EU/1/16/1159/001-002	Solution for injection	- H05AA - H05AA02	- Teriparatide	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Tesavel 100 mg film-coated tablets	Merck Sharp & Dohme BV	EU/1/07/435/13-18 Interchangeable List Code: IC0131-024-003	Film-coated tablet		- Sitagliptin as monohydrate phosphate salt	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Tesavel 25 mg film-coated tablets	Merck Sharp & Dohme BV,	EU/1/07/435/1-6 Interchangeable List Code: IC0131-022-003	Film-coated tablet		- Sitagliptin as monohydrate phosphate salt	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Tesavel 50 mg film-coated tablets	Merck Sharp & Dohme BV	EU/1/07/435/7-12 Interchangeable List Code: IC0131-023-003	Film-coated tablet		- Sitagliptin as monohydrate phosphate salt	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Testarzon 20 mg/g Transdermal gel	The Simple Pharma Company Limited	PA23202/001/001	Transdermal gel	- G03BA - G03BA03	- Testosterone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Testogel 16.2 mg/g, gel	Laboratoires Besins International	PA1054/002/004	Gel	- G03BA - G03BA03	- Testosterone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Testogel 25 mg transdermal gel in sachet	Laboratoires Besins International	PA1054/002/001	Transdermal gel in sachet	- G03BA - G03BA03	- Testosterone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Testogel 40.5 mg transdermal gel in sachet	Laboratoires Besins International	PA1054/002/005	Transdermal gel in sachet	- G03B - G03BA03	- Testosterone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Testogel 50 mg transdermal gel in sachet	Laboratoires Besins International	PA1054/002/002	Transdermal gel in sachet	- G03BA - G03BA03	- Testosterone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Testosterone Besins 1000 mg/4 ml solution for injection	Besins Healthcare Ireland Limited	PA22624/002/001	Solution for injection	- G03BA03	- Testosterone Undecanoate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use
Tetagam P, prefilled syringeSolution for injection for intramuscular use	CSL Behring GmbH	PA0800/009/002	Solution for injection	- J06BB - J06BB02	- Human plasma protein	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Tetrabenazine 25 mg Tablets	Aop Orphan Pharmaceuticals GmbH	PA0934/004/001	Tablet	- N07XX - N07XX06	- Tetrabenazine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tetralysal 300 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/256/001	Capsule, hard	- J01AA - J01AA04	- Lymecycline	ZZZ PPA	- Oral use
Tetralysal 300 mg hard capsules	IMED Healthcare Ltd.	PPA1463/133/001	Capsule, hard	- J01AA - J01AA04	- Tetracycline		- Oral use
Tetralysal 300mg Hard Capsules	Galderma International	PA22743/016/001	Capsule, hard	- J01AA - J01AA04	- Tetracycline	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Tetravac, suspension for injection in prefilled syringeDiphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine,(adsorbed).	Sanofi Pasteur	PA2131/009/001	Suspension for injection in pre-filled syringe	- J07CA - J07CA02	- Purified tetanus toxoid - Purified diphtheria toxoid ph. eur. - Adsorbed purified pertussis toxoid - Adsorbed purified filamentous haemagglutinin - Inactivated Poliomyelitis Virus Ph. Eur - Inactivated type 1 poliovirus - Inactivated type 2 poliovirus - Inactivated type 3 poliovirus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Tetridar 20 micrograms/80 microlitres Solution for Injection in pre-filled pen	Teva B.V.	PA1986/053/001	Solution for injection in pre-filled pen	- H05AA - H05AA02	- Teriparatide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Teuro 10,000 IU (100 mg)/1 mL solution for injection in pre-filled syringe	Laboratorios Farmacéuticos ROVI, S.A.	PA1995/002/001	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Haemodialysis - Intravenous use - Subcutaneous use
Teuro 2,000 IU (20 mg)/0.2 mL solution for injection in pre-filled syringe	Laboratorios Farmacéuticos ROVI, S.A.	PA1995/002/002	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Haemodialysis - Intravenous use - Subcutaneous use
Teuro 4,000 IU (40 mg)/0.4 mL solution for injection in pre-filled syringe	Laboratorios Farmacéuticos ROVI, S.A.	PA1995/002/003	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Haemodialysis - Intravenous use - Subcutaneous use
Teuro 6,000 IU (60 mg)/0.6 mL solution for injection in pre-filled syringe	Laboratorios Farmacéuticos ROVI, S.A.	PA1995/002/004	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Haemodialysis - Intravenous use - Subcutaneous use
Teuro 8,000 IU (80 mg)/0.8 mL solution for injection in pre-filled syringe	Laboratorios Farmacéuticos ROVI, S.A.	PA1995/002/005	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Haemodialysis - Intravenous use - Subcutaneous use
Tevagrastim	Teva Generics Gmb	EU/1/08/445/1-4	Solution for injection/infusion	- L03AA - L03AA02	- Filgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Tevagrastim 48 MIU/0.8 ml solution for injection o	Teva Generics Gmb	EU/1/08/445/5-8	Solution for injection/infusion	- L03AA - L03AA02	- Filgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Tevanate Once Weekly 70mg Tablets	Teva Pharma B.V.	PA0749/016/001 Interchangeable List Code: IC0051-101-002	Tablet		- Alendronic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tevaquel 100 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/060/002 Interchangeable List Code: IC0019-024-003	Film-coated tablet		- Quetiapine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tevaquel 200 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/060/004 Interchangeable List Code: IC0019-067-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tevaquel 25 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/060/001 Interchangeable List Code: IC0019-022-003	Film-coated tablet		- Quetiapine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tevaquel 300 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/060/005 Interchangeable List Code: IC0019-029-003	Film-coated tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Tevaquel XL 200 mg Prolonged-release tablets	Teva Pharma B.V.	PA0749/060/007 Interchangeable List Code: IC0019-067-024	Prolonged-release tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tevaquel XL 300 mg Prolonged-release tablets	Teva Pharma B.V.	PA0749/060/008 Interchangeable List Code: IC0019-029-024	Prolonged-release tablet		- Quetiapine fumarate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tevaquel XL 400 mg Prolonged-release tablets	Teva Pharma B.V.	PA0749/060/009 Interchangeable List Code: IC0019-068-024	Prolonged-release tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tevaquel XL 50 mg Prolonged-release tablets	Teva Pharma B.V.	PA0749/060/006 Interchangeable List Code: IC0019-023-024	Prolonged-release tablet		- Quetiapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
TEVETEN 400 mg, film-coated tablets	Mylan IRE Healthcare Limited	PA2010/017/001	Film-coated tablet	- C09CA - C09CA02	- Eprosartan mesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Teveten 600 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/469/001	Film-coated tablet	- C09CA - C09CA02	- Eprosartan	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Teveten 600 mg, film-coated tablets	IMED Healthcare Ltd.	PPA1463/091/001	Film-coated tablet	- C09CA - C09CA02	- Eprosartan		- Oral use
Teveten 600 mg, film-coated tablets	Mylan IRE Healthcare Limited	PA2010/017/002	Film-coated tablet	- C09CA - C09CA02	- Eprosartan mesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Teveten Plus 600 mg/12.5 mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/018/001	Film-coated tablet	- C09DA - C09DA02	- Eprosartan - Hydrochlorothiazide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Teveten Plus 600 mg/12.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/448/001	Film-coated tablet	- C09DA02	- Hydrochlorothiazide - Eprosartan		- Oral use
Tevimbra	BeiGene Ireland Limited	EU/1/23/1758/001-002	Concentrate for solution for infusion	- L01 - L01FF09	- Tislelizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Teysuno	Nordic Group B.V.	EU/1/11/669/001-002	Capsule, hard	- L01BC - L01BC53	- Tegafur - Gimeracil - Oteracil (as monopotassium salt)		- Oral use
Teysuno	Nordic Group B.V.	EU/1/11/669/003-004	Capsule, hard	- L01BC - L01BC53	- Gimeracil - Oteracil (as monopotassium salt) - Tegafur		- Oral use
TEZSPIRE	AstraZeneca AB	EU/1/22/1677/001-002	Solution for injection	- R03DX11	- Tezepelumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Thalidomide BMS	Bristol-Myers Squibb Pharmaceuticals uc	EU/1/08/443/1	Capsule, hard	- L04AX - L04AX02	- Thalidomide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Thalidomide Lipomed	Lipomed GmbH	EU/1/22/1676/001	Coated tablet	- L04AX02	- Thalidomide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Thallous (Tl201) chloride injection 37 MBq/ml solution for injection	Curium Netherlands B.V.	PA0690/016/001	Solution for injection	- V09GX - V09GX01	- Thallous chloride (201 tl)		- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Thamicarb 84mg/ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/017/001	Oral solution	- A02AH	- Sodium hydrogen carbonate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Thiotepa Fresenius Kabi 100 mg powder for concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/079/002	Powder for concentrate for solution for infusion	- L01AC01	- Thiotepa	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Thiotepa Fresenius Kabi 15 mg powder for concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/079/001	Powder for concentrate for solution for infusion	- L01AC01	- Thiotepa	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Thiotepa Riemser	Riemser Pharma GmbH	EU/1/21/1536/001	Powder for concentrate for solution for infusion	- L01AC01	- Thiotepa	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Thiotepa Riemser	Riemser Pharma GmbH	EU/1/21/1536/002	Powder for concentrate for solution for infusion	- L01AC01	- Thiotepa	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
THORENS 10 000 I.U. /ml oral drops, solution	Galen Pharma Ireland Limited	PA22680/005/001	Oral drops, solution	- A11CC - A11CC05	- Cholecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
THORENS 25 000 I.U. /2.5 ml oral solution	Galen Pharma Ireland Limited	PA22680/005/002	Oral solution	- A11CC - A11CC05	- Cholecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Thorens 25 000 I.U. capsules, hard	Galen Pharma Ireland Limited	PA22680/005/003	Capsule, hard	- A11CC - A11CC05	- Colecalciferol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Thorinane	Techdow Pharma Netherlands B.V	EU/1/16/1131/001-002	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intraarterial use - Intravenous use - Subcutaneous use
Thorinane	Pharmathen S.A.	EU/1/16/1131/003-004	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intraarterial use - Intravenous use - Subcutaneous use
Thorinane	Pharmathen S.A.	EU/1/16/1131/005-006	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intraarterial use - Intravenous use - Subcutaneous use
Thorinane	Pharmathen S.A.	EU/1/16/1131/007-008	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intraarterial use - Intravenous use - Subcutaneous use
Thorinane	Pharmathen S.A.	EU/1/16/1131/009-010	Solution for injection in pre-filled syringe	- B01AB - B01AB05	- Enoxaparin sodium	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intraarterial use - Intravenous use - Subcutaneous use
Thwart 26% w/w Cutaneous Solution	Alliance Pharma (Ireland) Limited	PA2325/015/001	Cutaneous solution	- D02AF	- Salicylic acid		- Cutaneous use
Thymoglobuline 25 mg powder for solution for infusion	Genzyme Europe B.V.	PA0611/003/001	Powder for solution for infusion	- L04AA - L04AA04	- Rabbit anti-human thymocyte immunoglobulin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
THYROGEN	Genzyme Europe B.V.	EU/1/99/122/001	Powder for solution for injection	- H01AB01	- Thyrotropin alfa		- Intramuscular use
THYROGEN	Genzyme Europe B.V.	EU/1/99/122/002	Powder for solution for injection	- H01AB01	- Thyrotropin alfa		- Intramuscular use
Tibolone Aristo 2.5 mg tablets	Aristo Pharma GmbH	PA1983/003/001	Tablet	- G03CX - G03CX01	- Tibolone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Tibsovo	Les Laboratoires Servier	EU/1/23/1728/001	Film-coated tablet	- L01XX62	- Ivosidenib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ticagrelor Krka 60 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/102/001	Film-coated tablet	- B01AC24	- Ticagrelor	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ticagrelor Krka 90 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/102/002	Film-coated tablet	- B01AC24	- Ticagrelor	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ticagrelor Pinewood 90 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/258/001	Film-coated tablet	- B01AC24	- Ticagrelor	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ticagrelor Rowex 90 mg Film-coated tablets	Rowex Ltd	PA0711/299/001	Film-coated tablet	- B01AC24	- Ticagrelor	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ticagrelor Teva 90 mg Film-coated Tablets	Teva B.V.	PA1986/123/001	Film-coated tablet	- B01AC24	- Ticagrelor	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ticagrelor Viatris 60 mg film-coated tablets	Viatris Limited	PA23266/008/001	Film-coated tablet	- B01AC24	- Ticagrelor	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ticagrelor Viatris 90 mg film-coated tablets	Viatris Limited	PA23266/008/002	Film-coated tablet	- B01AC24	- Ticagrelor	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
TicoVac 0.5 ml Suspension for injection in a pre-filled syringeTick-Borne Encephalitis Vaccine (whole Virus, inactivated)	Pfizer Healthcare Ireland	PA0822/184/001	Suspension for injection in pre-filled syringe	- J07BA - J07BA01	- Tbe virus antigen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
TicoVac Junior 0.25 ml Suspension for injection in a pre-filled syringeTick-Borne Encephalitis Vaccine (whole Virus, inactivated)	Pfizer Healthcare Ireland	PA0822/184/002	Suspension for injection in pre-filled syringe	- J07BA - J07BA01	- TICK-BORNE ENCEPHALITIS VIRUS (INACTIVATED) NEUDOERFL		- Intravenous use
Tidimaz 20 mg/ml + 5 mg/ml eye drops, solution	Farmaprojects S.A.	PA1391/004/001	Eye drops, solution	- S01ED51	- Dorzolamide hydrochloride - Timolol Maleate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Tigecycline 50 mg powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/070/001	Powder for solution for infusion	- J01AA - J01AA12	- Tigecycline		- Intravenous use
Tigecycline Accord	Accord Healthcare S.L.U.	EU/1/19/1394/001-002	Powder for solution for infusion	- J01AA12	- Tigecycline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Tiger Balm Red Ointment	Chefaro Ireland DAC	PA1186/014/001	Ointment	- M02A	- Camphor - Menthol - Cajuput oil - Clove oil	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical use
Tiger Balm White Ointment	Chefaro Ireland DAC	PA1186/014/002	Ointment	- M02A	- Camphor - Levomenthol - Cajuput oil - Clove oil	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Cutaneous use
Timlatan 50 micrograms/ml + 5 mg/ml eye drops, solution	Bausch + Lomb Ireland Limited	PA23259/001/001 Interchangeable List Code: IC0100-153-045	Eye drops, solution		- Latanoprost - Timolol Maleate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Timofluid 1 mg/g eye gel in single-dose container	Laboratoires Thea	PA1107/003/001	Eye gel in single-dose container	- S01ED - S01ED01	- Timolol Maleate	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Ocular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Timolol 0.25% w/v Eye Drops, Solution	Brown & Burk IR Limited	PA23148/003/001	Eye drops, solution	- C07AA - C07AA06	- Timolol Maleate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intraocular use
Timolol 0.5% w/v Eye Drops, Solution	Brown & Burk IR Limited	PA23148/003/002	Eye drops, solution	- C07AA - C07AA06	- Timolol Maleate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intraocular use
Tiogiva, 18 microgram, inhalation powder, hard capsule	Glenmark Pharmaceuticals Nordic AB	PA22815/002/001	Inhalation powder, hard capsule	- R03BB04	- Tiotropium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Tiotropium Viatris 18 microgram, inhalation powder, hard capsule	Viatris Limited	PA23266/007/001	Inhalation powder, hard capsule	- R03BB04	- Tiotropium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Tipol 125 mg suppositories	Clonmel Healthcare Ltd	PA0126/331/002	Suppository	- N02BE - N02BE01	- Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Rectal use
Tipol 250 mg suppositories	Clonmel Healthcare Ltd	PA0126/331/003	Suppository	- N02BE - N02BE01	- Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Rectal use
Tipol 500 mg suppositories	Clonmel Healthcare Ltd	PA0126/331/004	Suppository	- N02BE - N02BE01	- Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Rectal use
Tipol 500mg granules in sachets	Clonmel Healthcare Ltd	PA0126/333/002	Granules in sachet	- N02BE - N02BE01	- Paracetamol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Tipol 75 mg suppositories	Clonmel Healthcare Ltd	PA0126/331/001	Suppository	- N02BE - N02BE01	- Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Rectal use
Tipol Junior 250mg granules in sachets	Clonmel Healthcare Ltd	PA0126/333/001	Granules in sachet	- N02BE - N02BE01	- Paracetamol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Tipol Max 1000 mg suppositories	Clonmel Healthcare Ltd	PA0126/331/005	Suppository	- N02BE - N02BE01	- Paracetamol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Rectal use
Tipol Max 1000mg granules in sachets	Clonmel Healthcare Ltd	PA0126/333/003	Granules in sachet	- N02BE - N02BE01	- Paracetamol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Tipuric 100 mg Tablets	Clonmel Healthcare Ltd	PA0126/038/001	Tablet	- M04AA - M04AA01	- Allopurinol		- Oral use
Tipuric 300 mg Tablets	Clonmel Healthcare Ltd	PA0126/038/002	Tablet	- M04AA - M04AA01	- Allopurinol		- Oral use
TISSEEL Lyo Powder and Solvent for Sealant	Baxter Holding B.V.	PA2299/025/002	Powder and solvent for sealant	- B02BC - V03AK	- Human fibrinogen - Human factor xiii - Aprotinin - Human thrombin - Calcium chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
TISSEEL Ready to use Solutions for Sealant	Baxter Holding B.V.	PA2299/025/001	Solution for sealant	- B02BC - V03AK	- Human fibrinogen - Aprotinin - Human factor xiii - Human thrombin - Calcium chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Epilesional use
Tivicay	ViiV Healthcare BV	EU/1/13/892/001-002	Film-coated tablet	- J05AX - J05AX12	- Dolutegravir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tivicay	ViiV Healthcare BV	EU/1/13/892/003-004	Film-coated tablet	- J05AX - J05AX12	- Dolutegravir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Tivicay	ViiV Healthcare BV	EU/1/13/892/005-006	Film-coated tablet	- J05AX - J05AX12	- Dolutegravir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tivicay	ViiV Healthcare BV	EU/1/13/892/007	Dispersible tablet	- J05AX12	- Dolutegravir sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
TOBI 300 mg/5 mL Nebuliser SolutionTobramycin 300 mg/5 ml Nebuliser Solution	Mylan IRE Healthcare Limited	PA2010/063/001	Nebuliser solution	- J01GB - J01GB01	- Tobramycin		- Inhalation use
Tobi Podhaler	Viatris Limited	EU/1/10/652/001-003	Inhalation powder, hard capsule	- J01GB - J01GB01	- Tobramycin		- Inhalation use
Tobramycin 40 mg/ml Solution for Injection	Pfizer Healthcare Ireland	PA0822/207/001	Solution for injection	- J01GB - J01GB01	- Tobramycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Tobramycin PARI	PARI Pharma GmbH	EU/1/18/1350/001	Nebuliser solution	- J01GB01	- Tobramycin	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Inhalation use
Tolterodine Tartrate 1 mg Film-coated Tablet	Accord Healthcare Ireland Ltd.	PA2315/041/001 Interchangeable List Code: IC0025-039-003	Film-coated tablet		- Tolterodine tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tolterodine Tartrate 2 mg Film-coated Tablet	Accord Healthcare Ireland Ltd.	PA2315/041/002 Interchangeable List Code: IC0025-006-003	Film-coated tablet		- Tolterodine tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Toltertan SR 2 mg Prolonged-Release Capsules, Hard	Clonmel Healthcare Ltd	PA0126/231/001 Interchangeable List Code: IC0025-006-032	Prolonged-release capsule, hard		- Tolterodine tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Toltertan SR 4 mg Prolonged-Release Capsules, Hard	Clonmel Healthcare Ltd	PA0126/231/002 Interchangeable List Code: IC0025-008-032	Prolonged-release capsule, hard		- Tolterodine tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tolucombi 40 mg/12.5 mg tablets	KRKA, d.d., Novo mesto	EU/1/13/821/001-010 Interchangeable List Code: IC0050-099-039	Tablet		- Telmisartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tolucombi 80 mg/12.5 mg tablets	KRKA, d.d., Novo mesto	EU/1/13/821/011-020 Interchangeable List Code: IC0050-081-039	Tablet		- Telmisartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tolucombi 80 mg/25 mg tablets	KRKA, d.d., Novo mesto	EU/1/13/821/021-030 Interchangeable List Code: IC0050-100-039	Tablet		- Telmisartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tolura 20 mg tablets	KRKA, d.d., Novo mesto	EU/1/10/632/001-7 Interchangeable List Code: IC0049-003-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tolura 40 mg tablets	KRKA, d.d., Novo mesto	EU/1/10/632/008-14 Interchangeable List Code: IC0049-004-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tolura 80 mg tablets	KRKA, d.d., Novo mesto	EU/1/10/632/015-21 Interchangeable List Code: IC0049-005-014	Tablet		- Telmisartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Tolvaptan Accord	Accord Healthcare S.L.U.	EU/1/23/1719/001-004	Tablet	- C03XA01	- Tolvaptan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tolvaptan Ascend 7.5 mg tablets	Ascend GmbH	PA23429/006/001	Tablet	- C03XA01	- Tolvaptan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tookad	STEBA Biotech S.A.	EU/1/17/1228/001	Powder for solution for injection	- L01XD - L01XD07	- Padeliporfin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Tookad	STEBA Biotech S.A.	EU/1/17/1228/002	Powder for solution for injection	- L01XD - L01XD07	- Padeliporfin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Topamax 100 mg Film-Coated Tablets	PCO Manufacturing Ltd.	PPA0465/196/003	Film-coated tablet	- N03AX - N03AX11	- Topiramate	ZZZ PPA	- Oral use
Topamax 100 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/136/001	Film-coated tablet	- N03AX11	- Topiramate		- Oral use
Topamax 100 mg film-coated tablets	Merit Pharmaceuticals Limited	PPA23080/016/003	Film-coated tablet	- N03AX11	- Topiramate	ZZZ PPA	- Oral use
Topamax 100 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/001/001	Film-coated tablet	- N03AX11	- Topiramate		- Oral use
TOPAMAX 100 mg Film-coated Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/001/002	Film-coated tablet	- N03AX - N03AX11	- Topiramate		- Oral use
TOPAMAX 100 mg Film-coated Tablets	Janssen Sciences Ireland UC	PA22612/013/003	Film-coated tablet	- N03AX - N03AX11	- Topiramate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Topamax 200 mg film-coated tablets	Originalis B.V.	PPA2306/003/001	Film-coated tablet	- N03AX - N03AX11	- Topiramate		- Oral use
Topamax 200 mg Film-coated Tablets	IMED Healthcare Ltd.	PPA1463/136/004	Film-coated tablet	- N03AX11	- Topiramate		- Oral use
Topamax 200 mg Film-Coated Tablets	PCO Manufacturing Ltd.	PPA0465/196/004	Film-coated tablet	- N03AX - N03AX11	- Topiramate	ZZZ PPA	- Oral use
TOPAMAX 200mg Film-coated Tablets	Janssen Sciences Ireland UC	PA22612/013/004	Film-coated tablet	- N03AX - N03AX11	- Topiramate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Topamax 25 mg Film-Coated Tablets	PCO Manufacturing Ltd.	PPA0465/196/001	Film-coated tablet	- N03AX - N03AX11	- Topiramate	ZZZ PPA	- Oral use
Topamax 25 mg Film-coated Tablets	IMED Healthcare Ltd.	PPA1463/136/002	Film-coated tablet	- N03AX11	- Topiramate		- Oral use
Topamax 25 mg film-coated tablets	Merit Pharmaceuticals Limited	PPA23080/016/001	Film-coated tablet	- N03AX11	- Topiramate	ZZZ PPA	- Oral use
TOPAMAX 25mg Film-coated Tablets	Janssen Sciences Ireland UC	PA22612/013/001	Film-coated tablet	- N03AX - N03AX11	- Topiramate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Topamax 50 mg film-coated tablets	Merit Pharmaceuticals Limited	PPA23080/016/002	Film-coated tablet	- N03AX11	- Topiramate	ZZZ PPA	- Oral use
Topamax 50 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/136/003	Film-coated tablet	- N03AX11	- Topiramate		- Oral use
Topamax 50 mg Film-Coated Tablets	PCO Manufacturing Ltd.	PPA0465/196/002	Film-coated tablet	- N03AX11	- Topiramate	ZZZ PPA	- Oral use
TOPAMAX 50mg Film-coated Tablets	Janssen Sciences Ireland UC	PA22612/013/002	Film-coated tablet	- N03AX - N03AX11	- Topiramate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Topamax Sprinkle 15 mg Hard Capsules	Janssen Sciences Ireland UC	PA22612/013/007	Capsule, hard	- N03AX - N03AX11	- Topiramate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Topamax Sprinkle 25 mg Hard Capsules	Janssen Sciences Ireland UC	PA22612/013/008	Capsule, hard	- N03AX - N03AX11	- Topiramate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Topotecan Accord 1mg/ml concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/121/001	Concentrate for solution for infusion	- L01XX - L01XX17	- Topotecan (as hydrochloride)	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Topotecan Hospira	Pfizer Europe MA EEIG	EU/1/10/633/001-2	Concentrate for solution for infusion	- L01XX - L01XX17	- Topotecan (as hydrochloride)	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Torisel	Pfizer Europe MA EEIG	EU/1/07/424/001	Concentrate and solvent for solution for infusion	- L01XE - L01XE09	- Temsirolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Tostran 2% Gel	Advanz Pharma Limited	PA23450/002/001	Gel	- G03BA - G03BA03	- Testosterone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Toujeo	Sanofi-Aventis Deutschland GmbH	EU/1/00/133/033-035	Solution for injection in pre-filled pen	- A10AE - A10AE04	- Insulin glargine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Tovanor Breezhaler	Novartis Europharm Limited	EU/1/12/790/001-006	Inhalation powder, hard capsule	- R03AB06	- Glycopyrronium bromide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
TOVIAZ 4 mg prolonged-release tablets	Pfizer Europe MA EEIG	EU/1/07/386/1-5 Interchangeable List Code: IC0139-008-024	Prolonged-release tablet		- Fesoterodine fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
TOVIAZ 8 mg prolonged-release tablets	Pfizer Europe MA EEIG	EU/1/07/386/6-10 Interchangeable List Code: IC0139-009-024	Prolonged-release tablet		- Fesoterodine fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tracleer	Janssen-Cilag International NV	EU/1/02/220/001	Film-coated tablet	- C02KX - C02KX01	- Bosentan		- Oral use
Tracleer	Janssen-Cilag International NV	EU/1/02/220/002	Film-coated tablet	- C02KX - C02KX01	- Bosentan		- Oral use
Tracleer	Janssen-Cilag International NV	EU/1/02/220/003	Film-coated tablet	- C02KX - C02KX01	- Bosentan		- Oral use
Tracleer	Janssen-Cilag International NV	EU/1/02/220/004	Film-coated tablet	- C02KX - C02KX01	- Bosentan		- Oral use
Tracleer	Janssen-Cilag International NV	EU/1/02/220/005	Film-coated tablet	- C02KX - C02KX01	- Bosentan		- Oral use
Tracleer	Janssen-Cilag International NV	EU/1/02/220/006	Dispersible tablet	- C02KX - C02KX01	- Bosentan		- Oral use
Tracrium 10 mg/ml, Solution for injection or infusion, vials	Aspen Pharma Trading Limited	PA1691/029/002	Solution for injection/infusion	- M03AC - M03AC04	- Atracurium besilate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Tracrium 10mg/ml, solution for injection or infusion, ampoules	Aspen Pharma Trading Limited	PA1691/029/001	Solution for injection/infusion	- M03AC - M03AC04	- Atracurium besilate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
TRACTOCILE	Ferring AB	EU/1/99/124/001	Solution for injection	- G02CX - G02CX01	- Atosiban acetate		- Intravenous use
Tractocile	Ferring AB	EU/1/99/124/002	Solution for injection	- G02CX - G02CX01	- Atosiban acetate		- Intravenous use
Tradol 50 mg Effervescent tablets	Rowa Pharmaceuticals Limited	PA0074/094/001	Effervescent tablet	- N02AX - N02AX02	- Tramadol hydrochloride		- Oral use
Tradol 50mg Hard Capsules	Rowex Ltd	PA0711/029/001 Interchangeable List Code: IC0074-023-008	Capsule, hard		- Tramadol hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tradol 50mg/ml Solution for Injection or Infusion	Rowex Ltd	PA0711/029/003	Solution for injection/infusion	- N02AX - N02AX02	- Tramadol hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Tradol SR 100 mg Prolonged release tablets	Rowex Ltd	PA0711/029/005 Interchangeable List Code: IC0074-024-030	Prolonged-release tablet		- Tramadol hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Tradol SR 150 mg Prolonged release tablets	Rowex Ltd	PA0711/029/006 Interchangeable List Code: IC0074-062-030	Prolonged-release tablet		- Tramadol hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tradol SR 200 mg Prolonged release tablets	Rowex Ltd	PA0711/029/007 Interchangeable List Code: IC0074-067-030	Prolonged-release tablet		- Tramadol hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Trajenta	Boehringer Ingelheim International GmbH	EU/1/11/707/001-011	Film-coated tablet	- A10BH - A10BH05	- Linagliptin		- Oral use
Tramadol /Paracetamol Rowa 37.5 mg/325 mg Film-coated Tablets	Rowa Pharmaceuticals Limited	PA0074/070/001 Interchangeable List Code: IC0077-133-014	Film-coated tablet		- Tramadol hydrochloride - Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tramadol hydrochloride 50 mg Hard Capsules	Accord Healthcare Ireland Ltd.	PA2315/214/001 Interchangeable List Code: IC0074-023-008	Capsule, hard		- Tramadol hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tramadol Hydrochloride/Paracetamol 37.5 mg/325 mg Film-Coated Tablets	Athlone Pharmaceuticals Limited	PA1418/009/001 Interchangeable List Code: IC0077-133-014	Film-coated tablet		- Tramadol hydrochloride - Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tramadol Krka 50mg hard capsules	KRKA, d.d., Novo mesto	PA1347/079/001 Interchangeable List Code: IC0074-023-008	Capsule, hard		- Tramadol hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tramadol/Paracetamol 37.5 mg/325 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/143/001 Interchangeable List Code: IC0077-133-014	Film-coated tablet		- Tramadol hydrochloride - Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tramadol/Paracetamol Krka 37.5mg/325mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/052/001 Interchangeable List Code: IC0077-133-014	Film-coated tablet		- Paracetamol - Tramadol hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Trandate 100mg Film-Coated Tablets	RPH Pharmaceuticals AB	PA1638/006/002	Film-coated tablet	- C07AG - C07AG01	- Labetalol hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Trandate 200mg Film-coated Tablets	RPH Pharmaceuticals AB	PA1638/006/003	Film-coated tablet	- C07AG - C07AG01	- Labetalol hydrochloride		- Oral use
Trandate 5mg/ml Solution for Injection	RPH Pharmaceuticals AB	PA1638/006/001	Solution for injection	- C07AG - C07AG01	- Labetalol hydrochloride		- Intravenous use
Tranexamic acid 100 mg/ml Solution for Injection	Accord Healthcare Ireland Ltd.	PA2315/178/001	Solution for injection	- B02AA - B02AA02	- Tranexamic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Tranexamic acid 100 mg/mL solution for injection/infusion	Baxter Holding B.V.	PA2299/048/001	Solution for injection/infusion	- B02AA02	- TRANEXAMIC ACID PH. EUR.	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Tranexamic Acid 100 mg/ml solution for injection/infusion	Ibigen Srl	PA1862/002/001	Solution for injection/infusion	- B02AA - B02AA02	- Tranexamic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Transiderm-Nitro 10milligram/24 hours Transdermal Patch	Sandoz Pharmaceuticals d.d.	PA23311/005/002	Transdermal patch	- C01DA - C01DA02	- Glyceryl trinitrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Transiderm-Nitro 15milligrams/24 hours Transdermal Patch	Sandoz Pharmaceuticals d.d.	PA23311/005/003	Transdermal patch	- C01DA - C01DA02	- Glyceryl trinitrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use
Transiderm-Nitro 5milligrams/24 hours Transdermal Patch	Sandoz Pharmaceuticals d.d.	PA23311/005/001	Transdermal patch	- C01DA - C01DA02	- Glyceryl trinitrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Transdermal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Transisoft 8.5 g powder for oral solution in sachet	Laboratoires Mayoly Spindler	PA1993/002/001	Powder for oral solution in sachet	- A06AD - A06AD15	- Macrogol 3350	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Translarna	PTC Therapeutics International Limited	EU/1/13/902/001	Granules for oral suspension	- M09AX - M09AX03	- Ataluren	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Translarna	PTC Therapeutics International Limited	EU/1/13/902/002	Granules for oral suspension	- M09AX - M09AX03	- Ataluren	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Translarna	PTC Therapeutics International Limited	EU/1/13/902/003	Granules for oral suspension	- M09AX - M09AX03	- Ataluren	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Transtec 35 micrograms/h Transdermal Patch	Grünenthal GmbH	PA1032/001/001	Transdermal patch	- N02AE - N02AE01	- Buprenorphine	Full application (Article 8(3) of Directive No 2001/83/EC)	
Transtec 52.5 micrograms/h Transdermal Patch	Grünenthal GmbH	PA1032/001/002	Transdermal patch	- N02AE - N02AE01	- Buprenorphine	Full application (Article 8(3) of Directive No 2001/83/EC)	
Transtec 70 micrograms/h Transdermal Patch	Grünenthal GmbH	PA1032/001/003	Transdermal patch	- N02AE - N02AE01	- Buprenorphine	Full application (Article 8(3) of Directive No 2001/83/EC)	
Trasylol 10,000 KIU/ml, solution for injection or infusion	Nordic Group B.V.	PA2252/001/001	Solution for injection/infusion	- B02AB - B02AB01	- APROTININ CONCENTRATED SOLUTION	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Travatan	Novartis Europharm Limited	EU/1/01/199/001	Eye drops, solution	- S01EE - S01EE04	- Travoprost		- Ocular use
Travatan	Novartis Europharm Limited	EU/1/01/199/002	Eye drops, solution	- S01EE - S01EE04	- Travoprost		- Ocular use
Travella 6C tablets	A. Nelson & Company Limited	HOA1149/004/001	Tablet		- Delphinium staphisagria - Anamirta cocculus - Petroleum rectificatum - Nicotiana tabacum - Strychnos nux-vomica	National Rules Authorisation (Article 16.2 Directive 2001/83/EC.)	
Travocort® 0.1 + 1% w/w Cream	LEO Pharma A/S	PA1025/012/001	Cream	- D01AC - D01AC05	- DIFLUCORTOLONE VALERATE - Isoconazole nitrate		- Cutaneous use - Topical
Traxam 3 %w/w Gel	Amdipharm Limited	PA1142/025/001	Gel	- M02AA - M02AA08	- Felbinac	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical
Trazimera	Pfizer Europe MA EEIG	EU/1/18/1295/001	Concentrate for solution for infusion	- L01XC03	- Trastuzumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Trazodone hydrochloride 100 mg Capsules, Hard	Brillpharma (Ireland) Limited	PA22749/010/002	Capsule, hard	- N06AX - N06AX05	- Trazodone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Trazodone Hydrochloride 100 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/122/002	Tablet	- N06AX - N06AX05	- Trazodone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Trazodone hydrochloride 150 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/010/003	Film-coated tablet	- N06AX - N06AX05	- Trazodone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Trazodone Hydrochloride 150 mg Film-Coated Tablets	Azure Pharmaceuticals Ltd.	PA22871/015/001	Film-coated tablet	- N06AX05	- Trazodone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Trazodone Hydrochloride 150 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/122/003	Tablet	- N06AX - N06AX05	- Trazodone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Trazodone hydrochloride 50 mg Capsules, Hard	Brillpharma (Ireland) Limited	PA22749/010/001	Capsule, hard	- N06AX - N06AX05	- Trazodone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Trazodone Hydrochloride 50 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/122/001	Tablet	- N06AX - N06AX05	- Trazodone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Trazodone Hydrochloride 50mg/5ml Oral Solution	Lexon Pharmaceuticals (Ireland) Limited	PA23176/005/001	Oral solution	- N06AX - N06AX05	- Trazodone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Trazodone Hydrochloride Azure 100 mg Hard Capsules	Azure Pharmaceuticals Ltd.	PA22871/018/002	Capsule, hard	- N06AX05	- Trazodone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Trazodone Hydrochloride Azure 50 mg Hard Capsule	Azure Pharmaceuticals Ltd.	PA22871/018/001	Capsule, hard	- N06AX05	- Trazodone hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Trebon 600 mg powder for oral solution	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	PA1732/003/001	Powder for oral solution	- R05CB - R05CB01	- Acetylcysteine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Treclin 10 mg/g + 0.25 mg/g Gel	Mylan IRE Healthcare Limited	PA2010/044/001	Gel	- D10AF - D10AF01	- Clindamycin - Tretinoin	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Cutaneous use
Trecondi	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/18/1351/001-002	Powder for solution for infusion	- L01AB - L01AB02		Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Trecondi	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/18/1351/003-004	Powder for solution for infusion	- L01AB02		Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Trelegy Ellipta	GlaxoSmithKline Trading Services Limited	EU/1/17/1236/001-003	Inhalation powder, pre-dispensed	- R03AL08	- Fluticasone furoate - Umeclidinium bromide - Vilanterol	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Tremelimumab AstraZeneca	AstraZeneca AB	EU/1/22/1712/001-002	Concentrate for solution for infusion	- L01FX20 - L01XC	- Tremelimumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Tremfya	Janssen-Cilag International NV	EU/1/17/1234/001	Solution for injection in pre-filled syringe	- L04A	- Guselkumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Treosulfan Tillomed 5 g powder for solution for infusion	Laboratorios Tillomed Spain, S.L.U.	PA2321/003/001	Powder for solution for infusion	- L01AB02	- Treosulfan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Treposuvi 1 mg/ml solution for infusion	Orpha-Devel Handels und Vertriebs GmbH	PA1353/006/001	Solution for infusion	- B01AC21	- Treprostinil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Treposuvi 10 mg/ml solution for infusion	Orpha-Devel Handels und Vertriebs GmbH	PA1353/006/004	Solution for infusion	- B01AC21	- Treprostinil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Treposuvi 2.5 mg/ml solution for infusion	Orpha-Devel Handels und Vertriebs GmbH	PA1353/006/002	Solution for infusion	- B01AC21	- Treprostinil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Treposuvi 5 mg/ml solution for infusion	Orpha-Devel Handels und Vertriebs GmbH	PA1353/006/003	Solution for infusion	- B01AC21	- Treprostinil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Treprostinil 1 mg/ml solution for infusion	Reddy Holding GmbH	PA23092/002/001	Solution for infusion	- B01AC21	- Treprostinil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Treprostinil 10 mg/ml solution for infusion	Reddy Holding GmbH	PA23092/002/004	Solution for infusion	- B01AC21	- Treprostinil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Treprostinil 2.5 mg/ml solution for infusion	Reddy Holding GmbH	PA23092/002/002	Solution for infusion	- B01AC21	- Treprostinil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Treprostinil 5 mg/ml solution for infusion	Reddy Holding GmbH	PA23092/002/003	Solution for infusion	- B01AC21	- Treprostinil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Treprostinil Tillomed 1 mg/ml solution for infusion	Tillomed Pharma GmbH	PA22720/011/001	Solution for infusion	- B01AC21	- Treprostinil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Treprostinil Tillomed 10 mg/ml solution for infusion	Tillomed Pharma GmbH	PA22720/011/004	Solution for infusion	- B01AC21	- Treprostinil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Treprostinil Tillomed 2.5 mg/ml solution for infusion	Tillomed Pharma GmbH	PA22720/011/002	Solution for infusion	- B01AC21	- Treprostinil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Treprostinil Tillomed 5 mg/ml solution for infusion	Tillomed Pharma GmbH	PA22720/011/003	Solution for infusion	- B01AC21	- Treprostinil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Trepulmix	Scipharm S.à.r.l.	EU/1/19/1419/001	Solution for infusion	- B01AC21	- Treprostinil sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Trepulmix	Scipharm S.à.r.l.	EU/1/19/1419/002	Solution for infusion	- B01AC21	- Treprostinil sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Trepulmix	Scipharm S.à.r.l.	EU/1/19/1419/003	Solution for infusion	- B01AC21	- Treprostinil sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Trepulmix	Scipharm S.à.r.l.	EU/1/19/1419/004	Solution for infusion	- B01AC21	- Treprostinil sodium	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Subcutaneous use
Tresiba	Novo Nordisk A/S	EU/1/12/807/1,4,5,7,8	Solution for injection	- A10AE - A10AE06	- Insulin degludec (ideg)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Tresiba	Novo Nordisk A/S	EU/1/12/807/9,12,13,15	Solution for injection in pre-filled pen	- A10AE - A10AE06	- Insulin degludec (ideg)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
TREVICTA	Janssen-Cilag International NV	EU/1/14/971/007	Prolonged-release suspension for injection	- N05AX - N05AX13	- Paliperidone palmitate (r092670)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
TREVICTA	Janssen-Cilag International NV	EU/1/14/971/008	Prolonged-release suspension for injection	- N05AX - N05AX13	- Paliperidone palmitate (r092670)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
TREVICTA	Janssen-Cilag International NV	EU/1/14/971/009	Prolonged-release suspension for injection	- N05AX - N05AX13	- Paliperidone palmitate (r092670)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
TREVICTA	Janssen-Cilag International NV	EU/1/14/971/010	Prolonged-release suspension for injection	- N05AX - N05AX13	- Paliperidone palmitate (r092670)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Triapin 2.5mg/2.5mg prolonged release tablet	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/082/001	Prolonged-release tablet	- C09BB - C09BB05	- Felodipine - Ramipril	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Triapin 5 mg/5 mg prolonged release tablets	IMED Healthcare Ltd.	PPA1463/098/001 Interchangeable List Code: IC0032-012-024	Prolonged-release tablet		- Felodipine - Ramipril		- Oral use
Triapin 5 mg/5 mg, prolonged release tablets	Merit Pharmaceuticals Limited	PPA23080/015/001 Interchangeable List Code: IC0032-012-024	Prolonged-release tablet		- Felodipine - Ramipril		- Oral use
Triapin 5mg/5mg prolonged release tablet	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/082/002 Interchangeable List Code: IC0032-012-024	Prolonged-release tablet		- Felodipine - Ramipril	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Triaxis, suspension for injection in a pre-filled syringeDiphtheria, Tetanus, Pertussis (acellular component) Vaccine (adsorbed, reduced antigen(s) content)	Sanofi Pasteur	PA2131/010/002	Suspension for injection in pre-filled syringe	- J07AJ - J07AJ52	- Diphtheria toxoid - Tetanus toxoid - Pertussis toxoid - Filamentous haemagglutinin - Pertactin (prn) - Fimbriae types 2 and 3	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Trientine 167 mg hard capsules	Tillomed Pharma GmbH	PA22720/010/001	Capsule, hard	- A16AX12	- TRIENTINE DIHYDROCHLORIDE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Trileptal 150 mg Film-coated tablets	Novartis Ireland Limited	PA0896/033/001	Film-coated tablet	- N03AF - N03AF02	- Oxcarbazepine		- Oral use
Trileptal 300 mg Film-coated tablets	Novartis Ireland Limited	PA0896/033/002	Film-coated tablet	- N03AF - N03AF02	- Oxcarbazepine		- Oral use
Trileptal 300 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/018/002	Film-coated tablet	- N03AF02	- Oxcarbazepine		- Oral use
Trileptal 300 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/154/002	Film-coated tablet	- N03AF - N03AF02	- Oxcarbazepine		- Oral use
Trileptal 300 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/308/001	Film-coated tablet	- N03AF - N03AF02	- Oxcarbazepine		- Oral use
Trileptal 60 mg/ml Oral Suspension	IMED Healthcare Ltd.	PPA1463/154/001	Oral suspension	- N03AF - N03AF02	- Oxcarbazepine		- Oral use
Trileptal 60 mg/ml Oral Suspension	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/018/001	Oral suspension	- N03AF02	- Oxcarbazepine	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Trileptal 60 mg/ml Oral Suspension	Originalis B.V.	PPA2306/004/001	Oral suspension	- N03AF02	- Oxcarbazepine		- Oral use
Trileptal 60 mg/ml Oral Suspension	Novartis Ireland Limited	PA0896/033/004	Oral suspension	- N03AF - N03AF02	- Oxcarbazepine		- Oral use
Trileptal 60 mg/ml oral suspension.	PCO Manufacturing Ltd.	PPA0465/308/003	Oral suspension	- N03AF - N03AF02	- Oxcarbazepine		- Oral use
Trileptal 600 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/308/002	Film-coated tablet	- N03AF - N03AF02	- Oxcarbazepine		- Oral use
Trileptal 600 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/154/003	Film-coated tablet	- N03AF - N03AF02	- Oxcarbazepine		- Oral use
Trileptal 600 mg Film-coated tablets	Novartis Ireland Limited	PA0896/033/003	Film-coated tablet	- N03AF - N03AF02	- Oxcarbazepine		- Oral use
Trimbow	Chiesi Farmaceutici S.p.A.	EU/1/17/1208/001-003	Pressurised inhalation, solution	- R03AL - R03AL09	- Beclometasone dipropionate anhydrous - Formoterol fumarate dihydrate - Glycopyrronium bromide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Trimbow	Chiesi Farmaceutici S.p.A.	EU/1/17/1208/004	Pressurised inhalation, solution	- R03AL - R03AL09	- Glycopyrronium bromide - Formoterol fumarate dihydrate - Beclometasone dipropionate anhydrous	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Trimbow	Chiesi Farmaceutici S.p.A.	EU/1/17/1208/005	Pressurised inhalation, solution	- R03AL - R03AL09	- Beclometasone dipropionate anhydrous - Glycopyrronium bromide - Formoterol fumarate dihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Trimbow	Chiesi Farmaceutici S.p.A.	EU/1/17/1208/006-009	Pressurised inhalation, solution	- R03AL09	- Beclometasone dipropionate - Formoterol fumarate dihydrate - Glycopyrronium bromide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Trimbow	Chiesi Farmaceutici S.p.A.	EU/1/17/1208/010-012	Inhalation powder	- R03AL09	- Beclometasone dipropionate - Formoterol fumarate dihydrate - GLYCOPYRRONIUM - Glycopyrronium bromide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Trimega 1000 mg Capsules	Clonmel Healthcare Ltd	PA0126/236/001	Capsule, soft	- C10AX - C10AX06	- Omega-3-acid ethyl esters 90	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Trimethoprim 10mg/ml Oral Suspension	Athlone Pharmaceuticals Limited	PA1418/005/001	Oral suspension	- J01EA01	- Trimethoprim	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tri-Minulet Coated* Tablets	Pfizer Healthcare Ireland	PA0822/099/001	Coated tablet	- G03AA - G03AA10	- Ethinyloestradiol - Gestodene - Ethinylestradiol - Gestodene - Ethinylestradiol - Gestodene	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Trimoptin Tablets 100 mg	Athlone Pharmaceuticals Limited	PA1418/008/001	Tablet	- J01EA - J01EA01	- Trimethoprim		- Oral use
Trimoptin Tablets 200 mg	Athlone Pharmaceuticals Limited	PA1418/008/002	Tablet	- J01EA - J01EA01	- Trimethoprim		- Oral use
Trinomia 100 mg/20 mg/10 mg hard capsules	Ferrer Internacional, S.A	PA1744/002/003	Capsule, hard	- C10BX - C10BX06	- Acetylsalicylic acid - Atorvastatin - Ramipril	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Trinomia 100 mg/20 mg/2.5 mg hard capsules	Ferrer Internacional, S.A	PA1744/002/001	Capsule, hard	- C10BX - C10BX06	- Acetylsalicylic acid - Atorvastatin - Ramipril	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Trinomia 100 mg/20 mg/5 mg hard capsules	Ferrer Internacional, S.A	PA1744/002/002	Capsule, hard	- C10BX - C10BX06	- Acetylsalicylic acid - Atorvastatin - Ramipril	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Trinomia 100 mg/40 mg/10 mg hard capsules	Ferrer Internacional, S.A	PA1744/002/006	Capsule, hard	- C10BX - C10BX06	- Acetylsalicylic acid - Ramipril - Atorvastatin	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Trinomia 100 mg/40 mg/2.5 mg hard capsules	Ferrer Internacional, S.A	PA1744/002/004	Capsule, hard	- C10BX - C10BX06	- Acetylsalicylic acid - Ramipril - Atorvastatin	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Trinomia 100 mg/40 mg/5 mg hard capsules	Ferrer Internacional, S.A	PA1744/002/005	Capsule, hard	- C10BX - C10BX06	- Acetylsalicylic acid - Ramipril - Atorvastatin	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Trinordiol Tablets	Pfizer Healthcare Ireland	PA0822/100/001	Coated tablet	- G03AA - G03AA10	- Levonorgestrel - Ethinyloestradiol - Levonorgestrel - Ethinyloestradiol - Levonorgestrel - Ethinyloestradiol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
TRIOMEL 12 g/l nitrogen 950 kcal/l with electrolytes, emulsion for infusion	Baxter Holding B.V.	PA2299/043/007	Emulsion for infusion	- B05BA - B05BA10	- Alanine - Arginine - Aspartic Acid - Glutamic acid - Glycine - Histidine - Isoleucine - Leucine - Lysine acetate - Methionine - Phenylalanine - Proline - Serine - Threonine - Tryptophan - Tyrosine - Valine - Magnesium chloride hexahydrate - Potassium chloride - Sodium acetate trihydrate - Sodium glycerophophate hydrate - Glucose monohydrate - Calcium chloride dihydrate - Olive oil, refined - Soya Bean Oil, Refined Ph.Eur	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
TRIOMEL 12 g/l nitrogen 950 kcal/l, emulsion for infusion	Baxter Holding B.V.	PA2299/043/008	Emulsion for infusion	- B05BA - B05BA10	- Alanine - Arginine - Aspartic Acid - Glutamic acid - Glycine - Histidine - Isoleucine - Leucine - Lysine acetate - Methionine - Phenylalanine - Proline - Serine - Threonine - Tryptophan - Tyrosine - Valine - Glucose monohydrate - Olive oil, refined - Soya Bean Oil, Refined Ph.Eur	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Triomel 5g/L nitrogen 990kcal/L with electrolytes, emulsion for infusion	Baxter Holding B.V.	PA2299/029/002	Emulsion for infusion	- B05BA - B05BA10	- Refined olive oil + refined soybean oil - Alanine - Arginine - Aspartic Acid - Glutamic acid - Glycine - Histidine - Isoleucine - Leucine - Lysine - Methionine - Phenylalanine - Proline - Serine - Threonine - Tryptophan - Tyrosine - Valine - Sodium acetate trihydrate - Sodium glycerophosphate, hydrated - Potassium chloride - Magnesium chloride hexahydrate - Calcium chloride dihydrate - Glucose monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Triomel 7g/L nitrogen 1140kcal/L emulsion for infusion	Baxter Holding B.V.	PA2299/029/004	Emulsion for infusion	- B05BA - B05BA10	- Refined olive oil + refined soybean oil - Alanine - Arginine - Aspartic Acid - Glutamic acid - Glycine - Histidine - Isoleucine - Leucine - Lysine - Methionine - Phenylalanine - Proline - Serine - Threonine - Tryptophan - Tyrosine - Valine - Glucose monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Triomel 7g/L nitrogen 1140kcal/L with electrolytes emulsion for infusion	Baxter Holding B.V.	PA2299/029/003	Emulsion for infusion	- B05BA - B05BA10	- Refined olive oil + refined soybean oil - Alanine - Arginine - Aspartic Acid - Glutamic acid - Glycine - Histidine - Isoleucine - Leucine - Lysine - Methionine - Phenylalanine - Proline - Serine - Threonine - Tryptophan - Tyrosine - Valine - Glucose monohydrate - Sodium acetate - Sodium glycerophosphate, hydrated - Potassium chloride - Magnesium chloride hexahydrate - Calcium chloride dihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Triomel 9g/L nitrogen 1070kcal/L emulsion for infusion	Baxter Holding B.V.	PA2299/029/006	Emulsion for infusion	- B05BA - B05BA10	- Refined olive oil + refined soybean oil - Alanine - Arginine - Aspartic Acid - Glutamic acid - Glycine - Histidine - Isoleucine - Leucine - Lysine - Methionine - Phenylalanine - Proline - Serine - Threonine - Tryptophan - Tyrosine - Valine - Glucose monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Triomel 9g/L nitrogen 1070kcal/L with electrolytes emulsion for infusion	Baxter Holding B.V.	PA2299/029/005	Emulsion for infusion	- B05BA - B05BA10	- Refined olive oil + refined soybean oil - Alanine - Arginine - Aspartic Acid - Glutamic acid - Glycine - Histidine - Isoleucine - Leucine - Lysine - Methionine - Phenylalanine - Proline - Serine - Threonine - Tryptophan - Tyrosine - Valine - Glucose monohydrate - Sodium acetate trihydrate - Sodium glycerophosphate, hydrated - Potassium chloride - Magnesium chloride hexahydrate - Calcium chloride dihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Triomel Peripheral 4g/L nitrogen 700kcal/L with electrolytes emulsion for infusion	Baxter Holding B.V.	PA2299/029/001	Emulsion for infusion	- B05BA - B05BA10	- Refined olive oil + refined soybean oil - Alanine - Arginine - Aspartic Acid - Glutamic acid - Glycine - Histidine - Isoleucine - Leucine - Lysine - Methionine - Phenylalanine - Proline - Serine - Threonine - Tryptophan - Tyrosine - Valine - Sodium acetate trihydrate - Sodium glycerophosphate, hydrated - Potassium chloride - Magnesium chloride hexahydrate - Calcium chloride dihydrate - Glucose monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Triregol coated tablets	Gedeon Richter Plc	PA1330/016/001	Coated tablet	- G03AB - G03AB03	- Ethinyloestradiol - Levonorgestrel - Levonorgestrel - Ethinylestradiol - Levonorgestrel - Ethinylestradiol		- Oral use
Trisenox	Teva B.V.	EU/1/02/204/001	Concentrate for solution for infusion	- L01XX - L01XX27	- Arsenic trioxide		- Intravenous use
Trisenox	Teva B.V.	EU/1/02/204/002	Concentrate for solution for infusion	- L01XX - L01XX27	- Arsenic trioxide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Trisequens film-coated tablets	Novo Nordisk A/S	PA0218/008/001	Film-coated tablet	- G03FB - G03FB05	- Estradiol - Estradiol - Norethisterone acetate - Estradiol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
TRITACE 1.25 mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/084/005 Interchangeable List Code: IC0016-044-008	Tablet		- Ramipril	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tritace 10 mg Tablet	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/084/008 Interchangeable List Code: IC0016-002-008	Tablet		- Ramipril	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tritace 2.5 mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/084/006 Interchangeable List Code: IC0016-018-008	Tablet		- Ramipril	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tritace 5 mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/084/007 Interchangeable List Code: IC0016-001-008	Tablet		- Ramipril	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
TRIUMEQ	ViiV Healthcare BV	EU/1/14/940/001-002	Film-coated tablet	- J05AR - J05AR13	- Dolutegravir - Abacavir - Lamivudine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Triumeq	ViiV Healthcare BV	EU/1/14/940/001-003	Film-coated tablet	- J05AR13	- Dolutegravir sodium - Lamivudine - Abacavir sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Trixeo Aerosphere	AstraZeneca AB	EU/1/20/1498/002-003	Pressurised inhalation, suspension	- R03AL11	- Budesonide micronised - Glycopyrronium bromide - Formoterol fumarate dihydrate (micronised)	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Trizivir	ViiV Healthcare BV	EU/1/00/156/001	Film-coated tablet	- J05A	- Lamivudine - Abacavir sulfate - Zidovudine		- Oral use
Trizivir	ViiV Healthcare BV	EU/1/00/156/002	Film-coated tablet	- J05AR - J05AR04	- Abacavir sulfate - Zidovudine - Lamivudine		- Oral use
Trizivir	ViiV Healthcare BV	EU/1/00/156/003-4	Film-coated tablet	- J05AR - J05AR04	- Abacavir sulfate - Zidovudine - Lamivudine		- Oral use
Trodelvy	Gilead Sciences Ireland UC	EU/1/21/1592/001	Powder for concentrate for solution for infusion	- L01 - L01XF17	- Sacituzumab Govitecan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Tropex 5% w/v Ear Drops Solution	Rowa Pharmaceuticals Limited	PA0074/002/001	Ear drops, solution	- S02DA - S02DA03	- Phenazone		- Auricular use
Trosyl 283 mg/ml Nail Solution	Pfizer Healthcare Ireland	PA0822/197/001	Cutaneous solution	- D01AC - D01AC07	- Tioconazole	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Trosyl 283 mg/ml Nail Solution	IMED Healthcare Ltd.	PPA1463/169/001	Cutaneous solution	- D01AC - D01AC07	- Tioconazole		- Topical use
Trosyl 283 mg/ml Nail Solution	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/030/001	Cutaneous solution	- D01AC - D01AC07	- Tioconazole		- Cutaneous use
Trosyl 283 mg/ml Nail Solution	PCO Manufacturing Ltd.	PPA0465/247/001	Cutaneous solution	- D01AC - D01AC07	- Tioconazole		- Cutaneous use
Trulicity	Eli Lilly Nederland B.V.	EU/1/14/956/001-005	Solution for injection	- A10BX	- Dulaglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Trulicity	Eli Lilly Nederland B.V.	EU/1/14/956/006-010	Solution for injection	- A10BX	- Dulaglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Trulicity	Eli Lilly Nederland B.V.	EU/1/14/956/011-0013	Solution for injection in pre-filled pen	- A10B	- Dulaglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Trulicity	Eli Lilly Nederland B.V.	EU/1/14/956/014-0016	Solution for injection in pre-filled pen	- A10B	- Dulaglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Trumenba	Pfizer Europe MA EEIG	EU/1/17/1187/001-006	Suspension for injection in pre-filled syringe	- J07AH - J07AH09	- Neisseria meningitidis serogroup b recombinant lipoprotein (rlp2086; sub family a) - Neisseria meningitidis serogroup b recombinant lipoprotein (rlp2086; sub family b)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Truoxin I.V. 200mg/100ml solution for infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/002/001	Solution for infusion	- J01MA - J01MA02	- Ciprofloxacin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Truoxin I.V. 400 mg/200 ml solution for infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/002/002	Solution for infusion	- J01MA - J01MA02	- Ciprofloxacin		- Intravenous use
Trusitev SR 2 mg Prolonged-release Capsules, hard	Teva Pharma B.V.	PA0749/191/001 Interchangeable List Code: IC0025-006-032	Prolonged-release capsule, hard		- Tolterodine tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Trusitev SR 4 mg Prolonged-release Capsules, hard	Teva Pharma B.V.	PA0749/191/002 Interchangeable List Code: IC0025-008-032	Prolonged-release capsule, hard		- Tolterodine tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
TRUSOPT 20 mg/ml eye drops, solution	Santen OY	PA0879/004/001	Eye drops, solution	- S01EC03	- Dorzolamide hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
TRUSOPT Preservative-Free 20 mg/ml eye drops, solution in single-dose container	Santen OY	PA0879/004/002	Eye drops, solution in single-dose container	- S01EC - S01EC03	- Dorzolamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Truvada 200 mg/245 mg film-coated tablets	Gilead Sciences Ireland UC	EU/1/04/305/001-002 Interchangeable List Code: IC0107-165-003	Film-coated tablet		- Emtricitabine - Tenofovir disoproxil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Truvelog Mix 30	Sanofi Winthrop Industrie	EU/1/22/1639/001-005	Suspension for injection	- A10AD05	- Insulin aspart	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Truxima	Celltrion Healthcare Hungary Kft.	EU/1/16/1167/001	Concentrate for solution for infusion	- L01XC - L01XC02	- Rituximab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Truxima	Celltrion Healthcare Hungary Kft.	EU/1/16/1167/002	Concentrate for solution for infusion	- L01XC - L01XC02			- Intravenous use
Trydonis	Chiesi Farmaceutici S.p.A.	EU/1/18/1274/001-005	Pressurised inhalation, solution	- R03AL - R03AL09	- Beclometasone dipropionate - Formoterol fumarate dihydrate - GLYCOPYRRONIUM	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Inhalation use
Trydonis	Chiesi Farmaceutici S.p.A.	EU/1/18/1274/006-008	Inhalation powder	- R03AL09	- Beclometasone dipropionate - Formoterol fumarate dihydrate - Glycopyrronium bromide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Tuberculin PPD RT23 AJV 2 T.U./0.1 mL, solution for injection	AJ Vaccines A/S	PA2160/004/001	Solution for injection	- V04CF - V04CF01	- Tuberculin ppd		- Intradermal use
Tukysa	Seagen Netherlands B.V.	EU/1/20/1526/001	Film-coated tablet	- L01	- Tucatinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tukysa	Seagen Netherlands B.V.	EU/1/20/1526/002	Film-coated tablet	- L01	- Tucatinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
TUXERDIV 1.5 mg film-coated tablets	Adamed Pharma S.A	PA23514/001/001	Film-coated tablet	- N07BA	- Cytisinicline	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/001	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis a vaccine - Hepatitis b surface antigen, recominant		- Intramuscular use
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/002	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis a vaccine - Hepatitis b surface antigen, recominant		- Intramuscular use
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/003	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis a vaccine - Hepatitis b surface antigen, recominant		- Intramuscular use
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/004	Suspension for injection	- J07BC - J07BC20	- Hepatitis a vaccine - Hepatitis b surface antigen, recominant		- Intramuscular use
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/005	Suspension for injection	- J07BC - J07BC20	- Hepatitis a vaccine - Hepatitis b surface antigen, recominant		- Intramuscular use
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/006	Suspension for injection	- J07BC - J07BC20	- Hepatitis a vaccine - Hepatitis b surface antigen, recominant		- Intramuscular use
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/007	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis a vaccine - Hepatitis b surface antigen, recominant		- Intramuscular use
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/008	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis a vaccine - Hepatitis b surface antigen, recominant		- Intramuscular use
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/009	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis a vaccine - Hepatitis b surface antigen, recominant		- Intramuscular use
Twinrix Paediatric	SmithKline Beecham Biologicals	EU/1/97/029/001	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis b surface antigen, recominant - Hepatitis a vaccine		- Intramuscular use
Twinrix Paediatric	SmithKline Beecham Biologicals	EU/1/97/029/002	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis b surface antigen, recominant - Hepatitis a vaccine		- Intramuscular use
Twinrix Paediatric	SmithKline Beecham Biologicals	EU/1/97/029/003	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis b surface antigen, recominant - Hepatitis a vaccine		- Intramuscular use
Twinrix Paediatric	SmithKline Beecham Biologicals	EU/1/97/029/004	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis b surface antigen, recominant - Hepatitis a vaccine		- Intramuscular use
Twinrix Paediatric	SmithKline Beecham Biologicals	EU/1/97/029/005	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis b surface antigen, recominant - Hepatitis a vaccine		- Intramuscular use
Twinrix Paediatric	SmithKline Beecham Biologicals	EU/1/97/029/006	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis b surface antigen, recominant - Hepatitis a vaccine		- Intramuscular use
Twinrix Paediatric	SmithKline Beecham Biologicals	EU/1/97/029/007	Suspension for injection in pre-filled syringe	- J07BC - J07BC20	- Hepatitis b surface antigen, recominant - Hepatitis a vaccine		- Intramuscular use
Twynsta	Boehringer Ingelheim International GmbH	EU/1/10/648/001-007	Tablet	- C09DB - C09DB04	- Telmisartan - Amlodipine besilate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Twynsta	Boehringer Ingelheim International GmbH	EU/1/10/648/008-014	Tablet	- C09D	- Amlodipine besilate - Telmisartan	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Twynsta	Boehringer Ingelheim International GmbH	EU/1/10/648/015-021	Tablet	- C09D	- Telmisartan - Amlodipine besilate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Twynsta	Boehringer Ingelheim International GmbH	EU/1/10/648/022-028	Tablet	- C09D	- Telmisartan - Amlodipine besilate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Tybost	Gilead Sciences Ireland UC	EU/1/13/872/001-002	Film-coated tablet	- V03AX - V03AX03	- Cobicistat on silicon dioxide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tyedra 1500 micrograms tablet	Laboratorios Leon Farma, S.A.	PA1474/013/001	Tablet	- G03AD - G03AD01	- Levonorgestrel micronized	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Tyenne	Fresenius Kabi Deutschland GmbH	EU/1/23/1754/001-006	Concentrate for solution for infusion	- L04AC07	- Tocilizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Tyenne	Fresenius Kabi Deutschland GmbH	EU/1/23/1754/007-009	Solution for injection in pre-filled syringe	- L04AC07	- Tocilizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Tyenne	Fresenius Kabi Deutschland GmbH	EU/1/23/1754/010-012	Solution for injection in pre-filled pen	- L04AC07	- Tocilizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Tygacil	Pfizer Europe MA EEIG	EU/1/06/336/01	Powder for solution for infusion	- J01AA - J01AA12	- Tigecycline		
Tylex 30 mg / 500 mg Hard Capsules	UCB (Pharma) Ireland Limited	PA0891/014/001	Capsule, hard	- N02AJ - N02AJ06	- Codeine phosphate hemihydrate - Paracetamol		- Oral use
Tymbrineb 300 mg/5 ml Nebuliser Solution	Teva Pharma B.V.	PA0749/117/001	Nebuliser solution	- J01GB - J01GB01	- Tobramycin	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Typhim Vi Solution for Injection Typhoid Polysaccharide Vaccine	Sanofi Pasteur	PA2131/011/001	Solution for injection	- J07AP03	- Salmonella typhi, vi antigen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Tyruko	Polpharma Biologics S.A.	EU/1/23/1745/001	Concentrate for solution for infusion	- L04AA23	- Natalizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Tysabri	Biogen Netherlands B.V.	EU/1/06/346/001	Concentrate for solution for infusion	- L04AA - L04AA23	- Natalizumab	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Tysabri	Biogen Netherlands B.V.	EU/1/06/346/002	Solution for injection	- L04AA23	- Natalizumab	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Tyvense 20mg Capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/005/001	Capsule, hard	- N06BA	- Lisdexamfetamine dimesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tyvense 30 mg Capsules, Hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/005/002	Capsule, hard	- N06	- Lisdexamfetamine dimesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tyvense 40mg Capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/005/003	Capsule, hard	- N06BA	- Lisdexamfetamine dimesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tyvense 50 mg Capsules, Hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/005/004	Capsule, hard	- N06	- Lisdexamfetamine dimesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tyvense 60mg Capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/005/005	Capsule, hard	- N06BA	- Lisdexamfetamine dimesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Tyvense 70 mg Capsules, Hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/005/006	Capsule, hard	- N06	- Lisdexamfetamine dimesylate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Tyverb	Novartis Europharm Limited	EU/1/07/440/1-2	Film-coated tablet	- L01XE - L01XE07	- Lapatinib ditosylate monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ucedane	Eurocept International BV	EU/1/17/1202/001-002	Dispersible tablet	- A16AA - A16AA05	- Carglumic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ulipristal Acetate Rowex 30 mg Film-coated Tablets	Rowex Ltd	PA0711/292/001	Film-coated tablet	- G03AD - G03AD02	- Ulipristal acetate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ultibro Breezhaler	Novartis Europharm Limited	EU/1/13/862/001-006	Inhalation powder, hard capsule	- R03AL - R03AL04	- Indacaterol maleate - Glycopyrronium bromide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Ultiva 1 mg Powder for Concentrate for Solution for Infusion	Aspen Pharma Trading Limited	PA1691/032/001	Powder for concentrate for solution for infusion	- N01AH - N01AH06	- Remifentanil hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ultiva 2 mg Powder for Concentrate for Solution for Infusion	Aspen Pharma Trading Limited	PA1691/032/002	Powder for concentrate for solution for infusion	- N01AH - N01AH06	- Remifentanil hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ultiva 5 mg Powder for Concentrate for Solution for Infusion	Aspen Pharma Trading Limited	PA1691/032/003	Powder for concentrate for solution for infusion	- N01AH - N01AH06	- Remifentanil hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ultomiris	Alexion Europe SAS	EU/1/19/1371/001	Concentrate for solution for infusion	- L04AA43	- RAVULIZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ultomiris	Alexion Europe S.A.S.	EU/1/19/1371/002	Concentrate for solution for infusion	- L04AA	- RAVULIZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ultomiris	Alexion Europe S.A.S.	EU/1/19/1371/003	Concentrate for solution for infusion	- L04AA	- RAVULIZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ultomiris	Alexion Europe S.A.S.	EU/1/19/1371/004	Solution for injection	- L04AA43	- RAVULIZUMAB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Ultraproct 0.92mg/g + 0.95mg/g + 5mg/g Rectal Ointment	Karo Pharma AB	PA22650/004/001	Rectal ointment	- C05AA - C05AA08	- FLUOCORTOLONE PIVALATE - Fluocortolone caproate - Cinchocaine Hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Rectal use
Ultra-TechneKow FM 2.15-43.00 GBq radionuclide generator	Curium Netherlands B.V.	PA0690/017/001	Radionuclide generator	- V09FX - V09FX01	- Sodium Molybdate.99 Mo	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use - Ocular use
Ulunar Breezhaler	Novartis Europharm Limited	EU/1/14/917/001-006	Inhalation powder, hard capsule	- R03AL - R03AL04	- Indacaterol maleate - Glycopyrronium bromide	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Inhalation use
Uniflu Plus with Vitamin C Tablets	Phoenix Labs	PA1113/006/001	Film-coated tablet + tablet	- N02BE - N02BE51	- Paracetamol - Codeine phosphate hemihydrate - Diphenhydramine hydrochloride - Phenylephrine hydrochloride - Caffeine - Ascorbic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Uniflu with Vitamin C Tablets	Phoenix Labs	PA1113/005/001	Film-coated tablet + tablet	- N02BE - N02BE51	- Caffeine - Diphenhydramine hydrochloride - Paracetamol - Phenylephrine hydrochloride - Ascorbic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
UNIPHYLLIN Continus 200 mg Prolonged-Release Tablets	Ennogen Healthcare (Europe) Limited	PA23369/003/001	Prolonged-release tablet	- R03DA - R03DA04	- Theophylline		- Oral use
UNIPHYLLIN Continus 300 mg Prolonged-Release Tablets	Ennogen Healthcare (Europe) Limited	PA23369/003/002	Prolonged-release tablet	- R03DA - R03DA04	- Theophylline		- Oral use
UNIPHYLLIN Continus 400 mg Prolonged-Release Tablets	Ennogen Healthcare (Europe) Limited	PA23369/003/003	Prolonged-release tablet	- R03DA - R03DA04	- Theophylline		- Oral use
Uplizna	Horizon Therapeutics Ireland Designated Activity Company	EU/1/21/1602/001	Concentrate for solution for infusion	- L04AA - L04AA47	- Inebilizumab	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Upstaza	PTC Therapeutics International Limited	EU/1/22/1653/001	Solution for infusion		- Eladocagene Exuparvovec	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intracerebral use
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/001-003	Film-coated tablet	- B01AC - B01AC27	- Selexipag	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/004	Film-coated tablet	- B01AC - B01AC27	- Selexipag	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/005	Film-coated tablet	- B01AC - B01AC27	- Selexipag	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/006	Film-coated tablet	- B01AC - B01AC27	- Selexipag	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/007	Film-coated tablet	- B01AC - B01AC27	- Selexipag	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/008	Film-coated tablet	- B01AC - B01AC27	- Selexipag	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/009	Film-coated tablet	- B01AC - B01AC27	- Selexipag	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/010	Film-coated tablet	- B01AC - B01AC27	- Selexipag	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Urispas 200 mg Film-coated Tablets	Recordati Ireland Limited	PA1404/001/001	Film-coated tablet	- G04BD - G04BD02	- Flavoxate hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Urografin 30 %w/v Solution for infusion	Bayer Limited	PA1410/012/001	Solution for infusion	- V08AA01	- Meglumine - Sodium hydroxide - Sodium amidotrizoate	Full application (Article 8(3) of Directive No 2001/83/EC)	
Uromitexan 100mg/ml Solution for Injection or Infusion	Baxter Holding B.V.	PA2299/024/001	Solution for injection/infusion	- V03AF - V03AF01	- Mesna	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Uromitexan Tablets 400mg	Baxter Holding B.V.	PA2299/024/002	Film-coated tablet	- V03AF - V03AF01	- Mesna	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Uromitexan Tablets 600mg	Baxter Holding B.V.	PA2299/024/003	Film-coated tablet	- V03AF - V03AF01	- Mesna	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Urorec	Recordati Ireland Limited	EU/1/09/608/1-7	Capsule, hard	- G04CA - G04CA04	- Silodosin		- Oral use
Urorec	Recordati Ireland Limited	EU/1/09/608/8-14	Capsule, hard	- G04CA - G04CA04	- Silodosin		- Oral use
Ursodeoxycholic Acid 250 mg capsules, hard	Amdipharm Limited	PA1142/018/001	Capsule, hard	- A05AA - A05AA02	- Ursodeoxycholic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ursodeoxycholic acid Strides 250 mg Hard Capsules	Strides Pharma (Cyprus) Limited	PA22639/001/001	Capsule, hard	- A05AA - A05AA02	- Ursodeoxycholic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Ursofalk 250 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/183/001	Capsule, hard	- A05AA02 - A05B	- Ursodeoxycholic acid		- Oral use
Ursofalk 250 mg Hard Capsules	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/006/001	Capsule, hard	- A05AA - A05AA02	- Ursodeoxycholic acid		- Oral use
Ursofalk 250 mg hard capsules	Primecrown 2010 Limited	PPA1633/016/001	Capsule, hard	- A05AA02	- Ursodeoxycholic acid		- Oral use
Ursofalk 250 mg Hard Capsules	IMED Healthcare Ltd.	PPA1463/144/001	Capsule, hard	- A05AA - A05AA02	- Ursodeoxycholic acid		- Oral use
Ursofalk 250 mg/5 ml Suspension	Dr. Falk Pharma GmbH	PA0573/005/002	Oral suspension	- A05AA - A05AA02	- Ursodeoxycholic acid		- Oral use
Ursofalk 500 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/183/002	Film-coated tablet	- A05AA - A05AA02	- Ursodeoxycholic acid		- Oral use
Ursofalk 500mg film-coated tablets	Dr. Falk Pharma GmbH	PA0573/005/003	Film-coated tablet	- A05AA - A05AA02	- Ursodeoxycholic acid		- Oral use
Ursofalk® 250 mg Hard Capsules	Dr. Falk Pharma GmbH	PA0573/005/001	Capsule, hard	- A05AA - A05AA02	- Ursodeoxycholic acid	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Ursogrix 250 mg hard capsules	AS Grindeks	PA22992/002/001	Capsule, hard	- A05AA02	- Ursodeoxycholic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Utrogestan 100 mg capsules, soft	Laboratoires Besins International	PA1054/003/001	Capsule, soft	- G03DA04	- Progesterone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Utrogestan Vaginal 200 mg vaginal capsule, soft	Besins Healthcare Ireland Limited	PA22624/001/001	Vaginal capsule, soft	- G03DA04	- PROGESTERONE, MICRONISED	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
Utrogestan Vaginal 300 mg Vaginal Capsules, soft	Besins Healthcare Ireland Limited	PA22624/001/002	Vaginal capsule, soft	- G03DA04	- Progesterone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Vaginal use
UZPRUVO	Stada Arzneimittel AG	EU/1/23/1784/001	Solution for injection in pre-filled syringe	- L04AC05	- Ustekinumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
UZPRUVO	Stada Arzneimittel AG	EU/1/23/1784/004	Solution for injection in pre-filled syringe	- L04AC05	- Ustekinumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Vaborem	Menarini International Operations Luxembourg S.A.	EU/1/18/1334/001	Powder for concentrate for solution for infusion	- J01DH52	- VABORBACTAM - Meropenem - Meropenem Trihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Vabysmo	Roche Registration GmbH	EU/1/22/1683/001	Solution for injection	- S01LA09	- Faricimab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravitreal use
Vafseo	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/23/1725/001-002	Film-coated tablet	- B03XA - B03XA08	- Vadadustat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Vafseo	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/23/1725/003-004	Film-coated tablet	- B03XA - B03XA08	- Vadadustat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vafseo	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/23/1725/005-006	Film-coated tablet	- B03XA - B03XA08	- Vadadustat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vagifem 10 micrograms vaginal tablets	Novo Nordisk A/S	PA0218/030/002	Vaginal tablet	- G03CA - G03CA04	- Estradiol		- Vaginal use
Vagirux 10 microgram vaginal tablets	Gedeon Richter Plc	PA1330/028/001	Vaginal tablet	- G03CA03	- Estradiol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Vaginal use
Valaciclovir 500 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/102/001 Interchangeable List Code: IC0132-117-003	Film-coated tablet		- Valaciclovir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valaciclovir Bluefish 500 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/005/001 Interchangeable List Code: IC0132-117-003	Film-coated tablet		- Valaciclovir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valaciclovir Teva 500 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/036/001 Interchangeable List Code: IC0132-117-003	Film-coated tablet		- Valaciclovir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valcyte 450 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/023/001	Film-coated tablet	- J05AB - J05AB14	- Valganciclovir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Valcyte 50 mg/ml powder for oral solution	CHEPLAPHARM Arzneimittel GmbH	PA2239/023/002	Powder for oral solution	- J05AB - J05AB14	- Valganciclovir hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Valdoxan 25 mg film-coated tablets	Les Laboratoires Servier	EU/1/08/499/1-8 Interchangeable List Code: IC0136-022-003	Film-coated tablet		- Agomelatine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Valdrian hard capsules	HUK Europe Limited	TR25313/001/001	Capsule, hard			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Valerian Complex Stress Relief Oral Drops	A.Vogel Ireland Limited	TR2309/020/001	Oral drops, solution			Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Valganciclovir Accord 450 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/179/001	Film-coated tablet	- J05AB - J05AB14	- Valganciclovir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valoid 50 mg Tablets	Amdipharm Limited	PA1142/001/002	Tablet	- R06AE - R06AE03	- CYCLIZINE HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Valoid 50 mg/ml Solution for Injection	Amdipharm Limited	PA1142/001/001	Solution for injection	- R06AE - R06AE03	- Cyclizine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Valotix 500mg film-coated tablets	Rowex Ltd	PA0711/173/001 Interchangeable List Code: IC0132-117-003	Film-coated tablet		- Valaciclovir	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Valsartan / Hydrochlorothiazide Teva 160 mg/25 mg Film-coated tablets	Teva Pharma B.V.	PA0749/047/002 Interchangeable List Code: IC0040-078-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan / Hydrochlorothiazide Teva 80 mg/12.5 mg Film-coated tablets	Teva Pharma B.V.	PA0749/047/001 Interchangeable List Code: IC0040-081-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan 160 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/188/003 Interchangeable List Code: IC0038-082-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan 40 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/188/001 Interchangeable List Code: IC0038-004-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan 80 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/188/002 Interchangeable List Code: IC0038-005-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan Krka 160 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/010/008 Interchangeable List Code: IC0038-082-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan Krka 320 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/010/009 Interchangeable List Code: IC0038-083-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan Krka 40 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/010/006 Interchangeable List Code: IC0038-004-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan Krka 80 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/010/007 Interchangeable List Code: IC0038-005-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan Rowa 160 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/083/003 Interchangeable List Code: IC0038-082-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan Rowa 320 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/083/004 Interchangeable List Code: IC0038-083-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan Rowa 40 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/083/001 Interchangeable List Code: IC0038-004-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan Rowa 80 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/083/002 Interchangeable List Code: IC0038-005-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan Teva 160 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/084/003 Interchangeable List Code: IC0038-082-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan Teva 40 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/084/001 Interchangeable List Code: IC0038-004-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Valsartan Teva 80 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/084/002 Interchangeable List Code: IC0038-005-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan Viatris 160 mg Film-coated Tablets	Viatris Limited	PA23266/006/003 Interchangeable List Code: IC0038-082-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan Viatris 320 mg Film-coated Tablets	Viatris Limited	PA23266/006/004 Interchangeable List Code: IC0038-083-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan Viatris 40 mg Film-coated Tablets	Viatris Limited	PA23266/006/001 Interchangeable List Code: IC0038-004-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan Viatris 80 mg Film-coated Tablets	Viatris Limited	PA23266/006/002 Interchangeable List Code: IC0038-005-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan/Hydrochlorothiazide 160 mg/ 12.5 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/181/002 Interchangeable List Code: IC0040-077-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan/Hydrochlorothiazide 160 mg/ 25 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/181/003 Interchangeable List Code: IC0040-078-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan/Hydrochlorothiazide 80 mg/ 12.5 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/181/001 Interchangeable List Code: IC0040-081-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan/hydrochlorothiazide Krka 160 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/004/002 Interchangeable List Code: IC0040-077-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan/hydrochlorothiazide Krka 160 mg/25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/004/003 Interchangeable List Code: IC0040-078-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan/hydrochlorothiazide Krka 320 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/004/004 Interchangeable List Code: IC0040-079-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan/hydrochlorothiazide Krka 320 mg/25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/004/005 Interchangeable List Code: IC0040-080-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan/hydrochlorothiazide Krka 80 mg/12.5 mg Film-coated Tablets	KRKA, d.d., Novo mesto	PA1347/004/001 Interchangeable List Code: IC0040-081-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsartan/Hydrochlorothiazide Teva 160 mg/12.5 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/047/003 Interchangeable List Code: IC0040-077-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valsol plus 160 mg/25 mg film-coated tablets	Laboratorios LICONSA, S.A.	PA1239/007/003 Interchangeable List Code: IC0040-078-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Valsol plus 80 mg/12.5 mg film-coated tablets	Laboratorios LICONSA, S.A.	PA1239/007/001 Interchangeable List Code: IC0040-081-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valtan 160 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/211/003 Interchangeable List Code: IC0038-082-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valtan 40 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/211/001 Interchangeable List Code: IC0038-004-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valtan 80 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/211/002 Interchangeable List Code: IC0038-005-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valtan Comp 80mg/12.5mg Film-coated tablets	Clonmel Healthcare Ltd	PA0126/216/001 Interchangeable List Code: IC0040-081-003	Film-coated tablet		- Valsartan - Hydrochlorothiazide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Valtrex 250 mg Film-Coated Tablets	GlaxoSmithKline (Ireland) Limited	PA1077/082/001	Film-coated tablet	- J05AB - J05AB11	- Valaciclovir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Valtrex 500 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/459/001 Interchangeable List Code: IC0132-117-003	Film-coated tablet		- Valaciclovir		- Oral use
Valtrex 500 mg Film-coated tablets	IMED Healthcare Ltd.	PPA1463/173/001 Interchangeable List Code: IC0132-117-003	Film-coated tablet		- Valaciclovir		- Oral use
Valtrex 500 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/026/001 Interchangeable List Code: IC0132-117-003	Film-coated tablet		- Valaciclovir		- Oral use
Valtrex 500mg Film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/082/002 Interchangeable List Code: IC0132-117-003	Film-coated tablet		- Valaciclovir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vaminolact solution for infusion, 100 ml bottle	Fresenius Kabi Deutschland GmbH	PA2059/065/001	Solution for infusion	- B05BA - B05BA01	- Alanine - Arginine - Aspartic Acid - Cysteine - Glutamic acid - Glycine - Histidine - Isoleucine - Leucine - Lysine - Methionine - Phenylalanine - Proline - Serine - Threonine - Tryptophan - Tyrosine - Valine - Taurine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Vaminolact solution for infusion, 500 ml bottle	Fresenius Kabi Deutschland GmbH	PA2059/065/002	Solution for infusion	- B05BA - B05BA01	- Alanine - Arginine - Cysteine - Glutamic acid - Glycine - Histidine - Isoleucine - Leucine - Lysine - Methionine - Phenylalanine - Proline - Serine - Threonine - Tryptophan - Tyrosine - Valine - Taurine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Vancocin 1 g powder for concentrate for solution for infusion and powder for oral solution	Flynn Pharma Limited	PA1226/005/004	Powder for concentrate for solution for infusion	- J01XA - J01XA01	- Vancomycin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use - Oral use
Vancocin 500 mg powder for concentrate for solution for infusion and powder for oral solution	Flynn Pharma Limited	PA1226/005/003	Powder for concentrate for solution for infusion	- J01XA - J01XA01	- Vancomycin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use - Oral use
Vancocin Matrigel 125mg Hard Capsules	Flynn Pharma Limited	PA1226/005/001	Capsule, hard	- J01XA - J01XA01	- VANCOMYCIN HYDROCHLORIDE	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Vancomycin 1000 mg Powder for concentrate for solution for infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/009/002	Powder for concentrate for solution for infusion	- J01XA - J01XA01	- VANCOMYCIN HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Vancomycin 1000 mg powder for concentrate for solution for infusion	Laboratórios Azevedos - Indústria Farmacêutica S.A	PA1852/004/002	Powder for concentrate for solution for infusion	- J01XA - J01XA01	- VANCOMYCIN HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Vancomycin 1000 mg powder for concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/066/002	Powder for concentrate for solution for infusion	- J01XA - J01XA01	- VANCOMYCIN HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Vancomycin 1000 mg Powder for concentrate for solution for infusion and oral solution	Noridem Enterprises Limited	PA1122/008/002	Powder for concentrate for solution for infusion	- J01XA - J01XA01	- VANCOMYCIN HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vancomycin 500 mg Powder for concentrate for solution for infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/009/001	Powder for concentrate for solution for infusion	- J01XA - J01XA01	- VANCOMYCIN HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Vancomycin 500 mg powder for concentrate for solution for infusion	Laboratórios Azevedos - Indústria Farmacêutica S.A	PA1852/004/001	Powder for concentrate for solution for infusion	- J01XA - J01XA01	- VANCOMYCIN HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Vancomycin 500 mg powder for concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/066/001	Powder for concentrate for solution for infusion	- J01XA - J01XA01	- VANCOMYCIN HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Vancomycin 500 mg Powder for concentrate for solution for infusion and oral solution	Noridem Enterprises Limited	PA1122/008/001	Powder for concentrate for solution for infusion	- J01XA - J01XA01	- VANCOMYCIN HYDROCHLORIDE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vancomycin Viatris 1000 mg, powder for solution for infusion	Viatris Limited	PA23266/004/002	Powder for solution for infusion	- J01XA - J01XA01	- Vancomycin	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use - Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Vancomycin Viatris 500 mg, powder for solution for infusion	Viatris Limited	PA23266/004/001	Powder for solution for infusion	- J01XA - J01XA01	- Vancomycin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Oral use
Vanflyta	Daiichi Sankyo Europe GmbH	EU/1/23/1768/001-002	Film-coated tablet	- L01EX11	- QUIZARTINIB DIHYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vanflyta	Daiichi Sankyo Europe GmbH	EU/1/23/1768/003-005	Film-coated tablet	- L01EX11	- QUIZARTINIB DIHYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vaniqa 11.5%	Almirall, S.A.	EU/1/01/173/001	Cream	- P01CX - P01CX03	- Eflornithine	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Vaniqa 11.5%	Almirall, S.A.	EU/1/01/173/002	Cream	- P01CX - P01CX03	- Eflornithine	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Vaniqa 11.5%	Almirall, S.A.	EU/1/01/173/003	Cream	- D11AX - D11AX16	- Eflornithine	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
VANTAVO	Merck Sharp & Dohme Ltd	EU/1/09/572/6-9	Tablet	- M05BB	- Alendronic acid - Vitamin d3 100.000 iu/g	Informed consent application (Article 10c of Directive No 2001/83/EC)	
VANTAVO 70 mg/2800 IU tablets	N.V. Organon	EU/1/09/572/001-005 Interchangeable List Code: IC0052-102-002	Tablet		- Alendronic acid - Vitamin D3	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
VANTAVO 70 mg/5600 IU tablets	N.V. Organon	EU/1/09/572/006-008 Interchangeable List Code: IC0052-103-002	Tablet		- Vitamin d3 - Alendronic acid	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
VAQTA Adult 50 U/1 ml, suspension for injection in a prefilled syringe. Hepatitis A vaccine, inactivated, adsorbed. For adults	Merck Sharp & Dohme Ireland (Human Health) Limited	PA1286/056/002	Suspension for injection in pre-filled syringe	- J07BC - J07BC02	- Strain cr 326f hepatitis a virus, inactivated 50 u	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
VAQTA Paediatric 25 U/0.5 mL, suspension for injection in a prefilled syringe. Hepatitis A vaccine, inactivated, adsorbed. For children and adolescents	Merck Sharp & Dohme Ireland (Human Health) Limited	PA1286/056/001	Suspension for injection in pre-filled syringe	- J07BC - J07BC02	- Strain cr 326f hepatitis a virus, inactivated 50 u	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Vardenafil Accord 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/123/002	Film-coated tablet	- G04BE - G04BE09	- VARDENAFIL HYDROCHLORIDE TRIHYDRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vardenafil Accord 20 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/123/003	Film-coated tablet	- G04BE - G04BE09	- Vardenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vardenafil Accord 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/123/001	Film-coated tablet	- G04BE - G04BE09	- Vardenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vardenafil Chanelle 10 mg Orodispersible Tablets	Chanelle Medical Unlimited Company	PA0688/051/001	Orodispersible tablet	- G04BE - G04BE09	- VARDENAFIL HYDROCHLORIDE TRIHYDRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Vardenafil Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/073/002	Film-coated tablet	- G04BE - G04BE09	- VARDENAFIL HYDROCHLORIDE TRIHYDRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vardenafil Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/073/003	Film-coated tablet	- G04BE - G04BE09	- VARDENAFIL HYDROCHLORIDE TRIHYDRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vardenafil Krka 5mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/073/001	Film-coated tablet	- G04BE - G04BE09	- VARDENAFIL HYDROCHLORIDE TRIHYDRATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vargatef	Boehringer Ingelheim International GmbH	EU/1/14/954/001-003	Capsule, soft	- L01XE - L01XE31	- Nintedanib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vargatef	Boehringer Ingelheim International GmbH	EU/1/14/954/004	Capsule, soft	- L01XE - L01XE31	- Nintedanib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
VARIVAX powder and solvent for suspension for injection in a pre-filled syringeVaricella Vaccine (live)	Merck Sharp & Dohme Ireland (Human Health) Limited	PA1286/057/001	Powder and solvent for suspension for injection	- J07BK01	- Varicella virus (oka strain) live attenuated	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Vastarel 20 mg Film-coated Tablets	Les Laboratoires Servier	PA0568/033/001	Film-coated tablet	- C01EB - C01EB15	- Trimetazidine dihydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vatan 160 mg Film-coated Tablets	Rowex Ltd	PA0711/183/003 Interchangeable List Code: IC0038-082-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vatan 40 mg Film-coated Tablets	Rowex Ltd	PA0711/183/001 Interchangeable List Code: IC0038-004-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vatan 80 mg Film-coated Tablets	Rowex Ltd	PA0711/183/002 Interchangeable List Code: IC0038-005-003	Film-coated tablet		- Valsartan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vaxchora	Bavarian Nordic A/S	EU/1/20/1423/001	Effervescent powder and suspension for oral suspension	- J07AE02	- V.Chloerae CVD 103-HGR	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vaxelis	MCM Vaccine B.V.	EU/1/15/1079/001-007	Suspension for injection	- J07CA - J07CA09	- Diphtheria toxoid adsorbed - Tetanus toxoid adsorbed	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Vaxneuvance	Merck Sharp & Dohme BV,	EU/1/21/1591/001-006	Solution for injection in pre-filled syringe	- J07AL	- Pneumococcal Polysaccharide Serotype 1 Conjugated to CRM197 - Pneumococcal Polysaccharide Serotype 3 Conjugated to CRM197 - Pneumococcal Polysaccharide Serotype 4 Conjugated to CRM197 - Pneumococcal Polysaccharide Serotype 5 Conjugated to CRM197 - Pneumococcal Polysaccharide Serotype 6A Conjugated to CRM197 - Pneumococcal Polysaccharide Serotype 7F Conjugated to CRM197 - Pneumococcal Polysaccharide Serotype 9V Conjugated to CRM197 - Pneumococcal Polysaccharide Serotype 14 Conjugated to CRM197 - Pneumococcal Polysaccharide Serotype 18C Conjugated to CRM197 - Pneumococcal Polysaccharide Serotype 19A Conjugated to CRM197 - Pneumococcal Polysaccharide Serotype 19F Conjugated to CRM197 - Pneumococcal Polysaccharide Serotype 22F Conjugated to CRM197 - Pneumococcal Polysaccharide Serotype 23F Conjugated to CRM197 - Pneumococcal Polysaccharide Serotype 33F Conjugated to CRM197 - Pneumococcal Polysaccharide Serotype 6B Conjugated to CRM197	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Vaxzevria	AstraZeneca AB	EU/1/21/1529/001-002	Suspension for injection	- J07BX03	- Chimpanzee Adenovirus encoding the SARS-CoV 2-Spike glycoprotein (ChAdOx1-S)	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Vazkepa	Amarin Pharmaceuticals Ireland Limited	EU/1/20/1524/001-002	Capsule, soft	- C10AX - C10AX06	- Icosapent ethyl	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vectavir Cold Sore Cream	Chefaro Ireland DAC	PA1186/020/001	Cream	- D06BB - D06BB06	- Penciclovir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical use
Vectibix	Amgen Europe B.V.	EU/1/07/423/001-003	Concentrate for solution for infusion	- L01XC - L01XC08	- Panitumumab		- Intravenous use
Vedixal 37.5mg Tablets	Rowex Ltd	PA0711/161/002	Tablet	- N06AX - N06AX16	- Venlafaxine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vedixal 75mg Tablets	Rowex Ltd	PA0711/161/004	Tablet	- N06AX - N06AX16	- Venlafaxine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vedixal XL 150mg Prolonged release capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/016/002 Interchangeable List Code: IC0026-062-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vedixal XL 75 mg prolonged release capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/016/001 Interchangeable List Code: IC0026-028-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vedrop	Recordati Rare Diseases	EU/1/09/533/1-3	Oral solution	- A11HA08	- Tocofersolan d-alpha tocopheryl polyethylene glycol 1000 succinate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Veganin Plus Tablets	Chefaro Ireland DAC	PA1186/006/001	Film-coated tablet	- N02AJ - N02AJ06	- Paracetamol - Caffeine - Codeine phosphate hemihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vegzelma	Celltrion Healthcare Hungary Kft.	EU/1/22/1667/001-004	Concentrate for solution for infusion	- L01XC07	- Bevacizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Veklury	Gilead Sciences Ireland UC	EU/1/20/1459/001-002	Powder for concentrate for solution for infusion	- J05AB16	- Remdesivir	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
VELCADE	Janssen-Cilag International NV	EU/1/04/274/001	Powder for solution for injection	- L01XX - L01XX32	- Bortezomib		- Intravenous use
Velcade	Janssen-Cilag International NV	EU/1/04/274/002	Powder for solution for injection	- L01XX - L01XX32	- Ps-341 as boronic acid (bortezomib)		- Subcutaneous use
Veletri 0.5 Milligram Powder for Solution for Infusion	Janssen-Cilag International NV	PA0885/001/001	Powder for solution for infusion	- B01AC - B01AC09	- Epoprostenol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Veletri 1.5 Milligram Powder for Solution for Infusion	Janssen-Cilag International NV	PA0885/001/002	Powder for solution for infusion	- B01AC - B01AC09	- Epoprostenol	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Velmetia	Merck Sharp & Dohme BV,	EU/1/08/456/1-7 Interchangeable List Code: IC0070-121-003	Film-coated tablet		- Sitagliptin phosphate - Metformin Hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Velmetia	Merck Sharp & Dohme BV	EU/1/08/456/8-14 Interchangeable List Code: IC0070-122-003	Film-coated tablet		- Sitagliptin phosphate - Metformin Hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Velphoro	Vifor Fresenius Medical Care Renal Pharma France	EU/1/14/943/005	Oral powder in sachet	- V03AE05	- Sucroferric Oxyhydroxide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Velphoro	Vifor Fresenuis Medical Care Renal Pharma France	EU/1/14/943/001-004	Chewable tablet	- V03AE - V03AE05	- Mixture of iron(iii)-oxyhydroxide, sucrose, starches	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Velsipity	Pfizer Europe MA EEIG	EU/1/23/1790/001-003	Film-coated tablet	- L04AE05	- Etrasimod arginine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Veltassa	Vifor Fresenius Medical Care Renal Pharma France	EU/1/17/1179/001-003	Powder for oral suspension	- V03AE - V03AE09	- Patiromer sorbitex calcium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Veltassa	Vifor Fresenius Medical Care Renal Pharma France	EU/1/17/1179/004-006	Powder for oral suspension	- V03AE - V03AE09	- Patiromer sorbitex calcium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Veltassa	Vifor Fresenius Medical Care Renal Pharma France	EU/1/17/1179/007-008	Powder for oral suspension	- V03AE - V03AE09	- Patiromer sorbitex calcium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Veltassa	Vifor Fresenius Medical Care Renal Pharma France	EU/1/17/1179/011	Powder for oral suspension	- V03AE09	- Patiromer sorbitex calcium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vemlidy (formely Tenofovir alafenamide)	Gilead Sciences Ireland UC	EU/1/16/1154/001-002	Film-coated tablet	- J05AF - J05AF13	- Tenofovir alafenamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Venaforce Varicose Veins gastro-resistant tablets	A.Vogel Ireland Limited	TR2309/011/001	Gastro-resistant tablet		- Extract (as dry extract) from fresh horse chesnut seeds (aesculus hippocastanum l. semen)	Traditional use registration for herbal medicinal product application (Article 16a of Directive No 2001/83/EC)	- Oral use
Venclyxto	AbbVie Deutschland GmbH & Co. KG	EU/1/16/1138/001-002	Film-coated tablet	- L01X	- Venetoclax	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Venclyxto	AbbVie Deutschland GmbH & Co. KG	EU/1/16/1138/003-004	Film-coated tablet	- L01X	- Venetoclax	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Venclyxto	AbbVie Deutschland GmbH & Co. KG	EU/1/16/1138/005-007	Film-coated tablet	- L01X	- Venetoclax	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Venex XL 150 mg Prolonged-release Capsules, hard	Clonmel Healthcare Ltd	PA0126/285/003 Interchangeable List Code: IC0026-062-030	Prolonged-release capsule, hard		- Venlafaxine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Venex XL 37.5 mg Prolonged-release Capsules, hard	Clonmel Healthcare Ltd	PA0126/285/001 Interchangeable List Code: IC0026-063-030	Prolonged-release capsule, hard		- Venlafaxine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Venex XL 75 mg prolonged-release capsules, hard	Clonmel Healthcare Ltd	PA0126/285/002 Interchangeable List Code: IC0026-028-030	Prolonged-release capsule, hard		- Venlafaxine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Venlablue XL 150mg Prolonged Release Capsules, Hard	Bluefish Pharmaceuticals AB	PA1436/006/002 Interchangeable List Code: IC0026-062-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Venlablue XL 75 mg prolonged-release capsules, hard	Bluefish Pharmaceuticals AB	PA1436/006/001 Interchangeable List Code: IC0026-028-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Venlafex XL 150 mg prolonged-release capsules, hard	KRKA, d.d., Novo mesto	PA1347/036/003 Interchangeable List Code: IC0026-062-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Venlafex XL 37.5 mg prolonged-release capsules, hard	KRKA, d.d., Novo mesto	PA1347/036/001 Interchangeable List Code: IC0026-063-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Venlafex XL 75 mg prolonged-release capsules, hard	KRKA, d.d., Novo mesto	PA1347/036/002 Interchangeable List Code: IC0026-028-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Venlatev 150 mg hard prolonged-release capsules	Teva B.V.	PA1986/099/003 Interchangeable List Code: IC0026-062-030	Prolonged-release capsule, hard		- Venlafaxine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Venlatev 37.5 mg hard prolonged-release capsules	Teva B.V.	PA1986/099/001 Interchangeable List Code: IC0026-063-030	Prolonged-release capsule, hard		- Venlafaxine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Venlatev 75 mg hard prolonged-release capsules	Teva B.V.	PA1986/099/002 Interchangeable List Code: IC0026-028-030	Prolonged-release capsule, hard		- Venlafaxine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Venlofex 150 mg prolonged-release hard capsules	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/100/002 Interchangeable List Code: IC0026-062-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Venlofex 75 mg prolonged-release hard capsules	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/100/001 Interchangeable List Code: IC0026-028-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Venofer 20 mg iron/mL solution for injection or concentrate for solution for infusion, ampoule	Vifor France	PA0949/001/001	Solution for injection/infusion	- B03AB - B03AB02	- IRON (III)		- Intravenous use
Venofer 20 mg iron/mL solution for injection or concentrate for solution for infusion, vial	Vifor France	PA0949/001/002	Solution for injection/infusion	- B03AB - B03AB02	- Iron (iii) - hydroxide sucrose complex		- Intravenous use
Vensir XL 150 mg prolonged-release hard capsules	Morningside Healthcare (Malta) Limited	PA23142/002/002 Interchangeable List Code: IC0026-062-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vensir XL 75 mg prolonged-release hard capsules	Morningside Healthcare (Malta) Limited	PA23142/002/001 Interchangeable List Code: IC0026-028-030	Prolonged-release capsule, hard		- Venlafaxine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Ventavis	Bayer Pharma AG	EU/1/03/255/009-010,012	Nebuliser solution	- B01AC - B01AC11	- Iloprost trometanol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Ventavis	Bayer AG	EU/1/03/255/1-3	Nebuliser solution	- B01AC - B01AC11	- Iloprost trometanol		- Inhalation use
Ventizolve 1.26 mg nasal spray, solution in single-dose container	DNE Pharma AS	PA22993/001/001	Nasal spray, solution in single-dose container	- V03AB15	- Naloxone	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Nasal use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Ventolin 1mg/ml Concentrate for Solution for Intravenous Infusion	GlaxoSmithKline (Ireland) Limited	PA1077/049/002	Concentrate for solution for infusion	- R03CC - R03CC02	- Salbutamol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ventolin 2mg/5ml Oral Solution	GlaxoSmithKline (Ireland) Limited	PA1077/049/012	Oral solution	- R03CC - R03CC02	- SALBUTAMOL SULFATE		- Oral use
Ventolin 500 micrograms/ml Solution for Injection	GlaxoSmithKline (Ireland) Limited	PA1077/049/001	Solution for injection	- R03AC - R03AC02	- Salbutamol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Ventolin Diskus 200 micrograms Inhalation Powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/049/011	Inhalation powder, pre-dispensed	- R03AC - R03AC02	- Salbutamol		- Inhalation use
Ventolin Evohaler 100 micrograms pressurised inhalation, suspension	GlaxoSmithKline (Ireland) Limited	PA1077/049/010 Interchangeable List Code: IC0078-138-053	Pressurised inhalation, suspension		- Salbutamol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Inhalation use
Ventolin Evohaler 100 micrograms Pressurised Inhalation, Suspension	PCO Manufacturing Ltd.	PPA0465/064/001 Interchangeable List Code: IC0078-138-053	Pressurised inhalation, suspension		- Salbutamol		- Inhalation use
Veoza	Astellas Pharma Europe B.V.	EU/1/23/1771/001-003	Film-coated tablet	- G02CX06	- Fezolinetant	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
VEPESID 100 mg capsule, soft	CHEPLAPHARM Arzneimittel GmbH	PA2239/006/002	Capsule, soft	- L01CB - L01CB01	- Etoposide		- Oral use
VEPESID 50 mg capsule, soft	CHEPLAPHARM Arzneimittel GmbH	PA2239/006/001	Capsule, soft	- L01CB - L01CB01	- Etoposide		- Oral use
Verap 120mg Prolonged Release Tablets	Rowex Ltd	PA0711/016/004	Prolonged-release tablet	- C08DA - C08DA01	- Verapamil hydrochloride		- Oral use
Verap 240mg prolonged release tablets	Rowex Ltd	PA0711/016/005	Prolonged-release tablet	- C08DA - C08DA01	- Verapamil hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
VeraSeal	Instituto Grifols S.A.	EU/1/17/1239/001-002	Solution for sealant	- B02BC	- Human fibrinogen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Epilesional use
VeraSeal	Instituto Grifols S.A.	EU/1/17/1239/003-004	Solution for sealant	- B02BC	- Human fibrinogen	Full application (Article 8(3) of Directive No 2001/83/EC)	- Epilesional use
Verdye 5 mg/ml powder for solution for injection	Diagnostic Green Limited	PA23409/001/001	Powder for solution for injection	- V04CX	- Indocyanine green	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intravenous use
Verkazia	Santen OY	EU/1/17/1219/001-004	Eye drops, emulsion	- S01XA - S01XA18	- Ciclosporin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vermox 100 mg tablets	Johnson & Johnson (Ireland) Limited	PA0330/046/002	Tablet	- P02CA - P02CA01	- Mebendazole		- Oral use
Vermox 100 mg Tablets	PCO Manufacturing Ltd.	PPA0465/440/001	Tablet	- P02CA - P02CA01	- Mebendazole		- Oral use
Vermox 100mg/5ml Oral Suspension	JNTL Consumer Health I (Ireland) Limited	PA23490/026/001	Oral suspension	- P02CA - P02CA01	- Mebendazole		- Oral use
Verorab, powder and solvent for suspension for injection. Rabies vaccine, inactivated.	Sanofi Pasteur	PA2131/016/001	Powder and solvent for suspension for injection in pre-filled syringe	- J07BG01	- Rabies virus (inactivated) strain wistar (PM/WI 38-1503-3M)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intradermal use - Intramuscular use
Verquvo	Bayer AG	EU/1/21/1561/001-011	Film-coated tablet	- C01 - C01DX22	- Vericiguat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Verquvo	Bayer AG	EU/1/21/1561/012-022	Film-coated tablet	- C01 - C01DX22	- Vericiguat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Verquvo	Bayer AG	EU/1/21/1561/023-025	Film-coated tablet	- C01 - C01DX22	- Vericiguat	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Versatis 700 mg medicated plaster	Grunenthal Pharma Ltd	PA2242/007/001	Medicated plaster	- N01BB - N01BB02	- Lidocaine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Versatis 700 mg medicated plaster	PCO Manufacturing Ltd.	PPA0465/299/001	Medicated plaster	- N01BB - N01BB02	- Lidocaine		- Cutaneous use
Versatis 700 mg medicated plaster	Merit Pharmaceuticals Limited	PPA23080/013/001	Medicated plaster	- N01BB02	- Lidocaine	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Cutaneous use
Versatis 700 mg medicated plaster	IMED Healthcare Ltd.	PPA1463/135/001	Medicated plaster	- N01BB - N01BB02	- Lidocaine		- Cutaneous use
Vertigon 16 mg tablets	Aurobindo Pharma (Malta) Limited	PA1445/023/002 Interchangeable List Code: IC0084-038-002	Tablet		- Betahistine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vertigon 8 mg tablets	Aurobindo Pharma (Malta) Limited	PA1445/023/001 Interchangeable List Code: IC0084-009-002	Tablet		- Betahistine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
VERZENIOS	Eli Lilly Nederland B.V.	EU/1/18/1307/001-003	Film-coated tablet	- L01XE50	- ABEMACICLIB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
VERZENIOS	Eli Lilly Nederland B.V.	EU/1/18/1307/004-006	Film-coated tablet	- L01XE50	- ABEMACICLIB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
VERZENIOS	Eli Lilly Nederland B.V.	EU/1/18/1307/007-009	Film-coated tablet	- L01XE50	- ABEMACICLIB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vesanoid 10 mg soft capsules	Cheplapharm Arzneimittel GmbH	PA1868/001/001	Capsule, soft	- L01XF01	- Tretinoin		- Oral use
Vesitirim 1 mg/ml oral suspension	Astellas Pharma Co. Limited	PA1241/009/003	Oral suspension	- G04BD - G04BD08	- Solifenacin succinate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vesitirim 10 mg film-coated tablets	Astellas Pharma Co. Limited	PA1241/009/002 Interchangeable List Code: IC0116-002-003	Film-coated tablet		- Solifenacin succinate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vesitirim 10 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/130/002 Interchangeable List Code: IC0116-002-003	Film-coated tablet		- Solifenacin succinate		- Oral use
Vesitirim 10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/262/002 Interchangeable List Code: IC0116-002-003	Film-coated tablet		- Solifenacin succinate	ZZZ PPA	- Oral use
Vesitirim 5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/262/001 Interchangeable List Code: IC0116-001-003	Film-coated tablet		- Solifenacin succinate	ZZZ PPA	- Oral use
Vesitirim 5 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/130/001 Interchangeable List Code: IC0116-001-003	Film-coated tablet		- Solifenacin succinate		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Vesitirim 5 mg film-coated tablets	Astellas Pharma Co. Limited	PA1241/009/001 Interchangeable List Code: IC0116-001-003	Film-coated tablet		- Solifenacin succinate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vesomni 6 mg/0.4 mg modified-release tablets	Astellas Pharma Co. Limited	PA1241/016/001 Interchangeable List Code: IC0101-154-021	Modified-release tablet		- Solifenacin succinate - Tamsulosin hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Vesomni 6 mg/0.4 mg modified-release tablets	IMED Healthcare Ltd.	PPA1463/139/001 Interchangeable List Code: IC0101-154-021	Modified-release tablet		- Solifenacin succinate - Tamsulosin hydrochloride	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Vesomni 6 mg/0.4 mg modified-release tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/012/001 Interchangeable List Code: IC0101-154-021	Modified-release tablet		- Solifenacin succinate - Tamsulosin hydrochloride		- Oral use
Vesomni 6 mg/0.4 mg modified-release tablets	Merit Pharmaceuticals Limited	PPA23080/033/001	Modified-release tablet	- G04CA53	- Solifenacin succinate - Tamsulosin hydrochloride	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Vesomni 6 mg/0.4 mg modified-release tablets	PCO Manufacturing Ltd.	PPA0465/452/001 Interchangeable List Code: IC0101-154-021	Modified-release tablet		- Solifenacin succinate - Tamsulosin hydrochloride		- Oral use
Veyann 0.02 mg/3 mg Film-coated tablets	Theramex Ireland Limited	PA22668/005/001	Film-coated tablet	- G03AA - G03AA12	- Drospirenone - Ethinyl estradiol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
VEYVONDI	Baxalta Innovations GmbH	EU/1/18/1298/001	Powder and solvent for solution for injection	- B02BD10	- VONICOG ALFA	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
VEYVONDI	Baxalta Innovations GmbH	EU/1/18/1298/002	Powder and solvent for solution for injection	- B02BD10	- VONICOG ALFA	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Vfend	Pfizer Europe MA EEIG	EU/1/02/212/001-009	Film-coated tablet	- J02AC03	- Voriconazole	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vfend	Pfizer Europe MA EEIG	EU/1/02/212/013-021	Film-coated tablet	- J02AC03	- Voriconazole	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vfend	Pfizer Europe MA EEIG	EU/1/02/212/025	Powder for solution for infusion	- J02AC - J02AC03	- Voriconazole		- Intravenous use
VFEND	Pfizer Europe MA EEIG	EU/1/02/212/026	Powder for oral suspension	- J02AC - J02AC03	- Voriconazole		- Oral use
Viacoram 3.5mg/2.5mg Tablets	Les Laboratoires Servier	PA0568/027/001	Tablet	- C09BB - C09BB04	- Perindopril arginine - Amlodipine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Viacoram 7mg/5mg Tablets	Les Laboratoires Servier	PA0568/027/002	Tablet	- C09BB - C09BB04	- Perindopril arginine - Amlodipine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Viagra	Upjohn EESV	EU/1/98/077/020-023 Interchangeable List Code: IC0063-023-004	Orodispersible tablet		- Sildenafil citrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Viagra	Upjohn EESV	EU/1/98/077/026-029	Orodispersible film	- G04BE03	- Sildenafil	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Viagra 100 mg film-coated tablets	Upjohn EESV	EU/1/98/077/10-11 Interchangeable List Code: IC0063-024-014	Film-coated tablet		- Sildenafil		- Oral use
Viagra 25 mg film-coated tablets	Upjohn EESV	EU/1/98/077/2-4 Interchangeable List Code: IC0063-022-014	Film-coated tablet		- Sildenafil	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Viagra 50 mg film-coated tablets	Upjohn EESV	EU/1/98/077/6-8 Interchangeable List Code: IC0063-023-003	Film-coated tablet		- Sildenafil	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Viagra Connect 50 mg Film-Coated Tablet	Upjohn EESV	PA23055/016/001	Film-coated tablet	- G04BE03	- Sildenafil	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Viaredin 25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/373/001 Interchangeable List Code: IC0063-022-014	Film-coated tablet		- Sildenafil citrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Viaredin 50 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/373/002 Interchangeable List Code: IC0063-023-003	Film-coated tablet		- Sildenafil citrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Viartril 1500 mg Powder for Oral Solution	Rottapharm Ltd	PA0868/005/001	Powder for oral solution	- M01AX - M01AX05	- Glucosamine sulphate sodium chloride	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ViATIM, Suspension and solution for suspension for injection in pre-filled syringe. Hepatitis A (inactivated, adsorbed) and Typhoid polysaccharide vaccine	Sanofi Pasteur	PA2131/014/001	Solution and suspension for suspension for injection in pre-filled syringe	- J07CA - J07CA10	- Vi polysaccharide of salmonella typhi - Hepatitis a virus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Vibramycin Capsules 100 mg	Pfizer Healthcare Ireland	PA0822/193/001	Capsule, hard	- J01AA - J01AA02	- Doxycycline	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vicks Inhaler Nasal StickMenthol 125mgCamphor 50mgSiberian Pine Needle Oil 10mg	WICK Pharma - Zweigniederlassung der Procter & Gamble GmbH	PA2294/005/001	Nasal stick	- R01AX - R01AX10	- Siberian fir oil - Camphor - Menthol	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Inhalation use
Vicks Sinex Micromist 0.05% w/v Nasal Spray, Solution	WICK Pharma - Zweigniederlassung der Procter & Gamble GmbH	PA2294/004/001	Nasal spray, solution	- R01AA - R01AA05	- Oxymetazoline hydrochloride	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Nasal use
Vicks Vaporub Inhalation Vapour, Ointment Levomenthol 2.75% w/wCamphor 5.00% w/wEucalyptus Oil 1.50% w/w Turpentine Oil 5.00% w/w	WICK Pharma - Zweigniederlassung der Procter & Gamble GmbH	PA2294/003/001	Inhalation vapour, ointment	- R05X	- Levomenthol - Camphor - Eucalyptus oil - Turpentine oil	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical use
Victoza	Novo Nordisk A/S	EU/1/09/529/1-5	Solution for injection in pre-filled pen	- A10BJ02	- Liraglutide	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Vidaza	Bristol-Myers Squibb Pharma EEIG	EU/1/08/488/001	Powder for suspension for injection	- L01BC - L01BC07	- Azacitidine		- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Videne 10% w/w Alcoholic Tincture	Ecolab Deutschland GmbH	PA1843/002/003	Cutaneous solution	- D08AG - D08AG02	- Iodinated povidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Topical use
Videne 7.5% w/w Surgical Scrub	Ecolab Deutschland GmbH	PA1843/002/001	Cutaneous solution	- D08AG - D08AG02	- Iodinated povidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Topical use
Videne Antiseptic Solution 10% w/w Cutaneous Solution	Ecolab Deutschland GmbH	PA1843/002/002	Cutaneous solution	- D08AG - D08AG02	- Iodinated povidone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Topical use
Vidisic 0.2 % w/w eye gel	Bausch + Lomb Ireland Limited	PA23259/008/001	Eye gel	- S01XA - S01XA20	- Carbomer		- Ocular use
Vidisic Preservative Free Single Dose Unit	Bausch + Lomb Ireland Limited	PA23259/008/002	Eye gel	- S01XA - S01XA20	- Carbomer		- Ocular use
VidPrevtyn Beta	Sanofi Pasteur	EU/1/21/1580/001	Emulsion for injection	- J07BX03	- SARS-CoV-2 prefusion Spike delta TM protein, recombinant	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Viekirax	AbbVie Deutschland GmbH & Co. KG	EU/1/14/982/001	Film-coated tablet	- J05AX - J05AX67	- Ombitasvir - Paritaprevir - Ritonavir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vihuma	Octapharma AB	EU/1/16/1168/001	Powder and solvent for solution for injection	- B02BD - B02BD02	- Simoctocog alfa	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intravenous use
Vihuma	Octapharma AB	EU/1/16/1168/002	Powder and solvent for solution for injection	- B02BD - B02BD02	- Simoctocog alfa	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intravenous use
Vihuma	Octapharma AB	EU/1/16/1168/003	Powder and solvent for solution for injection	- B02BD - B02BD02	- Simoctocog alfa	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intravenous use
Vihuma	Octapharma AB	EU/1/16/1168/004	Powder and solvent for solution for injection	- B02BD - B02BD02	- Simoctocog alfa	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intravenous use
Vihuma	Octapharma AB	EU/1/16/1168/004-005	Powder and solvent for solution for injection	- B02BD02	- Simoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Vihuma	Octapharma AB	EU/1/16/1168/006	Powder and solvent for solution for injection	- B02BD02	- Simoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Vihuma	Octapharma AB	EU/1/16/1168/007	Powder and solvent for solution for injection	- B02BD02	- Simoctocog alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Vildagliptin Krka 50 mg tablets	KRKA, d.d., Novo mesto	PA1347/076/001	Tablet	- A10BH - A10BH02	- Vildagliptin	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vildagliptin/Metformin hydrochloride Accord	Accord Healthcare S.L.U.	EU/1/21/1611/00-004	Film-coated tablet	- A10BD08	- Vidagliptin - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vildagliptin/Metformin hydrochloride Accord	Accord Healthcare S.L.U.	EU/1/21/1611/001-002	Film-coated tablet	- A10BD08	- Vidagliptin - Metformin Hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vimizim	BioMarin International Limited	EU/1/14/914/001	Concentrate for solution for infusion	- A16AB - A16AB12	- Rhgalns	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
VIMOVO 500 mg/20 mg modified-release tablets	PCO Manufacturing Ltd.	PPA0465/328/001 Interchangeable List Code: IC0027-049-021	Modified-release tablet		- Naproxen - Esomeprazole		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
VIMOVO 500 mg/20 mg modified-release tablets	Merit Pharmaceuticals Limited	PPA23080/031/001 Interchangeable List Code: IC0027-049-021	Modified-release tablet		- Naproxen - Esomeprazole		- Oral use
VIMOVO 500 mg/20 mg modified-release tablets	IMED Healthcare Ltd.	PPA1463/152/001 Interchangeable List Code: IC0027-049-021	Modified-release tablet		- Esomeprazole - Naproxen		- Oral use
VIMOVO 500 mg/20 mg modified-release tablets	Grunenthal Pharma Ltd	PA2242/014/001 Interchangeable List Code: IC0027-049-021	Modified-release tablet		- Naproxen - Esomeprazole magnesium trihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Vimpat	UCB Pharma SA	EU/1/08/470/13	Film-coated tablet	- N03AX - N03AX18	- Lacosamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vimpat 10 mg/ml solution for infusion	UCB Pharma SA	EU/1/08/470/16	Solution for infusion	- N03AX - N03AX18	- Lacosamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Vimpat 10 mg/ml syrup	UCB Pharma SA	EU/1/08/470/018-019	Syrup	- N03AX - N03AX18	- Lacosamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vimpat 100 mg film-coated tablets	UCB Pharma SA	EU/1/08/470/4-6	Film-coated tablet	- N03AX - N03AX18	- Lacosamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vimpat 15 mg/ml syrup	UCB Pharma SA	EU/1/08/470/14-15	Syrup	- N03AX - N03AX18	- Lacosamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vimpat 150 mg film-coated tablets	UCB Pharma SA	EU/1/08/470/7-9	Film-coated tablet	- N03AX - N03AX18	- Lacosamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vimpat 200 mg film-coated tablets	UCB Pharma SA	EU/1/08/470/10-12	Film-coated tablet	- N03AX - N03AX18	- Lacosamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vimpat 50 mg film-coated tablets	UCB Pharma SA	EU/1/08/470/1-3	Film-coated tablet	- N03AX - N03AX18	- Lacosamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vinblastine Sulfate 1mg/ml Solution for Injection or Infusion	Pfizer Healthcare Ireland	PA0822/208/001	Solution for injection/infusion	- L01CA - L01CA01	- VINBLASTINE SULFATE		- Not Currently Available
Vincristine Sulfate 1mg/ml Solution for Injection or Infusion	Pfizer Healthcare Ireland	PA0822/232/001	Solution for injection/infusion	- L01CA - L01CA02	- Vincristine sulfate		- Intravenous use
Vinorelbine Accord 20 mg soft capsules	Accord Healthcare Ireland Ltd.	PA2315/253/001	Capsule, soft	- L01CA04	- Vinorelbine tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vinorelbine Accord 30 mg soft capsules	Accord Healthcare Ireland Ltd.	PA2315/253/002	Capsule, soft	- L01CA04	- Vinorelbine tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Violite 100/20 micrograms film-coated tablets	Gedeon Richter Plc	PA1330/030/001	Film-coated tablet	- G03AA - G03AA07	- Levonorgestrel - Ethinylestradiol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vipdomet	Takeda Pharma A/S	EU/1/13/843/001-012	Film-coated tablet	- A10BD - A10BD13	- Metformin Hydrochloride - Alogliptin (as benzoate)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vipdomet	Takeda Pharma A/S	EU/1/13/843/013-024	Film-coated tablet	- A10BD	- Alogliptin (as benzoate) - Metformin Hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Vipidia	Takeda Pharma A/S	EU/1/13/844/001-009	Film-coated tablet	- A10BH - A10BH04	- Alogliptin (as benzoate)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vipidia	Takeda Pharma A/S	EU/1/13/844/010-018	Film-coated tablet	- A10B	- Alogliptin (as benzoate)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vipidia	Takeda Pharma A/S	EU/1/13/844/019-027	Film-coated tablet	- A10B	- Alogliptin (as benzoate)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
VIRAFERON	Schering Plough Europe	EU/1/99/128/015	Solution for Injection	- L03AB05	- INTERFERON ALFA-2B		- Subcutaneous
ViraferonPeg 0.5 ml 100mcg ampoule	Schering Plough Europe	EU/1/00/132/039	Powder and solvent for solution for injection	- L03AB10	- Peginterferon alfa-2b		
ViraferonPeg 0.5 ml 120 mcg ampoule	Schering Plough Europe	EU/1/00/132/043	Powder and solvent for solution for injection	- L03AB10	- Peginterferon alfa-2b		
ViraferonPeg 0.5 ml 120 mcg ampoule	Schering Plough Europe	EU/1/00/132/044	Powder and solvent for solution for injection	- L03AB10	- Peginterferon alfa-2b		
ViraferonPeg 0.5 ml 120 mcg ampoule	Schering Plough Europe	EU/1/00/132/046	Powder and solvent for solution for injection	- L03AB10	- Peginterferon alfa-2b		
ViraferonPeg 0.5ml 100 mcg ampoule	Schering Plough Europe	EU/1/00/132/042	Powder and solvent for solution for injection	- L03AB10	- Peginterferon alfa-2b		
ViraferonPeg 0.5ml 100 mcg ampoule	Schering Plough Europe	EU/1/00/132/040	Powder and solvent for solution for injection	- L03AB10	- Peginterferon alfa-2b		
ViraferonPeg 0.5ml 120 mcg ampoule	Schering Plough Europe	EU/1/00/132/045	Powder and solvent for solution for injection	- L03AB10	- Peginterferon alfa-2b		
ViraferonPeg 2b 150 mcg / 0.5 ml 150 mcg ampoule	Schering Plough Europe	EU/1/00/132/050	Powder and solvent for solution for injection	- L03AB10	- Peginterferon alfa-2b		
ViraferonPeg 2b 150 mcg / 0.5 ml 150 mcg ampoule	Schering Plough Europe	EU/1/00/132/047	Powder and solvent for solution for injection	- L03AB10	- Peginterferon alfa-2b		
ViraferonPeg 2b 150 mcg / 0.5 ml 150 mcg ampoule	Schering Plough Europe	EU/1/00/132/048	Powder and solvent for solution for injection	- L03AB10	- Peginterferon alfa-2b		
ViraferonPeg 2b 150mcg / 0.5 ml 150 mcg ampoule	Schering Plough Europe	EU/1/00/132/049	Powder and solvent for solution for injection	- L03AB10	- Peginterferon alfa-2b		
ViraferonPeg 2b 80 mcg / 0.5 ml 80 mcg ampoule	Schering Plough Europe	EU/1/00/132/037	Powder and solvent for solution for injection	- L03AB10	- Peginterferon alfa-2b		
ViraferonPeg 2b 80mcg / 0.5ml 80 mcg ampoule	Schering Plough Europe	EU/1/00/132/038	Powder and solvent for solution for injection	- L03AB10	- Peginterferon alfa-2b		
ViraferonPeg0.5ml 100mcg ampoule	Schering Plough Europe	EU/1/00/132/041	Powder and solvent for suspension for injection	- L03AB10	- Peginterferon alfa-2b		
Viralief 50 mg/g Cream	Clonmel Healthcare Ltd	PA0126/201/001	Cream	- D06BB - D06BB03	- ACICLOVIR		- Topical use
Viramune	Boehringer Ingelheim International GmbH	EU/1/97/055/001	Tablet	- J05AG - J05AG01	- Nevirapine		- Oral use
VIRAMUNE	Boehringer Ingelheim International GmbH	EU/1/97/055/002	Oral suspension	- J05AG - J05AG01	- Nevirapine hemihydrate		- Oral use
Viramune	Boehringer Ingelheim International GmbH	EU/1/97/055/006	Prolonged-release tablet	- J05AG - J05AG01	- Nevirapine		- Oral use
Viramune	Boehringer Ingelheim International GmbH	EU/1/97/055/007-009	Prolonged-release tablet	- J05AG - J05AG01	- Nevirapine		- Oral use
VIREAD	Gilead Sciences Ireland UC	EU/1/01/200/001-002	Film-coated tablet	- J05AF - J05AF07	- Tenofovir disoproxil fumarate		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Viread	Gilead Sciences Ireland UC	EU/1/01/200/003	Granules	- J05AF - J05AF07	- Tenofovir disoproxil fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Viread	Gilead Sciences Ireland UC	EU/1/01/200/004-005	Film-coated tablet	- J05AF - J05AF07	- Tenofovir disoproxil fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Viread	Gilead Sciences Ireland UC	EU/1/01/200/006-007	Film-coated tablet	- J05AF - J05AF07	- Tenofovir disoproxil fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Viread	Gilead Sciences Ireland UC	EU/1/01/200/008-009	Film-coated tablet	- J05AF - J05AF07	- Tenofovir disoproxil fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Viscolex Syrup 250 mg / 5 ml Oral Solution	Pinewood Laboratories Ltd	PA0281/070/001	Oral solution	- R05CB - R05CB03	- Carbocysteine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
VISIPAQUE 270 mg I/ml Solution for Injection, glass container	GE Healthcare AS	PA0735/009/003	Solution for injection	- V08AB - V08AB09	- Iodixanol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intrathecal use
VISIPAQUE 270 mg I/ml Solution for Injection, polypropylene container	GE Healthcare AS	PA0735/009/012	Solution for injection	- V08AB - V08AB09	- Iodixanol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraarterial use - Intrathecal use - Intravenous use
VISIPAQUE 320 mg I/ml Solution for Injection, glass container	GE Healthcare AS	PA0735/009/007	Solution for injection	- V08AB - V08AB09	- Iodixanol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraarterial use - Intrathecal use - Intravenous use
Visipaque 320 mg I/ml Solution for Injection, polypropylene container	GE Healthcare AS	PA0735/009/013	Solution for injection	- V08AB - V08AB09	- Iodixanol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraarterial use - Intrathecal use - Intravenous use
VISTABEL, 4 Allergan Units/0.1ml, Powder for solution for injection	AbbVie Limited	PA1824/020/001	Powder for solution for injection	- M03AX - M03AX01	- Botulinum Toxin Type A	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Visudyne	CHEPLAPHARM Arzneimittel GmbH	EU/1/00/140/001	Powder for solution for infusion	- S01LA - S01LA01	- Verteporfin		- Intravenous use
Vitafen 100mg Film-coated Tablets	Phoenix Labs	PA1113/009/001	Film-coated tablet	- M01AB - M01AB16	- Aceclofenac	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vitaros 2 mg/g cream	Recordati Ireland Limited	PA1404/003/001	Cream	- G04BE - G04BE01	- Alprostadil		- Cutaneous use
Vitaros 3 mg/g cream	Recordati Ireland Limited	PA1404/003/002	Cream	- G04BE - G04BE01	- Alprostadil		- Cutaneous use
Vitlipid N Adult concentrate for emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/067/001	Concentrate for emulsion for infusion	- B05XC	- Ergocalciferol - Phytomenadione - Retinol palmitate - Dl-alpha-tocopherol		- Intravenous use
Vitlipid N Infant concentrate for emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/067/002	Concentrate for emulsion for infusion	- B05XC	- Retinol palmitate - Ergocalciferol - Dl-alpha-tocopherol - Phytomenadione	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
VITRAKVI	Bayer AG	EU/1/19/1385/001	Capsule, hard	- L01XE53	- LAROTRECTINIB - LAROTRECTINIB SULFATE	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
VITRAKVI	Bayer AG	EU/1/19/1385/002	Capsule, hard	- L01XE	- LAROTRECTINIB SULFATE - LAROTRECTINIB	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vivanza	Bayer Schering Pharma AG	EU/1/03/249/016	Orodispersible tablet	- G04BE - G04BE09	- Vardenafil hydrochloride trihydrate (micronized)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Vividrin Antiallergic Eye Drops, Solution 2% w/v	Bausch + Lomb Ireland Limited	PA23259/005/001	Eye drops, solution	- S01GX - S01GX01	- Sodium cromoglycate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Vividrin Preservative Free SDU 2% w/v Eye Drops solution	Bausch + Lomb Ireland Limited	PA23259/005/002	Eye drops, solution	- S01GX - S01GX01	- Sodium cromoglycate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Vizamyl	GE Healthcare AS	EU/1/14/941/001-002	Solution for injection	- V09AX	- Flutemetamol (18F)	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Vizarsin	KRKA, d.d., Novo mesto	EU/1/09/551/013-017	Orodispersible tablet	- G04BE - G04BE03	- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vizarsin	KRKA, d.d., Novo mesto	EU/1/09/551/018-022 Interchangeable List Code: IC0063-023-004	Orodispersible tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vizarsin	KRKA, d.d., Novo mesto	EU/1/09/551/023-027	Orodispersible tablet	- G04BE - G04BE03	- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vizarsin 100 mg film-coated tablets	KRKA, d.d., Novo mesto	EU/1/09/551/9-12 Interchangeable List Code: IC0063-024-014	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vizarsin 25 mg film-coated tablets	KRKA, d.d., Novo mesto	EU/1/09/551/1-4 Interchangeable List Code: IC0063-022-014	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vizarsin 50 mg film-coated tablets	KRKA, d.d., Novo mesto	EU/1/09/551/5-8 Interchangeable List Code: IC0063-023-003	Film-coated tablet		- Sildenafil	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vizimpro	Pfizer Europe MA EEIG	EU/1/19/1354/001	Film-coated tablet	- L01XE47	- DACOMITINIB MONOHYDRATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vizimpro	Pfizer Europe MA EEIG	EU/1/19/1354/002	Film-coated tablet	- L01XE47	- DACOMITINIB MONOHYDRATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vizimpro	Pfizer Europe MA EEIG	EU/1/19/1354/003	Film-coated tablet	- L01XE47	- DACOMITINIB MONOHYDRATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
VOCABRIA	ViiV Healthcare BV	EU/1/20/1481/001	Film-coated tablet	- J05AJ04 - J05AX	- cabotegravir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
VOCABRIA	ViiV Healthcare BV	EU/1/20/1481/002	Prolonged-release suspension for injection	- J05AJ04	- cabotegravir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
VOCABRIA	ViiV Healthcare BV	EU/1/20/1481/003	Prolonged-release suspension for injection	- J05AJ04 - J05AX	- cabotegravir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Vokanamet	Janssen-Cilag International NV	EU/1/14/918/001-003	Film-coated tablet	- A10BD16	- Metformin Hydrochloride - Purified water - Croscarmellose sodium - Hypromellose 2910, 15 mpa.s - MICROCRYSTALLINE CELLULOSE - Canagliflozin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Vokanamet	Janssen-Cilag International NV	EU/1/14/918/004-006	Film-coated tablet	- A10BD16	- Metformin Hydrochloride - MICROCRYSTALLINE CELLULOSE - Hypromellose 2910, 15 mpa.s - Purified water - Croscarmellose sodium - Canagliflozin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vokanamet	Janssen-Cilag International NV	EU/1/14/918/007-009	Film-coated tablet	- A10BD16	- MICROCRYSTALLINE CELLULOSE - Croscarmellose sodium - Canagliflozin - Purified water - Metformin Hydrochloride - Hypromellose 2910, 15 mpa.s	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vokanamet	Janssen-Cilag International NV	EU/1/14/918/010-012	Film-coated tablet	- A10BD16	- Purified water - Hypromellose 2910, 15 mpa.s - Canagliflozin - Croscarmellose sodium - MICROCRYSTALLINE CELLULOSE - Metformin Hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Volibris	GlaxoSmithKline (Ireland) Limited	EU/1/08/451/001-002	Film-coated tablet	- C02KX02	- Ambrisentan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Volibris	GlaxoSmithKline (Ireland) Limited	EU/1/08/451/003-004	Film-coated tablet	- C02KX02	- Ambrisentan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Volibris	GlaxoSmithKline (Ireland) Limited	EU/1/08/451/005	Film-coated tablet	- C02KX02	- Ambrisentan	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Voltarol 1% w/w Gel	Haleon Ireland Limited	PA0678/140/001 Interchangeable List Code: IC0056-115-043	Gel		- Diclofenac sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Voltarol 50 mg Gastro-Resistant Tablets	Novartis Ireland Limited	PA0896/034/001 Interchangeable List Code: IC0056-023-016	Gastro-resistant tablet		- Diclofenac sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Voltarol Emulgel 1% w/w Gel	PCO Manufacturing Ltd.	PPA0465/442/001	Gel	- M02AA15	- Diclofenac sodium		- Topical
Voltarol Emulgel 1% w/w Gel	Haleon Ireland Limited	PA0678/140/002	Gel	- D11AX - M02AA15	- Diclofenac sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Topical
Voltarol Emulgel Extra Strength 2% w/w gel	Haleon Ireland Limited	PA0678/140/003	Gel	- M02AA - M02AA15	- Diclofenac sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Cutaneous use
Voltarol Emulgel Extra Strength 2% w/w gel	PCO Manufacturing Ltd.	PPA0465/442/002	Gel	- M02AA15	- Diclofenac sodium (as diclofenac diethylammonium)		- Cutaneous use
Voltarol Emulgel Extra Strength 2% w/w gel	IMED Healthcare Ltd.	PPA1463/221/001	Gel	- M02AA - M02AA15	- Diclofenac sodium	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Cutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Voltarol Ophtha Multidose 1mg/ml Eye Drops Solution	Laboratoires Thea	PA1107/009/002	Eye drops, solution	- S01BC - S01BC03	- Diclofenac sodium		- Ocular use
Voltarol Retard 100 mg Film-coated Prolonged Release Tablets	Novartis Ireland Limited	PA0896/034/002 Interchangeable List Code: IC0056-024-024	Prolonged-release tablet		- Diclofenac sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Voltarol Retard 75 mg Film-coated Prolonged-release Tablets	Novartis Ireland Limited	PA0896/034/003 Interchangeable List Code: IC0056-028-024	Prolonged-release tablet		- Diclofenac sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Voltfast Sachets 50mg Powder for Oral Solution	Wisdom Pharmaceutical Technology Co Limited	PA2308/001/001	Powder for oral solution	- M01AB - M01AB05	- Diclofenac potassium	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Voncento	CSL Behring GmbH	EU/1/13/857/001	Powder and solvent for solution for injection/infusion	- B02BD - B02BD06	- Human coagulation factor viii - Von willebrand factor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Voncento	CSL Behring GmbH	EU/1/13/857/002	Powder and solvent for solution for injection/infusion	- B02BD - B02BD06	- Von willebrand factor - Human coagulation factor viii	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Voncento	CSL Behring GmbH	EU/1/13/857/003	Powder and solvent for solution for injection/infusion	- B02BD - B02BD06	- Human coagulation factor viii - Von willebrand factor	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Voncento	CSL Behring GmbH	EU/1/13/857/004	Powder and solvent for solution for injection/infusion	- B02BD - B02BD06	- Von willebrand factor - Human coagulation factor viii	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Vonodiol 100 mcg / 20 mcg Film-coated Tablets	Theramex Ireland Limited	PA22668/004/001	Film-coated tablet	- G03AA - G03AA07	- Levonorgestrel - Ethinylestradiol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Voquily 1 mg/ml oral solution	Clinigen Healthcare B.V.	PA22701/002/001	Oral solution	- N05CH01	- Melatonin	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Voraxaze	Serb S.A.S.	EU/1/21/1586/001	Powder for solution for injection	- V03AF09	- Glucarpidase	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Voriconazole 200mg powder for solution for infusion	hameln pharma gmbh	PA2237/006/001	Powder for solution for infusion	- J02AC03	- Voriconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Voriconazole 200mg powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/020/001	Powder for solution for infusion	- J02AC - J02AC03	- Voriconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Voriconazole Accord	Accord Healthcare S.L.U.	EU/1/13/835/001-009	Film-coated tablet	- J02AC - J02AC03	- Voriconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Voriconazole Accord	Accord Healthcare S.L.U.	EU/1/13/835/010-018	Film-coated tablet	- J02AC - J02AC03	- Voriconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Voriconazole Hospira	Hikma Farmacêutica (Portugal) S.A.	EU/1/15/1004/001-002	Powder for solution for infusion	- J02AC - J02AC03	- Voriconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Voriconazole Ibisqus 200 mg powder for solution for infusion	Instituto Biochimico Italiano G. Lorenzini S.p.A.	PA2220/001/001	Powder for solution for infusion	- J02AC - J02AC03	- Voriconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Voriconazole Teva 200 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/181/001	Film-coated tablet	- J02AC - J02AC03	- Voriconazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vortioxetine Clonmel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/385/002	Film-coated tablet	- N06AX26	- Vortioxetine hydrobromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vortioxetine Clonmel 15 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/385/003	Film-coated tablet	- N06AX26	- Vortioxetine hydrobromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vortioxetine Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/385/004	Film-coated tablet	- N06AX26	- Vortioxetine hydrobromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vortioxetine Clonmel 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/385/001	Film-coated tablet	- N06AX26	- Vortioxetine hydrobromide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Vosevi	Gilead Sciences Ireland UC	EU/1/17/1223/001	Film-coated tablet	- J05A	- Sofosbuvir - Velpatasvir - Voxilaprevir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vosevi	Gilead Sciences Ireland UC	EU/1/17/1223/002	Film-coated tablet	- J05A	- Sofosbuvir - Velpatasvir - Voxilaprevir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Votrient	Novartis Europharm Limited	EU/1/10/628/001-2	Film-coated tablet	- L01XE - L01XE11	- Pazopanib hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Votrient	Novartis Europharm Limited	EU/1/10/628/003-4	Film-coated tablet	- L01XE - L01XE11	- Pazopanib hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Votubia	Novartis Europharm Limited	EU/1/11/710/001-003	Tablet	- L01XE - L01XE10	- Rad n bht		- Oral use
Votubia	Novartis Europharm Limited	EU/1/11/710/004-005	Tablet	- L01XE - L01XE10	- Rad n bht		- Oral use
Votubia	Novartis Europharm Limited	EU/1/11/710/006-007	Tablet	- L01XE - L01XE10	- Rad n bht		- Oral use
Votubia	Novartis Europharm Limited	EU/1/11/710/009-011	Dispersible tablet	- L01XE - L01XE10	- Rad n bht	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Votubia	Novartis Europharm Limited	EU/1/11/710/012-013	Dispersible tablet	- L01XE - L01XE10	- Rad n bht	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Votubia	Novartis Europharm Limited	EU/1/11/710/014-015	Dispersible tablet	- L01XE - L01XE10	- Rad n bht	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Votubia	Novartis Europharm Limited	EU/1/11/710/016	Dispersible tablet	- L01XE - L01XE10	- Everolimus	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Voxzogo	BioMarin International Limited	EU/1/21/1577/001	Powder and solvent for solution for injection	- M05BX - M05BX07	- Vosoritide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Voxzogo	BioMarin International Limited	EU/1/21/1577/002	Powder and solvent for solution for injection	- M05BX07	- Vosoritide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Voxzogo	BioMarin International Limited	EU/1/21/1577/003	Powder and solvent for solution for injection	- M05BX07	- Vosoritide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
VPRIV	Shire Pharmaceuticals Ireland Limited	EU/1/10/646/002	Powder for solution for infusion	- A16AB10	- Velaglucerase alfa		- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Vumerity	Biogen Netherlands B.V.	EU/1/21/1585/001-002	Gastro-resistant capsule, hard	- L04AX - L04AX09	- Diroximel Fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vydura	Biohaven Pharmaceutical Ireland DAC	EU/1/22/1645/001-002	Orodispersible tablet	- N02C - N02CD06	- Rimegepant sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vydura	Pfizer Europe MA EEIG	EU/1/22/1645/001-003	Oral lyophilisate	- N02C - N02CD06	- Rimegepant sulfate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vyepti	H. Lundbeck A/S	EU/1/21/1599/001	Concentrate for solution for infusion	- N02C - N02CD05	- Eptinezumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Vyepti	H. Lundbeck A/S	EU/1/21/1599/003	Concentrate for solution for infusion	- N02CD05	- Eptinezumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Vyndaqel	Pfizer Europe MA EEIG	EU/1/11/717/001	Capsule, soft	- N07XX - N07XX08	- Tafamidis	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vyndaqel	Pfizer Europe MA EEIG	EU/1/11/717/003-004	Capsule, soft	- N07XX08	- Tafamidis	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Vyvgart	Argenx	EU/1/22/1674/001	Concentrate for solution for infusion	- L04AA - L04AA58	- Efgartigimod ALFA	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Vyvgart	Argenx	EU/1/22/1674/002	Solution for injection	- L04AA58	- Efgartigimod ALFA	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Vyxeos	Jazz Pharmaceuticals Ireland Limited	EU/1/18/1308/001-003	Powder for concentrate for solution for infusion	- L01XY01	- Cytarabine - DAUNOMYCIN HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Wakix	Bioprojet Pharma	EU/1/15/1068/001	Film-coated tablet	- N07XX - N07XX11	- Pitolisant hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Wakix	Bioprojet Pharma	EU/1/15/1068/002	Film-coated tablet	- N07XX - N07XX11	- Pitolisant hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Warfant 1 mg Tablets	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/139/001	Tablet	- B01AA - B01AA03	- WARFARIN SODIUM		- Oral use
Warfant 3 mg Tablets	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/139/002	Tablet	- B01AA - B01AA03	- WARFARIN SODIUM		- Oral use
Warfant 5 mg Tablets	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/139/003	Tablet	- B01AA - B01AA03	- WARFARIN SODIUM		- Oral use
Warfarin Teva 0.5mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/001	Tablet	- B01AA - B01AA03	- Warfarin sodium clathrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Warfarin Teva 1 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/002	Tablet	- B01AA - B01AA03	- Warfarin sodium clathrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Warfarin Teva 10 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/009	Tablet	- B01AA - B01AA03	- Warfarin sodium clathrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Warfarin Teva 2 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/003	Tablet	- B01AA - B01AA03	- Warfarin sodium clathrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Warfarin Teva 2.5 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/004	Tablet	- B01AA - B01AA03	- Warfarin sodium clathrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Warfarin Teva 3 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/005	Tablet	- B01AA - B01AA03	- Warfarin sodium clathrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Warfarin Teva 5 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/006	Tablet	- B01AA - B01AA03	- Warfarin sodium clathrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Warfarin Teva 6 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/007	Tablet	- B01AA - B01AA03	- Warfarin sodium clathrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Warfarin Teva 7.5 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/008	Tablet	- B01AA - B01AA03	- Warfarin sodium clathrate	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use
Warticon 0.15% w/w Cream	Phoenix Labs	PA1113/017/001	Cream	- D06BB - D06BB04	- Podophyllotoxin		- Cutaneous use
Water for Injections Ph Eur	Noridem Enterprises Limited	PA1122/001/001	Solvent for parenteral use	- V07AB	- Water for injections	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Water for Injections Ph. Eur	B. Braun Medical Limited	PA0179/009/003	Solvent for parenteral use	- V07AB	- Water for injections		- Intravenous use
Water for Injections Ph. Eur., viaflo container	Baxter Holding B.V.	PA2299/013/001	Solvent for parenteral use	- V07AB	- Water for injection	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
Water for Injections solvent for parenteral use	CSL Behring GmbH	PA0800/011/001	Solvent for parenteral use	- V07AB	- Water for injection	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Water for injections, solvent for parenteral use	Fresenius Kabi Deutschland GmbH	PA2059/035/001	Solvent for parenteral use	- V07AB	- Water for injections	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use - Subcutaneous use
WAXSOL 0.5% w/v Ear Drops Solution	Mylan IRE Healthcare Limited	PA2010/056/001	Ear drops, solution	- S02DC	- Docusate sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	
Waylivra	Akcea Therapeutics Ireland Ltd	EU/1/19/1360/001-002	Solution for injection in pre-filled syringe	- C10AX18	- VOLANESORSEN SODIUM		- Subcutaneous use
Wecol 6.9 g powder for oral solution	Stirling Anglian Pharmaceuticals Ireland Limited	PA23138/001/001	Powder for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium chloride - Potassium chloride - Sodium hydrogen carbonate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Wecol Paediatric 6.9 g powder for oral solution	Stirling Anglian Pharmaceuticals Ireland Limited	PA23138/001/002	Powder for oral solution	- A06AD - A06AD65	- Macrogol 3350 - Sodium chloride - Potassium chloride - Sodium hydrogen carbonate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Wegovy	Novo Nordisk A/S	EU/1/21/1608/001	Solution for injection in pre-filled pen	- A10BJ06	- Semaglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Wegovy	Novo Nordisk A/S	EU/1/21/1608/002	Solution for injection in pre-filled pen	- A10BJ06	- Semaglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Wegovy	Novo Nordisk A/S	EU/1/21/1608/003	Solution for injection in pre-filled pen	- A10BJ06	- Semaglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Wegovy	Novo Nordisk A/S	EU/1/21/1608/004	Solution for injection in pre-filled pen	- A10BJ06	- Semaglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Wegovy	Novo Nordisk A/S	EU/1/21/1608/005	Solution for injection in pre-filled pen	- A10BJ06	- Semaglutide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Whitfield's Antifungal 3% w/w & 6% w/w Ointment	Ovelle Limited	PA0206/024/001	Ointment	- D01AE - D01AE12	- Salicylic acid - Benzoic acid	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical use
Wilate, 1000 IU VWF/1000 IU FVIII, powder and solvent for solution for injection	Octapharma (IP) SPRL	PA2219/008/002	Powder and solvent for solution for injection	- B02BD - B02BD06	- Human factor viii - Von willebrand factor human	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Wilate, 500 IU VWF/500 IU FVIII, powder and solvent for solution for injection	Octapharma (IP) SPRL	PA2219/008/001	Powder and solvent for solution for injection	- B02BD - B02BD06	- Human factor viii - Von willebrand factor human	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
WILZIN	Recordati Rare Diseases	EU/1/04/286/1-2	Capsule, hard	- A16AX - A16AX05	- Zinc acetate dihydrate		- Oral use
Wynzora 50 micrograms/g + 0.5 mg/g cream	Almirall, S.A.	PA0968/006/001	Cream	- D05AX52	- Calcipotriol - Betamethasone	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Xadago	Zambon S.p.A.	EU/1/14/984/001-005	Film-coated tablet	- N04B	- Safinamide methanesulfonate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xadago	Zambon S.p.A.	EU/1/14/984/006-010	Film-coated tablet	- N04B	- Safinamide methanesulfonate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
XAGRID	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/04/295/001	Capsule, hard	- L01XX - L01XX35	- Anagrelide hydrochloride		- Oral use
Xalacom 50 micrograms/mL + 5 mg/mL, eye drops, solution	Upjohn EESV	PA23055/008/001 Interchangeable List Code: IC0100-153-045	Eye drops, solution		- Latanoprost - Timolol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Xalacom 50 micrograms/ml + 5 mg/ml, eye drops, solution	PCO Manufacturing Ltd.	PPA0465/406/001 Interchangeable List Code: IC0100-153-045	Eye drops, solution		- Latanoprost - Timolol	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Ocular use
Xalatan 50 micrograms/mL Eye drops, solution	Upjohn EESV	PA23055/009/001 Interchangeable List Code: IC0096-152-045	Eye drops, solution		- Latanoprost	Full application (Article 8(3) of Directive No 2001/83/EC)	- Ocular use
Xalkori	Pfizer Europe MA EEIG	EU/1/12/793/001-002	Capsule, hard	- L01XE16	- Crizotinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xalkori	Pfizer Europe MA EEIG	EU/1/12/793/003-004	Capsule, hard	- L01XE16	- Crizotinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Xaluprine	Nova Laboratories Ireland Limited	EU/1/11/727/001	Oral suspension	- L01BB02	- Mercaptopurine monohydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Xamiol 50 micrograms/g + 0.5 mg/g gel	LEO Pharma A/S	PA1025/003/001	Gel	- D05AX - D05AX52	- Calcipotriol - Betamethasone	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Cutaneous use
Xanax 1 mg Tablets	Upjohn EESV	PA23055/010/001 Interchangeable List Code: IC0094-039-002	Tablet		- Alprazolam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xanax 250 microgram Tablets	Upjohn EESV	PA23055/010/002 Interchangeable List Code: IC0094-145-002	Tablet		- Alprazolam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xanax 500 microgram Tablets	Upjohn EESV	PA23055/010/003 Interchangeable List Code: IC0094-040-002	Tablet		- Alprazolam	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xarelto	Bayer AG	EU/1/08/472/011-016	Film-coated tablet	- B01AF - B01AF01	- Rivaroxaban	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xarelto	Bayer AG	EU/1/08/472/017-021	Film-coated tablet	- B01AF - B01AF01	- Rivaroxaban	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xarelto	Bayer AG	EU/1/08/472/025-033	Film-coated tablet	- B01AF - B01AF01	- Rivaroxaban	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xarelto	Bayer AG	EU/1/08/472/1-8	Film-coated tablet	- B01AF - B01AF01	- Rivaroxaban	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xarelto 1 mg/ml granules for oral suspension	Bayer AG	EU/1/08/472/050-051	Granules for oral suspension	- B01AF01	- Rivaroxaban	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xatger 10mg prolonged release tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/079/002	Prolonged-release tablet	- G04CA - G04CA01	- Alfuzosin hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Xatral 10mg Prolonged Release Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/162/003	Prolonged-release tablet	- G04CA - G04CA01	- Alfuzosin hydrochloride		- Oral use
Xelevia 100 mg film-coated tablets	Merck Sharp & Dohme BV	EU/1/07/382/13-18 Interchangeable List Code: IC0131-024-003	Film-coated tablet		- Sitagliptin phosphate monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xelevia 25 mg film-coated tablets	Merck Sharp & Dohme BV	EU/1/07/382/1-6 Interchangeable List Code: IC0131-022-003	Film-coated tablet		- Sitagliptin phosphate monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xelevia 50 mg film-coated tablets	Merck Sharp & Dohme BV	EU/1/07/382/7-12 Interchangeable List Code: IC0131-023-003	Film-coated tablet		- Sitagliptin phosphate monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xeljanz	Pfizer Europe MA EEIG	EU/1/17/1178/001-003	Film-coated tablet	- L04AA - L04AA29	- Tofacitinib citrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
XELJANZ	Pfizer Europe MA EEIG	EU/1/17/1178/005-009	Film-coated tablet	- L04AA29	- Tofacitinib citrate		- Oral use
Xeljanz	Pfizer Europe MA EEIG	EU/1/17/1178/010-013	Prolonged-release tablet	- L01XC32 - L04AA	- TOFACITINIB	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Xeljanz	Pfizer Europe MA EEIG	EU/1/17/1178/015	Oral solution	- L04AA29	- TOFACITINIB	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xeloda	Cheplapharm Arzneimittel GmbH	EU/1/00/163/001 Interchangeable List Code: IC0079-062-003	Film-coated tablet		- Capecitabine		- Oral use
Xeloda	Cheplapharm Arzneimittel GmbH	EU/1/00/163/002 Interchangeable List Code: IC0079-117-003	Film-coated tablet		- Capecitabine		- Oral use
Xenetix 250mg I/ml Solution for Injection	Guerbet	PA0686/002/001	Solution for injection	- V08AB - V08AB11	- Iobitridol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraarterial use
Xenetix 300mg I/ml Solution for Injection	Guerbet	PA0686/002/002	Solution for injection	- V08AB - V08AB11	- Iobitridol	Full application (Article 8(3) of Directive No 2001/83/EC)	
Xenetix 300mg I/ml Solution for injection, polypropylene bag	Guerbet	PA0686/002/004	Solution for injection	- V08AB11	- Iobitridol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Xenetix 350mg I/ml Solution for Injection	Guerbet	PA0686/002/003	Solution for injection	- V08AB - V08AB11	- Iobitridol	Full application (Article 8(3) of Directive No 2001/83/EC)	
Xenetix 350mg I/ml Solution for injection, polypropylene bag	Guerbet	PA0686/002/005	Solution for injection	- V08AB11	- Iobitridol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Xenical	Cheplapharm Arzneimittel GmbH	EU/1/98/071/001	Capsule, hard	- A08AB - A08AB01	- Orlistat		- Oral use
Xenical	CHEPLAPHARM Arzneimittel GmbH	EU/1/98/071/002	Capsule, hard	- A08AB - A08AB01	- Orlistat		- Oral use
Xenical	Cheplapharm Arzneimittel GmbH	EU/1/98/071/003	Capsule, hard	- A08AB - A08AB01	- Orlistat		
Xenical	Cheplapharm Arzneimittel GmbH	EU/1/98/071/004	Capsule, hard	- A08AB - A08AB01	- Orlistat		- Oral use
Xenical	Cheplapharm Arzneimittel GmbH	EU/1/98/071/005	Capsule, hard	- A08AB - A08AB01	- Orlistat		- Oral use
Xenical	Cheplapharm Arzneimittel GmbH	EU/1/98/071/006	Capsule, hard	- A08AB - A08AB01	- Orlistat		- Oral use
Xenleta	Nabriva Therapeutics Ireland DAC	EU/1/20/1457/001	Concentrate and solvent for solution for infusion	- J01XX - J01XX12	- Lefamulin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Oral use
Xenleta	Nabriva Therapeutics Ireland DAC	EU/1/20/1457/002	Film-coated tablet	- J01XX - J01XX12	- Lefamulin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Oral use
Xenpozyme	Genzyme Europe B.V.	EU/1/22/1659/001-004	Powder for concentrate for solution for infusion	- A16AB - A16AB25	- Olipudase Alfa	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
XEOMIN 100 units powder for solution for injection	Merz Pharmaceuticals GmbH	PA1907/001/002	Powder for solution for injection	- M03AX01	- Clostridium botulinum neuro-toxin type a (150 kd), free from complexing proteins	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraglandular use - Intramuscular use
XEOMIN 200 units powder for solution for injection	Merz Pharmaceuticals GmbH	PA1907/001/003	Powder for solution for injection	- M03AX01	- Clostridium botulinum neuro-toxin type a (150 kd), free from complexing proteins	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraglandular use - Intramuscular use
XEOMIN 50 units powder for solution for injection	Merz Pharmaceuticals GmbH	PA1907/001/001	Powder for solution for injection	- M03AX01	- Clostridium botulinum neuro-toxin type a (150 kd), free from complexing proteins	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intraglandular use - Intramuscular use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Xeplion 100 mg prolonged-release suspension for injection	Janssen-Cilag International NV	EU/1/11/672/004 Interchangeable List Code: IC0130-024-064	Prolonged-release suspension for injection		- Paliperidone palmitate (r092670)		- Intramuscular use
Xeplion 150 mg prolonged-release suspension for injection	Janssen-Cilag International NV	EU/1/11/672/005-006 Interchangeable List Code: IC0130-062-064	Prolonged-release suspension for injection		- Paliperidone palmitate (r092670)		- Intramuscular use
Xeplion 25 mg prolonged-release suspension for injection	Janssen-Cilag International NV	EU/1/11/672/001 Interchangeable List Code: IC0130-022-064	Prolonged-release suspension for injection		- Paliperidone palmitate (r092670)		- Intramuscular use
Xeplion 50 mg prolonged-release suspension for injection	Janssen-Cilag International NV	EU/1/11/672/002 Interchangeable List Code: IC0130-023-064	Prolonged-release suspension for injection		- Paliperidone palmitate (r092670)		- Intramuscular use
Xeplion 75 mg prolonged-release suspension for injection	Janssen-Cilag International NV	EU/1/11/672/003 Interchangeable List Code: IC0130-028-064	Prolonged-release suspension for injection		- Paliperidone palmitate (r092670)		- Intramuscular use
Xerava	Paion Deutschland GmbH	EU/1/18/1312/001	Powder for concentrate for solution for infusion	- J01AA13	- ERAVACYCLINE		- Intravenous use
Xerava	Tetraphase Pharmaceuticals Ireland Limited	EU/1/18/1312/003-004	Powder for concentrate for solution for infusion	- J01AA13	- ERAVACYCLINE	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Xermelo	Serb S.A.S.	EU/1/17/1224/001-002	Film-coated tablet	- A16AX	- Telotristat etiprate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xevudy	GlaxoSmithKline Trading Services Limited	EU/1/21/1562/001	Concentrate for solution for infusion	- J06BD05	- Sotrovimab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
XGEVA	Amgen Europe B.V.	EU/1/11/703/001-002	Solution for injection	- M05BX - M05BX04	- Denosumab		- Subcutaneous use
Xigduo	AstraZeneca AB	EU/1/13/900/001-006 Interchangeable List Code: IC0090-143-003	Film-coated tablet		- Dapagliflozin propanediol monohydrate - Metformin Hydrochloride	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Xigduo	AstraZeneca AB	EU/1/13/900/007-012 Interchangeable List Code: IC0090-142-003	Film-coated tablet		- Metformin Hydrochloride - Dapagliflozin propanediol monohydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
Xiliarx	Novartis Europharm Limited	EU/1/08/486/1-11	Tablet	- A10BD08	- Vildagliptin	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Xilmac 4 mg/ml Solution for injection	Macure Healthcare Limited	PA23314/001/001	Solution for injection	- N05BA - N05BA06	- Lorazepam		- Intramuscular use - Intravenous use
Ximluci	Stada Arzneimittel AG	EU/1/22/1691/001	Solution for injection	- S01LA04	- Ranibizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravitreal use
Ximluci	Stada Arzneimittel AG	EU/1/22/1691/002	Solution for injection	- S01LA04	- Ranibizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravitreal use
Xofigo	Bayer AG	EU/1/13/873/001	Solution for injection	- V10XX - V10XX03	- Radium-223 chloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Xofluza	Roche Registration GmbH	EU/1/20/1500/001	Film-coated tablet	- J05AX25	- Baloxavir Marboxil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xofluza	Roche Registration GmbH	EU/1/20/1500/002	Film-coated tablet		- Baloxavir Marboxil	New active substance (Article 8(3) of Directive No 2001/83/EC)	
Xofluza	Roche Registration GmbH	EU/1/20/1500/003	Film-coated tablet	- J05AX25	- Baloxavir Marboxil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xofluza	Roche Registration GmbH	EU/1/20/1500/005	Granules for oral suspension	- J05AX25	- Baloxavir Marboxil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xolair	Novartis Europharm Limited	EU/1/05/319/001	Powder and solvent for solution for injection	- R03DX - R03DX05	- Omalizumab		- Subcutaneous use
Xolair	Novartis Europharm Limited	EU/1/05/319/002	Powder and solvent for solution for injection	- R03DX - R03DX05	- Omalizumab		- Subcutaneous use
Xolair	Novartis Europharm Limited	EU/1/05/319/012-014	Solution for injection in pre-filled syringe	- R03DX05	- Omalizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Xolair	Novartis Europharm Limited	EU/1/05/319/015-017	Solution for injection in pre-filled pen	- R03DX05	- Omalizumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Xolair	Novartis Europharm Limited	EU/1/05/319/5-7	Solution for injection in pre-filled syringe	- R03DX - R03DX05	- Omalizumab		- Subcutaneous use
Xolair 150 mg solution for injection in pre-filled syringe	Novartis Europharm Limited	EU/1/05/319/8-10	Solution for injection in pre-filled syringe	- R03DX - R03DX05	- Omalizumab		- Subcutaneous use
Xonvea 10 mg/10 mg gastro-resistant tablets	Exeltis healthcare S.L.	PA22998/006/001	Gastro-resistant tablet	- R06AA59	- Doxylamine hydrogen succinate - Pyridoxine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xonvea MR 20 mg/20 mg modified-release tablets	Exeltis healthcare S.L.	PA22998/003/001	Modified-release tablet	- R06AA59	- Doxylamine hydrogen succinate - Pyridoxine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
XOSPATA	Astellas Pharma Europe B.V.	EU/1/19/1399/001	Film-coated tablet	- L01XE	- Gilteritinib Fumarate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xoterna Breezhaler	Novartis Europharm Limited	EU/1/13/863/001-006	Inhalation powder, hard capsule	- R03AL - R03AL04	- Indacaterol maleate - Glycopyrronium bromide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use
Xromi	Nova Laboratories Ireland Limited	EU/1/19/1366/001	Oral solution	- L01XX - L01XX05	- Hydroxycarbamide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Xtandi	Astellas Pharma Europe BV	EU/1/13/846/001	Capsule, soft	- L02BB04	- Enzalutamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xtandi	Astellas Pharma Europe B.V.	EU/1/13/846/002	Film-coated tablet	- L02BB - L02BB04	- Enzalutamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xtandi	Astellas Pharma Europe B.V.	EU/1/13/846/003	Film-coated tablet	- L02BB - L02BB04	- Enzalutamide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xtex 250 mg /5 ml oral solution	Rowa Pharmaceuticals Limited	PA0074/071/001	Oral solution	- R05CB - R05CB03	- Carbocisteine	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Xultophy	Novo Nordisk A/S	EU/1/14/947/001-004	Solution for injection	- A10	- Insulin degludec - Liraglutide	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Subcutaneous use
Xydalba	AbbVie Deutschland GmbH & Co. KG	EU/1/14/986/001	Powder for concentrate for solution for infusion	- J01XA - J01XA04	- Dalbavancin hcl	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Xylocaine 10 mg/delivered dose Mucosal Spray	Aspen Pharma Trading Limited	PA1691/028/001	Oromucosal spray, solution	- N01BB02	- Lidocaine		- Oromucosal use
Xylocaine 2% w/v with Adrenaline (Epinephrine) 1:80,000 DENTAL Solution for Injection	DENTSPLY DeTrey GmbH	PA1045/003/001	Solution for injection	- N01BB - N01BB04	- Lidocaine hydrochloride - Adrenaline tartrate		- Intravenous use
Xylocaine 2% with Adrenaline (Epinephrine) (1:200,000) Solution for Injection	Aspen Pharma Trading Limited	PA1691/027/001	Solution for injection	- N01BB - N01BB52	- Adrenaline tartrate - Lidocaine hydrochloride		- Infiltration
Xylonor, 50 mg/g + 1.5 mg/g, gingival gel	Septodont	PA0196/014/002	Gingival gel	- N01BB - N01BB52	- Lidocaine - Cetrimide		- Topical
Xymel 50 mg Capsules	Clonmel Healthcare Ltd	PA0126/099/001 Interchangeable List Code: IC0074-023-008	Capsule, hard		- Tramadol hydrochloride		- Oral use
Xymel Comp 37.5mg/325mg Film-Coated Tablets	Clonmel Healthcare Ltd	PA0126/244/001 Interchangeable List Code: IC0077-133-014	Film-coated tablet		- Tramadol hydrochloride - Paracetamol	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Xyrem	UCB Pharma SA	EU/1/05/312/001	Oral solution	- N07XX04	- Sodium Oxybate		- Oral use
Xyzal 0.5 mg/ml oral solution	UCB (Pharma) Ireland Limited	PA0891/003/003 Interchangeable List Code: IC0095-155-019	Oral solution		- Levocetirizine dihydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xyzal 0.5 mg/ml oral solution	PCO Manufacturing Ltd.	PPA0465/169/002 Interchangeable List Code: IC0095-155-019	Oral solution		- Levocetirizine dihydrochloride		- Oral use
Xyzal 0.5 mg/ml oral solution	IMED Healthcare Ltd.	PPA1463/170/001 Interchangeable List Code: IC0095-155-019	Oral solution		- Levocetirizine dihydrochloride		- Oral use
Xyzal 5 mg film-coated tablets	UCB (Pharma) Ireland Limited	PA0891/003/001 Interchangeable List Code: IC0095-001-003	Film-coated tablet		- Levocetirizine dihydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Xyzal 5 mg/ml oral drops, solution	UCB (Pharma) Ireland Limited	PA0891/003/002	Oral drops, solution	- R06AE - R06AE09	- Levocetirizine dihydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Yargesa	Piramal Critical Care B.V.	EU/1/17/1176/001	Capsule, hard	- A16AX - A16AX06	- Miglustat	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Yasmin 0.03 mg / 3 mg film-coated tablets	Bayer Limited	PA1410/023/001	Film-coated tablet	- G03AA - G03AA12	- Drospirenone - Ethinylestradiol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Yasminelle 0.02 mg/3 mg film-coated tablets	Bayer Limited	PA1410/024/001	Film-coated tablet	- G03AA - G03AA12	- Ethinylestradiol - Drospirenone	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Yaz 0.02 mg/3 mg film-coated tablets	Bayer Limited	PA1410/056/001	Film-coated tablet	- G03AA - G03AA12	- Ethinylestradiol - Drospirenone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Yellox	Bausch Health Ireland Limited	EU/1/11/692/001	Eye drops, solution	- S01BC - S01BC11	- Bromfenac sodium sesquihydrate		- Ocular use
Yentreve	Eli Lilly Nederland B.V.	EU/1/04/280/001 Interchangeable List Code: IC0091-003-006	Gastro-resistant capsule, hard		- Duloxetine hydrochloride	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Yentreve	Eli Lilly Nederland B.V.	EU/1/04/280/1-6 Interchangeable List Code: IC0091-004-006	Gastro-resistant capsule, hard		- Duloxetine hydrochloride	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Yervoy	Bristol-Myers Squibb Pharma EEIG	EU/1/11/698/001-002	Concentrate for solution for infusion	- L01XC - L01XC11	- Ipilimumab	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Yesafili	Biosimilar Collaborations Ireland Limited	EU/1/23/1751/001-002	Solution for injection	- S01LA05	- Aflibercept	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravitreal use
YESCARTA	Kite Pharma EU B.V.	EU/1/18/1299/001	Dispersion for infusion	- L01X	- AXICABTAGENE CILOLEUCEL	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Yondelis	Pharma Mar S.A.	EU/1/07/417/1	Powder for concentrate for solution for infusion	- L01CX - L01CX01	- Trabectedin		- Intravenous use
Yondelis	Pharma Mar S.A.	EU/1/07/417/2	Powder for concentrate for solution for infusion	- L01CX - L01CX01	- Trabectedin		- Intravenous use
Yorvipath	Ascendis Pharma Bone Diseases A/S	EU/1/23/1766/001	Solution for injection in pre-filled pen	- H05AA05	- Palopegteriparatide - Teriparatide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Yorvipath	Ascendis Pharma Bone Diseases A/S	EU/1/23/1766/002	Solution for injection in pre-filled pen	- H05AA05	- Palopegteriparatide - Teriparatide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Yorvipath	Ascendis Pharma Bone Diseases A/S	EU/1/23/1766/003	Solution for injection in pre-filled pen	- H05AA05	- Palopegteriparatide - Teriparatide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Yselty 100 mg film-coated tablets	Theramex Ireland Limited	EU/1/21/1606/001	Film-coated tablet	- H01CC	- Linzagolix Choline	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Yselty 200 mg film-coated tablets	Theramex Ireland Limited	EU/1/21/1606/002	Film-coated tablet	- H01CC	- Linzagolix Choline	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Yttriga	Eckert & Ziegler Radiopharm GmbH	EU/1/05/322/001	Radiopharmaceutical precursor, solution	- V09	- Yttrium (90 y)		
Yuflyma	Celltrion Healthcare Hungary Kft.	EU/1/20/1513/001-012	Solution for injection	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Yuflyma	Celltrion Healthcare Hungary Kft.	EU/1/20/1513/013-016	Solution for injection	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Yuflyma	Celltrion Healthcare Hungary Kft.	EU/1/20/1513/017	Solution for injection	- L04AB04	- Adalimumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
ZABDENO	Janssen-Cilag International NV	EU/1/20/1444/001	Suspension for injection	- J07BX02	- AD26.ZEBOV	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Zacin 0.025% w/w Cream	Teva B.V.	PA1986/090/001	Cream	- M02AB	- Capsaicin		- Cutaneous use
Zaditen 0.25 mg/ml, eye drops, solution	Laboratoires Thea	PA1107/010/001	Eye drops, solution	- S01GX - S01GX08	- KETOTIFEN FUMARATE		

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Zaditen 1 mg Tablets	Alfasigma S.p.A	PA2206/004/002	Tablet	- R06AX - R06AX17	- KETOTIFEN FUMARATE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zaditen 1mg/5ml oral solution	Alfasigma S.p.A	PA2206/004/001	Oral solution	- R06AX - R06AX17	- KETOTIFEN FUMARATE		- Oral use
Zafrilla 2mg tablets	Gedeon Richter Plc	PA1330/023/001	Tablet	- G03DB08	- Dienogest	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/006 Interchangeable List Code: IC0007-001-038	Tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/11-15 Interchangeable List Code: IC0007-041-038	Tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/1-5 Interchangeable List Code: IC0007-018-035	Tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/16-21 Interchangeable List Code: IC0007-002-038	Tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/22-26 Interchangeable List Code: IC0007-032-038	Tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/27-31 Interchangeable List Code: IC0007-003-038	Tablet		- Olanzapine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/32-36 Interchangeable List Code: IC0007-001-038	Orodispersible tablet		- Olanzapine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/37-41 Interchangeable List Code: IC0007-041-038	Orodispersible tablet		- Olanzapine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/42-46 Interchangeable List Code: IC0007-002-038	Orodispersible tablet		- Olanzapine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/47-51 Interchangeable List Code: IC0007-032-038	Orodispersible tablet		- Olanzapine	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/52-56 Interchangeable List Code: IC0007-003-038	Orodispersible tablet		- Olanzapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zaltrap	Sanofi Winthrop Industrie	EU/1/12/814/001-003	Concentrate for solution for infusion	- L01XX44	- Aflibercept	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Zanaflex 2 mg Tablets	Teva Pharma B.V.	PA0749/054/001	Tablet	- M03BX - M03BX02	- Tizanidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zanaflex 2 mg Tablets	PCO Manufacturing Ltd.	PPA0465/474/001	Tablet	- M03BX - M03BX02	- Tizanidine		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Zanaflex 4 mg Tablets	PCO Manufacturing Ltd.	PPA0465/474/002	Tablet	- M03BX - M03BX02	- Tizanidine		- Oral use
Zanaflex 4 mg Tablets	Teva Pharma B.V.	PA0749/054/002	Tablet	- M03BX - M03BX02	- Tizanidine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zanidip 10 mg film-coated tablets	Recordati Industria Chimica e Farmaceutica SpA	PA0812/001/001 Interchangeable List Code: IC0020-002-003	Film-coated tablet		- Lercanidipine hydrochloride		- Oral use
Zanidip 10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/481/001 Interchangeable List Code: IC0020-002-003	Film-coated tablet		- Lercanidipine hydrochloride		- Oral use
Zanidip 10 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/203/001 Interchangeable List Code: IC0020-002-003	Film-coated tablet		- Lercanidipine hydrochloride	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Zanidip 20 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/203/002	Film-coated tablet	- C08CA13	- Lercanidipine hydrochloride	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Zanidip 20 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/481/002 Interchangeable List Code: IC0020-003-003	Film-coated tablet		- Lercanidipine hydrochloride		- Oral use
Zanidip 20mg film-coated tablets	Recordati Industria Chimica e Farmaceutica SpA	PA0812/001/002 Interchangeable List Code: IC0020-003-003	Film-coated tablet		- Lercanidipine hydrochloride		- Oral use
Zarontin 250 mg/5 ml Syrup	PCO Manufacturing Ltd.	PPA0465/456/001	Syrup	- N03AD - N03AD01	- Ethosuximide		- Oral use
Zarontin 250 mg/5 ml Syrup	IMED Healthcare Ltd.	PPA1463/181/001	Syrup	- N03AD - N03AD01	- Ethosuximide		- Oral use
Zarontin 250 mg/5 ml Syrup	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/042/001	Syrup	- N03AD01	- Ethosuximide	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Zarontin 250mg/5ml Syrup	Originalis B.V.	PPA2306/031/001	Syrup	- N03AD01	- Ethosuximide	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Zarontin 250mg/5ml Syrup	Essential Pharma (M) Limited	PA22644/005/001	Syrup	- N03AD - N03AD01	- Ethosuximide		- Oral use
Zarzio 30 MU (60 MU/ml) Solution for injection or	Sandoz GmbH	EU/1/08/495/1-4,9-12	Solution for injection/infusion in pre-filled syringe	- L03AA - L03AA02	- Ep2006 (recombinant human granulocyte-colony stimulating factor)	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Zarzio 48 MU (96 MU/ml) Solution for injection or	Sandoz GmbH	EU/1/08/495/5-8,13-16	Solution for injection/infusion in pre-filled syringe	- L03AA - L03AA02	- Ep2006 (recombinant human granulocyte-colony stimulating factor)	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use - Subcutaneous use
Zavedos 1mg/ml solution for injection	Pfizer Healthcare Ireland	PA0822/142/005	Solution for injection	- L01DB - L01DB06	- Idarubicin hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Zavesca	Janssen-Cilag International NV	EU/1/02/238/001	Capsule, hard	- A16AX - A16AX06	- Miglustat		- Oral use
Zavicefta	Pfizer Ireland Pharmaceuticals	EU/1/16/1109/001	Powder for concentrate for solution for infusion	- J01DD - J01DD52	- Avibactam sodium - Ceftazidime pentahydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Zebinix	BIAL-Portela & Ca, S.A.	EU/1/09/514/021-023	Tablet	- N03AF - N03AF04	- Eslicarbazepine acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zebinix	BIAL-Portela & Ca, S.A.	EU/1/09/514/024	Oral suspension	- N03AF - N03AF04	- Eslicarbazepine acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zebinix	BIAL-Portela & Ca, S.A.	EU/1/09/514/12-20	Tablet	- N03AF - N03AF04	- Eslicarbazepine acetate		- Oral use
Zebinix	BIAL-Portela & Ca, S.A.	EU/1/09/514/1-6	Tablet	- N03AF - N03AF04	- Eslicarbazepine acetate		- Oral use
Zebinix	BIAL-Portela & Ca, S.A.	EU/1/09/514/7-11	Tablet	- N03AF - N03AF04	- Eslicarbazepine acetate		- Oral use
Zedbac 500 mg powder for concentrate for solution for infusion	Morningside Healthcare (Malta) Limited	PA23142/010/001	Powder for concentrate for solution for infusion	- J01FA - J01FA10	- Azithromycin dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Zeffix	GlaxoSmithKline (Ireland) Limited	EU/1/99/114/001	Film-coated tablet	- J05AF - J05AF05	- Lamivudine		- Oral use
Zeffix	GlaxoSmithKline (Ireland) Limited	EU/1/99/114/002	Film-coated tablet	- J05AF - J05AF05	- Lamivudine		- Oral use
Zeffix	GlaxoSmithKline (Ireland) Limited	EU/1/99/114/003	Oral solution	- J05AF - J05AF05	- Lamivudine		- Oral use
Zejula	GlaxoSmithKline (Ireland) Limited	EU/1/17/1235/001-003	Capsule, hard	- L01XX - L01XX54	- Niraparib tosylate monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zejula	GlaxoSmithKline (Ireland) Limited	EU/1/17/1235/004-005	Film-coated tablet	- L01XK02	- Niraparid tosylate monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zelboraf	Roche Registration GmbH	EU/1/12/751/001	Film-coated tablet	- L01EC01	- Vemurafenib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zemplar 1 microgram capsules, soft	AbbVie Limited	PA1824/005/001	Capsule, soft	- H05BX - H05BX02	- Paricalcitol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zemplar 2 micrograms capsules, soft	AbbVie Limited	PA1824/005/002	Capsule, soft	- H05BX - H05BX02	- Paricalcitol	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zemplar 5 micrograms/ml solution for injection	AbbVie Limited	PA1824/005/004	Solution for injection	- H05BX - H05BX02	- Paricalcitol	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Zepatier	Merck Sharp & Dohme BV,	EU/1/16/1119/001	Film-coated tablet	- J05AX - J05AX68	- Grazoprevir - Elbasvir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zeposia	Bristol-Myers Squibb Pharma EEIG	EU/1/20/1442/001	Capsule, hard	- L04AA - L04AA38	- OZANIMOD	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zeposia	Bristol-Myers Squibb Pharma EEIG	EU/1/20/1442/002-003	Capsule, hard	- L04AA - L04AA38	- OZANIMOD	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zerbaxa	Merck Sharp & Dohme BV,	EU/1/15/1032/001	Powder for concentrate for solution for infusion	- J01DI - J01DI54	- Ceftolozane sulfate - Tazobactam sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Zercepac	Accord Healthcare S.L.U.	EU/1/20/1456/001	Powder for concentrate for solution for infusion	- L01XC03	- Trastuzumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Zerlinda 4 mg/100 ml solution for infusion	Teva B.V.	PA1986/119/001	Solution for infusion	- M05BA - M05BA08	- Zoledronic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Zerseos 0.5 mg/2.5 mg per 2.5 ml nebuliser solution	Azure Pharmaceuticals Ltd	PA22871/011/001 Interchangeable List Code: IC0081-136-052	Nebuliser solution		- Ipratropium bromide monohydrate - SALBUTAMOL SULFATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Zessly	Sandoz GmbH	EU/1/18/1280/001-005	Powder for concentrate for solution for infusion	- L04AB - L04AB02	- Infliximab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Zestan 10 mg tablets	Clonmel Healthcare Ltd	PA0126/112/003	Tablet	- C09AA - C09AA03	- Lisinopril Dihydrate		- Oral use
Zestan 2.5mg Tablet	Clonmel Healthcare Ltd	PA0126/112/001	Tablet	- C09AA - C09AA03	- Lisinopril Dihydrate		- Oral use
Zestan 20 mg tablets	Clonmel Healthcare Ltd	PA0126/112/004	Tablet	- C09AA - C09AA03	- Lisinopril Dihydrate		- Oral use
Zestan 5mg Tablets	Clonmel Healthcare Ltd	PA0126/112/002	Tablet	- C09AA - C09AA03	- Lisinopril Dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zestoretic 10 mg /12.5 mg Tablets	Atnahs Pharma Netherlands B.V.	PA23140/001/001	Tablet	- C09BA - C09BA03	- Lisinopril Dihydrate - Hydrochlorothiazide	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zestoretic 20 mg/12.5 mg Tablets	Atnahs Pharma Netherlands B.V.	PA23140/001/002	Tablet	- C09BA - C09BA03	- Hydrochlorothiazide - lisinopril anhydrous		- Oral use
Zestril 10 mg Tablets	Atnahs Pharma Netherlands B.V.	PA23140/002/002	Tablet	- C09AA - C09AA03	- Lisinopril		- Oral use
Zestril 20mg Tablets	Atnahs Pharma Netherlands B.V.	PA23140/002/003	Tablet	- C09AA - C09AA03	- Lisinopril		- Oral use
Zestril 5 mg Tablets	PCO Manufacturing Ltd.	PPA0465/066/005	Tablet	- C09AA - C09AA03	- Lisinopril		- Oral use
Zestril 5mg Tablets	Atnahs Pharma Netherlands B.V.	PA23140/002/001	Tablet	- C09AA - C09AA03	- Lisinopril		- Oral use
Zevalin	Ceft Biopharma s.r.o	EU/1/03/264/001	Kit for radiopharmaceutical preparation	- V10XX - V10XX02	- Ibritumomabum tiuxetan		
Ziagen	ViiV Healthcare BV	EU/1/99/112/001	Film-coated tablet	- J05AF - J05AF06	- Abacavir sulfate		- Oral use
Ziagen	ViiV Healthcare BV	EU/1/99/112/002	Oral solution	- J05A	- Abacavir sulfate		- Oral use
Zibor 2,500 IU anti Xa/0.2 ml solution for injection in pre-filled syringes	Rovi Pharma Industrial Services S.A.	PA1769/001/001	Solution for injection in pre-filled syringe	- B01AB12	- Bemiparin sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Zibor 25,000 IU anti-Xa/ml solution for injection in pre-filled syringes	Rovi Pharma Industrial Services S.A.	PA1769/001/003	Solution for injection in pre-filled syringe	- B01AB - B01AB12	- Bemiparin sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Zibor 3,500 IU anti Xa/0.2 ml solution for injection in pre-filled syringes	Rovi Pharma Industrial Services S.A.	PA1769/001/002	Solution for injection in pre-filled syringe	- B01AB12	- Bemiparin sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Ziextenzo	Sandoz GmbH	EU/1/18/1327/001	Solution for injection in pre-filled syringe	- L03AA13	- Pegfilgrastim	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Subcutaneous use
Zilbrysq	UCB Pharma S.A.	EU/1/23/1764/001-002	Solution for injection in pre-filled syringe	- L04AJ06	- Zilucoplan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Zilbrysq	UCB Pharma S.A.	EU/1/23/1764/003-004	Solution for injection in pre-filled syringe	- L04AJ06	- Zilucoplan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Zilbrysq	UCB Pharma S.A.	EU/1/23/1764/005-006	Solution for injection in pre-filled syringe	- L04AJ06	- Zilucoplan	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Zimbus Breezhaler 114 micrograms/46 micrograms/136 micrograms inhalation powder, hard capsules	Novartis Europharm Limited	EU/1/20/1440/001-05	Inhalation powder, hard capsule	- R03AL12	- Indacaterol acetate - Glycopyrronium bromide - Mometasone furoate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Inhalation use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Zimoclone 7.5 mg film-coated tablets	Viatris Limited	PA23266/009/001 Interchangeable List Code: IC0055-041-003	Film-coated tablet		- Zopiclone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zimovane 7.5 mg Film-coated Tablets	Viatris Healthcare Limited	PA23355/017/001 Interchangeable List Code: IC0055-041-003	Film-coated tablet		- Zopiclone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zinacef 750 mg Powder for Solution or Suspension for Injection	Sandoz Pharmaceuticals d.d.	PA23311/002/002	Powder for solution for injection	- J01DC - J01DC02	- Cefuroxime Sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Zinacef 1.5 g Powder for Solution for Injection or Infusion	Sandoz Pharmaceuticals d.d.	PA23311/002/003	Powder for solution for injection/infusion	- J01DC - J01DC02	- Cefuroxime Sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Zinacef 250 mg Powder for Solution or Suspension for Injection	Sandoz Pharmaceuticals d.d.	PA23311/002/001	Powder for solution for injection	- J01DC - J01DC02	- Cefuroxime Sodium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use - Intravenous use
Zinc & Castor Oil OintmentZinc Oxide 7.5%w/wCastor Oil 50%w/w	Ovelle Limited	PA0206/027/001	Ointment	- D02AB	- Zinc oxide - Castor oil	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical use
Zinc 15% w/w Ointment	Ovelle Limited	PA0206/028/001	Ointment	- D02AB	- Zinc oxide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Topical use
Zindaclin 1% Gel	Canute Pharma (Ireland) Limited	PA23139/001/001	Gel	- D10AF - D10AF01	- CLINDAMYCIN PHOSPHATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Topical use
Zineryt 40 mg + 12 mg powder and solvent for cutaneous solution	CHEPLAPHARM Arzneimittel GmbH	PA2239/018/001	Powder and solvent for cutaneous solution	- D10AF - D10AF52	- Erythromycin - Zinc acetate dihydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Cutaneous use
Zineryt 40 mg + 12 mg powder and solvent for cutaneous solution	IMED Healthcare Ltd.	PPA1463/067/001	Powder and solvent for cutaneous solution	- D10AF52	- Erythromycin - Zinc acetate dihydrate	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Cutaneous use
Zinforo	Pfizer Ireland Pharmaceuticals	EU/1/12/785/001	Powder for concentrate for solution for infusion	- J01DI - J01DI02	- Ceftaroline fosamil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Zinnat 125 mg film-coated tablets	Sandoz Pharmaceuticals d.d.	PA23311/003/002	Film-coated tablet	- J01DC - J01DC02	- Cefuroxime	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zinnat 125 mg/5 ml granules for oral suspension	Sandoz Pharmaceuticals d.d.	PA23311/003/005	Granules for oral suspension	- J01DC - J01DC02	- Cefuroxime axetil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zinnat 250 mg film-coated tablets	Sandoz Pharmaceuticals d.d.	PA23311/003/003	Film-coated tablet	- J01DC - J01DC02	- Cefuroxime	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zinnat 250mg/5ml granules for oral suspension	Sandoz Pharmaceuticals d.d.	PA23311/003/001	Granules for oral suspension	- J01DC - J01DC02	- Cefuroxime axetil	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zinnat 500 mg film-coated tablets	Sandoz Pharmaceuticals d.d.	PA23311/003/004	Film-coated tablet	- J01DC - J01DC02	- Cefuroxime	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ZINPLAVA (Formely known Bezlotoxumab MSD))	Merck Sharp & Dohme BV	EU/1/16/1156/001	Concentrate for solution for infusion	- J06BB - J06BB21	- Bezlotoxumab	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Zipzoc 20%, Impregnated Dressing	Evolan Pharma AB	PA2262/001/001	Impregnated dressin	- D09AB - D09AB01	- Zinc oxide	Well-established use application (Article 10a of Directive No 2001/83/EC)	- Transdermal use
Zirabev	Pfizer Europe MA EEIG	EU/1/18/1344/001-002	Concentrate for solution for infusion	- L01XC07	- Bevacizumab	Similar biological application (Article 10(4) of Directive No 2001/83/EC)	- Intravenous use
Zirpine 1mg/ml Oral Solution	Pinewood Laboratories Ltd	PA0281/178/001	Oral solution	- R06AE07	- Cetirizine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zirtek 1 mg/ml oral solution	IMED Healthcare Ltd.	PPA1463/214/001	Oral solution	- R06AE - R06AE07	- Cetirizine dihydrochloride		- Oral use
Zirtek 1 mg/ml oral solution	PCO Manufacturing Ltd.	PPA0465/502/001	Oral solution	- R06AE07	- Cetirizine dihydrochloride	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Zirtek 1 mg/ml oral solution	UCB (Pharma) Ireland Limited	PA0891/008/003	Oral solution	- R06AE - R06AE07	- Cetirizine dihydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zirtek 1 mg/ml oral solution	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/062/001	Oral solution	- R06AE - R06AE07	- Cetirizine dihydrochloride		- Oral use
Zirtek 10 mg film-coated tablets	UCB (Pharma) Ireland Limited	PA0891/008/002 Interchangeable List Code: IC0088-002-003	Film-coated tablet		- Cetirizine hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zirtek 10 mg/ml Oral Drops, Solution	UCB (Pharma) Ireland Limited	PA0891/008/004	Oral drops, solution	- R06AE - R06AE07	- Cetirizine dihydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zirtek Allergy Relief 10 mg film-coated tablets	UCB (Pharma) Ireland Limited	PA0891/008/005	Film-coated tablet	- R06AE - R06AE07	- Cetirizine dihydrochloride	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Oral use
Zirtek Plus Decongestant 5mg/120mg Prolonged Release Tablet	UCB (Pharma) Ireland Limited	PA0891/008/001	Prolonged-release tablet	- R01BA - R01BA52	- PSEUDOEPHEDRINE HYDROCHLORIDE - Cetirizine dihydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zirtene 10 mg film-coated tablets	Viatris Limited	PA23266/017/001 Interchangeable List Code: IC0088-002-003	Film-coated tablet		- Cetirizine dihydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zismirt 30mg Film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/059/001 Interchangeable List Code: IC0061-033-015	Film-coated tablet		- Mirtazapine	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zispin 15 mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/025/001 Interchangeable List Code: IC0061-032-015	Film-coated tablet		- Mirtazapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zispin 30 mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/025/002 Interchangeable List Code: IC0061-033-015	Film-coated tablet		- Mirtazapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zispin SolTab 15 mg orodispersible tablets	Organon Pharma (Ireland) Limited	PA23198/015/001 Interchangeable List Code: IC0061-032-015	Orodispersible tablet		- Mirtazapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Zispin SolTab 30 mg orodispersible tablets	Organon Pharma (Ireland) Limited	PA23198/015/002 Interchangeable List Code: IC0061-033-015	Orodispersible tablet		- Mirtazapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zispin SolTab 45 mg orodispersible tablets	Organon Pharma (Ireland) Limited	PA23198/015/003 Interchangeable List Code: IC0061-110-015	Orodispersible tablet		- Mirtazapine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zithromax capsules 250 mg	Pfizer Healthcare Ireland	PA0822/191/001 Interchangeable List Code: IC0113-130-009	Capsule, hard		- Azithromycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zithromax Powder for Oral Suspension 200mg/5ml	Pfizer Healthcare Ireland	PA0822/191/002	Powder for oral suspension	- J01FA - J01FA10	- Azithromycin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zitrease Allergy 10 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/042/001 Interchangeable List Code: IC0088-002-003	Film-coated tablet		- Cetirizine hydrochloride	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zocor 10 mg, film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/008/001 Interchangeable List Code: IC0018-002-003	Film-coated tablet		- Simvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zocor 20 mg, film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/008/002 Interchangeable List Code: IC0018-003-003	Film-coated tablet		- Simvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zocor 40 mg, film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/008/003 Interchangeable List Code: IC0018-004-003	Film-coated tablet		- Simvastatin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zoely	Theramex Ireland Limited	EU/1/11/690/001-002	Film-coated tablet	- G03AA - G03AA14	- NOMEGESTROL ACETATE - Estradiol hemihydrate	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Oral use
ZOFENIL 30 mg film-coated tablet	Menarini International Operations Luxembourg S.A.	PA0865/003/003	Film-coated tablet	- C09AA - C09AA15	- Zofenopril calcium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ZOFENIL 7.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/003/001	Film-coated tablet	- C09AA - C09AA15	- Zofenopril calcium	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zofenil Plus 30 mg/12.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/012/001	Film-coated tablet	- C09BA - C09BA15	- Zofenopril calcium - Hydrochlorothiazide		- Oral use
Zofran 4 mg film-coated tablets	Rowex Ltd	PA0711/327/003 Interchangeable List Code: IC0114-008-061	Film-coated tablet		- Ondansetron	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zofran 4 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/113/001 Interchangeable List Code: IC0114-008-061	Film-coated tablet		- Ondansetron	ZZZ PPA	- Oral use
Zofran 4 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/158/002 Interchangeable List Code: IC0114-008-061	Film-coated tablet		- Ondansetron		- Oral use
Zofran 4 mg/5 ml syrup	Rowex Ltd	PA0711/327/002 Interchangeable List Code: IC0114-170-062	Syrup		- Ondansetron	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Zofran 4mg/2ml Solution for Injection or Infusion	Rowex Ltd	PA0711/327/001	Solution for injection/infusion	- A04AA - A04AA01	- Ondansetron hydrochloride dihydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Zofran 8 mg film-coated tablets	Rowex Ltd	PA0711/327/004 Interchangeable List Code: IC0114-009-061	Film-coated tablet		- Ondansetron	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zofran 8 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/158/003 Interchangeable List Code: IC0114-009-061	Film-coated tablet		- Ondansetron		- Oral use
Zofran 8 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/113/002 Interchangeable List Code: IC0114-009-061	Film-coated tablet		- Ondansetron	ZZZ PPA	- Oral use
Zofran Zydis 4 mg oral lyophilisate	PCO Manufacturing Ltd.	PPA0465/445/001 Interchangeable List Code: IC0114-008-061	Oral lyophilisate		- Ondansetron		- Oral use
Zofran Zydis 4 mg oral lyophilisate	Originalis B.V.	PPA2306/006/001 Interchangeable List Code: IC0114-008-061	Oral lyophilisate		- Ondansetron		- Oral use
Zofran Zydis 4 mg oral lyophilisate	Rowex Ltd	PA0711/327/005 Interchangeable List Code: IC0114-008-061	Oral lyophilisate		- Ondansetron		- Oral use
Zofran Zydis 8 mg oral lyophilisate	Rowex Ltd	PA0711/327/006 Interchangeable List Code: IC0114-009-061	Oral lyophilisate		- Ondansetron		- Oral use
Zoftacot 3.35 mg/ml eye drops, solution in single-dose container	Laboratoires Thea	PA1107/013/001	Eye drops, solution in single-dose container	- S01BA - S01BA02	- Hydrocortisone sodium phosphate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Ocular use
Zokinvy	Eigerbio Europe Limited	EU/1/22/1660/001	Capsule, hard	- A16AX - A16AX20	- Lonafarnib	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zokinvy	Eigerbio Europe Limited	EU/1/22/1660/002	Capsule, hard	- A16AX20	- Lonafarnib	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zoladex 3.6 mg implant	AstraZeneca AB	PA1019/027/001	Implant	- L02AE - L02AE03	- Goserelin		- Subcutaneous use
Zoladex 3.6 mg implant	IMED Healthcare Ltd.	PPA1463/125/001	Implant	- L02AE - L02AE03	- Goserelin		- Subcutaneous use
Zoladex LA 10.8 mg implant	IMED Healthcare Ltd.	PPA1463/125/002	Implant	- L02AE - L02AE03	- Goserelin		- Subcutaneous use
Zoladex LA 10.8 mg Implant	Originalis B.V.	PPA2306/027/001	Implant	- L02AE - L02AE03	- Goserelin		- Subcutaneous use
Zoladex LA 10.8 mg implant	AstraZeneca AB	PA1019/027/002	Implant	- L02AE - L02AE03	- Goserelin	Full application (Article 8(3) of Directive No 2001/83/EC)	- Subcutaneous use
Zoledronic Acid 4 mg / 5 mL Concentrate for solution for infusion	Noridem Enterprises Limited	PA1122/016/001	Concentrate for solution for infusion	- M05BA - M05BA08	- Zoledronic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Zoledronic acid 4 mg/5 ml concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/019/001	Concentrate for solution for infusion	- M05BA - M05BA08	- Zoledronic acid	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Zoledronic Acid Accord	Accord Healthcare S.L.U.	EU/1/13/834/001-003	Concentrate for solution for infusion	- M05BA - M05BA08	- Zoledronic acid monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Zoledronic acid Actavis	Actavis Group hf	EU/1/12/759/001-003	Concentrate for solution for infusion	- M05BA - M05BA08	- Zoledronic acid monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Zoledronic Acid Hospira	Pfizer Europe MA EEIG	EU/1/12/800/001-002	Concentrate for solution for infusion	- M05BA - M05BA08	- Zoledronic acid monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Zoledronic Acid Hospira	Pfizer Europe MA EEIG	EU/1/12/800/003	Solution for infusion	- M05BA - M05BA08	- Zoledronic acid monohydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Zoledronic Acid Hospira	Pfizer Europe MA EEIG	EU/1/12/800/004	Solution for infusion	- M05BA - M05BA08	- Zoledronic acid monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Zoledronic acid medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/12/779/001-003	Concentrate for solution for infusion	- M05BA - M05BA08	- Zoledronic acid monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
Zoledronic acid medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/12/779/004-006	Solution for infusion	- M05BA - M05BA08	- Zoledronic acid monohydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Zoledronic acid Mylan	Mylan Pharmaceuticals Limited	EU/1/12/786/001-003	Concentrate for solution for infusion	- M05BA - M05BA08	- Zoledronic acid monohydrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intravenous use
ZOLEDRONIC ACID TEVA	Teva B.V.	EU/1/12/771/007-009	Solution for Infusion	- M05BA08	- ZOLEDRONIC ACID TEVA	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Intra-venous
ZOLEDRONIC ACID TEVA PHARMA	Teva B.V.	EU/1/12/771/001-006	Solution for Infusion	- M05BA08	- ZOLEDRONIC ACID	Article 10(1) - Generic Application	- Intra-venous
Zolepant 20 mg gastro-resistant tablets	Pinewood Laboratories Ltd	PA0281/140/001 Interchangeable List Code: IC0013-003-005	Gastro-resistant tablet		- Pantoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zolepant 40 mg gastro-resistant tablets	Pinewood Laboratories Ltd	PA0281/140/002 Interchangeable List Code: IC0013-004-005	Gastro-resistant tablet		- Pantoprazole	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zolgensma	Novartis Europharm Limited	EU/1/20/1443/001-0037	Solution for infusion	- M09AX - M09AX09	- Onasemnogene Abeparvovec	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Zolmitriptan 2.5 mg Orodispersible Tablets	Accord Healthcare Ireland Ltd.	PA2315/232/001	Orodispersible tablet	- N02CC - N02CC03	- Zolmitriptan	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zolnod 10 mg film-coated tablets	Rowex Ltd	PA0711/039/001 Interchangeable List Code: IC0135-002-003	Film-coated tablet		- Zolpidem tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zolpidem Tartrate Teva 10 mg film-coated tablets	Teva Pharma B.V.	PA0749/095/002 Interchangeable List Code: IC0135-002-003	Film-coated tablet		- Zolpidem tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zolpidem Tartrate Teva 5 mg film-coated tablets	Teva Pharma B.V.	PA0749/095/001 Interchangeable List Code: IC0135-001-003	Film-coated tablet		- Zolpidem tartrate	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zolsketil Pegylated Liposomal	Accord Healthcare S.L.U.	EU/1/22/1629/001-0004	Concentrate for dispersion for infusion	- L01DB01	- Doxorubicin Hydrochloride, Liposomal	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Intravenous use
Zomarist	Novartis Europharm Limited	EU/1/08/483/1-6	Film-coated tablet	- A10BD08			- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Zomarist	Novartis Europharm Limited	EU/1/08/483/7-18	Film-coated tablet	- A10BD			- Oral use
Zomel 15 mg gastro-resistant capsule, hard	Clonmel Healthcare Ltd	PA0126/147/001 Interchangeable List Code: IC0008-032-033	Gastro-resistant capsule, hard		- Lansoprazole		- Oral use
Zomel 30 mg gastro-resistant capsule, hard	Clonmel Healthcare Ltd	PA0126/147/002 Interchangeable List Code: IC0008-033-033	Gastro-resistant capsule, hard		- Lansoprazole		- Oral use
Zometa	Phoenix Labs	EU/1/01/176/001	Powder and solvent for solution for infusion	- M05BA - M05BA08	- Zoledronic acid		- Intravenous use
Zometa	Phoenix Labs	EU/1/01/176/002	Powder and solvent for solution for injection	- M05BA08	- Zoledronic acid		- Intravenous use
Zometa	Phoenix Labs	EU/1/01/176/003	Powder and solvent for solution for injection	- M05BA08	- Zoledronic acid		- Intravenous use
Zometa	Phoenix Labs	EU/1/01/176/004	Concentrate for solution for infusion	- M05BA08	- Zoledronic acid		
Zometa	Phoenix Labs	EU/1/01/176/007-009	Powder and solvent for solution for infusion	- M05BA - M05BA08	- Zoledronic acid monohydrate		- Intravenous use
Zomig 2.5 mg Tablet	IMED Healthcare Ltd.	PPA1463/168/001	Film-coated tablet	- N02CC03	- Zolmitriptan		- Oral use
Zomig 2.5 mg tablets	PCO Manufacturing Ltd.	PPA0465/099/001	Film-coated tablet	- N02CC - N02CC03	- Zolmitriptan	ZZZ PPA	- Oral use
Zomig 2.5 mg Tablet	Grunenthal Pharma Ltd	PA2242/004/001	Film-coated tablet	- N02CC - N02CC03	- Zolmitriptan		- Oral use
Zomig Rapimelt 2.5 mg orodispersible Tablets	Grunenthal Pharma Ltd	PA2242/004/002	Orodispersible tablet	- N02CC - N02CC03	- Zolmitriptan		- Oral use
Zomig Rapimelt 2.5 mg Orodispersible Tablets	PCO Manufacturing Ltd.	PPA0465/099/002	Orodispersible tablet	- N02CC - N02CC03	- Zolmitriptan		- Oral use
Zomig Rapimelt 2.5 mg orodispersible Tablets	IMED Healthcare Ltd.	PPA1463/168/002	Orodispersible tablet	- N02CC - N02CC03	- Zolmitriptan		- Oral use
Zonegran	Amdipharm Limited	EU/1/04/307/003	Capsule, hard	- N03AX - N03AX15	- Zonisamide		- Oral use
Zonegran	Amdipharm Limited	EU/1/04/307/004	Capsule, hard	- N03AX - N03AX15	- Zonisamide		- Oral use
Zonegran	Amdipharm Limited	EU/1/04/307/1-4	Capsule, hard	- N03AX - N03AX15	- Zonisamide		- Oral use
Zonisamide Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1093/001-004	Capsule, hard	- N03AX - N03AX15	- Zonisamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	
Zonisamide Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1093/005-008	Capsule, hard	- N03AX - N03AX15	- Zonisamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	
Zonisamide Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1093/009-013	Capsule, hard	- N03AX - N03AX15	- Zonisamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	
Zonisamide Neuraxpharm 100 mg tablets	Neuraxpharm Ireland Limited	PA23229/006/003	Tablet	- N03AX15	- Zonisamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zonisamide Neuraxpharm 200 mg tablets	Neuraxpharm Ireland Limited	PA23229/006/004	Tablet	- N03AX15	- Zonisamide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use
Zonisamide Neuraxpharm 25 mg tablets	Neuraxpharm Ireland Limited	PA23229/006/001	Tablet	- N03AX15	- Zonisamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zonisamide Neuraxpharm 300 mg tablets	Neuraxpharm Ireland Limited	PA23229/006/005	Tablet	- N03AX15	- Zonisamide	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Zonisamide Neuraxpharm 50 mg tablets	Neuraxpharm Ireland Limited	PA23229/006/002	Tablet	- N03AX15	- Zonisamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zonisamide Rowex 100 mg hard capsules	Rowex Ltd	PA0711/336/003	Capsule, hard	- N03AX15	- Zonisamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zonisamide Rowex 25 mg hard capsules	Rowex Ltd	PA0711/336/001	Capsule, hard	- N03AX15	- Zonisamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zonisamide Rowex 50 mg hard capsules	Rowex Ltd	PA0711/336/002	Capsule, hard	- N03AX15	- Zonisamide	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zoonotic Influenza Vaccine Seqirus	Seqirus S.r.l.	EU/1/23/1761/001-002	Suspension for injection	- J07BB02	- A/TURKEY/TURKEY/1/05 (H5N1)-LIKE STRAIN (NIBRG-23)	Informed consent application (Article 10c of Directive No 2001/83/EC)	- Intramuscular use
Zopiclone Pinewood 3.75 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/257/002	Film-coated tablet	- N05CF01	- Zopiclone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zopiclone Pinewood 7.5 mg Film-Coated Tablets	Pinewood Laboratories Ltd	PA0281/257/001 Interchangeable List Code: IC0055-041-003	Film-coated tablet		- Zopiclone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zopitan 3.75 mg Film-Coated Tablet	Clonmel Healthcare Ltd	PA0126/104/001	Film-coated tablet	- N05CF - N05CF01	- Zopiclone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zopitan 7.5 mg Film-Coated Tablet	Clonmel Healthcare Ltd	PA0126/104/002 Interchangeable List Code: IC0055-041-003	Film-coated tablet		- Zopiclone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zorclone 7.5 mg Film-Coated Tablets	Teva B.V.	PA1986/080/001 Interchangeable List Code: IC0055-041-003	Film-coated tablet		- Zopiclone	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zoreeda 25 microgram/125 microgram per actuation pressurised inhalation, suspension	Cipla Europe NV	PA1963/009/001 Interchangeable List Code: IC0128-176-053	Pressurised inhalation, suspension		- Fluticasone propionate - SALMETEROL XINAFOATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Zoreeda 25 microgram/250 microgram per actuation pressurised inhalation, suspension	Cipla Europe NV	PA1963/009/002 Interchangeable List Code: IC0128-177-053	Pressurised inhalation, suspension		- Fluticasone propionate - SALMETEROL XINAFOATE	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Inhalation use
Zostavax	Merck Sharp & Dohme BV,	EU/1/06/341/003	Powder and solvent for suspension for injection in pre-filled syringe	- J07BK - J07BK02	- Varicella-zoster virus, oka/merck strain (live attenuated)		- Subcutaneous use
Zostavax	Merck Sharp & Dohme BV,	EU/1/06/341/01-13	Powder and solvent for suspension for injection	- J07BK - J07BK02	- Varicella virus vaccine live (oka/merck)		- Intramuscular use - Subcutaneous use
Zoton FasTab 15 mg Oro-Dispersible Tablets	Pfizer Healthcare Ireland	PA0822/101/002 Interchangeable List Code: IC0008-032-033	Orodispersible tablet		- Lansoprazole		- Oral use
Zoton FasTab 15 mg oro-dispersible tablets	Merit Pharmaceuticals Limited	PPA23080/004/001 Interchangeable List Code: IC0008-032-033	Orodispersible tablet		- Lansoprazole	ZZZ PPA	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Zoton FasTab 30 mg oro-dispersible tablets	Pfizer Healthcare Ireland	PA0822/101/003 Interchangeable List Code: IC0008-033-033	Orodispersible tablet		- Lansoprazole		- Oral use
Zoton FasTab 30mg oro-dispersible tablets	Merit Pharmaceuticals Limited	PPA23080/004/002 Interchangeable List Code: IC0008-033-033	Orodispersible tablet		- Lansoprazole	ZZZ PPA	- Oral use
Zovirax 200 mg Dispersible Tablets	IMED Healthcare Ltd.	PPA1463/199/001	Dispersible tablet	- J05AB - J05AB01	- Aciclovir		- Oral use
Zovirax 200 mg dispersible tablets	PCO Manufacturing Ltd.	PPA0465/038/005	Dispersible tablet	- J05AB - J05AB01	- Acyclovir		- Oral use
Zovirax 200 mg Dispersible Tablets	GlaxoSmithKline (Ireland) Limited	PA1077/084/007	Dispersible tablet	- J05AB - J05AB01	- Aciclovir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zovirax 200 mg/5 mL Oral Suspension	GlaxoSmithKline (Ireland) Limited	PA1077/084/005	Oral suspension	- J05AB - J05AB01	- Aciclovir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use - Oral use
Zovirax 200 mg/5 mL oral suspension	PCO Manufacturing Ltd.	PPA0465/038/008	Oral suspension	- J05AB01	- Aciclovir	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Oral use
Zovirax 200 mg/5 mL Oral Suspension	IMED Healthcare Ltd.	PPA1463/199/003	Oral suspension	- J05AB - J05AB01	- Aciclovir	Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC	- Intravenous use - Oral use
Zovirax 5 % w/w Cream	GlaxoSmithKline (Ireland) Limited	PA1077/084/001	Cream	- D06BB - D06BB03	- Acyclovir		- Topical
Zovirax 800 mg Dispersible Tablets	GlaxoSmithKline (Ireland) Limited	PA1077/084/009	Dispersible tablet	- J05AB - J05AB01	- Aciclovir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zovirax 800 mg Dispersible Tablets	Originalis B.V.	PPA2306/030/001	Dispersible tablet	- J05AB01	- Aciclovir	Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC	- Oral use
Zovirax 800 mg Dispersible Tablets	Merit Pharmaceuticals Limited	PPA23080/029/001	Dispersible tablet	- J05AB - J05AB01	- Aciclovir		- Oral use
Zovirax 800 mg Dispersible Tablets	IMED Healthcare Ltd.	PPA1463/199/002	Dispersible tablet	- J05AB - J05AB01	- Aciclovir		- Oral use
Zovirax 800 mg Dispersible Tablets	PCO Manufacturing Ltd.	PPA0465/038/007	Dispersible tablet	- J05AB - J05AB01	- Aciclovir		- Oral use
Zovirax 800 mg Dispersible Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/058/001	Dispersible tablet	- J05AB - J05AB01	- Aciclovir		- Oral use
Zovirax Cold Sore 5% w/w cream	PCO Manufacturing Ltd.	PPA0465/038/004	Cream	- D06BB03	- Aciclovir		- Cutaneous use
Zovirax Cold Sore 5% w/w Cream	Haleon Ireland Limited	PA0678/090/002	Cream	- D06BB - D06BB03	- Aciclovir		- Topical
Zovirax Double Strength 400 mg/5 mL Oral Suspension	GlaxoSmithKline (Ireland) Limited	PA1077/084/006	Oral suspension	- J05AB - J05AB01	- Acyclovir	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zovirax Duo 50 mg/g and 10 mg/g Cream	Haleon Ireland Limited	PA0678/143/001	Cream	- D06BB - D06BB53	- ACICLOVIR PH. EUR. - HYDROCORTISONE PH. EUR.	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Cutaneous use
Zovirax IV for Infusion 250 mg, Powder for solution for infusion	GlaxoSmithKline (Ireland) Limited	PA1077/084/003	Powder for solution for infusion	- J05AB - J05AB01	- Aciclovir		- Intravenous use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
ZTALMY	Marinus Pharmaceuticals Emerald Limited	EU/1/23/1743/001-002	Oral suspension	- N03AX - N03AX27	- Ganaxolone	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zubsolv	Accord Healthcare S.L.U.	EU/1/17/1233/001	Sublingual tablet	- N07BC - N07BC51	- Buprenorphine hydrochloride - Naloxone hydrochloride dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Sublingual use
Zubsolv	Accord Healthcare S.L.U.	EU/1/17/1233/002	Sublingual tablet	- N07BC - N07BC51	- Buprenorphine hydrochloride - Naloxone hydrochloride dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Sublingual use
Zubsolv	Accord Healthcare S.L.U.	EU/1/17/1233/003	Sublingual tablet	- N07BC - N07BC51	- Naloxone hydrochloride dihydrate - Buprenorphine hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Sublingual use
Zubsolv	Accord Healthcare S.L.U.	EU/1/17/1233/004	Sublingual tablet	- N07BC - N07BC51	- Naloxone hydrochloride dihydrate - Buprenorphine hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Sublingual use
Zubsolv	Accord Healthcare S.L.U.	EU/1/17/1233/005	Sublingual tablet	- N07BC - N07BC51	- Buprenorphine hydrochloride - Naloxone hydrochloride dihydrate	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Sublingual use
Zubsolv	Accord Healthcare S.L.U.	EU/1/17/1233/006	Sublingual tablet	- N07BC - N07BC51	- Naloxone hydrochloride dihydrate - Buprenorphine hydrochloride	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Sublingual use
Zutectra	Biotest Pharma GmbH	EU/1/09/600/001	Solution for injection in pre-filled syringe	- J06BB - J06BB04	- Human plasma protein >96% immunoglobulins - Hbs antibodies		- Subcutaneous use
Zyban 150 mg prolonged release tablets	GlaxoSmithKline (Ireland) Limited	PA1077/017/001	Prolonged-release tablet	- N06AX - N06AX12	- BUPROPION HYDROCHLORIDE	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zyban 150 mg prolonged release tablets	Originalis B.V.	PPA2306/005/001	Prolonged-release tablet	- N06AX12	- Bupropion hydrochloride		- Oral use
Zyban 150 mg prolonged release tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/047/001	Prolonged-release tablet	- N06AX - N06AX12	- BUPROPION HYDROCHLORIDE		- Oral use
Zyban 150 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/496/001	Prolonged-release tablet	- N06AX - N06AX12	- BUPROPION HYDROCHLORIDE		- Oral use
Zyclara	Viatris Healthcare Limited	EU/1/12/783/001-003	Cream	- D06BB - D06BB10	- Imiquimod	Hybrid application (Article 10(3) of Directive No 2001/83/EC)	- Cutaneous use
Zydelig	Gilead Sciences Ireland UC	EU/1/14/938/001	Film-coated tablet	- L01XX - L01XX47	- Idelalisib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zydelig	Gilead Sciences Ireland UC	EU/1/14/938/002	Film-coated tablet	- L01XX - L01XX47	- Idelalisib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ZYDOL 50 mg Hard Capsules	Grunenthal Pharma Ltd	PA2242/005/001 Interchangeable List Code: IC0074-023-008	Capsule, hard		- Tramadol hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ZYDOL SR 100 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/005/003 Interchangeable List Code: IC0074-024-030	Prolonged-release tablet		- Tramadol hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
ZYDOL SR 150 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/005/004 Interchangeable List Code: IC0074-062-030	Prolonged-release tablet		- Tramadol hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ZYDOL SR 200 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/005/005 Interchangeable List Code: IC0074-067-030	Prolonged-release tablet		- Tramadol hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ZYDOL SR 50mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/005/006 Interchangeable List Code: IC0074-023-030	Prolonged-release tablet		- Tramadol hydrochloride	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zykadia	Novartis Europharm Limited	EU/1/15/999/001	Capsule, hard	- L01X	- Ceritinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zykadia	Novartis Europharm Limited	EU/1/15/999/002-003	Film-coated tablet	- L01XE28	- Ceritinib	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
ZYLLT	Krka d.d., Novo mesto	EU/1/09/553/001-10 Interchangeable List Code: IC0005-028-003	Film-coated tablet		- CLOPIDOGREL HYDROGEN SULPHATE	Generic application (Article 10(1) of Directive No 2001/83/EC)	- Oral use
Zyloric 100 mg Tablets	Aspen Pharma Trading Limited	PA1691/002/001	Tablet	- M04AA - M04AA01	- Allopurinol		- Oral use
Zyloric 300 mg Tablets	Aspen Pharma Trading Limited	PA1691/002/002	Tablet	- M04AA - M04AA01	- Allopurinol		- Oral use
Zynlonta	Swedish Orphan Biovitrum AB	EU/1/22/1695/001	Powder for concentrate for solution for infusion	- L01FX22 - L01XC	- Loncastuximab Tesirine	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Zynrelef	Heron Therapeutics B.V.	EU/1/20/1478/001	Prolonged-release wound solution		- Bupivacaine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Infiltration
Zynrelef	Heron Therapeutics B.V.	EU/1/20/1478/002	Prolonged-release wound solution		- Bupivacaine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Infiltration
Zynrelef	Heron Therapeutics B.V.	EU/1/20/1478/003	Prolonged-release wound solution		- Bupivacaine	Fixed combination application (Article 10b of Directive No 2001/83/EC)	- Intralesional use
Zypadhera	Eli Lilly Nederland B.V.	EU/1/08/479/001	Powder and solvent for prolonged-release suspension for injection	- N05AH - N05AH03	- Olanzapine pamoate monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Zypadhera	Eli Lilly Nederland B.V.	EU/1/08/479/002	Powder and solvent for prolonged-release suspension for injection	- N05AH - N05AH03	- Olanzapine pamoate monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Zypadhera	Eli Lilly Nederland B.V.	EU/1/08/479/003	Powder and solvent for prolonged-release suspension for injection	- N05AH - N05AH03	- Olanzapine pamoate monohydrate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Intramuscular use
Zyprexa	Eli Lilly Nederland B.V.	EU/1/96/022/002 Interchangeable List Code: IC0007-018-035	Coated tablet		- Olanzapine		- Oral use
Zyprexa	Eli Lilly Nederland B.V.	EU/1/96/022/004 Interchangeable List Code: IC0007-001-038	Coated tablet		- Olanzapine		- Oral use
Zyprexa	Eli Lilly Nederland B.V.	EU/1/96/022/006 Interchangeable List Code: IC0007-041-038	Coated tablet		- Olanzapine		- Oral use

Trade Name	Licence Holder	Licence Number	Dosage Form	ATC	Active Ingredient	Legal Basis	Routes of Administration
Zyprexa	Eli Lilly Nederland B.V.	EU/1/96/022/009 Interchangeable List Code: IC0007-002-038	Coated tablet		- Olanzapine		- Oral use
Zyprexa	Eli Lilly Nederland B.V.	EU/1/96/022/012 Interchangeable List Code: IC0007-032-038	Coated tablet		- Olanzapine		- Oral use
Zyprexa	Eli Lilly Nederland B.V.	EU/1/96/022/014 Interchangeable List Code: IC0007-003-038	Coated tablet		- Olanzapine		- Oral use
Zyprexa	Eli Lilly Nederland B.V.	EU/1/96/022/016	Powder for solution for injection	- N05AH - N05AH03	- Olanzapine		- Intramuscular use
ZYPREXA VELOTAB	Eli Lilly Nederland B.V.	EU/1/99/125/001 Interchangeable List Code: IC0007-001-038	Orodispersible tablet		- Olanzapine		- Oral use
Zyprexa Velotab	Eli Lilly Nederland B.V.	EU/1/99/125/002 Interchangeable List Code: IC0007-002-038	Orodispersible tablet		- Olanzapine		- Oral use
Zyprexa Velotab	Eli Lilly Nederland B.V.	EU/1/99/125/003 Interchangeable List Code: IC0007-032-038	Orodispersible tablet		- Olanzapine		- Oral use
Zyprexa Velotab	Eli Lilly Nederland B.V.	EU/1/99/125/004 Interchangeable List Code: IC0007-003-038	Orodispersible tablet		- Olanzapine		- Oral use
Zytiga	Janssen-Cilag International NV	EU/1/11/714/001 Interchangeable List Code: IC0123-130-002	Tablet		- Abiraterone acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zytiga	Janssen-Cilag International NV	EU/1/11/714/002-003 Interchangeable List Code: IC0123-117-003	Film-coated tablet		- Abiraterone acetate	Full application (Article 8(3) of Directive No 2001/83/EC)	- Oral use
Zyvox 100 mg/5 ml granules for oral suspension	Pfizer Healthcare Ireland	PA0822/143/001	Granules for oral suspension	- J01XX - J01XX08	- Linezolid		- Oral use
Zyvox 2 mg/ml solution for infusion	Pfizer Healthcare Ireland	PA0822/143/002	Solution for infusion	- J01XX - J01XX08	- Linezolid	New active substance (Article 8(3) of Directive No 2001/83/EC)	- Intravenous use
Zyvox 600 mg Film-Coated Tablets	Pfizer Healthcare Ireland	PA0822/143/004	Film-coated tablet	- J01XX - J01XX08	- Linezolid	Known active substance (Article 8(3) of Directive No 2001/83/EC)	- Oral use