

Supply through pharmacy only.
This list was last updated on Saturday, May 11, 2024

Please Note

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For any conditions associated with this general sale classification please refer to the detailed product information on the Human Medicines Product listing on the HPRA website.

Please note that at time of print some products listed below may not be currently marketed.

Part 1. Supply through pharmacy only

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Anhydrous glucose -Sodium chloride
0.9 % w/v Sodium Chloride Injection BP	B. Braun Medical Limited	PA0179/002/013	Solution for injection	-Sodium chloride
0.9% Sodium Chloride Intravenous Infusion Solution	Laboratoire AGUETTANT	PA1968/018/001	Solution for infusion	-Sodium chloride
1% w/v Lidocaine Hydrochloride Injection BP	B. Braun Melsungen AG	PA0736/044/001	Solution for injection	-Lidocaine Hydrochloride Monohydrate
2% w/v Lidocaine Hydrochloride Injection BP	B. Braun Melsungen AG	PA0736/044/002	Solution for injection	-Lidocaine Hydrochloride Monohydrate
5% Glucose Intravenous Infusion Solution	Laboratoire AGUETTANT	PA1968/019/001	Solution for infusion	-Glucose
8.4% w/v Sodium Bicarbonate Intravenous Infusion B	B. Braun Medical Limited	PA0179/006/001	Solution for infusion	-Sodium bicarbonate
A.Vogel Uva-ursi & Echinacea Cystitis oral drops	A.Vogel Ireland Limited	TR2309/021/001	Oral drops, solution	
Abacavir/Lamivudine Mylan 600 mg/300 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/193/001	Film-coated tablet	-Abacavir -Lamivudine
Abacavir/Lamivudine Mylan Pharma 600 mg/300 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/216/001	Film-coated tablet	-Abacavir sulfate -Lamivudine
Abasaglar	Eli Lilly Nederland B.V.	EU/1/14/944/001-004	Solution for injection in cartridge	-Insulin glargine
Abasaglar	Eli Lilly Nederland B.V.	EU/1/14/944/005-008	Solution for injection in pre-filled pen	-Insulin glargine
Abecma	Bristol-Myers Squibb Pharmaceuticals uc	EU/1/21/1539/001	Dispersion for infusion	-Idcabtagene Vicleucef
Abevmy	Biosimilar Collaborations Ireland Limited	EU/1/20/1515/001-005	Concentrate for solution for infusion	-Bevacizumab

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Abidec Multivitamin Oral Drops Solution	Chefaro Ireland DAC	PA1186/001/001	Oral drops, solution	-Vitamin a palmitate -Ergocalciferol -Thiamine hydrochloride -Riboflavin sodium phosphate -Pyridoxine hydrochloride -Nicotinamide -Ascorbic acid
Abilify	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/001-005	Tablet	-Aripiprazole
ABILIFY	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/006-010	Tablet	-Aripiprazole
ABILIFY	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/011-015	Tablet	-Aripiprazole
ABILIFY	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/016-020	Tablet	-Aripiprazole
Abilify	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/024-026	Orodispersible tablet	-Aripiprazole
Abilify	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/027-029	Orodispersible tablet	-Aripiprazole
Abilify	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/030-032	Orodispersible tablet	-Aripiprazole
Abilify	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/033-035	Oral solution	-Aripiprazole
Abilify	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276/036	Solution for injection	-Aripiprazole
Abilify Maintena	Otsuka Pharmaceutical Netherlands B.V.	EU/1/13/882/001,003	Powder and solvent for prolonged-release suspension for injection	-Aripiprazole
Abilify Maintena	Otsuka Pharmaceutical Netherlands B.V.	EU/1/13/882/002,004	Powder and solvent for prolonged-release suspension for injection	-Aripiprazole
Abiraterone 500 mg film-coated tablets	Rowex Ltd	PA0711/304/002	Film-coated tablet	-Abiraterone acetate
Abiraterone Accord	Accord Healthcare S.L.U.	EU/1/20/1512/001	Tablet	-Abiraterone acetate
Abiraterone Accord	Accord Healthcare S.L.U.	EU/1/20/1512/002-003	Film-coated tablet	-Abiraterone acetate
Abiraterone Aristo 250 mg tablets	Aristo Pharma GmbH	PA1983/008/001	Tablet	-Abiraterone acetate
Abiraterone Aristo 500 mg film-coated tablets	Aristo Pharma GmbH	PA1983/008/002	Film-coated tablet	-Abiraterone acetate
Abiraterone Clonmel 500 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/336/001	Film-coated tablet	-Abiraterone acetate
Abiraterone Krka	KRKA, d.d., Novo mesto	EU/1/21/1553/001-003	Film-coated tablet	-Abiraterone acetate
Abiraterone Mylan	Mylan IRE Healthcare Limited	EU/1/21/1571/001-008	Film-coated tablet	-Abiraterone acetate
Abiraterone Mylan	Mylan IRE Healthcare Limited	EU/1/21/1571/009-012	Film-coated tablet	-Abiraterone acetate
Abiraterone Rowa 500 mg Film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/092/001	Film-coated tablet	-Abiraterone acetate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Abiraterone Teva 500 mg film-coated tablets	Teva B.V.	PA1986/103/001	Film-coated tablet	-Abiraterone acetate
Abraxane	Bristol-Myers Squibb Pharma EEIG	EU/1/07/428/001	Powder for concentrate for dispersion for infusion	-Paclitaxel (formulated as albumin bound nanoparticles)
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	-Respiratory syncytial virus, subgroup A, stabilized prefusion F protein 847A -Respiratory syncytial virus, subgroup B, stabilized prefusion F protein 847B
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/021-22	Solution for injection in pre-filled syringe	-Epoetin alfa
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/023-24	Solution for injection in pre-filled syringe	-Epoetin alfa
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/025-26	Solution for injection in pre-filled syringe	-Epoetin alfa
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/11-12	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/1-2	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/13-14	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/15-16	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/3-4	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/5-6	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/7-8	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Abseamed	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/07/412/9-10	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Abstral 100 microgram sublingual tablets	Kyowa Kirin Holdings B.V.	PA2288/004/002	Sublingual tablet	-Fentanyl
Abstral 200 microgram sublingual tablets	Kyowa Kirin Holdings B.V.	PA2288/004/003	Sublingual tablet	-Fentanyl
Abstral 300 microgram sublingual tablets	Kyowa Kirin Holdings B.V.	PA2288/004/004	Sublingual tablet	-Fentanyl
Abstral 400 microgram sublingual tablets	Kyowa Kirin Holdings B.V.	PA2288/004/005	Sublingual tablet	-Fentanyl
Abstral 600 microgram sublingual tablets	Kyowa Kirin Holdings B.V.	PA2288/004/006	Sublingual tablet	-Fentanyl
Abstral 800 microgram sublingual tablets	Kyowa Kirin Holdings B.V.	PA2288/004/007	Sublingual tablet	-Fentanyl
ACARIZAX 12 SQ-HDM sublingual lyophilisate	ALK-Abello A/S	PA1255/010/001	Sublingual lyophilisate	-Dermatophagoides Farinae Extract -Dermatophagoides Pteronyssinus Extract
Accofil	Accord Healthcare S.L.U.	EU/1/14/943/003-004	Solution for injection in pre-filled syringe	-Filgrastim
Accofil	Accord Healthcare S.L.U.	EU/1/14/946/001-002	Solution for injection in pre-filled syringe	-Filgrastim

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Accupro 10 mg film-coated tablets	Pfizer Healthcare Ireland	PA0822/007/002	Film-coated tablet	-Quinapril
Accupro 20 mg film-coated tablets	Pfizer Healthcare Ireland	PA0822/007/003	Film-coated tablet	-Quinapril
Accupro 40 mg film-coated tablets	Pfizer Healthcare Ireland	PA0822/007/004	Film-coated tablet	-Quinapril
Accupro 5 mg film-coated tablets	Pfizer Healthcare Ireland	PA0822/007/001	Film-coated tablet	-Quinapril
Accuretic 20 mg/12.5 mg film-coated tablets	Pfizer Healthcare Ireland	PA0822/008/002	Film-coated tablet	-Quinapril -Hydrochlorothiazide
Accusol 35 Potassium 2 mmol/l Solution for haemofiltration, haemodialysis and haemodiafiltration	Nikkiso Belgium bvba	PA2021/002/001	Solution for haemodialysis/haemofiltration	-Sodium chloride -Calcium chloride -Magnesium chloride -Sodium bicarbonate -Potassium chloride -Glucose anhydrous
Accusol 35 Potassium 4 mmol/l Solution for haemofiltration, haemodialysis and haemodiafiltration	Nikkiso Belgium bvba	PA2021/002/002	Solution for haemodialysis/haemofiltration	-Sodium chloride -Calcium chloride -Magnesium chloride -Sodium bicarbonate -Potassium chloride -Glucose anhydrous
Accusol 35 Solution for haemofiltration, haemodialysis and haemodiafiltration	Nikkiso Belgium bvba	PA2021/001/001	Solution for haemofiltration	-Sodium chloride -Calcium chloride -Magnesium chloride -Sodium bicarbonate
Acerycal 10mg/10mg tablets	Les Laboratoires Servier	PA0568/018/004	Tablet	-Perindopril arginine -Amlodipine
Acerycal 5mg/10mg tablets	Les Laboratoires Servier	PA0568/018/002	Tablet	-Perindopril arginine -Amlodipine
Acerycal 10mg/5mg tablets	Les Laboratoires Servier	PA0568/018/003	Tablet	-Perindopril arginine -Amlodipine
Acerycal 5mg/5mg tablets	Les Laboratoires Servier	PA0568/018/001	Tablet	-Perindopril arginine -Amlodipine
Acetylcysteine Essential-Healthcare 600 mg effervescent tablets	Ascot Laboratories (Ireland) Limited	PA23163/003/001	Effervescent tablet	-Acetylcysteine
Acetylcysteine Stirling Anglian 600 mg effervescent tablets	Stirling Anglian Pharmaceuticals Ireland Limited	PA23138/003/001	Effervescent tablet	-Acetylcysteine
Acic 5% Cream	Rowex Ltd	PA0711/017/001	Cream	-Aciclovir
Aciclovir 200mg/5ml Oral Suspension	Syri Pharma Limited t/a Thame Laboratories	PA22697/001/001	Oral suspension	-Aciclovir
Aciclovir 25mg/ml Concentrate for solution for infusion	Baxter Holding B.V.	PA2299/041/001	Concentrate for solution for infusion	-Aciclovir
Aciclovir 25mg/ml concentrate for solution for infusion	Pfizer Healthcare Ireland	PA0822/215/001	Concentrate for solution for infusion	-Aciclovir sodium
Aciclovir 400mg/5ml Oral Suspension	Syri Pharma Limited t/a Thame Laboratories	PA22697/001/002	Oral suspension	-ACICLOVIR
Aciclovir Agepha 30 mg/g eye ointment	AGEPHA Pharma s.r.o.	PA22584/001/001	Eye ointment	-Aciclovir
Aciclovir Azevedos 250 mg Powder for solution for infusion	Laboratórios Azevedos - Indústria Farmacêutica S.A	PA1852/003/001	Powder for solution for infusion	-Aciclovir sodium
Acidex Oral Suspension, Sodium Alginate 500mg, Sodium Bicarbonate 267mg, Calcium Carbonate 160mg/10ml	Pinewood Laboratories Ltd	PA0281/075/001	Oral suspension	-Sodium alginate -Sodium bicarbonate -Calcium carbonate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Aclasta	Sandoz Pharmaceuticals d.d.	EU/1/05/308/001	Solution for infusion	-Zoledronic acid
Acnecide 5% w/w Gel	Galderma International	PA22743/001/001	Gel	-Benzoyl Peroxide
Acnecide 5% w/w Gel	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/054/001	Gel	-Benzoyl Peroxide
Acnecide Wash 5 % w/w Gel	Galderma International	PA22743/001/002	Gel	-Benzoyl Peroxide
ACTAIR 100 IR & 300 IR sublingual tablets	STALLERGENES	PA2113/002/002	Sublingual tablet	-Dermatophagoides Pteronyssinus Extract -Dermatophagoides Farinae Extract
ACTAIR 100 IR sublingual tablets	STALLERGENES	PA2113/002/001	Sublingual tablet	-Dermatophagoides Pteronyssinus Extract -Dermatophagoides Farinae Extract
ACTAIR 300 IR sublingual tablets	STALLERGENES	PA2113/002/003	Sublingual tablet	-Dermatophagoides Pteronyssinus Extract -Dermatophagoides Farinae Extract
Actelsar HCT 40 mg/12.5 mg tablets	Actavis Group hf	EU/1/13/817/001-013	Tablet	-Hydrochlorothiazide -Telmisartan
Actelsar HCT 80 mg/12.5 mg tablets	Actavis Group hf	EU/1/13/817/014-028	Tablet	-Hydrochlorothiazide -Telmisartan
Actelsar HCT 80 mg/25 mg tablets	Actavis Group hf	EU/1/13/817/029-041	Tablet	-Hydrochlorothiazide -Telmisartan
ACTIFED 30mg/1.25mg per 5ml Syrup	JNTL Consumer Health I (Ireland) Limited	PA23490/029/001	Syrup	-PSEUDOEPHEDRINE HYDROCHLORIDE -TRIPROLDINE HYDROCHLORIDE
Actifed 60mg/2.5mg Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/029/002	Tablet	-PSEUDOEPHEDRINE HYDROCHLORIDE -TRIPROLDINE HYDROCHLORIDE
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	-Alteplase
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	-Alteplase
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	-Alteplase
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	-Alteplase
Actiprofen 200 mg tablets	Haleon Ireland Limited	PA0678/061/002	Film-coated tablet	-Ibuprofen
Actiq 200 micrograms compressed lozenge with integral oromucosal applicator	Teva Pharma B.V.	PA0749/195/001	Compressed lozenge	-Fentanyl
Actiq 200 micrograms compressed lozenge with integral oromucosal applicator	PCO Manufacturing Ltd.	PPA0465/407/001	Compressed lozenge	-Fentanyl
Actiq 400 micrograms compressed lozenge with integral oromucosal applicator	PCO Manufacturing Ltd.	PPA0465/407/002	Compressed lozenge	-Fentanyl

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Actiq 400 micrograms compressed lozenge with integral oromucosal applicator	Teva Pharma B.V.	PA0749/195/002	Compressed lozenge	-Fentanyl
Actiq 600 micrograms compressed lozenge with integral oromucosal applicator	Teva Pharma B.V.	PA0749/195/003	Compressed lozenge	-Fentanyl
Activelle 1 mg/0.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/199/001	Film-coated tablet	-Estradiol -Norethisterone acetate
Activelle 1 mg/0.5 mg film-coated tablets	Novo Nordisk A/S	PA0218/052/001	Film-coated tablet	-estradiol anhydrous -Norethisterone acetate
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	-Risedronate sodium -Calcium carbonate -Colecalciferol
Actos	CHEPLAPHARM Arzneimittel GmbH	EU/1/00/150/001	Tablet	-Pioglitazone
Actos	CHEPLAPHARM Arzneimittel GmbH	EU/1/00/150/002	Tablet	-Pioglitazone
Actos	CHEPLAPHARM Arzneimittel GmbH	EU/1/00/150/003	Tablet	-Pioglitazone
Actos	CHEPLAPHARM Arzneimittel GmbH	EU/1/00/150/004	Tablet	-Pioglitazone
Actos	CHEPLAPHARM Arzneimittel GmbH	EU/1/00/150/005	Tablet	-Pioglitazone
Actos	CHEPLAPHARM Arzneimittel GmbH	EU/1/00/150/006	Tablet	-Pioglitazone
Actos	Takeda Pharma A/S	EU/1/00/150/011	Tablet	-Pioglitazone
Actraphane	Novo Nordisk A/S	EU/1/02/229/001-035	Solution for injection	-Insulin human
Actraphane 30	Novo Nordisk A/S	EU/1/02/229/036-037	Suspension for injectio	-Insulin human -Insulin human
Actrapid	Novo Nordisk A/S	EU/1/02/230/001-015	Solution for injection	-Insulin human
Actrapid	Novo Nordisk A/S	EU/1/02/230/016-017	Solution for injection	-Insulin human
ACULAR 0.5% w/v Eye drops, solution	PCO Manufacturing Ltd.	PPA0465/287/001	Eye drops, solution	-Ketorolac trometamol
Acular 0.5% w/v Eye Drops, solution	IMED Healthcare Ltd.	PPA1463/200/001	Eye drops, solution	-Ketorolac trometamol
Acular 0.5% w/v Eye Drops, solution	AbbVie Limited	PA1824/015/001	Eye drops, solution	-Ketorolac trometamol
Adaluzis 500mg Powder for concentrate for solution for infusion	Correvio	PA2319/001/001	Powder for concentrate for solution for infusion	-CEFTOBIPROLE MEDOCARIL SODIUM
Adasuve	Ferrer Internacional, S.A	EU/1/13/823/001	Inhalation powder, pre-dispensed	-Loxapine
Adasuve	Ferrer Internacional, S.A	EU/1/13/823/002	Inhalation powder, pre-dispensed	-Loxapine
Adcetris	Takeda Pharma A/S	EU/1/12/794/001	Powder for concentrate for solution for infusion	-Brentuximab vedotin
Adcirca	Eli Lilly Nederland B.V.	EU/1/08/476/005-06	Film-coated tablet	-Tadalafil
Adcirca (previously Tadalafil Lilly)	Eli Lilly Nederland B.V.	EU/1/08/476/001-004	Film-coated tablet	-Tadalafil
Adcortyl Intra-articular/Intradermal Injection 10 mg/ml, Suspension for Injection, 5ml	Bristol-Myers Squibb Pharmaceuticals uc	PA0002/018/003	Suspension for injectio	-Triamcinolone acetonide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Addiphos concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/024/001	Concentrate for solution for infusion	-Potassium dihydrogen phosphate -Potassium hydroxide -Disodium phosphate dihydrate
Additrac N concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/023/002	Concentrate for solution for infusion	-Chromic chloride hexahydrate -Copper chloride dihydrate -Ferric chloride hexahydrate -Manganese chloride tetrahydrate -Potassium iodide -Sodium fluoride -Sodium molybdate dihydrate -Sodium selenite anhydrous -Zinc chloride
Adempas	Bayer AG	EU/1/13/907/001-003	Film-coated tablet	-Riociguat
Adempas	Bayer AG	EU/1/13/907/004-006	Film-coated tablet	-Riociguat
Adempas	Bayer AG	EU/1/13/907/007-009	Film-coated tablet	-Riociguat
Adempas	Bayer AG	EU/1/13/907/010-012	Film-coated tablet	-Riociguat
Adempas	Bayer AG	EU/1/13/907/013-015	Film-coated tablet	-Riociguat
Adenocor 3 mg/ml solution for injection	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/139/001	Solution for injection	-Adenosine
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	-Adenosine
Adenuric	Menarini International Operations Luxembourg S.A.	EU/1/08/447/001-002	Film-coated tablet	-Febuxostat
Adenuric	Menarini International Operations Luxembourg S.A.	EU/1/08/447/003-004	Film-coated tablet	-Febuxostat
Adizem-SR 120 mg Prolonged Release Capsules	Mundipharma Pharmaceuticals Limited	PA1688/001/002	Prolonged-release capsule, hard	-Diltiazem hydrochloride
Adizem-SR 180 mg Prolonged Release Capsules	Mundipharma Pharmaceuticals Limited	PA1688/001/003	Prolonged-release capsule, hard	-Diltiazem hydrochloride
Adizem-SR 90 mg Prolonged Release Capsules	Mundipharma Pharmaceuticals Limited	PA1688/001/001	Prolonged-release capsule, hard	-Diltiazem hydrochloride
ADIZEM-XL 120mg prolonged release capsules	Mundipharma Pharmaceuticals Limited	PA1688/001/004	Prolonged-release capsule, hard	-Diltiazem hydrochloride
ADIZEM-XL 180mg prolonged release capsules	Mundipharma Pharmaceuticals Limited	PA1688/001/005	Prolonged-release capsule, hard	-Diltiazem hydrochloride
ADIZEM-XL 240 mg prolonged release capsules	Mundipharma Pharmaceuticals Limited	PA1688/001/006	Prolonged-release capsule, hard	-Diltiazem hydrochloride
ADIZEM-XL 300 mg prolonged release capsules	Mundipharma Pharmaceuticals Limited	PA1688/001/007	Prolonged-release capsule, hard	-Diltiazem hydrochloride
Adjupanrix	GlaxoSmithKline Biologicals S.A.	EU/1/09/578/001	Emulsion and suspension for emulsion for injection	-Purified antigen fractions of inactivated split virions a/vietnam/1194/2004 nibrg-14 (h5n1)
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	-Adrenaline tartrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Adrenaline (Epinephrine) 1:1,000 Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/035/001	Solution for injection	-Adrenaline (epinephrine)
Adavance 70 mg/2800 IU tablets	N.V. Organon	EU/1/06/364/001-004	Tablet	-Vitamin D3 -Alendronic acid
Adavance 70 mg/5600 IU tablets	N.V. Organon	EU/1/06/364/006-008	Tablet	-Vitamin D3 -Alendronic acid
Adtralza	LEO Pharma A/S	EU/1/21/1554/001	Solution for injection in pre-filled syringe	-Tralokinumab
Adtralza	LEO Pharma A/S	EU/1/21/1554/001-003	Solution for injection in pre-filled syringe	-Tralokinumab
Adtralza	LEO Pharma A/S	EU/1/21/1554/004-005	Solution for injection	-Tralokinumab
Advagraf	Astellas Pharma Europe BV	EU/1/07/387/11-13	Prolonged-release capsule, hard	-Tacrolimus
Advagraf	Astellas Pharma Europe BV	EU/1/07/387/1-2	Prolonged-release capsule, hard	-Tacrolimus
Advagraf	Astellas Pharma Europe BV	EU/1/07/387/3-6	Prolonged-release capsule, hard	-Tacrolimus
Advagraf	Astellas Pharma Europe BV	EU/1/07/387/7-8	Prolonged-release capsule, hard	-Tacrolimus
ADVATE	Takeda Manufacturing Austria AG	EU/1/03/271/001	Powder and solvent for solution for injection	-Recombinant coagulation fviii (octocog alfa)
Advate	Takeda Manufacturing Austria AG	EU/1/03/271/002	Powder and solvent for solution for injection	-Recombinant coagulation fviii (octocog alfa)
Advate	Takeda Manufacturing Austria AG	EU/1/03/271/003	Powder and solvent for solution for injection	-Recombinant coagulation fviii (octocog alfa)
Advate	Takeda Manufacturing Austria AG	EU/1/03/271/004	Powder and solvent for solution for injection	-Recombinant coagulation fviii (octocog alfa)
ADVATE	Takeda Manufacturing Austria AG	EU/1/03/271/005	Powder and solvent for solution for injection	-Recombinant coagulation fviii (octocog alfa)
ADVATE	Takeda Manufacturing Austria AG	EU/1/03/271/006	Powder and solvent for solution for injection	-Recombinant coagulation fviii (octocog alfa)
Advate	Takeda Manufacturing Austria AG	EU/1/03/271/007	Powder and solvent for solution for injection	-Recombinant coagulation fviii (octocog alfa)
Advate	Takeda Manufacturing Austria AG	EU/1/03/271/008	Powder and solvent for solution for injection	-Recombinant coagulation fviii (octocog alfa)
Advate	Takeda Manufacturing Austria AG	EU/1/03/271/009	Powder and solvent for solution for injection	-Recombinant coagulation fviii (octocog alfa)
Advil Cold & Flu Coated Tablets Ibuprofen 200mg Pseudoephedrine Hydrochloride 30mg	Haleon Ireland Limited	PA0678/147/001	Coated tablet	-Ibuprofen -PSEUDOEPHEDRINE HYDROCHLORIDE
Advil Cold & Flu Relief Soft Capsules Ibuprofen 200mg Pseudoephedrine Hydrochloride 30mg	Haleon Ireland Limited	PA0678/147/002	Capsule, soft	-Ibuprofen -PSEUDOEPHEDRINE HYDROCHLORIDE
Advil Liquid 200mg Soft capsules	Haleon Ireland Limited	PA0678/146/001	Capsule, soft	-Ibuprofen
ADYNOVI	Baxalta Innovations GmbH	EU/1/17/1247/001-004	Powder and solvent for solution for injection	-Rurioctocog alfa pegol
ADYNOVI	Baxalta Innovations GmbH	EU/1/17/1247/005-008	Powder and solvent for solution for injection	-Rurioctocog alfa pegol

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
ADYNOVI	Baxalta Innovations GmbH	EU/1/17/1247/010-012	Powder and solvent for solution for injection	-Rurioctocog alfa pegol
ADYNOVI	Baxalta Innovations GmbH	EU/1/17/1247/013-014	Powder and solvent for solution for injection	-Rurioctocog alfa pegol
Adynovi	Baxalta Innovations GmbH	EU/1/17/1247/015-016	Powder for solution for injection	-Rurioctocog alfa pegol
Aerinaze	N.V. Organon	EU/1/07/399/001-006	Modified-release tablet	-Desloratidine -Pseudoephedrine sulfate
AERIUS	N.V. Organon	EU/1/00/160/001	Film-coated tablet	-Desloratidine
AERIUS	N.V. Organon	EU/1/00/160/001-013	Film-coated tablet	-Desloratidine
Aerius	N.V. Organon	EU/1/00/160/61-69	Oral solution	-Desloratidine, micronized
Afinitor	Novartis Europharm Limited	EU/1/09/538/001	Tablet	-Everolimus
Afinitor	Novartis Europharm Limited	EU/1/09/538/004	Tablet	-Everolimus
Afinitor	Novartis Europharm Limited	EU/1/09/538/009-010	Tablet	-Rad n bht
Aflunov	Seqirus S.r.l.	EU/1/10/658/001-002	Suspension for injection in pre-filled syringe	-H5n1 (a/vietnam/1194/2004)
Afstyla	CSL Behring GmbH	EU/1/16/1158/001	Powder and solvent for solution for injection	-Lonoctocog alfa
Afstyla	CSL Behring GmbH	EU/1/16/1158/002	Powder and solvent for solution for injection	-Lonoctocog alfa
Afstyla	CSL Behring GmbH	EU/1/16/1158/003	Powder and solvent for solution for injection	-Lonoctocog alfa
Afstyla	CSL Behring GmbH	EU/1/16/1158/004	Powder and solvent for solution for injection	-Lonoctocog alfa
Afstyla	CSL Behring GmbH	EU/1/16/1158/005	Powder and solvent for solution for injection	-Lonoctocog alfa
Afstyla	CSL Behring GmbH	EU/1/16/1158/006	Powder and solvent for solution for injection	-Lonoctocog alfa
Afstyla	CSL Behring GmbH	EU/1/16/1158/007	Powder and solvent for solution for injection	-Lonoctocog alfa
AGAMREE	Santhera Pharmaceuticals (Deutschland) GmbH	EU/1/23/1776/001	Oral suspension	-Vamorolone
Agerdex 1 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/088/001	Film-coated tablet	-Anastrozole
Agomelatine Mylan 25 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/189/001	Film-coated tablet	-Agomelatine
Aimovig	Novartis Europharm Limited	EU/1/18/1293/001-003	Solution for injection	-ERENUMAB
Aimovig	Novartis Pharma GmbH	EU/1/18/1293/004-006	Solution for injection in pre-filled syringe	-ERENUMAB
AirBuFo Forspiro 160 microgram/4.5 microgram/dose inhalation powder, pre-dispensed	Rowex Ltd	PA0711/284/001	Inhalation powder, pre-dispensed	-Budesonide -Formoterol fumarate dihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
AirBuFo Forspiro 320 microgram/9 microgram/dose inhalation powder, pre-dispensed	Rowex Ltd	PA0711/284/002	Inhalation powder, pre-dispensed	-Budesonide -Formoterol fumarate dihydrate
AirFluSal Forspiro 50 microgram/500 microgram/dose, inhalation powder, predispensed	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/004/002	Inhalation powder, pre-dispensed	-SALMETEROL XINAFOATE -Fluticasone propionate
AirFluSal MDI 25 microgram/125 microgram/dose pressurised inhalation, suspension	Rowex Ltd	PA0711/270/001	Pressurised inhalation, suspension	-SALMETEROL XINAFOATE -Fluticasone propionate
AirFluSal MDI 25 microgram/250 microgram/dose pressurised inhalation, suspension	Rowex Ltd	PA0711/270/002	Pressurised inhalation, suspension	-SALMETEROL XINAFOATE -Fluticasone propionate
AirFluSal® Forspiro® 50 microgram/250 microgram/dose, inhalation powder, predispensed	Rowex Ltd	PA0711/237/001	Inhalation powder, pre-dispensed	-Salmeterol -Fluticasone propionate
AirFluSal® Forspiro® 50 microgram/250 microgram/dose, inhalation powder, predispensed	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/004/001	Inhalation powder, pre-dispensed	-Salmeterol -FLUTICASONE PROPIONATE
AirFluSal® Forspiro® 50 microgram/500 microgram/dose, inhalation powder, predispensed	Rowex Ltd	PA0711/237/002	Inhalation powder, pre-dispensed	-Salmeterol -Fluticasone propionate
AJOVY	TEVA GmbH	EU/1/19/1358/001-002	Solution for injection in pre-filled syringe	-FREMANEZUMAB
Akeega	Janssen-Cilag International NV	EU/1/23/1722/001	Film-coated tablet	-Niraparib Tosilate Monohydrate -Abiraterone acetate
Akeega	Janssen-Cilag International NV	EU/1/23/1722/002	Film-coated tablet	-Niraparib Tosilate Monohydrate -Abiraterone acetate
Akineton 2 mg tablets	Laboratorio Farmaceutico S.I.T.	PA1253/001/001	Tablet	-Biperiden hydrochloride
Akineton 2mg Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/010/001	Tablet	-Biperiden hydrochloride
Akineton Retard 4 mg prolonged release tablets	Laboratorio Farmaceutico S.I.T.	PA1253/002/001	Prolonged-release tablet	-Biperiden hydrochloride
Aklief 50 microgram/g Cream	Galderma International	PA22743/017/001	Cream	-Trifarotene
Akynzeo	Helsinn Birex Pharmaceuticals Limited	EU/1/15/1001/003	Powder for concentrate for solution for infusion	-FOSNETUPITANT CHLORIDE HYDROCHLORIDE -Palonosetron hydrochloride
Akynzeo	Helsinn Birex Pharmaceuticals Limited	EU/1/15/1001/004	Concentrate for solution for infusion	-FOSNETUPITANT CHLORIDE HYDROCHLORIDE -Palonosetron hydrochloride
Akynzeo 300 mg/0.5 mg hard capsules	Helsinn Birex Pharmaceuticals Limited	EU/1/15/1001/001	Capsule, hard	-Netupitant -Palonosetron (as hydrochloride)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Alacare 8 mg medicated plaster	Photonamic GmbH & Co. KG	PA2071/001/001	Medicated plaster	-5-aminolevulinic acid hydrochloride
Albunorm 20%, 200g/l, solution for infusion	Octapharma (IP) SPRL	PA2219/007/002	Solution for infusion	-Human plasma protein not containing less than 96% human albumin
Albunorm 5%, 50 g/l, solution for infusion	Octapharma (IP) SPRL	PA2219/007/001	Solution for infusion	-Human plasma protein not containing less than 96% human albumin
Alburex 20, 200 g/l, solution for infusion	CSL Behring GmbH	PA0800/008/002	Solution for infusion	-Human albumin
Alburex 5, 50 g/l, solution for infusion	CSL Behring GmbH	PA0800/008/001	Solution for infusion	-Human albumin
Albutein, 200 gram(s)/litre, solution for infusion	Instituto Grifols S.A.	PA0849/006/002	Solution for infusion	-Human albumin solution
Albutein, 50 gram(s)/litre, solution for infusion	Instituto Grifols S.A.	PA0849/006/001	Solution for infusion	-Human albumin solution
Aldactone 100 mg Film-coated tablet	IMED Healthcare Ltd.	PPA1463/223/002	Film-coated tablet	-Spironolactone
Aldactone 100 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/418/002	Film-coated tablet	-Spironolactone
Aldactone 100 mg Film-coated tablets	Pfizer Healthcare Ireland	PA0822/110/003	Film-coated tablet	-Spironolactone
Aldactone 25 mg Film-coated Tablets	Pfizer Healthcare Ireland	PA0822/110/001	Film-coated tablet	-Spironolactone
Aldactone 25 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/418/001	Film-coated tablet	-Spironolactone
Aldactone 25 mg Film-coated Tablets	Primecrown 2010 Limited	PPA1633/030/001	Film-coated tablet	-Spironolactone
Aldactone 25 mg Film-coated Tablets	IMED Healthcare Ltd.	PPA1463/223/001	Film-coated tablet	-Spironolactone
Aldactone 25 mg Film-coated Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/043/001	Film-coated tablet	-Spironolactone
Aldactone 50 mg Film-coated tablets	Pfizer Healthcare Ireland	PA0822/110/002	Film-coated tablet	-Spironolactone
ALDARA	Viatrix Healthcare Limited	EU/1/98/080/001	Cream	-Imiquimod
Aldomet 250 mg Film-coated Tablets	Aspen Pharma Trading Limited	PA1691/012/001	Film-coated tablet	-Methyldopa
Aldomet 500 mg Film-coated Tablets	Aspen Pharma Trading Limited	PA1691/012/002	Film-coated tablet	-Methyldopa
ALDURAZYME	Genzyme Europe B.V.	EU/1/03/253/01-3	Concentrate for solution for infusion	-Laronidase
Alecensa	Roche Registration GmbH	EU/1/16/1169/001	Capsule, hard	-Alectinib hydrochloride
Alendronate/Colecalciferol Teva 70 mg/2800 IU tablets	Teva Pharma B.V.	PA0749/196/001	Tablet	-Vitamin d3 -Alendronic acid
Alendronate/Colecalciferol Teva 70 mg/5600 IU tablets	Teva Pharma B.V.	PA0749/196/002	Tablet	-Vitamin d3 -Alendronic acid
Alendronic Acid Bluefish Once weekly 70 mg tablets	Bluefish Pharmaceuticals AB	PA1436/004/001	Tablet	-Sodium alendronate
Alendronic Acid Once Weekly 70 mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/032/001	Tablet	-Alendronic acid
Alendronic acid/Cholecalciferol Accord 70 mg/5600 IU tablets	Accord Healthcare Ireland Ltd.	PA2315/020/002	Tablet	-Vitamin d3 -Alendronic acid

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Alendronic acid/Cholecalciferol Accord 70mg/2800IU tablets	Accord Healthcare Ireland Ltd.	PA2315/020/001	Tablet	-Alendronic acid -Vitamin d3
Alendronic acid/Colecalciferol Rowex 70 mg/2 800 IU tablets	Rowex Ltd	PA0711/319/001	Tablet	-Alendronate sodium trihydrate -Colecalciferol
Alendronic acid/Colecalciferol Rowex 70 mg/5 600 IU tablets	Rowex Ltd	PA0711/319/002	Tablet	-Alendronate sodium trihydrate -Colecalciferol
Alexette 0.02mg/3mg film-coated tablets	Gedeon Richter Plc	PA1330/009/001	Film-coated tablet	-Drospirenone -Ethinylestradiol
Alfentanil 500 micrograms/ml solution for injection/infusion	AS Kalceks	PA2165/006/001	Solution for injection/infusion	-Alfentanil
Alfu 10 mg Prolonged-release Tablets	Aurobindo Pharma (Malta) Limited	PA1445/018/001	Prolonged-release tablet	-Alfuzosin hydrochloride
ALIMTA	Eli Lilly Nederland B.V.	EU/1/04/290/001	Powder for concentrate for solution for infusion	-Pemetrexed
Alimta	Eli Lilly Nederland B.V.	EU/1/04/290/002	Powder for concentrate for solution for infusion	-Pemetrexed
Alkeran 2 mg Film-coated Tablets	Aspen Pharma Trading Limited	PA1691/004/002	Film-coated tablet	-Melphalan
Alkeran 50mg, Powder and Solvent for Solution for Infusion	Aspen Pharma Trading Limited	PA1691/004/001	Powder and solvent for solution for infusion	-Melphalan
Alkindi	Diurnal Europe B.V.	EU/1/17/1260/001	Granules	-Hydrocortisone
Alkindi	Diurnal Europe B.V.	EU/1/17/1260/002	Granules	-Hydrocortisone
Alkindi	Diurnal Europe B.V.	EU/1/17/1260/003	Granules	-Hydrocortisone
Alkindi	Diurnal Europe B.V.	EU/1/17/1260/004	Granules	-Hydrocortisone
Alli	GlaxoSmithKline Dungarvan Limited	EU/1/07/401/12-15	Capsule, hard	-Orlistat
Alli	GlaxoSmithKline Dungarvan Limited	EU/1/07/401/1-6	Capsule, hard	-Orlistat
Alli	GlaxoSmithKline Dungarvan Limited	EU/1/07/401/7-11	Capsule, hard	-Orlistat
Allopurinol 100 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/219/001	Tablet	-Allopurinol
Allopurinol 300 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/219/002	Tablet	-Allopurinol
Allopurinol Teva 100 mg tablets	Teva Pharma B.V.	PA0749/099/001	Tablet	-Allopurinol
Allopurinol Teva 300 mg tablets	Teva Pharma B.V.	PA0749/099/003	Tablet	-Allopurinol
Alluzience, 200 Speywood units/mL, solution for injection	Ipsen Pharma	PA1613/004/001	Solution for injection	-Botulinum Toxin A - Haemagglutinin Complex
Almogran 12.5 mg film-coated tablet	Almirall, S.A.	PA0968/001/001	Film-coated tablet	-Almotriptan
Alofisel	Takeda Pharma A/S	EU/1/17/1261/001	Suspension for injectio	-Expanded human allogeneic mesenchymal adult stem
Alopur 100 mg Tablets	Rowex Ltd	PA0711/154/001	Tablet	-Allopurinol
Alopur 300 mg Tablets	Rowex Ltd	PA0711/154/002	Tablet	-Allopurinol
ALOXI	Helsinn Birex Pharmaceuticals Limited	EU/1/04/306/2-3	Capsules, Soft	-PALONOSETRON (AS HYDROCHLORIDE)
ALOXI	Helsinn Birex Pharmaceuticals Limited	EU/1/04/306/001	Solution for injection	-Palonosetron (as hydrochloride)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Aloxi 500 micrograms soft capsules	Helsinn Birex Pharmaceuticals Limited	EU/1/04/306/002-003	Capsule, soft	-Palonosetron (as hydrochloride)
Alphagan 0.2% w/v (2 mg/ml) eye drops, solution	AbbVie Limited	PA1824/007/001	Eye drops, solution	-Brimonidine tartrate
Alphagan 0.2% w/v (2 mg/ml) eye drops, solution	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/007/001	Eye drops, solution	-Brimonidine tartrate
Alphagan 0.2% w/v (2 mg/ml) eye drops, solution	PCO Manufacturing Ltd.	PPA0465/413/001	Eye drops, solution	-Brimonidine tartrate
Alprazolam 0.25 mg Tablets	Rowex Ltd	PA0711/140/001	Tablet	-Alprazolam
Alprazolam 0.5 mg Tablets	Rowex Ltd	PA0711/140/002	Tablet	-Alprazolam
Alprazolam Krka 1 mg tablets	KRKA, d.d., Novo mesto	PA1347/097/003	Tablet	-Alprazolam
Alprazolam Krka 250 microgram tablets	KRKA, d.d., Novo mesto	PA1347/097/001	Tablet	-Alprazolam
Alprazolam Krka 500 microgram tablets	KRKA, d.d., Novo mesto	PA1347/097/002	Tablet	-Alprazolam
Alprolix	Swedish Orphan Biovitrum AB	EU/1/16/1098/001	Powder and solvent for solution for injection	-Eftrenonacog alfa
Alprolix	Swedish Orphan Biovitrum AB	EU/1/16/1098/002	Powder and solvent for solution for injection	-Eftrenonacog alfa
Alprolix	Swedish Orphan Biovitrum AB	EU/1/16/1098/003	Powder and solvent for solution for injection	-Eftrenonacog alfa
Alprolix	Swedish Orphan Biovitrum AB	EU/1/16/1098/004	Powder and solvent for solution for injection	-Eftrenonacog alfa
Alprolix	Swedish Orphan Biovitrum AB	EU/1/16/1098/005	Powder and solvent for solution for injection	-Eftrenonacog alfa
Altavita D3 50,000 IU oral solution	Consilient Health Limited	PA1876/002/001	Oral solution	-Cholecalciferol
altavitaD3 1,000 IU soft capsules	Consilient Health Limited	PA1876/005/001	Capsule, soft	-Cholecalciferol
altavitaD3 25,000 IU soft capsules	Consilient Health Limited	PA1876/004/003	Capsule, soft	-Cholecalciferol (02)
AltavitaD3 25,000IU oral solution	Consilient Health Limited	PA1876/002/002	Oral solution	-Colecalciferol
altavitaD3 50,000 IU soft capsules	Consilient Health Limited	PA1876/004/004	Capsule, soft	-Cholecalciferol (02)
altavitaD3 7,000 IU soft capsules	Consilient Health Limited	PA1876/005/002	Capsule, soft	-Cholecalciferol
Alunbrig	Takeda Pharma A/S	EU/1/18/1264/001-004	Film-coated tablet	-Brigatinib
Alunbrig	Takeda Pharma A/S	EU/1/18/1264/005-008	Film-coated tablet	-Brigatinib
Alunbrig	Takeda Pharma A/S	EU/1/18/1264/009-010	Film-coated tablet	-Brigatinib
ALUTARD SQ Bee 100 000 SQ-U/ml suspension for injection	ALK-Abello A/S	PA1255/008/001	Suspension for injectio	-Apis mellifera
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 injectio	-Apis mellifera -Apis mellifera -Apis mellifera -Apis mellifera
ALUTARD SQ Wasp 100 000 SQ-U/ml suspension for injection	ALK-Abello A/S	PA1255/009/001	Suspension for injectio	-Vespula spp.

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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 injectio	-Vespula spp. -Vespula spp. -Vespula spp. -Vespula spp.
Alverine Mayoly Spindler 60mg Hard Capsules	Laboratoires Mayoly Spindler	PA1993/001/001	Capsule, hard	-ALVERINE CITRATE
Alvesco 160 micrograms pressurised inhalation, solution	IMED Healthcare Ltd.	PPA1463/175/001	Pressurised inhalation, solution	-Ciclesonide
Alvesco 160 micrograms pressurised inhalation, solution	Covis Pharma Europe B.V.	PA22986/001/002	Pressurised inhalation, solution	-Ciclesonide
Alvesco 80 micrograms pressurised inhalation, solution	Covis Pharma Europe B.V.	PA22986/001/001	Pressurised inhalation, solution	-Ciclesonide
Alymsys	Mabxience Research, S.L.	EU/1/20/1509/001-002	Concentrate for solution for infusion	-Bevacizumab
Amantadine hydrochloride Renata 100 mg Capsules, hard	Renata Pharmaceuticals (Ireland) Limited	PA22865/005/001	Capsule, hard	-AMANTADINE HYDROCHLORIDE
Ambirix	GlaxoSmithKline Biologicals S.A.	EU/1/02/224/001	Suspension for injection in pre-filled syringe	-Hepatitis b surface antigen (hbs ag) -Hepatitis a virus
Ambirix	GlaxoSmithKline Biologicals S.A.	EU/1/02/224/002	Suspension for injection in pre-filled syringe	-Hepatitis b surface antigen (hbs ag) -Hepatitis a virus
Ambirix	GlaxoSmithKline Biologicals S.A.	EU/1/02/224/003	Suspension for injection in pre-filled syringe	-Hepatitis a virus -Hepatitis b surface antigen (hbs ag)
Ambirix	GlaxoSmithKline Biologicals S.A.	EU/1/02/224/004	Suspension for injection in pre-filled syringe	-Hepatitis a virus -Hepatitis b surface antigen (hbs ag)
Ambirix	GlaxoSmithKline Biologicals S.A.	EU/1/02/224/005	Suspension for injection in pre-filled syringe	-Hepatitis b surface antigen (hbs ag) -Hepatitis a virus
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	-Amphotericin b
Ambrisentan Accord 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/235/002	Film-coated tablet	-Ambrisentan
Ambrisentan Accord 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/235/001	Film-coated tablet	-Ambrisentan
Ambrisentan Mylan	Mylan Pharmaceuticals Limited	EU/1/19/1368/001-002	Film-coated tablet	-Ambrisentan
Ambrisentan Mylan	Mylan S.A.S.	EU/1/19/1368/003-004	Film-coated tablet	-Ambrisentan
Ameluz	Biofrontera Bioscience GmbH	EU/1/11/740/001	Gel	-5-aminolevulinic acid hydrochloride
Ametop 40 mg/g Gel	Alliance Pharma (Ireland) Limited	PA2325/002/001	Gel	-Tetracaine base
Amgevita	Amgen Europe B.V.	EU/1/16/1164/001	Solution for injection in pre-filled syringe	-Adalimumab
Amgevita	Amgen Europe B.V.	EU/1/16/1164/002-009	Solution for injection	-Adalimumab
AMGLIDIA	AMMTek	EU/1/18/1279/001-002	Oral suspension	-Glibenclamide
AMGLIDIA	AMMTek	EU/1/18/1279/003-004	Oral suspension	-Glibenclamide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Amidex 1 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/189/001	Film-coated tablet	-Anastrozole
AMIFAMPRIDINE SERB	SERB S.A.,	EU/1/22/1646/001-003	Tablet	-Amifampridine Phosphate
Amikacin 5 mg/ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/072/001	Solution for infusion	-Amikacin
Amikacin Caragen 250 mg/ml solution for injection/infusion	Caragen Limited	PA22939/001/001	Solution for injection/infusion	-Amikacin
Aminophylline Hydrate 25mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/099/001	Solution for injection	-AMINOPHYLLINE HYDRATE
Aminoven 16, solution for infusion, bottle	Fresenius Kabi Deutschland GmbH	PA2059/025/002	Solution for infusion	-Isoleucine -Leucine -Lysine acetate -Methionine -Phenylalanine -Threonine -Tryptophan -Valine -Arginine -Histidine -Alanine -Glycine -Proline -Serine -Tyrosine -Taurine
Aminoven 25, solution for infusion, bottle	Fresenius Kabi Deutschland GmbH	PA2059/025/003	Solution for infusion	-Isoleucine -Leucine -Lysine acetate -Methionine -Phenylalanine -Threonine -Tryptophan -Valine -Arginine -Histidine -Alanine -Glycine -Proline -Serine -Tyrosine -Taurine
Aminoven 8, solution for infusion, bottle	Fresenius Kabi Deutschland GmbH	PA2059/025/001	Solution for infusion	-Isoleucine -Leucine -Lysine acetate -Methionine -Phenylalanine -Threonine -Tryptophan -Valine -Arginine -Histidine -Alanine -Glycine -Proline -Serine -Tyrosine -Taurine
Amisulpride 200 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/182/002	Tablet	-Amisulpride
Amisulpride 50 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/182/001	Tablet	-Amisulpride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Amitriptyline 25 mg Film-Coated Tablets	Clonmel Healthcare Ltd	PA0126/041/001	Film-coated tablet	-Amitriptyline hydrochloride
Amitriptyline hydrochloride 10mg/5ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/002/001	Oral solution	-Amitriptyline hydrochloride
Amitriptyline Hydrochloride 25 mg/ 5 ml Oral Solution	Pinewood Laboratories Ltd	PA0281/233/001	Oral solution	-Amitriptyline hydrochloride
Amitriptyline hydrochloride 25mg/5ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/002/002	Oral solution	-Amitriptyline hydrochloride
Amitriptyline Hydrochloride 50 mg/ 5 ml Oral Solution	Pinewood Laboratories Ltd	PA0281/233/002	Oral solution	-Amitriptyline hydrochloride
Amitriptyline hydrochloride 50mg/5ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/002/003	Oral solution	-Amitriptyline hydrochloride
Amlode 10 mg Tablets	Rowex Ltd	PA0711/138/002	Tablet	-Amlodipine
Amlode 5 mg tablets	Rowex Ltd	PA0711/138/001	Tablet	-Amlodipine
Amlodipine 10 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/075/002	Tablet	-Amlodipine besilate
Amlodipine 5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/075/001	Tablet	-Amlodipine besilate
Amlodipine Bluefish 10 mg tablets	Bluefish Pharmaceuticals AB	PA1436/016/002	Tablet	-Amlodipine besilate
Amlodipine Bluefish 5 mg tablets	Bluefish Pharmaceuticals AB	PA1436/016/001	Tablet	-Amlodipine besilate
Amlodipine Clonmel 10 mg tablets	Clonmel Healthcare Ltd	PA0126/258/002	Tablet	-Amlodipine
Amlodipine Clonmel 5 mg tablets	Clonmel Healthcare Ltd	PA0126/258/001	Tablet	-Amlodipine
Amlodipine Fair-Med 10mg Tablets	Pharmsol Europe Limited	PA25291/001/002	Tablet	-Amlodipine besilate
Amlodipine Fair-Med 5mg Tablets	Pharmsol Europe Limited	PA25291/001/001	Tablet	-Amlodipine besilate
Amlodipine Krka 10 mg Tablets	KRKA, d.d., Novo mesto	PA1347/034/002	Tablet	-Amlodipine
Amlodipine Krka 5 mg Tablets	KRKA, d.d., Novo mesto	PA1347/034/001	Tablet	-Amlodipine
Amlodipine Pinewood 10 mg tablets	Pinewood Laboratories Ltd	PA0281/165/002	Tablet	-Amlodipine besilate
Amlodipine Pinewood 5 mg Tablets	Pinewood Laboratories Ltd	PA0281/165/001	Tablet	-Amlodipine besilate
Amlodipine Teva 10 mg Tablets	Teva Pharma B.V.	PA0749/067/002	Tablet	-Amlodipine
Amlodipine Teva 5 mg Tablets	Teva Pharma B.V.	PA0749/067/001	Tablet	-Amlodipine
Amlodipine Thame 10mg/5ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/003/002	Oral solution	-Amlodipine besilate
Amlodipine Thame 5mg/5ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/003/001	Oral solution	-Amlodipine besilate
Amlodipine Upjohn 10 mg tablets	Upjohn EESV	PA23055/013/002	Tablet	-Amlodipine
Amlodipine Upjohn 5 mg tablets	Upjohn EESV	PA23055/013/001	Tablet	-Amlodipine
Amlodipine Viatrix 10 mg tablets	Viatrix Limited	PA23266/002/002	Tablet	-Amlodipine besilate
Amlodipine Viatrix 5 mg tablets	Viatrix Limited	PA23266/002/001	Tablet	-Amlodipine besilate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Amlodipine/Valsartan Clonmel 10 mg/160 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/274/003	Film-coated tablet	-Amlodipine -Valsartan
Amlodipine/Valsartan Clonmel 5 mg/160 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/274/002	Film-coated tablet	-Amlodipine -Valsartan
Amlodipine/Valsartan Clonmel 5 mg/80 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/274/001	Film-coated tablet	-Amlodipine -Valsartan
Amlodipine/Valsartan Krka 10 mg / 160 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/055/003	Film-coated tablet	-Amlodipine -Valsartan
Amlodipine/Valsartan Krka 10 mg / 320 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/055/005	Film-coated tablet	-Amlodipine -Valsartan
Amlodipine/Valsartan Krka 5 mg / 320 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/055/004	Film-coated tablet	-Amlodipine -Valsartan
Amlodipine/Valsartan Krka 5 mg/ 160 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/055/002	Film-coated tablet	-Amlodipine -Valsartan
Amlodipine/Valsartan Krka 5 mg/ 80 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/055/001	Film-coated tablet	-Amlodipine -Valsartan
Amlodipine/Valsartan Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1092/001-013	Film-coated tablet	-Amlodipine besilate -Valsartan
Amlodipine/Valsartan Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1092/014-026	Film-coated tablet	-Amlodipine besilate -Valsartan
Amlodipine/Valsartan Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1092/027-039	Film-coated tablet	-Amlodipine besilate -Valsartan
Amlodipine/Valsartan/ Hydrochlorothiazide Clonmel 10 mg/160 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/303/002	Film-coated tablet	-Amlodipine besilate -Valsartan -Hydrochlorothiazide
Amlodipine/Valsartan/ Hydrochlorothiazide Clonmel 10 mg/160 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/303/004	Film-coated tablet	-Amlodipine besilate -Valsartan -Hydrochlorothiazide
Amlodipine/Valsartan/ Hydrochlorothiazide Clonmel 10 mg/320 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/303/005	Film-coated tablet	-Amlodipine besilate -Valsartan -Hydrochlorothiazide
Amlodipine/Valsartan/ Hydrochlorothiazide Clonmel 5 mg/160 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/303/001	Film-coated tablet	-Amlodipine besilate -Valsartan -Hydrochlorothiazide
Amlodipine/Valsartan/ Hydrochlorothiazide Clonmel 5 mg/160 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/303/003	Film-coated tablet	-Amlodipine besilate -Valsartan -Hydrochlorothiazide
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	-Amlodipine -Valsartan -Hydrochlorothiazide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Amlodipine -Valsartan -Hydrochlorothiazide
Amlodipine/Valsartan/ Hydrochlorothiazide Krka 5 mg/160 mg/25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/106/003	Film-coated tablet	-Amlodipine -Valsartan -Hydrochlorothiazide
Amlotan 10 mg tablet	Athlone Pharmaceuticals Limited	PA1418/003/002	Tablet	-Amlodipine
Amlotan 5 mg tablet	Athlone Pharmaceuticals Limited	PA1418/003/001	Tablet	-Amlodipine
AMMONAPS	Immedica Pharma AB	EU/1/99/120/001	Tablet	-Sodium phenylbutyrate
AMMONAPS	Immedica Pharma AB	EU/1/99/120/002	Tablet	-Sodium phenylbutyrate
AMMONAPS	Immedica Pharma AB	EU/1/99/120/003	Granules	-Sodium phenylbutyrate
AMMONAPS	Immedica Pharma AB	EU/1/99/120/004	Granules	-Sodium phenylbutyrate
Amoclav 125mg/31.25mg per 5ml Powder for Oral Suspension	Rowex Ltd	PA0711/162/001	Powder for oral suspension	-potassium clavulanate -Amoxicillin trihydrate
Amoclav 250mg/125mg Film-coated Tablets	Rowex Ltd	PA0711/162/002	Film-coated tablet	-Amoxicillin trihydrate -potassium clavulanate
Amoclav 500mg/125mg Film-coated tablets	Rowex Ltd	PA0711/162/003	Film-coated tablet	-potassium clavulanate -Amoxicillin trihydrate
Amorolfine 5 % w/v medicated nail lacquer	Rowex Ltd	PA0711/309/001	Medicated nail lacquer	-Amorolfine hydrochloride
Amorolfine 5% w/v medicated nail lacquer	Bluefish Pharmaceuticals AB	PA1436/029/001	Medicated nail lacquer	-Amorolfine
Amoxicillin 125 mg/5 ml powder for oral suspension	Clonmel Healthcare Ltd	PA0126/282/003	Powder for oral suspension	-Amoxicillin
Amoxicillin 250 mg hard capsules	Clonmel Healthcare Ltd	PA0126/282/001	Capsule, hard	-Amoxicillin
Amoxicillin 250 mg/5 ml powder for oral suspension	Clonmel Healthcare Ltd	PA0126/282/004	Powder for oral suspension	-Amoxicillin
Amoxicillin 500 mg hard capsules	Clonmel Healthcare Ltd	PA0126/282/002	Capsule, hard	-Amoxicillin
Amoxicillin Delbert 500 mg, powder for solution for injection or infusion	Laboratoires DELBERT	PA23217/001/001	Powder for solution for injection/infusion	-Amoxicillin sodium
Amoxicillin DSM Sinochem Pharmaceuticals 500 mg hard capsules	Centrient Pharmaceuticals Netherlands B.V	PA1832/001/002	Capsule, hard	-Amoxicillin (as trihydrate)
Amoxicillin/clavulanic acid Krka 500 mg/125 mg Film-Coated Tablets	KRKA, d.d., Novo mesto	PA1347/044/001	Film-coated tablet	-Amoxicillin -Clavulanic acid
Ampres 10mg/ml solution for injection	B. Braun Melsungen AG	PA0736/043/001	Solution for injection	-CHLOROPROCAINE HYDROCHLORIDE
Ampres 20 mg/ml solution for injection	B. Braun Melsungen AG	PA0736/043/002	Solution for injection	-Chloroprocaine hydrochloride
Amsalyo 75 mg powder for concentration for solution infusion	Eurocept International BV	PA1591/003/001	Powder for solution for infusion	-Amsacrine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Amsacrine
Amsparity	Pfizer Service Company BVBA	EU/1/19/1415/001	Solution for injection in pre-filled syringe	-Adalimumab
Amsparity	Pfizer Service Company BVBA	EU/1/19/1415/002	Solution for injection	-Adalimumab
Amsparity	Pfizer Service Company BVBA	EU/1/19/1415/003-006	Solution for injection in pre-filled syringe	-Adalimumab
Amsparity	Pfizer Service Company BVBA	EU/1/19/1415/007-010	Solution for injection in pre-filled pen	-Adalimumab
Amversio	SERB S.A.,	EU/1/22/1640/001	Oral powder	-Betaine anhydrous
Amvuttra	Alynam Netherlands B.V.	EU/1/22/1681/001	Solution for injection in pre-filled syringe	-Vutrisiran Sodium
AMYViD	Eli Lilly Nederland B.V.	EU/1/12/805/001-002	Solution for injection	-Florbetapir (18f)
AMYViD	Eli Lilly Nederland B.V.	EU/1/12/805/003-004	Solution for injection	-Florbetapir (18f)
Anafranil SR 75 mg Prolonged-release Tablets	zr pharma& GmbH	PA23086/001/001	Prolonged-release tablet	-Clomipramine hydrochloride
Anagrelide 0.5 mg Hard Capsules	Athlone Pharmaceuticals Limited	PA1418/006/001	Capsule, hard	-Anagrelide
Anagrelide Mylan	Mylan Pharmaceuticals Limited	EU/1/17/1253/002	Capsule, hard	-Anagrelide hydrochloride monohydrate
Anagrelide Mylan	Mylan Pharmaceuticals Limited	EU/1/17/1256/001	Capsule, hard	-Anagrelide hydrochloride monohydrate
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	-Epinephrine
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	-Epinephrine
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	-Epinephrine
Anastrozole 1 mg Film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/068/001	Film-coated tablet	-Anastrozole
Anastrozole 1mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/076/001	Film-coated tablet	-Anastrozole
Anastrozole Bluefish 1 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/010/001	Film-coated tablet	-Anastrozole
Anastrozole Synthon 1 mg, film-coated tablets	Synthon BV	PA0840/004/001	Film-coated tablet	-Anastrozole
Anastrozole Teva 1 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/028/001	Film-coated tablet	-Anastrozole
Anbesol Anaesthetic Antiseptic Oromucosal Solution	Alliance Pharma (Ireland) Limited	PA2325/003/001	Oromucosal solution	-Lidocaine hydrochloride -Chlorocresol -Cetylpyridinium chloride
Androcur 100 mg Tablets	Bayer Limited	PA1410/001/001	Tablet	-Cyproterone acetate
Androgel 25 mg, transdermal gel in sachet	Laboratoires Besins International	PA1054/001/001	Transdermal gel in sachet	-Testosterone

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Androgel 50 mg, transdermal gel in sachet	Laboratoires Besins International	PA1054/001/002	Transdermal gel in sachet	-Testosterone
Anexate 500 micrograms/5ml, solution for injection or infusion	Cheplapharm Arzneimittel GmbH	PA1868/002/001	Solution for injection/infusion	-Flumazenil
Angeliq 1 mg/2 mg film-coated tablets	Bayer Limited	PA1410/013/001	Film-coated tablet	-Estradiol -Drospirenone
Angusta 25 microgram tablets	Norgine B.V.	PA1336/010/001	Tablet	-Misoprostol
Anhydrol Forte 20% w/v Cutaneous Solution	Dermal Laboratories (Ireland) Limited	PA23128/004/001	Cutaneous solution	-Aluminium chloride hexahydrate
Anidulafungin 100 mg powder for concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/021/001	Powder for concentrate for solution for infusion	-Anidulafungin
Anidulafungin 100 mg Powder for concentrate for solution for infusion	Rowex Ltd	PA0711/278/001	Powder for concentrate for solution for infusion	-Anidulafungin
Anidulafungin Teva 100 mg Powder for Concentrate for Solution for Infusion	Teva B.V.	PA1986/045/001	Powder for concentrate for solution for infusion	-Anidulafungin
Anoro Ellipta	GlaxoSmithKline (Ireland) Limited	EU/1/14/898/001-003	Inhalation powder, pre-dispensed	-Vilanterol trifenate -Umeclidinium bromide
Antabuse 400 mg Effervescent Tablets	Teva B.V.	PA1986/110/001	Effervescent tablet	-Disulfiram
Anthisan Cream 2% w/w	Phoenix Labs	PA1113/024/001	Cream	-Mepyramine maleate
Anti-Hist Allergy 10mg Film-coated tablets	Clonmel Healthcare Ltd	PA0126/267/001	Film-coated tablet	-Cetirizine dihydrochloride
Anti-Hist Allergy 1mg/ml Oral Solution	Clonmel Healthcare Ltd	PA0126/267/002	Oral solution	-Cetirizine dihydrochloride
Anusol HC Ointment	SOFIBEL	PA22647/002/001	Ointment	-HYDROCORTISONE ACETATE -Benzyl benzoate -Bismuth subgallate -Bismuth oxide -Balsam peru -Zinc oxide
Anusol HC Suppositories	SOFIBEL	PA22647/002/002	Suppository	-HYDROCORTISONE ACETATE -Benzyl benzoate -Bismuth oxide -Balsam peru -Zinc oxide -Bismuth subgallate
Anusol Suppositories	SOFIBEL	PA22647/001/003	Suppository	-Bismuth oxide -Zinc oxide -Balsam peru -Bismuth subgallate
Anxicalm 10 mg Tablets	Clonmel Healthcare Ltd	PA0126/011/003	Tablet	-Diazepam
Anxicalm 2 mg Tablets	Clonmel Healthcare Ltd	PA0126/011/001	Tablet	-Diazepam
Anxicalm 5 mg Tablets	Clonmel Healthcare Ltd	PA0126/011/002	Tablet	-Diazepam
Apeneta 100 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/105/002	Prolonged-release tablet	-Tapentadol maleate hemihydrate
Apeneta 150 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/105/003	Prolonged-release tablet	-Tapentadol maleate hemihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Apeneta 200 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/105/004	Prolonged-release tablet	-Tapentadol maleate hemihydrate
Apeneta 250 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/105/005	Prolonged-release tablet	-Tapentadol maleate hemihydrate
Apeneta 50 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/105/001	Prolonged-release tablet	-Tapentadol maleate hemihydrate
Apexxnar	Pfizer Europe MA EEIG	EU/1/21/1612/001-006	Suspension for injectio	-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
Apidra	Sanofi-Aventis Deutschland GmbH	EU/1/04/285/021-036	Solution for injection	-Insulin glulisine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
APIDRA	Aventis Pharma Deutschland GmbH	EU/1/04/285/1-20	Solution for injection	-Insulin glulisine
Apixaban 2.5 mg film-coated tablets	Norton Waterford	PA0436/049/001	Film-coated tablet	-Apixaban
Apixaban 2.5 mg film-coated tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/009/001	Film-coated tablet	-Apixaban
Apixaban 5 mg film-coated tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/009/002	Film-coated tablet	-Apixaban
Apixaban 5 mg film-coated tablets	Norton Waterford	PA0436/049/002	Film-coated tablet	-Apixaban
Apixaban Accord 2.5 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/20/1458/001-020	Film-coated tablet	-Apixaban
Apixaban Accord 5 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/20/1458/021-046	Film-coated tablet	-Apixaban
Apixaban Clonmel 2.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/328/001	Film-coated tablet	-Apixaban
Apixaban Clonmel 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/328/002	Film-coated tablet	-Apixaban
Apixaban Krka 2.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/107/001	Film-coated tablet	-Apixaban
Apixaban Krka 5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/107/002	Film-coated tablet	-Apixaban
Apixaban Mylan 2.5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/233/001	Film-coated tablet	-Apixaban
Apixaban Mylan 5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/233/002	Film-coated tablet	-Apixaban
Apixaban Pinewood 2.5 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/259/001	Film-coated tablet	-Apixaban
Apixaban Pinewood 5 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/259/002	Film-coated tablet	-Apixaban
Apixaban Rowex 2.5 mg film-coated tablets	Rowex Ltd	PA0711/303/001	Film-coated tablet	-Apixaban
Apixaban Rowex 5 mg film-coated tablets	Rowex Ltd	PA0711/303/002	Film-coated tablet	-Apixaban
Apixaban Teva 2.5 mg film-coated tablets	Norton Waterford	PA0436/052/001	Film-coated tablet	-Apixaban
Apixaban Teva 5 mg film-coated tablets	Norton Waterford	PA0436/052/002	Film-coated tablet	-Apixaban
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	-Apomorphine hydrochloride
APO-go POD 5 mg/ml solution for infusion in cartridge	Stada Arzneimittel AG	PA0593/042/004	Solution for infusion in cartridge	-Apomorphine hydrochloride hemihydrate
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	-Apomorphine hydrochloride
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	-Apomorphine hydrochloride
Aprepitant Accord 125 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/148/002	Capsule, hard	-Aprepitant
Aprepitant Accord 125 mg/80 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/148/003	Capsule, hard	-Aprepitant -Aprepitant
Aprepitant Accord 80 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/148/001	Capsule, hard	-Aprepitant

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
APRETUDE	ViiV Healthcare BV	EU/1/23/1760/001	Film-coated tablet	-Cabotegravir Sodium -cabotegravir
Aprok 50mg powder for solution for injection	Laboratoires Thea	PA1107/006/001	Powder for solution for injection	-Cefuroxime Sodium
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/001	Tablet	-Irbesartan
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/001-003	Tablet	-Irbesartan
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/002	Tablet	-Irbesartan
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/003	Tablet	-Irbesartan
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/004	Tablet	-Irbesartan
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/004-006	Tablet	-Irbesartan
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/005	Tablet	-Irbesartan
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/006	Tablet	-Irbesartan
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/007	Tablet	-Irbesartan
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/007-009	Tablet	-Irbesartan
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/008	Tablet	-Irbesartan
Aprovel	Sanofi Winthrop Industrie	EU/1/97/046/009	Tablet	-Irbesartan
Aptivus	Boehringer Ingelheim International GmbH	EU/1/05/315/001	Capsule, soft	-Tipranavir
Aptivus	Boehringer Ingelheim International GmbH	EU/1/05/315/002	Oral solution	-Tipranavir
AQUIPTA	AbbVie Deutschland GmbH & Co. KG	EU/1/23/1750/001-002	Tablet	-Atogepant monohydrate
AQUIPTA	AbbVie Deutschland GmbH & Co. KG	EU/1/23/1750/003-004	Tablet	-Atogepant monohydrate
Aqumeldi	Proveca Pharma Limited	EU/1/23/1717/001-003	Orodispersible tablet	-Enalapril maleate
ARANESP	Amgen Europe B.V.	EU/1/01/185/001-002	Solution for injection in pre-filled syringe	-Darbepoetin alfa
Aranesp	Amgen Europe B.V.	EU/1/01/185/009-010	Solution for injection in pre-filled syringe	-Darbepoetin alfa
Aranesp	Amgen Europe B.V.	EU/1/01/185/013-014	Solution for injection in pre-filled syringe	-Darbepoetin alfa
Aranesp	Amgen Europe B.V.	EU/1/01/185/031-032	Solution for injection in pre-filled syringe	-Darbepoetin alfa
ARAVA	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/001	Film-coated tablet	-Leflunomide
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/002	Film-coated tablet	-Leflunomide
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/003	Film-coated tablet	-Leflunomide
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/004	Film-coated tablet	-Leflunomide
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/005	Film-coated tablet	-Leflunomide
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/006	Film-coated tablet	-Leflunomide
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/007	Film-coated tablet	-Leflunomide
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/008	Film-coated tablet	-Leflunomide
Arava	Sanofi-Aventis Deutschland GmbH	EU/1/99/118/009	Film-coated tablet	-Leflunomide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Arcoxia 120 mg film-coated tablets	NV Organon	PA0964/009/004	Film-coated tablet	-Etoricoxib
Arcoxia 30 mg film-coated tablets	NV Organon	PA0964/009/001	Film-coated tablet	-Etoricoxib
Arcoxia 30 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/176/004	Film-coated tablet	-Etoricoxib
Arcoxia 60 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/176/001	Film-coated tablet	-Etoricoxib
Arcoxia 60 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/041/001	Film-coated tablet	-Etoricoxib
Arcoxia 60 mg film-coated tablets	NV Organon	PA0964/009/002	Film-coated tablet	-Etoricoxib
Arcoxia 90 mg film-coated tablets	NV Organon	PA0964/009/003	Film-coated tablet	-Etoricoxib
Arcoxia 90 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/041/002	Film-coated tablet	-Etoricoxib
Arcoxia 90 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/176/002	Film-coated tablet	-Etoricoxib
Areloger 15 mg tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/057/002	Tablet	-Meloxicam
Areloger 7.5 mg tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/057/001	Tablet	-Meloxicam
AREXVY	GlaxoSmithKline Biologicals	EU/1/23/1740/001-002	Powder and suspension for injection	-Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E
ARICEPT 10 mg film coated tablets	Pfizer Healthcare Ireland	PA0822/002/002	Film-coated tablet	-Donepezil hydrochloride
ARICEPT 5 mg film coated tablets	Pfizer Healthcare Ireland	PA0822/002/001	Film-coated tablet	-Donepezil hydrochloride
ARICEPT EVESS 10 mg orodispersible table	Pfizer Healthcare Ireland	PA0822/002/004	Orodispersible tablet	-Donepezil hydrochloride
ARICEPT EVESS 5 mg orodispersible tablet	Pfizer Healthcare Ireland	PA0822/002/003	Orodispersible tablet	-Donepezil hydrochloride
ARIKAYCE liposomal	Insmed Netherlands B.V.	EU/1/20/1469/001	Nebuliser dispersion	-AMIKACIN SULFATE
Arimidex 1 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/218/001	Film-coated tablet	-Anastrozole
Arimidex 1 mg Film-coated Tablets	IMED Healthcare Ltd.	PPA1463/070/001	Film-coated tablet	-Anastrozole
Arimidex 1 mg film-coated tablets	Originalis B.V.	PPA2306/017/001	Film-coated tablet	-Anastrozole
Arimidex 1mg Film-coated Tablets	Laboratoires Juvise Pharmaceutiques	PA23154/001/001	Film-coated tablet	-Anastrozole
Aripil 10 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/099/002	Film-coated tablet	-Donepezil hydrochloride
Aripil 5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/099/001	Film-coated tablet	-Donepezil hydrochloride
Aripiprazole 10 mg tablets	Brillpharma (Ireland) Limited	PA22749/016/002	Tablet	-Aripiprazole
Aripiprazole 15 mg tablets	Brillpharma (Ireland) Limited	PA22749/016/003	Tablet	-Aripiprazole
Aripiprazole 20 mg tablets	Brillpharma (Ireland) Limited	PA22749/016/004	Tablet	-Aripiprazole
Aripiprazole 30 mg tablets	Brillpharma (Ireland) Limited	PA22749/016/005	Tablet	-Aripiprazole
Aripiprazole 5 mg tablets	Brillpharma (Ireland) Limited	PA22749/016/001	Tablet	-Aripiprazole

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Aripiprazole Accord	Accord Healthcare S.L.U.	EU/1/15/1045/001-006	Tablet	-Aripiprazole
Aripiprazole Accord	Accord Healthcare S.L.U.	EU/1/15/1045/007-012	Tablet	-Aripiprazole
Aripiprazole Accord	Accord Healthcare S.L.U.	EU/1/15/1045/013-018	Tablet	-Aripiprazole
Aripiprazole Accord	Accord Healthcare S.L.U.	EU/1/15/1045/019-022	Tablet	-Aripiprazole
Aripiprazole Clonmel 10 mg tablets	Clonmel Healthcare Ltd	PA0126/266/002	Tablet	-Aripiprazole
Aripiprazole Clonmel 15 mg tablets	Clonmel Healthcare Ltd	PA0126/266/003	Tablet	-Aripiprazole
Aripiprazole Clonmel 30 mg tablets	Clonmel Healthcare Ltd	PA0126/266/004	Tablet	-Aripiprazole
Aripiprazole Clonmel 5 mg tablets	Clonmel Healthcare Ltd	PA0126/266/001	Tablet	-Aripiprazole
Aripiprazole Krka 10mg Tablets	KRKA, d.d., Novo mesto	PA1347/089/002	Tablet	-Aripiprazole
Aripiprazole Krka 15mg Tablets	KRKA, d.d., Novo mesto	PA1347/089/003	Tablet	-Aripiprazole
Aripiprazole Krka 30mg Tablets	KRKA, d.d., Novo mesto	PA1347/089/004	Tablet	-Aripiprazole
Aripiprazole Krka 5mg Tablets	KRKA, d.d., Novo mesto	PA1347/089/001	Tablet	-Aripiprazole
Aripiprazole Mylan Pharma	Mylan S.A.S.	EU/1/15/1005/001-003	Tablet	-Aripiprazole
Aripiprazole Mylan Pharma	Mylan S.A.S.	EU/1/15/1005/004-006	Tablet	-Aripiprazole
Aripiprazole Mylan Pharma	Mylan S.A.S.	EU/1/15/1005/007-009	Tablet	-Aripiprazole
Aripiprazole Mylan Pharma	Mylan S.A.S.	EU/1/15/1005/010-012	Tablet	-Aripiprazole
Aripiprazole Pinewood 10 mg tablets	Pinewood Laboratories Ltd	PA0281/214/002	Tablet	-Aripiprazole
Aripiprazole Pinewood 15 mg tablets	Pinewood Laboratories Ltd	PA0281/214/003	Tablet	-Aripiprazole
Aripiprazole Pinewood 30 mg tablets	Pinewood Laboratories Ltd	PA0281/214/004	Tablet	-Aripiprazole
Aripiprazole Pinewood 5 mg tablets	Pinewood Laboratories Ltd	PA0281/214/001	Tablet	-Aripiprazole
Aripiprazole Sandoz	Sandoz GmbH	EU/1/15/1029/001-014	Tablet	-Aripiprazole
Aripiprazole Sandoz	Sandoz GmbH	EU/1/15/1029/015-028	Tablet	-Aripiprazole
Aripiprazole Sandoz	Sandoz GmbH	EU/1/15/1029/029-042	Tablet	-Aripiprazole
Aripiprazole Sandoz	Sandoz GmbH	EU/1/15/1029/043-047	Tablet	-Aripiprazole
Aripiprazole Sandoz	Sandoz GmbH	EU/1/15/1029/048-061	Tablet	-Aripiprazole
Aripiprazole Teva 10 mg tablets	Teva B.V.	PA1986/019/002	Tablet	-Aripiprazole
Aripiprazole Teva 15 mg tablets	Teva B.V.	PA1986/019/003	Tablet	-Aripiprazole
Aripiprazole Teva 30 mg tablets	Teva B.V.	PA1986/019/004	Tablet	-Aripiprazole
Aripiprazole Teva 5 mg tablets	Teva B.V.	PA1986/019/001	Tablet	-Aripiprazole
Aripiprazole Zentiva	Zentiva k.s.	EU/1/15/1009/001-005	Tablet	-Aripiprazole
ARIPIPRAZOLE ZENTIVA	Zentiva k.s.	EU/1/15/1009/006-010	Tablet	-ARIPIPRAZOLE
ARIPIPRAZOLE ZENTIVA	Zentiva k.s.	EU/1/15/1009/011-015	Tablet	-ARIPIPRAZOLE
ARIPIPRAZOLE ZENTIVA	Zentiva k.s.	EU/1/15/1009/016-020	Tablet	-ARIPIPRAZOLE
ARIPIPRAZOLE ZENTIVA	Zentiva k.s.	EU/1/15/1009/021-023	Orodispersible Tablet	-ARIPIPRAZOLE
ARIPIPRAZOLE ZENTIVA	Zentiva k.s.	EU/1/15/1009/024-026	Orodispersible Tablet	-ARIPIPRAZOLE
ARIPIPRAZOLE ZENTIVA	Zentiva k.s.	EU/1/15/1009/027-029	Orodispersible Tablet	-ARIPIPRAZOLE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
ARIXTRA	Viartis Healthcare Limited	EU/1/02/206/001-004	Solution for injection in pre-filled syringe	-Fondaparinux sodium
Arixtra	Viartis Healthcare Limited	EU/1/02/206/005-008	Solution for injection in pre-filled syringe	-Fondaparinux sodium
Arixtra	Viartis Healthcare Limited	EU/1/02/206/009-011	Solution for injection in pre-filled syringe	-Fondaparinux sodium
Arixtra	Viartis Healthcare Limited	EU/1/02/206/012-014	Solution for injection in pre-filled syringe	-Fondaparinux sodium
Arixtra	Viartis Healthcare Limited	EU/1/02/206/015-017	Solution for injection in pre-filled syringe	-Fondaparinux sodium
Arixtra	Viartis Healthcare Limited	EU/1/02/206/018	Solution for injection in pre-filled syringe	-Fondaparinux sodium
Arixtra	Viartis Healthcare Limited	EU/1/02/206/031-032	Solution for injection in pre-filled syringe	-Fondaparinux sodium
Arlevert 20 mg/40 mg tablets	Hennig Arzneimittel GmbH & Co KG	PA1238/001/001	Tablet	-Cinnarizine -Dimenhydrinate
Armisarte (Previously Pemetrexed Actavis)	Actavis Group hf	EU/1/15/1063/001-003	Concentrate for solution for infusion	-Pemetrexed diacid
Aromasin 25 mg coated tablets	Pfizer Healthcare Ireland	PA0822/111/001	Coated tablet	-Exemestane
Aromasin 25 mg coated tablets	PCO Manufacturing Ltd.	PPA0465/236/001	Coated tablet	-Exemestane
Aromasin 25 mg coated tablets	Originalis B.V.	PPA2306/015/001	Coated tablet	-Exemestane
Aromasin 25 mg coated tablets	IMED Healthcare Ltd.	PPA1463/069/001	Coated tablet	-Exemestane
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
Arquist 125 microgram per actuation pressurised inhalation, suspension	Cipla Europe NV	PA1963/012/001	Pressurised inhalation, suspension	-Fluticasone propionate
Arquist 250 microgram per actuation pressurised inhalation, suspension	Cipla Europe NV	PA1963/012/002	Pressurised inhalation, suspension	-Fluticasone propionate
Arret 2 mg Hard Capsules	PCO Manufacturing Ltd.	PPA0465/155/001	Capsule, hard	-Loperamide hydrochloride
Arret 2mg Hard Capsules	Johnson & Johnson (Ireland) Limited	PA0330/042/001	Capsule, hard	-Loperamide hydrochloride
Arsenic Trioxide Accord	Accord Healthcare S.L.U.	EU/1/19/1398/001-003	Concentrate for solution for infusion	-Arsenic Trioxide
Arsenic trioxide medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/20/1475/001	Concentrate for solution for infusion	-Arsenic Trioxide
Arsenic Trioxide Mylan	Mylan IRE Healthcare Limited	EU/1/20/1427/001-002	Concentrate for solution for infusion	-Arsenic Trioxide
Artelac 3.2 mg/ml Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/004/001	Eye drops, solution	-Hypromellose

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Artelac Preservative Free Single Dose Unit	Bausch + Lomb Ireland Limited	PA23259/004/002	Eye drops, solution in single-dose container	-Hypromellose
Artelac Preservative Free Single Dose Unit	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/023/001	Eye drops, solution in single-dose container	-Hypromellose
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	-Hypromellose
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	-Hypromellose
Artesunate Amivas	Amivas Ireland Limited	EU/1/21/1582/001-002	Powder and solution for solution for injection	-Artesunate
Arthrimel 1500mg Film Coated Tablets	Phoenix Labs	PA1113/011/003	Film-coated tablet	-Glucosamine sulfate
Arthrimel 500 mg Film-Coated Tablets	Phoenix Labs	PA1113/011/001	Film-coated tablet	-Glucosamine sulfate
Arthrimel 750mg Film Coated Tablets	Phoenix Labs	PA1113/011/002	Film-coated tablet	-Glucosamine sulfate
Arthrotec 50 modified-release tablets	Pfizer Healthcare Ireland	PA0822/112/001	Modified-release tablet	-Diclofenac sodium -Misoprostol
Arthrotec 50 modified-release tablets	PCO Manufacturing Ltd.	PPA0465/114/001	Modified-release tablet	-Misoprostol -DICLOFENAC SODIUM
Arthrotec 75 modified-release tablets	PCO Manufacturing Ltd.	PPA0465/114/002	Modified-release tablet	-Diclofenac sodium -Misoprostol
Arthrotec 75 modified-release tablets	IMED Healthcare Ltd.	PPA1463/159/001	Modified-release tablet	-Diclofenac sodium -Misoprostol
Arthrotec 75 modified-release tablets	Pfizer Healthcare Ireland	PA0822/112/002	Modified-release tablet	-Diclofenac sodium -Lactose monohydrate -Misoprostol
ARTISS Solutions for Sealant, deep frozen	Baxter Holding B.V.	PA2299/026/001	Solution for sealant	-Human fibrinogen -Human thrombin -Calcium chloride -Aprotinin
ASACARD 162.5 mg prolonged release hard capsules	New Haven Pharma (UK) Limited	PA1966/001/001	Prolonged-release capsule, hard	-Acetylsalicylic acid
Asacolon 1000 mg Suppository	Tillotts Pharma GmbH	PA2018/005/001	Suppository	-Mesalazine
Asacolon 1600 mg modified-release tablet	Tillotts Pharma GmbH	PA2018/004/001	Modified-release tablet	-Mesalazine
Asacolon 400mg Gastro-Resistant Tablets	Tillotts Pharma GmbH	PA2018/001/001	Gastro-resistant tablet	-Mesalazine
Asacolon 500 mg Suppositories	Tillotts Pharma GmbH	PA2018/001/003	Suppository	-Mesalazine
Asacolon 800 mg Gastro-resistant Tablets	PCO Manufacturing Ltd.	PPA0465/465/001	Gastro-resistant tablet	-Mesalazine
Asacolon 800mg Gastro-resistant Tablets	Tillotts Pharma GmbH	PA2018/001/002	Gastro-resistant tablet	-Mesalazine
Asmanex Twisthaler 200 micrograms Inhalation Powder	Organon Pharma (Ireland) Limited	PA23198/012/001	Inhalation powder	-Mometasone furoate
Asmanex Twisthaler 400 micrograms Inhalation Powder	Organon Pharma (Ireland) Limited	PA23198/012/002	Inhalation powder	-Mometasone furoate
Aspaveli	Apellis Ireland Limited	EU/1/21/1595/001-002	Solution for infusion	-Pegcetacoplan
Aspirin 75mg gastro-resistant tablets	Clonmel Healthcare Ltd	PA0126/246/001	Gastro-resistant tablet	-Acetyl salicylic acid

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Aspirin Krka 75 mg gastro-resistant tablets	KRKA, d.d., Novo mesto	PA1347/070/001	Gastro-resistant tablet	-Acetylsalicylic acid
Astepro 1.5 mg/ml nasal spray, solution	Mylan IRE Healthcare Limited	PA2010/045/001	Nasal spray, solution	-Azelastine hydrochloride
Astilin 10 mg film-coated tablets	Ascot Laboratories (Ireland) Limited	PA23163/001/001	Film-coated tablet	-Amitriptyline
Astilin 25 mg film-coated tablets	Ascot Laboratories (Ireland) Limited	PA23163/001/002	Film-coated tablet	-Amitriptyline hydrochloride
Atacand 16 mg tablets	PCO Manufacturing Ltd.	PPA0465/116/002	Tablet	-Candesartan cilexetil
Atacand 16 mg tablets	IMED Healthcare Ltd.	PPA1463/031/002	Tablet	-Candesartan cilexetil
Atacand 16 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/010/003	Tablet	-Candesartan cilexetil
Atacand 4 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/010/001	Tablet	-Candesartan cilexetil
Atacand 8 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/010/002	Tablet	-Candesartan cilexetil
Atacand 8 mg tablets	IMED Healthcare Ltd.	PPA1463/031/001	Tablet	-Candesartan cilexetil
Atacand 8 mg tablets	PCO Manufacturing Ltd.	PPA0465/116/001	Tablet	-Candesartan cilexetil
Atacand Plus 16 mg/12.5 mg tablets	PCO Manufacturing Ltd.	PPA0465/117/001	Tablet	-Candesartan cilexetil -Hydrochlorothiazide
Atacand Plus 16 mg/12.5 mg tablets	IMED Healthcare Ltd.	PPA1463/053/001	Tablet	-Candesartan cilexetil -Hydrochlorothiazide
Atacand Plus 16 mg/12.5 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/011/002	Tablet	-Candesartan cilexetil -Hydrochlorothiazide
Atacand Plus 8 mg/12.5 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/011/001	Tablet	-Hydrochlorothiazide -Candesartan cilexetil
Atazanavir Krka	KRKA, d.d., Novo mesto	EU/1/19/1353/001	Capsule, hard	-Atazanavir sulfate
Atazanavir Krka	KRKA, d.d., Novo mesto	EU/1/19/1353/002	Capsule, hard	-Atazanavir sulfate
Atazanavir Krka	KRKA, d.d., Novo mesto	EU/1/19/1353/003-004	Capsule, hard	-Atazanavir sulfate
Atazanavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1091/001-003	Capsule, hard	-Atazanavir sulfate
Atazanavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1091/004-006	Capsule, hard	-Atazanavir sulfate
Atazanavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1091/007-010	Capsule, hard	-Atazanavir sulfate
Atazanavir Rowex 300 mg Capsules hard	Rowex Ltd	PA0711/287/004	Capsule, hard	-Atazanavir sulfate
Atecor 100mg Tablets	Rowex Ltd	PA0711/003/003	Film-coated tablet	-Atenolol
Atecor 25mg Tablets	Rowex Ltd	PA0711/003/001	Film-coated tablet	-Atenolol
Atecor 50mg Tablets	Rowex Ltd	PA0711/003/002	Film-coated tablet	-Atenolol
Atecor CT 100 mg/25 mg Film-coated tablets	Rowex Ltd	PA0711/020/002	Film-coated tablet	-Chlortalidone -Atenolol
Atecor CT 50 mg/12.5 mg Film-coated tablets	Rowex Ltd	PA0711/020/001	Film-coated tablet	-Chlortalidone -Atenolol
Aectura Breezhaler 125 micrograms/127.5 micrograms inhalation powder, hard capsules	Novartis Europharm Limited	EU/1/20/1439/005-008	Inhalation powder, hard capsule	-Indacaterol acetate -Mometasone furoate
Aectura Breezhaler 125 micrograms/260 micrograms inhalation powder, hard capsules	Novartis Europharm Limited	EU/1/20/1439/009-012	Inhalation powder, hard capsule	-Indacaterol acetate -Mometasone furoate
Aectura Breezhaler 125 micrograms/62.5 micrograms inhalation powder, hard capsules	Novartis Europharm Limited	EU/1/20/1439/001-004	Inhalation powder, hard capsule	-Indacaterol acetate -Mometasone furoate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Atenolol 5mg/ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/004/001	Oral solution	-Atenolol
Atenomel 100 mg Tablets	Clonmel Healthcare Ltd	PA0126/069/002	Tablet	-Atenolol
Atenomel 25 mg Tablets	Clonmel Healthcare Ltd	PA0126/069/003	Tablet	-Atenolol
Atenomel 50 mg Tablets	Clonmel Healthcare Ltd	PA0126/069/001	Tablet	-Atenolol
Atgam 50 mg/ml concentrate for solution for infusion	Pfizer Healthcare Ireland	PA0822/238/001	Concentrate for solution for infusion	-Anti-T Lymphocyte Immunoglobulin for Human Use, Horse
Ativan 1 mg Tablets	Pfizer Healthcare Ireland	PA0822/090/001	Tablet	-Lorazepam
Atomoxetine Accord 10 mg Hard Capsules	Accord Healthcare Ireland Ltd.	PA2315/019/001	Capsule, hard	-Atomoxetine hydrochloride
Atomoxetine Accord 100 mg Hard Capsules	Accord Healthcare Ireland Ltd.	PA2315/019/007	Capsule, hard	-Atomoxetine hydrochloride
Atomoxetine Accord 18 mg Hard Capsules	Accord Healthcare Ireland Ltd.	PA2315/019/002	Capsule, hard	-Atomoxetine hydrochloride
Atomoxetine Accord 25 mg Hard Capsules	Accord Healthcare Ireland Ltd.	PA2315/019/003	Capsule, hard	-Atomoxetine hydrochloride
Atomoxetine Accord 40 mg Hard Capsules	Accord Healthcare Ireland Ltd.	PA2315/019/004	Capsule, hard	-Atomoxetine hydrochloride
Atomoxetine Accord 60 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/019/005	Capsule, hard	-Atomoxetine hydrochloride
Atomoxetine Accord 80 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/019/006	Capsule, hard	-Atomoxetine hydrochloride
Atorvas 10 mg film-coated tablets	Rowex Ltd	PA0711/180/001	Film-coated tablet	-Atorvastatin
Atorvas 20 mg film-coated tablets	Rowex Ltd	PA0711/180/002	Film-coated tablet	-Atorvastatin
Atorvas 40 mg film-coated tablets	Rowex Ltd	PA0711/180/003	Film-coated tablet	-Atorvastatin
Atorvas 80 mg film-coated tablets	Rowex Ltd	PA0711/180/004	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin 10 mg Film-Coated Tablets	Pinewood Laboratories Ltd	PA0281/236/001	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin 10 mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/195/001	Film-coated tablet	-Atorvastatin
Atorvastatin 10 mg film-coated tablets	Dexcel Pharma GmbH	PA2261/004/001	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin 10mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/003/001	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin 20 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/003/002	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin 20 mg film-coated tablets	Dexcel Pharma GmbH	PA2261/004/002	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin 20 mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/195/002	Film-coated tablet	-Atorvastatin
Atorvastatin 20 mg Film-Coated Tablets	Pinewood Laboratories Ltd	PA0281/236/002	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin 40 mg Film-Coated Tablets	Pinewood Laboratories Ltd	PA0281/236/003	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin 40 mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/195/003	Film-coated tablet	-Atorvastatin
Atorvastatin 40 mg film-coated tablets	Dexcel Pharma GmbH	PA2261/004/003	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin 40 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/003/003	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin 80 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/003/004	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin 80 mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/195/004	Film-coated tablet	-Atorvastatin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Atorvastatin 80 mg Film-Coated Tablets	Pinewood Laboratories Ltd	PA0281/236/004	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Bluefish 10 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/027/001	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Bluefish 20 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/027/002	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Bluefish 30 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/027/003	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Bluefish 40 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/027/004	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Bluefish 60 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/027/005	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Bluefish 80 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/027/006	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Clonmel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/271/001	Film-coated tablet	-Atorvastatin
Atorvastatin Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/271/002	Film-coated tablet	-Atorvastatin
Atorvastatin Clonmel 40 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/271/003	Film-coated tablet	-Atorvastatin
Atorvastatin Clonmel 80 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/271/004	Film-coated tablet	-Atorvastatin
Atorvastatin Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/023/001	Film-coated tablet	-Atorvastatin
Atorvastatin Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/023/002	Film-coated tablet	-Atorvastatin
Atorvastatin Krka 40 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/023/003	Film-coated tablet	-Atorvastatin
Atorvastatin Krka 80 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/009/004	Film-coated tablet	-Atorvastatin
Atorvastatin Liconsa 10 mg film-coated tablets	Laboratorios LICONSA, S.A.	PA1239/028/001	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Liconsa 20 mg film-coated tablets	Laboratorios LICONSA, S.A.	PA1239/028/002	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Liconsa 40 mg film-coated tablets	Laboratorios LICONSA, S.A.	PA1239/028/003	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Liconsa 80 mg film-coated tablets	Laboratorios LICONSA, S.A.	PA1239/028/004	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin OPKO 40 mg film coated tablets	Opko Health Spain S.L.U.	PA23271/001/001	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Pinewood 10 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/218/001	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Pinewood 20 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/218/002	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Pinewood 40 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/218/003	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Pinewood 80 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/218/004	Film-coated tablet	-Atorvastatin calcium trihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Atorvastatin Rowa 10 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/079/001	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Rowa 20 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/079/002	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Rowa 40 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/079/003	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Rowa 80 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/079/004	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Teva 10 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/110/001	Film-coated tablet	-Atorvastatin
Atorvastatin Teva 20 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/110/002	Film-coated tablet	-Atorvastatin
Atorvastatin Teva 40 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/110/003	Film-coated tablet	-Atorvastatin
Atorvastatin Teva 80 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/110/004	Film-coated tablet	-Atorvastatin
Atorvastatin Viatris 10 mg film-coated tablets	Viatris Limited	PA23266/001/001	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Viatris 20 mg film-coated tablets	Viatris Limited	PA23266/001/002	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Viatris 40 mg film-coated tablets	Viatris Limited	PA23266/001/003	Film-coated tablet	-Atorvastatin calcium trihydrate
Atorvastatin Viatris 80 mg film-coated tablets	Viatris Limited	PA23266/001/004	Film-coated tablet	-Atorvastatin calcium trihydrate
Atosiban SUN	Sun Pharmaceutical Industries Europe B.V.	EU/1/13/852/001	Solution for injection	-Atosiban
ATOSIBAN SUN	Sun Pharmaceutical Industries Europe B.V.	EU/1/13/852/002	Concentrate for solution for infusion	-ATOSIBAN
Atovaquone/Proguanil Hydrochloride 250 mg /100 mg film-coated tablets	Glenmark Arzneimittel GmbH	PA22645/006/001	Film-coated tablet	-Atovaquone -PROGUANIL HYDROCHLORIDE
Atovaquone/Proguanil Hydrochloride 250 mg/100 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/209/001	Film-coated tablet	-Atovaquone -PROGUANIL HYDROCHLORIDE
Atozet 10 mg/10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/470/001	Film-coated tablet	-Atorvastatin -Ezetimibe
Atozet 10 mg/20 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/470/002	Film-coated tablet	-Ezetimibe -Atorvastatin
Atozet 10 mg/40 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/470/003	Film-coated tablet	-Ezetimibe -Atorvastatin
Atozet 10 mg/40 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/215/001	Film-coated tablet	-Ezetimibe -Atorvastatin
Atozet 10 mg/40 mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/022/003	Film-coated tablet	-Ezetimibe -Atorvastatin
Atozet 10 mg/80 mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/022/004	Film-coated tablet	-Ezetimibe -Atorvastatin
Atozet 10 mg/80 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/215/002	Film-coated tablet	-Ezetimibe -Atorvastatin
Atozet 10 mg/80 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/470/004	Film-coated tablet	-Ezetimibe -Atorvastatin
Atozet 10mg/10mg Film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/022/001	Film-coated tablet	-Ezetimibe -Atorvastatin
Atozet 10mg/20mg Film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/022/002	Film-coated tablet	-Ezetimibe -Atorvastatin
Atracurium 10 mg/ml solution for injection/infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/011/001	Solution for injection/infusion	-Atracurium besilate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Atracurium besilate 10 mg/ml solution for injection/infusion	AS Kalceks	PA2165/001/001	Solution for injection/infusion	-Atracurium besilate
ATRIANCE 5mg/ml Solution for Infusion	Sandoz Pharmaceuticals d.d.	EU/1/07/403/001	Solution for infusion	-Nelarabine
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	-Atropine Sulfate Monohydrate
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	-Atropine sulfate
Atrovent 250 UDVs 250 micrograms/ 1ml Nebuliser Solution	Boehringer Ingelheim International GmbH	PA0775/012/002	Nebuliser solution	-Ipratropium bromide
Atrovent 500 UDVs, 500 micrograms/ 2ml Nebuliser Solution	Boehringer Ingelheim International GmbH	PA0775/012/003	Nebuliser solution	-Ipratropium bromide
Atrovent Inhaler CFC-Free 20 micrograms per metered dose pressurised inhalation solution	Boehringer Ingelheim International GmbH	PA0775/012/001	Pressurised inhalation, solution	-Ipratropium bromide
Aubagio	Sanofi Winthrop Industrie	EU/1/13/838/001-005	Film-coated tablet	-Teriflunomide
Aubagio	Sanofi Winthrop Industrie	EU/1/13/838/006	Film-coated tablet	-Teriflunomide
Audax Ear Drops Solution Choline Salicylate 20%w/v Glycerol 12.6%w/v	LanesHealth (Ireland) Limited	PA22702/003/001	Ear drops, solution	-Choline salicylate -Glycerol
Augmentin 250 mg/125 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/093/007	Film-coated tablet	-Amoxicillin trihydrate -potassium clavulanate
Augmentin 500 mg/125 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/019/003	Film-coated tablet	-Amoxicillin -Clavulanic acid
Augmentin 875 mg/125 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/019/005	Film-coated tablet	-Amoxicillin -Clavulanic acid
Augmentin 875 mg/125 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/017/001	Film-coated tablet	-Amoxicillin trihydrate -Clavulanic acid
Augmentin Duo Mixed Fruit 400 mg/57 mg/5 ml Powder for Oral Suspension	GlaxoSmithKline (Ireland) Limited	PA1077/019/006	Powder for oral suspension	-Amoxicillin -Clavulanic acid
Augmentin Paediatric 125 mg/31.25 mg per 5 ml Powder for Oral Suspension	GlaxoSmithKline (Ireland) Limited	PA1077/093/004	Powder for oral suspension	-Amoxicillin -Clavulanic acid
Avamys	GlaxoSmithKline (Ireland) Limited	EU/1/07/434/001-003	Nasal spray, suspension	-Fluticasone furoate
AVASTIN	Roche Registration GmbH	EU/1/04/300/001-002	Concentrate for solution for infusion	-Bevacizumab
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	-Hepatitis a virus
Avelox 400 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/118/001	Film-coated tablet	-Moxifloxacin
Avelox 400 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/230/001	Film-coated tablet	-Moxifloxacin hydrochloride
Avodart 0.5 mg soft capsules	PCO Manufacturing Ltd.	PPA0465/211/001	Capsule, soft	-Dutasteride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Avodart 0.5 mg soft capsules	IMED Healthcare Ltd.	PPA1463/149/001	Capsule, soft	-Dutasteride
Avodart 0.5 mg soft capsules	GlaxoSmithKline (Ireland) Limited	PA1077/104/001	Capsule, soft	-Dutasteride
Avonex	Biogen Netherlands B.V.	EU/1/97/033/003	Solution for injection in pre-filled syringe	-Interferon beta - 1a
Axhidrox 2.2 mg/pump actuation cream	Dr. August Wolff GmbH & Co. KG Arzneimittel	PA0988/003/001	Cream	-Glycopyrronium bromide
Axsain 0.075% w/w Cream	Teva B.V.	PA1986/088/001	Cream	-Capsaicin
Axumin	Blue Earth Diagnostics Ireland Ltd	EU/1/17/1186/001	Solution for injection	-Fluciclovine (18f)
Axumin	Blue Earth Diagnostics Ireland Ltd	EU/1/17/1186/002	Solution for injection	-Fluciclovine (18f)
Axura	Merz Pharmaceuticals GmbH	EU/1/02/218/1-3	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
Axura	Merz Pharmaceuticals GmbH	EU/1/02/218/16	Film-coated tablet	-Memantine
Axura	Merz Pharmaceuticals GmbH	EU/1/02/218/17-22	Film-coated tablet	-Memantine
Axura 5 mg/pump actuation oral solution	Merz Pharmaceuticals GmbH	EU/1/02/218/5-6	Oral solution	-MEMANTINE HYDROCHLORIDE
Aybintio	Samsung Bioepis NL B.V.	EU/1/20/1451/002	Concentrate for solution for infusion	-Bevacizumab
Aybintio	Samsung Bioepis NL B.V.	EU/1/20/1451/001	Concentrate for solution for infusion	-Bevacizumab
Aybintio	Samsung Bioepis NL B.V.	EU/1/20/1454/001	Concentrate for solution for infusion	-Bevacizumab
Aybintio	Samsung Bioepis NL B.V.	EU/1/20/1454/001-002	Concentrate for solution for infusion	-Bevacizumab
Aybintio	Samsung Bioepis NL B.V.	EU/1/20/1454/002	Concentrate for solution for infusion	-Bevacizumab
AYVAKYT	Blueprint Medicines (Netherlands) B.V.	EU/1/20/1473/001	Film-coated tablet	-Avapritinib
AYVAKYT	Blueprint Medicines (Netherlands) B.V.	EU/1/20/1473/002	Film-coated tablet	-Avapritinib
AYVAKYT	Blueprint Medicines (Netherlands) B.V.	EU/1/20/1473/003	Film-coated tablet	-Avapritinib
AYVAKYT	Blueprint Medicines (Netherlands) B.V.	EU/1/20/1473/005	Film-coated tablet	-Avapritinib
Azacididine 25 mg/ml powder for suspension for injection	Clonmel Healthcare Ltd	PA0126/362/001	Powder for suspension for injection	-Azacididine
Azacididine Accord	Accord Healthcare S.L.U.	EU/1/19/1413/001	Powder for suspension for injection	-Azacididine
Azacididine betapharm	Betapharm Arzneimittel GmbH	EU/1/19/1416/001	Powder for suspension for injection	-Azacididine
Azacididine Clonmel 25 mg/ml powder for suspension for injection	Clonmel Healthcare Ltd	PA0126/316/001	Powder for suspension for injection	-Azacididine
Azacididine EVER Pharma 25 mg/ml powder for suspension for injection	EVER Valinject GmbH	PA1774/003/001	Powder for suspension for injection	-Azacididine
Azacididine Mylan	Mylan IRE Healthcare Limited	EU/1/20/1426/001-002	Powder for suspension for injection	-Azacididine
Azacididine Rowex 25 mg/ml Powder for suspension for injection	Rowex Ltd	PA0711/297/001	Powder for suspension for injection	-Azacididine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Azacitidine Seacross 25 mg/ml powder for suspension for injection	Seacross Pharma (Europe) Limited	PA22766/005/001	Powder for suspension for injection	-Azacitidine
Azactam 1 g Powder for Solution for Injection or Infusion	Bristol-Myers Squibb Pharmaceuticals uc	PA0002/052/002	Powder for solution for injection/infusion	-Aztreonam
Azactam 2 g Powder for Solution for Injection or Infusion	Bristol-Myers Squibb Pharmaceuticals uc	PA0002/052/003	Powder for solution for injection/infusion	-Aztreonam
Azalia 75 microgram film-coated tablets	Gedeon Richter Plc	PA1330/010/001	Film-coated tablet	-Desogestrel
AZARGA	Novartis Europharm Limited	EU/1/08/482/1-2	Eye drops, suspension	-TIMOLOL MALEATE -Brinzolamide
Azecort 137 micrograms/50 micrograms per actuation nasal spray, suspension	Mylan IRE Healthcare Limited	PA2010/061/001	Nasal spray, suspension	-Azelastine hydrochloride -Fluticasone propionate
Azelastine Eye Drops, 0.5 mg/ml, Eye Drops, solution	Mylan IRE Healthcare Limited	PA2010/046/001	Eye drops, solution	-Azelastine hydrochloride
Azelastine hydrochloride /Fluticasone propionate Rowex 137 micrograms/50 micrograms per actuation, nasal spray suspension	Rowex Ltd	PA0711/324/001	Nasal spray, suspension	-Azelastine hydrochloride -Fluticasone propionate
AZILECT 1 mg tablets	Teva B.V.	EU/1/04/304/1-7	Tablet	-Rasagiline
Azilsartan medoxomil/Chlortalidone 40 mg /12.5 mg Film-coated Tablets	Takeda Pharma A/S	PA2167/001/001	Film-coated tablet	-AZILSARTAN MEDOXOMIL POTASSIUM -Chlortalidone
Azilsartan medoxomil/Chlortalidone 40 mg/25 mg Film-coated tablets	Takeda Pharma A/S	PA2167/001/002	Film-coated tablet	-AZILSARTAN MEDOXOMIL POTASSIUM -Chlortalidone
Azithromycin Clonmel 250 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/150/001	Film-coated tablet	-Azithromycin dihydrate
Azithromycin Krka 250 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/047/001	Film-coated tablet	-Azithromycin
Azithromycin Teva 250 mg film-coated tablets	Teva Pharma B.V.	PA0749/039/002	Film-coated tablet	-Azithromycin
Azomyr	N.V. Organon	EU/1/00/157/001	Film-coated tablet	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/002	Film-coated tablet	-Desloratidine
Azomyr	Schering Plough Europe	EU/1/00/157/003	Film-coated tablet	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/004	Film-coated tablet	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/005	Film-coated tablet	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/006	Film-coated tablet	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/007	Film-coated tablet	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/008	Film-coated tablet	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/009	Film-coated tablet	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/010	Film-coated tablet	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/011	Film-coated tablet	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/012	Film-coated tablet	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/013	Film-coated tablet	-Desloratidine
AZOMYR	N.V. Organon	EU/1/00/157/014	Oral solution	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/015	Oral solution	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/016	Oral solution	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/017	Oral solution	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/018	Oral solution	-Desloratidine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Azomyr	N.V. Organon	EU/1/00/157/019	Oral solution	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/020	Oral solution	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/021	Oral solution	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/022	Oral lyophilisate	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/023	Oral lyophilisate	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/024	Oral lyophilisate	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/025	Oral lyophilisate	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/026	Oral lyophilisate	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/027	Oral lyophilisate	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/028	Oral lyophilisate	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/029	Oral lyophilisate	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/030	Oral lyophilisate	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/031	Oral lyophilisate	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/032	Oral lyophilisate	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/033	Oral lyophilisate	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/034	Oral lyophilisate	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/35-46	Orodispersible tablet	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/47-58	Orodispersible tablet	-Desloratidine
Azomyr	N.V. Organon	EU/1/00/157/59-67	Oral solution	-Desloratidine, micronized
Azopt	Novartis Europharm Limited	EU/1/00/129/002	Eye drops, suspension	-Brinzolamide
Azopt Eye Drops	Novartis Europharm Limited	EU/1/00/129/001	Eye drops, suspension	-Brinzolamide
Azromax 250 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/122/001	Film-coated tablet	-Azithromycin dihydrate
Azuzote 30 mg film-coated tablets	Azure Pharmaceuticals Ltd	PA22871/001/001	Film-coated tablet	-NEFOPAM HYDROCHLORIDE
Azyter 15 mg/g eye drops, solution, in single-dose container	Laboratoires Thea	PA1107/004/001	Eye drops, solution	-Azithromycin dihydrate
Azzalure, 125 Speywood units, powder for solution for injection	Ipsen Pharma	PA1613/001/001	Powder for solution for injection	-Clostridium botulinum toxin type a haemagglutinin complex
Baclofen 5mg/5ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/005/001	Oral solution	-Baclofen
Baclopar 10 mg Tablets	Viatrix Limited	PA23266/019/001	Tablet	-Baclofen
Bactroban 2% w/w Nasal Ointment	PCO Manufacturing Ltd.	PPA0465/312/001	Nasal ointment	-Mupirocin
Bactroban 2% w/w Nasal Ointment	GlaxoSmithKline (Ireland) Limited	PA1077/094/002	Nasal ointment	-Mupirocin calcium
Bactroban 2% w/w Ointment	GlaxoSmithKline (Ireland) Limited	PA1077/094/001	Ointment	-Mupirocin
Bactroban 2% w/w Ointment	PCO Manufacturing Ltd.	PPA0465/312/002	Ointment	-Mupirocin
BAQSIMI	Amphastar France Pharmaceuticals, S.A.S.	EU/1/19/1406/001-002	Nasal powder in single-dose container	-GLUCAGON
Baraclude	Bristol-Myers Squibb Pharma EEIG	EU/1//06/343/01	Film-coated tablet	-Entecavir
Baraclude	Bristol-Myers Squibb Pharma EEIG	EU/1/06/343/02,04,07	Film-coated tablet	-Entecavir
Baraclude	Bristol-Myers Squibb Pharma EEIG	EU/1/06/343/05	Oral solution	-Entecavir
Bavencio	Merck Europe B.V.	EU/1/17/1214/001	Concentrate for solution for infusion	-Avelumab
BCG medac, powder and solvent for intravesical suspension	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/004/001	Powder and solvent for intravesical suspension	-Bacillus Calmette Guérin (BCG)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
BCG VACCINE AJV	AJ Vaccines A/S	PA2160/003/001	Powder and solvent for suspension for injection	-Mycobacterium bovis (bcg) stam 1331
Beclazone 100 micrograms CFC-Free Inhaler Pressurised Inhalation Solution	Norton Waterford	PA0436/021/010	Pressurised inhalation, solution	-Beclometasone dipropionate
Beclazone 100 micrograms Easi-Breathe CFC-Free Inhaler Pressurised Inhalation Solution	Norton Waterford	PA0436/021/014	Pressurised inhalation, solution	-Beclometasone dipropionate
Beclazone 200 micrograms CFC-Free Inhaler, Pressurised Inhalation Solution	Norton Waterford	PA0436/021/011	Pressurised inhalation, solution	-Beclometasone dipropionate
Beclazone 200 micrograms Easi-Breathe CFC-Free Inhaler, Pressurised Inhalation Solution	Norton Waterford	PA0436/021/015	Pressurised inhalation, solution	-Beclometasone dipropionate
Beclazone 250 micrograms CFC-Free Inhaler Pressurised Inhalation Solution	Norton Waterford	PA0436/021/012	Pressurised inhalation, solution	-Beclometasone dipropionate
Beclazone 250 micrograms Easi-Breathe CFC-Free Inhaler Pressurised Inhalation Solution	Norton Waterford	PA0436/021/016	Pressurised inhalation, solution	-Beclometasone dipropionate
Beclazone 50 micrograms CFC-Free Inhaler Pressurised Inhalation Solution	Norton Waterford	PA0436/021/009	Pressurised inhalation, solution	-Beclometasone dipropionate
Becloneb 400 micrograms/1 ml nebuliser suspension	Chiesi Farmaceutici S.p.A.	PA0584/003/001	Nebuliser suspension	-Beclometasone dipropionate
Becloneb 800 micrograms/2 ml nebuliser suspension	Chiesi Farmaceutici S.p.A.	PA0584/003/002	Nebuliser suspension	-Beclometasone dipropionate
Beclospin 400 micrograms/1 ml nebuliser suspension	Chiesi Farmaceutici S.p.A.	PA0584/004/001	Nebuliser suspension	-Beclometasone dipropionate
Beclospin 800 micrograms/2 ml nebuliser suspension	Chiesi Farmaceutici S.p.A.	PA0584/004/002	Nebuliser suspension	-Beclometasone dipropionate
Beconase Hayfever nasal spray 50 micrograms per spray	Chefaro Ireland DAC	PA1186/008/001	Nasal spray, suspension	-Beclometasone dipropionate
Becotide Evohaler 100 micrograms, Pressurised Inhalation Solution	GlaxoSmithKline (Ireland) Limited	PA1077/042/007	Pressurised inhalation, solution	-Beclometasone dipropionate
Becotide Evohaler 250 micrograms, Pressurised Inhalation Solution	GlaxoSmithKline (Ireland) Limited	PA1077/042/009	Pressurised inhalation, solution	-Beclometasone dipropionate
Becotide Evohaler 50 micrograms, Pressurised Inhalation Solution	GlaxoSmithKline (Ireland) Limited	PA1077/042/006	Pressurised inhalation, solution	-Beclometasone dipropionate
Bekemv	Amgen Technology (Ireland) UC	EU/1/23/1727/001	Concentrate for solution for infusion	-Eculizumab
Belkya 10mg/ml solution for injection	AbbVie Limited	PA1824/021/001	Solution for injection	-Deoxycholic acid
Belladonna 0.25% w/w Medicated Plaster	Cuxson Gerrard Healthcare Limited	PA23188/002/001	Medicated plaster	-Belladonna alkaloids

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Bemfola	Gedeon Richter Plc	EU/1/13/909/001-005	Solution for injection	-Follitropin alfa
Bemrist Breezhaler 125 micrograms/127.5 micrograms inhalation powder, hard capsules	Novartis Europharm Limited	EU/1/20/1441/005-008	Inhalation powder, hard capsule	-Indacaterol acetate -Indacaterol -Mometasone furoate
Bemrist Breezhaler 125 micrograms/260 micrograms inhalation powder, hard capsules	Novartis Europharm Limited	EU/1/20/1441/009-012	Inhalation powder, hard capsule	-Indacaterol acetate -Indacaterol -Mometasone furoate
Bemrist Breezhaler 125 micrograms/62.5 micrograms inhalation powder, hard capsules	Novartis Europharm Limited	EU/1/20/1441/001-004	Inhalation powder, hard capsule	-Indacaterol acetate -Indacaterol -Mometasone furoate
Bendamustine 100 mg powder for concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/077/002	Powder for concentrate for solution for infusion	-Bendamustine hydrochloride
Bendamustine 100 mg Powder for Concentrate for Solution for Infusion	Teva B.V.	PA1986/121/002	Powder for concentrate for solution for infusion	-Bendamustine hydrochloride
Bendamustine 25 mg Powder for Concentrate for Solution for Infusion	Teva B.V.	PA1986/121/001	Powder for concentrate for solution for infusion	-Bendamustine hydrochloride
Bendamustine 25 mg powder for concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/077/001	Powder for concentrate for solution for infusion	-Bendamustine hydrochloride
Bendamustine 25 mg/ml concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/077/003	Concentrate for solution for infusion	-Bendamustine hydrochloride
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	-Bendamustine hydrochloride
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	-Bendamustine hydrochloride
Bendroflumethiazide 2.5 mg Tablets	Brillpharma (Ireland) Limited	PA22749/021/001	Tablet	-Bendroflumethiazide
Bendroflumethiazide 5 mg Tablets	Brillpharma (Ireland) Limited	PA22749/021/002	Tablet	-Bendroflumethiazide
BENEFIX	Pfizer Europe MA EEIG	EU/1/97/047/001	Powder and solvent for solution for injection	-Factor ix, human recombinant
BeneFIX	Pfizer Europe MA EEIG	EU/1/97/047/002	Powder and solvent for solution for injection	-Factor ix, human recombinant
BeneFIX	Pfizer Europe MA EEIG	EU/1/97/047/003	Powder and solvent for solution for injection	-Factor ix, human recombinant
Benefix	Pfizer Europe MA EEIG	EU/1/97/047/004	Powder and solvent for solution for injection	-Nonacog alfa
Benefix	Pfizer Europe MA EEIG	EU/1/97/047/005	Powder and solvent for solution for injection	-Nonacog alfa
Benefix	Pfizer Europe MA EEIG	EU/1/97/047/006	Powder and solvent for solution for injection	-Nonacog alfa
Benefix	Pfizer Europe MA EEIG	EU/1/97/047/007	Powder and solvent for solution for injection	-Nonacog alfa

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
BeneFIX	Pfizer Europe MA EEIG	EU/1/97/047/008	Powder and solvent for solution for injection	-Nonacog alfa
BeneFIX	Pfizer Europe MA EEIG	EU/1/97/047/009	Powder and solvent for solution for injection	-Nonacog alfa
Benepali	Samsung Bioepis NL B.V.	EU/1/15/1074/001	Solution for injection in pre-filled syringe	-Etanercept
Benepali	Samsung Bioepis NL B.V.	EU/1/15/1074/002	Solution for injection in pre-filled pen	-Etanercept
Benepali	Samsung Bioepis NL B.V.	EU/1/15/1074/005-007	Solution for injection in pre-filled syringe	-Etanercept
Benlysta	GlaxoSmithKline (Ireland) Limited	EU/1/11/700/001-002	Powder for concentrate for solution for infusion	-Belimumab
Benlysta	GlaxoSmithKline (Ireland) Limited	EU/1/11/700/003-005	Solution for injection in pre-filled pen	-Belimumab
Benlysta	GlaxoSmithKline (Ireland) Limited	EU/1/11/700/006-007	Solution for injection in pre-filled syringe	-Belimumab
Benylin Children's Chesty Cough 50mg/5ml Syrup	JNTL Consumer Health I (Ireland) Limited	PA23490/011/001	Syrup	-Guaifenesin
Benylin Children's Dry Coughs Syrup Diphenhydramine Hydrochloride 7mg/5ml Levomethol 0.55mg/5ml	JNTL Consumer Health I (Ireland) Limited	PA23490/008/001	Syrup	-Levomethol -Diphenhydramine hydrochloride
Benylin Cough Medicine Syrup Diphenhydramine hydrochloride 14mg/5ml Levomethol 1.1mg/5ml	JNTL Consumer Health I (Ireland) Limited	PA23490/005/001	Syrup	-Diphenhydramine hydrochloride -Levomethol
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	-Paracetamol -PSEUDOEPHEDRINE HYDROCHLORIDE -Paracetamol -Diphenhydramine hydrochloride
Benylin Dry Coughs Syrup Diphenhydramine hydrochloride 14mg/5ml Dextromethorphan hydrobromide 6.5mg/5ml Levomethol 2mg/5ml	JNTL Consumer Health I (Ireland) Limited	PA23490/004/001	Syrup	-Diphenhydramine hydrochloride -Dextromethorphan hydrobromide -Levomethol
Benylin Dual Action Dry Syrup, Pseudoephedrine 30mg, Dextromethorphan 10mg, Triprolidine 1.25mg	JNTL Consumer Health I (Ireland) Limited	PA23490/002/001	Syrup	-Dextromethorphan hydrobromide -PSEUDOEPHEDRINE HYDROCHLORIDE -TRIPROLIDINE HYDROCHLORIDE
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	-Paracetamol -PSEUDOEPHEDRINE HYDROCHLORIDE -Diphenhydramine hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup	JNTL Consumer Health I (Ireland) Limited	PA23490/041/001	Syrup	-Guaifenesin
Benylin Mucus Relief 250mg/5ml Syrup	McNeil Healthcare (Ireland) Ltd	PA0823/035/001	Syrup	-Carbocisteine
Benylin Non-Drowsy Dry Coughs, Syrup Dextromethorphan hydrobromide 7.5mg/5ml	JNTL Consumer Health I (Ireland) Limited	PA23490/010/001	Syrup	-Dextromethorphan hydrobromide
Benylin Phlegm Cough plus Decongestant SyrupGuaifenesin 100mg/5mlPseudoephedrine Hydrochloride 30mg/5ml	Johnson & Johnson (Ireland) Limited	PA0330/032/001	Syrup	-PSEUDOEPHEDRINE HYDROCHLORIDE -Guaifenesin
Benzyl Benzoate 25% w/v Application Cutaneous Emulsion	Ovelle Limited	PA0206/023/001	Cutaneous emulsion	-Benzyl benzoate
Benzylpenicillin sodium 3000 mg Powder for Injection/Infusion	Rowex Ltd	PA0711/310/002	Powder for solution for injection/infusion	-Benzylpenicillin
Benzylpenicillin sodium 600 mg Powder for Injection/Infusion	Rowex Ltd	PA0711/310/001	Powder for solution for injection/infusion	-Benzylpenicillin
Beovu	Novartis Europharm Limited	EU/1/19/1417/001-002	Solution for injection	-Brolucizumab
Beriner 1500 IU Powder and solvent for solution for injection	CSL Behring GmbH	PA0800/013/002	Powder and solvent for solution for injection	-C1 Esterase Inhibitor (Human)
Beriner 2000 IU Powder and solvent for solution for injection	CSL Behring GmbH	PA0800/013/003	Powder and solvent for solution for injection	-C1 Esterase Inhibitor (Human)
Beriner 3000 IU Powder and solvent for solution for injection	CSL Behring GmbH	PA0800/013/004	Powder and solvent for solution for injection	-C1 Esterase Inhibitor (Human)
Beriner 500 IU Powder and solvent for solution for injection/infusion.	CSL Behring GmbH	PA0800/013/001	Powder and solvent for solution for injection	-C1 Esterase Inhibitor (Human)
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	-Factor ii activity -Factor vii activity -Factor x activity -Factor ix activity -Protein c activity -Protein s antigen
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	-Factor ii activity -Factor vii activity -Factor x activity -Factor ix activity -Protein c activity -Protein s antigen
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	-Protein s antigen -Protein c activity -Factor ix activity -Factor x activity -Factor vii activity -Factor ii activity
BEROMUN	Belpharma S.A.	EU/1/99/097/001	Powder for solution for infusion	-Tumour necrosis factor alfa 1a

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Inotuzumab ozogamicin
Besremi	AOP Orphan Pharmaceuticals AG	EU/1/18/1352/001	Solution for injection in pre-filled pen	-Ropeginterferon alfa-2b
Besremi	AOP Orphan Pharmaceuticals AG	EU/1/18/1352/002	Solution for injection in pre-filled syringe	-Ropeginterferon alfa-2b
Betacap Scalp Application 0.1 % w/w cutaneous solution	Dermal Laboratories (Ireland) Limited	PA23128/010/001	Cutaneous solution	-Betamethasone valerate
Betaferon	Schering AG	EU/1/95/003/001	Powder and solvent for solution for injection	-Interferon beta-1b
Betaferon	Schering AG	EU/1/95/003/002	Powder and solvent for solution for injection	-Interferon beta-1b
Betaferon	Bayer AG	EU/1/95/003/003	Powder and solvent for solution for injection	-Interferon beta-1b
Betaferon	Schering AG	EU/1/95/003/004	Powder and solvent for solution for injection	-Interferon beta-1b
Betagan 0.5% w/v Unit Dose Eye Drops, Solution	AbbVie Limited	PA1824/012/001	Eye drops, solution	-Levobunolol hydrochloride
Betahistine dihydrochloride 16 mg Tablets	Azure Pharmaceuticals Ltd	PA22871/017/002	Tablet	-Betahistine dihydrochloride
Betahistine dihydrochloride 16mg tablets	Accord Healthcare Ireland Ltd.	PA2315/078/002	Tablet	-Betahistine dihydrochloride
Betahistine dihydrochloride 24 mg Tablets	Azure Pharmaceuticals Ltd	PA22871/017/003	Tablet	-Betahistine dihydrochloride
Betahistine dihydrochloride 8 mg Tablets	Azure Pharmaceuticals Ltd	PA22871/017/001	Tablet	-Betahistine dihydrochloride
Betahistine dihydrochloride 8mg tablets	Accord Healthcare Ireland Ltd.	PA2315/078/001	Tablet	-Betahistine dihydrochloride
Betaloc 1 mg/ml solution for injection	Recordati Ireland Limited	PA1404/007/001	Solution for injection	-METOPROLOL TARTRATE
Beta-Prograne 160mg Prolonged-Release Capsules	Tillomed Pharma GmbH	PA22720/002/001	Prolonged-release capsule, hard	-Propranolol hydrochloride
Betmiga	Astellas Pharma Europe BV	EU/1/12/809/001-007	Prolonged-release tablet	-Mirabegron (ym178)
Betmiga	Astellas Pharma Europe BV	EU/1/12/809/008-014	Prolonged-release tablet	-Mirabegron (ym178)
Betnesol 0.1% w/v Eye, Ear and Nasal Drops, solution	RPH Pharmaceuticals AB	PA1638/001/001	Ear/eye/nasal drops, solution	-BETAMETHASONE SODIUM PHOSPHATE
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	-Neomycin sulfate -BETAMETHASONE SODIUM PHOSPHATE
Betnovate Cream 0.1% w/w	GlaxoSmithKline (Ireland) Limited	PA1077/001/001	Cream	-Betamethasone
Betnovate Ointment 0.1% w/w	GlaxoSmithKline (Ireland) Limited	PA1077/001/002	Ointment	-Betamethasone valerate
Betnovate RD (Ready Diluted) 0.025% w/w Cream	GlaxoSmithKline (Ireland) Limited	PA1077/001/004	Cream	-Betamethasone valerate
Betnovate RD (Ready Diluted) 0.025% w/w Ointment	GlaxoSmithKline (Ireland) Limited	PA1077/001/005	Ointment	-Betamethasone valerate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Betnovate Scalp Application 0.1% w/v Cutaneous Solution	GlaxoSmithKline (Ireland) Limited	PA1077/001/003	Cutaneous solution	-Betamethasone
Betnovate-C 0.1% / 3% w/w Cream	GlaxoSmithKline (Ireland) Limited	PA1077/002/001	Cream	-Betamethasone -Clioquinol
Bettamousse 1mg/g (0.1%) cutaneous foam	RPH Pharmaceuticals AB	PA1638/009/001	Cutaneous foam	-Betamethasone valerate
Bevespi Aerosphere	AstraZeneca AB	EU/1/18/1339/001	Pressurised inhalation, suspension	-Formoterol fumarate dihydrate -GLYCOPYRRONIUM
Bexsero	GSK Vaccines S.r.l.	EU/1/12/812/001-004	Suspension for injection in pre-filled syringe	-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 membrane vesicles (omv)
Beyfortus	Sanofi Winthrop Industrie	EU/1/22/1689/001-003	Solution for injection in pre-filled syringe	-Nirsevimab
Bicalutamide 50 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/079/001	Film-coated tablet	-Bicalutamide
Bicalutamide 50 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/038/001	Film-coated tablet	-Bicalutamide
Bicalutamide Fair-Med 150mg Film-coated Tablets	Fairmed Healthcare GmbH	PA1789/001/002	Film-coated tablet	-Bicalutamide
Bicalutamide Fair-Med 50 mg film-coated tablets	Fairmed Healthcare GmbH	PA1789/001/001	Film-coated tablet	-Bicalutamide
Bicalutamide Teva 50 mg film-coated tablets	Teva Pharma B.V.	PA0749/032/001	Film-coated tablet	-Bicalutamide
Biktarvy	Gilead Sciences Ireland UC	EU/1/18/1289/001-002	Film-coated tablet	-BICTEGRAVIR -Emtricitabine -Tenofovir alafenamide
Biktarvy	Gilead Sciences Ireland UC	EU/1/18/1289/005-006	Film-coated tablet	-Bictegravir Sodium -Emtricitabine -Tenofovir alafenamide fumarate
Biluta 50 mg film-coated tablets	Rowex Ltd	PA0711/100/001	Film-coated tablet	-Bicalutamide
BIMERVAX	Hipra Human Health S.L.	EU/1/22/1709/001	Emulsion for injection	-SARS-CoV-2 virus, variants B.1.351-B.1.1.7, spike protein, receptor binding domain fusion heterodimer
Bimzelx	UCB Pharma S.A.	EU/1/21/1575/001-004	Solution for injection in pre-filled syringe	-Bimekizumab
Bimzelx	UCB Pharma S.A.	EU/1/21/1575/005-008	Solution for injection in pre-filled pen	-Bimekizumab
Binocrit	Sandoz GmbH	EU/1/07/410/11-12	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Binocrit	Sandoz GmbH	EU/1/07/410/1-2	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Binocrit	Sandoz GmbH	EU/1/07/410/13-014	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Binocrit	Sandoz GmbH	EU/1/07/410/15-16	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Binocrit	Sandoz GmbH	EU/1/07/410/21-22	Solution for injection in pre-filled syringe	-Epoetin alfa
Binocrit	Sandoz GmbH	EU/1/07/410/23-24	Solution for injection in pre-filled syringe	-Epoetin alfa
Binocrit	Sandoz GmbH	EU/1/07/410/25-26	Solution for injection in pre-filled syringe	-Epoetin alfa
Binocrit	Sandoz GmbH	EU/1/07/410/3-4	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Binocrit	Sandoz GmbH	EU/1/07/410/5-6	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Binocrit	Sandoz GmbH	EU/1/07/410/7-8	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Binocrit	Sandoz GmbH	EU/1/07/410/9-10	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Binosto Once Weekly 70 mg effervescent tablets	Clonmel Healthcare Ltd	PA0126/280/001	Effervescent tablet	-Alendronic acid
Biopoin	TEVA GmbH	EU/1/09/565/11-16	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Biopoin	TEVA GmbH	EU/1/09/565/1-2	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Biopoin	TEVA GmbH	EU/1/09/565/17-22	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Biopoin	TEVA GmbH	EU/1/09/565/23-28	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Biopoin	TEVA GmbH	EU/1/09/565/3-4	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Biopoin	TEVA GmbH	EU/1/09/565/5-6	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Biopoin	TEVA GmbH	EU/1/09/565/7-8	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Biopoin	TEVA GmbH	EU/1/09/565/9-10	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Biphozyl Solution for haemodialysis / haemofiltration	Baxter Holding B.V.	PA2299/055/001	Solution for haemodialysis/haemofiltration	-Magnesium chloride hexahydrate -Sodium chloride -Sodium hydrogen carbonate -Potassium chloride -Disodium phosphate dihydrate
Bisacor 10 mg Tablets	Unichem Laboratories Ltd	PA22654/003/002	Tablet	-Bisoprolol hemifumarate
Bisacor 5 mg Tablets	Unichem Laboratories Ltd	PA22654/003/001	Tablet	-BISOPROLOL FUMARATE
Bisolvon 4mg/5ml Oral Solution	Opella Healthcare France SAS T/A Sanofi	PA23180/015/001	Oral solution	-Bromhexine hydrochloride
Bisop 1.25 mg film-coated tablets	Rowex Ltd	PA0711/159/001	Film-coated tablet	-BISOPROLOL FUMARATE
Bisop 10 mg film-coated tablets	Rowex Ltd	PA0711/159/006	Film-coated tablet	-BISOPROLOL FUMARATE
Bisop 2.5 mg film-coated tablets	Rowex Ltd	PA0711/159/002	Film-coated tablet	-BISOPROLOL FUMARATE
Bisop 3.75 mg film-coated tablets	Rowex Ltd	PA0711/159/003	Film-coated tablet	-BISOPROLOL FUMARATE
Bisop 5 mg film-coated tablets	Rowex Ltd	PA0711/159/004	Film-coated tablet	-BISOPROLOL FUMARATE
Bisop 7.5 mg film-coated tablets	Rowex Ltd	PA0711/159/005	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/194/003	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol 2.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/194/001	Film-coated tablet	-BISOPROLOL FUMARATE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Bisoprolol 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/194/002	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol Fumarate 1.25mg Tablets	Chanelle Medical Unlimited Company	PA0688/014/001	Tablet	-BISOPROLOL FUMARATE
Bisoprolol Fumarate 10 mg Tablets	Chanelle Medical Unlimited Company	PA0688/014/005	Tablet	-BISOPROLOL FUMARATE
Bisoprolol Fumarate 2.5 mg Tablets	Chanelle Medical Unlimited Company	PA0688/014/002	Tablet	-BISOPROLOL FUMARATE
Bisoprolol Fumarate 2.5 mg tablets	Unichem Laboratories Ltd	PA22654/002/001	Tablet	-BISOPROLOL FUMARATE
Bisoprolol Fumarate 3.75 mg Tablets	Chanelle Medical Unlimited Company	PA0688/014/003	Tablet	-BISOPROLOL FUMARATE
Bisoprolol Fumarate 5 mg Tablets	Chanelle Medical Unlimited Company	PA0688/014/004	Tablet	-BISOPROLOL FUMARATE
Bisoprolol fumarate Pinewood 1.25 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/264/001	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol fumarate Pinewood 10 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/264/006	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol fumarate Pinewood 2.5 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/264/002	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol fumarate Pinewood 3.75 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/264/003	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol fumarate Pinewood 5 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/264/004	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol fumarate Pinewood 7.5 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/264/005	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/031/003	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol Krka 2.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/031/001	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol Krka 5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/031/002	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol Mylan 1.25 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/153/001	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol Mylan 10 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/153/006	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol Mylan 2.5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/153/002	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol Mylan 3.75 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/153/003	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol Mylan 5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/153/004	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol Mylan 7.5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/153/005	Film-coated tablet	-BISOPROLOL FUMARATE
Bisoprolol Zentiva 1.25mg tablets	Zentiva k.s.	PA1701/010/001	Tablet	-BISOPROLOL FUMARATE
Bisoprolol Zentiva 10 mg tablets	Zentiva k.s.	PA1701/010/006	Tablet	-BISOPROLOL FUMARATE
Bisoprolol Zentiva 2.5mg tablets	Zentiva k.s.	PA1701/010/002	Tablet	-BISOPROLOL FUMARATE
Bisoprolol Zentiva 3.75mg tablets	Zentiva k.s.	PA1701/010/003	Tablet	-BISOPROLOL FUMARATE
Bisoprolol Zentiva 5mg tablets	Zentiva k.s.	PA1701/010/004	Tablet	-BISOPROLOL FUMARATE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Bisoprolol Zentiva 7.5mg tablets	Zentiva k.s.	PA1701/010/005	Tablet	-BISOPROLOL FUMARATE
Bisoprololhemifumaraat Genthon 10 mg, film- coated tablets	Genthon B.V.	PA0740/007/002	Film-coated tablet	-Bisoprolol hemifumarate
Bisoprololhemifumaraat Genthon 5 mg film- coated tablets	Genthon B.V.	PA0740/007/001	Film-coated tablet	-Bisoprolol hemifumarate
Bitifrin 0.3 mg/ml + 5 mg/ml eye drops, solution	Farmaprojects S.A.	PA1391/005/001	Eye drops, solution	-Bimatoprost -Timolol Maleate
Blenrep	GlaxoSmithKline (Ireland) Limited	EU/1/20/1474/001	Powder for concentrate for solution for infusion	-Belantamab Mafodotin
Blincyto	Amgen Europe B.V.	EU/1/15/1047/001	Powder for concentrate and solution for solution for infusion	-Blinatumomab
Blissel 50 micrograms/g vaginal gel	Italfarmaco S.A.	PA2102/001/001	Vaginal gel	-Estriol
Blitzima	Celltrion Healthcare Hungary Kft.	EU/1/17/1205/001-002	Concentrate for solution for infusion	-Rituximab
Blomensy 10 mg film- coated tablets	EGIS Pharmaceuticals PLC	PA1470/006/002	Film-coated tablet	-Rivaroxaban
Blomensy 15 mg film- coated tablets	EGIS Pharmaceuticals PLC	PA1470/006/003	Film-coated tablet	-Rivaroxaban
Blomensy 2.5 mg film- coated tablets	EGIS Pharmaceuticals PLC	PA1470/006/001	Film-coated tablet	-Rivaroxaban
Blomensy 20 mg film- coated tablets	EGIS Pharmaceuticals PLC	PA1470/006/004	Film-coated tablet	-Rivaroxaban
Blopress 16 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/014/004	Tablet	-Candesartan cilexetil
Blopress 32 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/014/005	Tablet	-Candesartan cilexetil
Blopress 4 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/014/002	Tablet	-Candesartan cilexetil
Blopress 8 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/014/003	Tablet	-Candesartan cilexetil
Blopress Plus 16 mg/12.5 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/015/002	Tablet	-Candesartan cilexetil -Hydrochlorothiazide
Blopress Plus 32 mg/12.5 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/015/003	Tablet	-Candesartan cilexetil -Hydrochlorothiazide
Blopress Plus 32 mg/25 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/015/004	Tablet	-Candesartan cilexetil -Hydrochlorothiazide
Blopress Plus 8 mg/12.5 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/015/001	Tablet	-Candesartan cilexetil -Hydrochlorothiazide
BOCOUTURE 100 units powder for solution for injection	Merz Pharmaceuticals GmbH	PA1907/003/002	Powder for solution for injection	-CLOSTRIDIUM BOTULINUM NEUROTOXIN TYPE A (150KD), FREE OF COMPLEXING PROTEINS
BOCOUTURE 50 units powder for solution for injection	Merz Pharmaceuticals GmbH	PA1907/003/001	Powder for solution for injection	-CLOSTRIDIUM BOTULINUM NEUROTOXIN TYPE A (150KD), FREE OF COMPLEXING PROTEINS
Bonasol Once Weekly 70 mg Oral Solution	Xeolas Pharmaceuticals Limited	PA1572/001/001	Oral solution	-Alendronic acid
Bondronat	Atnahs Pharma Netherlands B.V.	EU/1/96/012/011-13	Concentrate for solution for infusion	-Ibandronic acid
Bondronat	Atnahs Pharma Netherlands B.V.	EU/1/96/012/001	Concentrate for solution for infusion	-Ibandronic acid monosodium monohydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Bondronat	Atnahs Pharma Netherlands B.V.	EU/1/96/012/004	Concentrate for solution for infusion	-Ibandronic acid monosodium monohydrate
Bondronat 50 mg film-coated tablets	Atnahs Pharma Netherlands B.V.	EU/1/96/012/009-010	Film-coated tablet	-Ibandronic acid
Bonviva	Atnahs Pharma Netherlands B.V.	EU/1/03/265/5-6	Solution for injection	-Ibandronic acid
Bonviva 150 mg film-coated tablets	Atnahs Pharma Netherlands B.V.	EU/1/03/265/3-4	Film-coated tablet	-Ibandronic acid
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	-Diphtheria toxoid -Tetanus toxoid -Pertussis toxoid -Filamentous haemagglutinin -Pertactin
Boots Ibuprofen and Codeine 200mg / 12.8 mg film-coated tablets	Taw Pharma (Ireland) Limited	PA23081/004/001	Film-coated tablet	-Ibuprofen -Codeine phosphate hemihydrate
Bortezomib 1 mg powder for solution for injection	Morningside Healthcare (Malta) Limited	PA23142/012/001	Powder for solution for injection	-Bortezomib
Bortezomib 2.5 mg powder for solution for injection	Morningside Healthcare (Malta) Limited	PA23142/012/003	Powder for solution for injection	-Bortezomib
Bortezomib 2.5 mg/ml solution for injection	EVER Valinject GmbH	PA1774/008/001	Solution for injection	-Bortezomib
Bortezomib 3.5 mg powder for solution for injection	Morningside Healthcare (Malta) Limited	PA23142/012/002	Powder for solution for injection	-Bortezomib
Bortezomib 3.5 mg powder for solution for injection	Reddy Holding GmbH	PA23092/003/001	Powder for solution for injection	-Bortezomib
Bortezomib 3.5 mg powder for solution for injection	Baxter Holding B.V.	PA2299/057/001	Powder for solution for injection	-Bortezomib
Bortezomib 3.5 mg powder for solution for injection	MSN Labs Europe Limited	PA23250/003/001	Powder for solution for injection	-Bortezomib
Bortezomib Accord	Accord Healthcare S.L.U.	EU/1/15/1019/001	Powder for solution for injection	-Bortezomib
Bortezomib Accord	Accord Healthcare S.L.U.	EU/1/15/1019/002	Powder for solution for injection	-Bortezomib
Bortezomib Accord	Accord Healthcare S.L.U.	EU/1/15/1019/003-006	Solution for injection	-Bortezomib
Bortezomib Biotech Pharma 3.5 mg powder for solution for injection	Target Healthcare Limited	PA25233/001/001	Powder for solution for injection	-Bortezomib
Bortezomib Clonmel 2.5 mg/ml Solution for Injection	Clonmel Healthcare Ltd	PA0126/297/001	Solution for injection	-Bortezomib
Bortezomib Fresenius Kabi	Fresenius Kabi Deutschland GmbH	EU/1/19/1397/001	Powder for solution for injection	-Bortezomib
Bortezomib Hospira	Pfizer Europe MA EEIG	EU/1/16/1114/001	Powder for solution for injection	-Bortezomib
Bortezomib medac 3.5 mg powder for solution for injection	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/018/001	Powder for solution for injection	-Bortezomib
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	-Bortezomib
Bortezomib Rowex 3.5 mg Powder for solution for injection	Rowex Ltd	PA0711/288/001	Powder for solution for injection	-Bortezomib (as mannitol boronic ester)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Bortezomib SUN	Sun Phamaceutical Industries Europe B.V.	EU/1/16/1102/001	Powder for solution for injection	-Bortezomib
Bosentan Zentiva 125 mg film-coated tablets	Zentiva k.s.	PA1701/011/002	Film-coated tablet	-Bosentan monohydrate
Bosentan Zentiva 62.5 mg film-coated tablets	Zentiva k.s.	PA1701/011/001	Film-coated tablet	-Bosentan monohydrate
Bosulif	Pfizer Europe MA EEIG	EU/1/13/818/001-002	Film-coated tablet	-Bosutinib monohydrate
Bosulif	Pfizer Europe MA EEIG	EU/1/13/818/003-004	Film-coated tablet	-Bosutinib monohydrate
BOSULIF	Pfizer Europe MA EEIG	EU/1/13/818/006-007	Film-coated tablet	-Bosutinib monohydrate
Bosutinib Clonmel 100 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/369/001	Film-coated tablet	-Bosutinib
Bosutinib Clonmel 400 mg film coated tablets	Clonmel Healthcare Ltd	PA0126/369/002	Film-coated tablet	-Bosutinib
Bosutinib Clonmel 500 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/369/003	Film-coated tablet	-Bosutinib
BOTOX 200 Allergan Units Powder for solution for injection	AbbVie Limited	PA1824/017/003	Powder for solution for injection	-Botulinum Toxin Type A
BOTOX 50 Allergan Units Powder for solution for injection	AbbVie Limited	PA1824/017/002	Powder for solution for injection	-Botulinum Toxin Type A
Botox100 Allergan Units Powder for solution for injection	AbbVie Limited	PA1824/017/001	Powder and solvent for solution for injection	-Botulinum Toxin Type A
Brabio 20 mg/ml solution for injection, pre-filled syringe	Viartis Limited	PA23266/010/001	Solution for injection in pre-filled syringe	-Glatiramer acetate
Brabio 40 mg/ml solution for injection in pre-filled syringe	Viartis Limited	PA23266/011/001	Solution for injection in pre-filled syringe	-Glatiramer acetate
Braftovi	Pierre Fabre Medicament	EU/1/18/1314/001	Capsule, hard	-ENCORAFENIB
Braftovi	Pierre Fabre Medicament	EU/1/18/1314/002	Capsule, hard	-ENCORAFENIB
Braltus 10 microgram per delivered dose inhalation powder, hard capsule	Teva B.V.	PA1986/006/001	Inhalation powder, hard capsule	-Tiotropium bromide
Bramitob 300mg/4ml Nebuliser Solution	Chiesi Farmaceutici S.p.A.	PA0584/007/001	Nebuliser solution	-Tobramycin
Bretaris Genuair	Covis Pharma Europe B.V.	EU/1/12/781/001-003	Inhalation powder	-Micronized acclidinium bromide
Brevibloc Premixed 10 mg/ml solution for Infusion	Baxter Holding B.V.	PA2299/021/002	Solution for infusion	-Esmolol Hydrochloride
Brevibloc Premixed 10 mg/ml Solution for Injection	Baxter Holding B.V.	PA2299/021/001	Solution for injection	-Esmolol Hydrochloride
Brevoxyl 40mg/g cream	Avianta Pharma EU Limited	PA23354/001/001	Cream	-Benzoyl peroxide
Breyanzi	Celgene Europe B.V.	EU/1/22/1631/001	Dispersion for infusion	-Lisocabtagene Maraleucel
Bricanyl 500 micrograms/ml solution for injection or infusion	AstraZeneca AB	PA1019/007/001	Solution for injection/infusion	-Terbutaline sulfate
Bricanyl Turbohaler 500 micrograms per metered dose, inhalation powder	AstraZeneca AB	PA1019/007/002	Inhalation powder	-Terbutaline sulfate
Bridion 100 mg/ml solution for injection	Merck Sharp & Dohme BV	EU/1/08/466/1-2	Solution for injection	-Sugammadex
Brilique	AstraZeneca AB	EU/1/10/655/001-006	Film-coated tablet	-Ticagrelor

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Brilique	AstraZeneca AB	EU/1/10/655/007-011	Film-coated tablet	-Ticagrelor
Brilique	AstraZeneca AB	EU/1/10/655/012-014	Orodispersible tablet	-Ticagrelor
Brillphalac 3.335 g/5 ml oral solution	Brillpharma (Ireland) Limited	PA22749/011/001	Oral solution	-Lactulose
Brimica Genuair	Covis Pharma Europe B.V.	EU/1/14/963/001-003	Inhalation powder	-Micronized formoterol fumarate dihydrate -Micronized acclidinium bromide
Brinavess	Correvio	EU/1/10/645/001-002	Concentrate for solution for infusion	-Vernakalant hydrochloride
Brineura	BioMarin International Limited	EU/1/17/1192/001	Solution for infusion	-Cerliponase
Brintellix	H. Lundbeck A/S	EU/1/13/891/001-007	Film-coated tablet	-Vortioxetine hydrobromide
Brintellix	H. Lundbeck A/S	EU/1/13/891/008-017	Film-coated tablet	-Vortioxetine hydrobromide
Brintellix	H. Lundbeck A/S	EU/1/13/891/018-026	Film-coated tablet	-Vortioxetine hydrobromide
Brintellix	H. Lundbeck A/S	EU/1/13/891/027-035	Film-coated tablet	-Vortioxetine hydrobromide
Brintellix	H. Lundbeck A/S	EU/1/13/891/036	Oral drops, solution	-Vortioxetine-dl-lactate
Brinzolamide 10 mg/ml eye drops, Suspension	Accord Healthcare Ireland Ltd.	PA2315/149/001	Eye drops, suspension	-Brinzolamide
Brinzolamide Sandoz 10mg/ml eye drops, suspension	Rowex Ltd	PA0711/226/001	Eye drops, suspension	-Brinzolamide
Briumvi	Neuraxpharm Pharmaceuticals S.L.	EU/1/23/1730/001	Concentrate for solution for infusion	-Ublituximab
Briviact	UCB Pharma SA	EU/1/15/1073/001-004	Film-coated tablet	-Brivaracetam
Briviact	UCB Pharma SA	EU/1/15/1073/005-008	Film-coated tablet	-Brivaracetam
Briviact	UCB Pharma SA	EU/1/15/1073/009-012	Film-coated tablet	-Brivaracetam
Briviact	UCB Pharma SA	EU/1/15/1073/013-016	Film-coated tablet	-Brivaracetam
Briviact	UCB Pharma SA	EU/1/15/1073/017-020	Film-coated tablet	-Brivaracetam
Briviact	UCB Pharma SA	EU/1/15/1073/021	Oral solution	-Brivaracetam
Briviact	UCB Pharma SA	EU/1/15/1073/022	Solution for injection/infusion	-Brivaracetam
Brodilaten 1.25 mg/2.5 ml Nebuliser solution	Noridem Enterprises Limited	PA1122/024/001	Nebuliser solution	-SALBUTAMOL SULFATE
Brodilaten 2.5 mg/2.5 ml nebuliser solution	Noridem Enterprises Limited	PA1122/024/002	Nebuliser solution	-SALBUTAMOL SULFATE
Brodilaten 5.0 mg/2.5 ml Nebuliser solution	Noridem Enterprises Limited	PA1122/024/003	Nebuliser solution	-SALBUTAMOL SULFATE
Brolene 0.1% w/v Eye Drops Solution	Clonmel Healthcare Ltd	PA0126/357/001	Eye drops, solution	-Propamidine isetionate
Brolene 0.15 % w/w Eye Ointment	Clonmel Healthcare Ltd	PA0126/357/002	Eye ointment	-Dibrompropamidine isetionate
Bronchitol	Pharmaxis Europe Limited	EU/1/12/760/001-002	Inhalation powder, hard capsule	-Mannitol
Bronx Airmaster 50 microgram/100 microgram/ dose inhalation powder, pre-dispensed	Neutec Inhaler Ireland Limited	PA23030/001/001	Inhalation powder, pre-dispensed	-Salmeterol -Fluticasone propionate
Bronx Airmaster 50 microgram/250 microgram/ dose inhalation powder, pre-dispensed	Neutec Inhaler Ireland Limited	PA23030/001/002	Inhalation powder, pre-dispensed	-Salmeterol -Fluticasone propionate
Bronx Airmaster 50 microgram/500 microgram/ dose inhalation powder, pre-dispensed	Neutec Inhaler Ireland Limited	PA23030/001/003	Inhalation powder, pre-dispensed	-Salmeterol -Fluticasone propionate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
BroPair® Spiromax®	Teva B.V.	EU/1/21/1534/001-002	Inhalation powder	-SALMETEROL XINAFOATE -Fluticasone propionate
BroPair® Spiromax®	Teva B.V.	EU/1/21/1534/003-004	Inhalation powder	-SALMETEROL XINAFOATE -Fluticasone propionate
Brufen 400mg film-coated tablets	Viartis Healthcare Limited	PA23355/012/001	Film-coated tablet	-Ibuprofen
Brufen 600mg film-coated tablets	Viartis Healthcare Limited	PA23355/012/002	Film-coated tablet	-Ibuprofen
Brufen Paediatric 100mg/5ml Oral Suspension	Viartis Healthcare Limited	PA23355/012/003	Oral suspension	-Ibuprofen
Brufen Retard 800mg prolonged release tablets	Viartis Healthcare Limited	PA23355/012/004	Prolonged-release tablet	-Ibuprofen
Brukinsa	BeiGene Ireland Limited	EU/1/21/1576/001	Capsule, hard	-Zanubrutinib
Brupro 200mg Film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/067/001	Film-coated tablet	-Ibuprofen
Brupro Cold & Flu 200 mg/30 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/067/006	Film-coated tablet	-Ibuprofen -PSEUDOEPHEDRINE HYDROCHLORIDE
Brupro for Children 100 mg/5 ml oral suspension	Rowa Pharmaceuticals Limited	PA0074/067/004	Oral suspension	-Ibuprofen
Brupro for Children Six Plus 200 mg/5 ml oral suspension	Rowa Pharmaceuticals Limited	PA0074/067/005	Oral suspension	-Ibuprofen
Brupro Max 400mg Film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/067/002	Film-coated tablet	-Ibuprofen
Brupro Rx 600mg Film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/067/003	Film-coated tablet	-Ibuprofen
Buccolam	Laboratorios Lesvi, S.L.	EU/1/11/709/001	Oromucosal solution	-Midazolam
Buccolam	Laboratorios Lesvi, S.L.	EU/1/11/709/002	Oromucosal solution	-Midazolam
Buccolam	Laboratorios Lesvi, S.L.	EU/1/11/709/003	Oromucosal solution	-Midazolam
Buccolam	Laboratorios Lesvi, S.L.	EU/1/11/709/004	Oromucosal solution	-Midazolam
Budenofalk 2mg/dose rectal foam	Dr. Falk Pharma GmbH	PA0573/002/002	Rectal foam	-Budesonide
Budenofalk 3 mg gastro-resistant capsules	Dr. Falk Pharma GmbH	PA0573/002/001	Gastro-resistant capsule, hard	-Budesonide
Budenofalk 4 mg suppositories	Dr. Falk Pharma GmbH	PA0573/008/001	Suppository	-Budesonide
Budenofalk® 9mg gastro-resistant granules	Dr. Falk Pharma GmbH	PA0573/002/003	Gastro-resistant granules	-Budesonide
Budesonide Teva Pharma 0.5 mg/2 ml Nebuliser Suspension	Teva Pharma B.V.	PA0749/207/002	Nebuliser suspension	-Budesonide
Budesonide Teva Pharma 1 mg/2 ml Nebuliser Suspension	Teva Pharma B.V.	PA0749/207/003	Nebuliser suspension	-Budesonide
Bufomix Easyhaler, 160 micrograms/4.5 micrograms/inhalation, inhalation powder	Orion Corporation	PA1327/015/002	Inhalation powder	-Budesonide -Formoterol fumarate dihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Bufomix Easyhaler, 320 micrograms/9 micrograms/inhalation, inhalation powder	Orion Corporation	PA1327/015/003	Inhalation powder	-Budesonide -Formoterol fumarate dihydrate
Bufomix Easyhaler, 80 micrograms/4.5 micrograms/inhalation, inhalation powder	Orion Corporation	PA1327/015/004	Inhalation powder	-Budesonide -Formoterol fumarate dihydrate
Bupivacaine 2.5 mg / mL Solution for injection	Noridem Enterprises Limited	PA1122/029/001	Solution for injection	-Bupivacaine hydrochloride, anhydrous
Bupivacaine 2.5 mg/ml Solution for Injection	Baxter Holding B.V.	PA2299/035/001	Solution for injection	-Bupivacaine hydrochloride, monohydrate
Bupivacaine 5 mg / mL Solution for injection	Noridem Enterprises Limited	PA1122/029/002	Solution for injection	-Bupivacaine hydrochloride, anhydrous
Bupivacaine 5 mg/ml Solution for Injection	Baxter Holding B.V.	PA2299/035/002	Solution for injection	-Bupivacaine hydrochloride, monohydrate
Bupivacaine Heavy 5 mg/ml Solution for Injection	Panpharma	PA2272/001/001	Solution for injection	-BUPIVACAINE HYDROCHLORIDE
Bupivacaine Hydrochloride 0.25% w/v Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/091/001	Solution for injection	-Bupivacaine hydrochloride
Bupivacaine Hydrochloride 0.5% w/v Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/091/002	Solution for injection	-Bupivacaine hydrochloride
Buplex 200mg film-coated tablets	Teva B.V.	PA1986/116/001	Film-coated tablet	-Ibuprofen
Buplex 400mg film-coated tablets	Teva B.V.	PA1986/116/002	Film-coated tablet	-Ibuprofen
Buplex 400mg film-coated tablets	Teva B.V.	MISPA1986/116/001_MISTAKE	Film-coated tablet	-Ibuprofen
Buplex Rx 200 mg film-coated tablets	Teva B.V.	PA1986/117/001	Film-coated tablet	-Ibuprofen
Buplex Rx 400 mg film-coated tablets	Teva B.V.	PA1986/117/002	Film-coated tablet	-Ibuprofen
Buplex Rx 600 mg film-coated tablets	Teva B.V.	PA1986/117/003	Film-coated tablet	-Ibuprofen
Buprenorphine 0.4 mg Sublingual Tablets	Activase Pharmaceuticals Limited	PA1567/001/001	Sublingual tablet	-Buprenorphine hydrochloride
Buprenorphine 2 mg Sublingual Tablets	Activase Pharmaceuticals Limited	PA1567/001/002	Sublingual tablet	-Buprenorphine hydrochloride
Buprenorphine 2 mg Sublingual Tablets	Morningside Healthcare (Malta) Limited	PA23142/003/001	Sublingual tablet	-Buprenorphine hydrochloride
Buprenorphine 8 mg Sublingual Tablets	Morningside Healthcare (Malta) Limited	PA23142/003/002	Sublingual tablet	-Buprenorphine hydrochloride
Buprenorphine 8 mg Sublingual Tablets	Activase Pharmaceuticals Limited	PA1567/001/003	Sublingual tablet	-Buprenorphine hydrochloride
Burinex 1 mg Tablets	KARO PHARMA AB	PA22650/001/001	Tablet	-Bumetanide
Burinex 5 mg Tablets	KARO PHARMA AB	PA22650/001/002	Tablet	-Bumetanide
Buscopan 10 mg Coated Tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/016/002	Coated tablet	-Hyoscine butylbromide
Buscopan Ampoules 20 mg/ml Solution for Injection	Opella Healthcare France SAS T/A Sanofi	PA23180/016/001	Solution for injection	-Hyoscine butylbromide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Buscopan Rx 10mg Coated Tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/022/001	Coated tablet	-Hyoscine butylbromide
Busulfan Fresenius Kabi	Fresenius Kabi Deutschland GmbH	EU/1/14/951/001	Concentrate for solution for infusion	-Busulfan
BuTrans 10 micrograms/hour transdermal patch	Mundipharma Pharmaceuticals Limited	PA1688/002/002	Transdermal patch	-Buprenorphine
BuTrans 15 microgram/hour transdermal patch	Mundipharma Pharmaceuticals Limited	PA1688/002/004	Transdermal patch	-Buprenorphine
BuTrans 20 micrograms/hour transdermal patch	Mundipharma Pharmaceuticals Limited	PA1688/002/003	Transdermal patch	-Buprenorphine
BuTrans 5 micrograms/hour transdermal patch	Mundipharma Pharmaceuticals Limited	PA1688/002/001	Transdermal patch	-Buprenorphine
Buttercup Bronchostop Day & Night Oral Solution	Kwizda Pharma GmbH	TR2006/002/001	Oral solution	
Buvidal	Camurus AB	EU/1/18/1336/001	Prolonged-release solution for injection	-Buprenorphine
Buvidal	Camurus AB	EU/1/18/1336/002	Prolonged-release solution for injection	-Buprenorphine
Buvidal	Camurus AB	EU/1/18/1336/003	Prolonged-release solution for injection	-Buprenorphine
Buvidal	Camurus AB	EU/1/18/1336/004	Prolonged-release solution for injection	-Buprenorphine
Buvidal	Camurus AB	EU/1/18/1336/005	Prolonged-release solution for injection	-Buprenorphine
Buvidal	Camurus AB	EU/1/18/1336/006	Prolonged-release solution for injection	-Buprenorphine
Buvidal	Camurus AB	EU/1/18/1336/007	Prolonged-release solution for injection	-Buprenorphine
Buvidal	Camurus AB	EU/1/18/1336/009	Prolonged-release solution for injection	-Buprenorphine
Byannli	Janssen-Cilag International NV	EU/1/20/1453/007	Prolonged-release suspension for injection	-Paliperidone palmitate
Byannli	Janssen-Cilag International NV	EU/1/20/1453/008	Prolonged-release suspension for injection	-Paliperidone palmitate
Bydureon	AstraZeneca AB	EU/1/11/696/001-004	Powder and solvent for prolonged-release suspension for injection in pre-filled pen	-Exenatide
Bydureon	AstraZeneca AB	EU/1/11/696/005-006	Prolonged-release suspension for injection in pre-filled pen	-Exenatide
Byetta	AstraZeneca AB	EU/1/06/362/1-2	Solution for injection in pre-filled pen	-Exenatide
Byetta	AstraZeneca AB	EU/1/06/362/3-4	Solution for injection in pre-filled pen	-Exenatide
Byfavo	Paion Deutschland GmbH	EU/1/20/1505/001	Powder for solution for injection/infusion	-Remimazolam besilate -Remimazolam (in house)
Byfavo	Paion Netherlands B.V.	EU/1/20/1505/002	Powder for concentrate for solution for injection/infusion	-Remimazolam besilate
Bylvay	Ipsen Pharma	EU/1/21/1566/001	Capsule, hard	-Odevixibat sesquihydrate
Bylvay	Ipsen Pharma	EU/1/21/1566/002	Capsule, hard	-Odevixibat sesquihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Bylvay	Ipsen Pharma	EU/1/21/1566/003	Capsule, hard	-Odevixibat sesquihydrate
Bylvay	Ipsen Pharma	EU/1/21/1566/004	Capsule, hard	-Odevixibat sesquihydrate
By-Madol SR 100 mg prolonged-release capsules, hard	Ethypharm	PA0549/016/002	Prolonged-release capsule, hard	-Tramadol hydrochloride
By-Madol SR 150 mg prolonged-release capsules, hard	Ethypharm	PA0549/016/003	Prolonged-release capsule, hard	-Tramadol hydrochloride
By-Madol SR 200 mg prolonged-release	Ethypharm	PA0549/016/004	Prolonged-release capsule, hard	-Tramadol hydrochloride
By-Madol SR 50 mg prolonged-release capsules, hard	Ethypharm	PA0549/016/001	Prolonged-release capsule, hard	-Tramadol hydrochloride
Byooviz	Samsung Bioepis NL B.V.	EU/1/21/1572/001	Solution for injection	-Ranibizumab
Cabaser 1 mg Tablet	Pfizer Healthcare Ireland	PA0822/114/001	Tablet	-Cabergoline
Cabazitaxel Accord	Accord Healthcare S.L.U.	EU/1/20/1448/001	Concentrate for solution for infusion	-Cabazitaxel
Cabazitaxel EVER Pharma 10 mg/ml concentrate for solution for infusion	EVER Valinject GmbH	PA1774/004/001	Concentrate for solution for infusion	-Cabazitaxel
Cabazitaxel Fresenius Kabi 20 mg/ml concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/082/001	Concentrate for solution for infusion	-Cabazitaxel
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	-Cabazitaxel
Cabergoline 1 mg Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/011/001	Tablet	-Cabergoline
Cabergoline 2 mg Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/011/002	Tablet	-Cabergoline
Cablivi	Ablynx NV	EU/1/18/1305/001	Powder and solvent for solution for injection	-caplacizumab
Cabometyx	Ipsen Pharma	EU/1/16/1136/001-002	Film-coated tablet	-Cabozantinib
Cabometyx	Ipsen Pharma	EU/1/16/1136/003-004	Film-coated tablet	-Cabozantinib
Cabometyx	Ipsen Pharma	EU/1/16/1136/005-006	Film-coated tablet	-Cabozantinib
Cadelius 600 mg / 2000 IU orodispersible tablets	Italfarmaco S.A.	PA2102/002/002	Orodispersible tablet	-Calcium carbonate -Colecalciferol
Cadelius 600mg/1000 IU ordispersible tablet	Italfarmaco S.A.	PA2102/002/001	Orodispersible tablet	-Calcium carbonate -Cholecalciferol
Caelyx	Baxter Holding B.V.	EU/1/96/011/001	Concentrate for solution for infusion	-DOXORUBICIN HYDROCHLORIDE
Caelyx	Baxter Holding B.V.	EU/1/96/011/002	Concentrate for solution for infusion	-DOXORUBICIN HYDROCHLORIDE
Calcichew 500 mg chewable tablets	PCO Manufacturing Ltd.	PPA0465/156/001	Chewable tablet	-Calcium
Calcichew 500mg Chewable Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/013/001	Chewable tablet	-Calcium carbonate
Calcichew-D3 Forte 500 mg/400 IU Chewable Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/013/002	Chewable tablet	-Cholecalciferol -Calcium carbonate
Calcichew-D3 Forte 500 mg/400 IU Chewable Tablets	PCO Manufacturing Ltd.	PPA0465/156/003	Chewable tablet	-Calcium carbonate -Colecalciferol

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Calcichew-D3 Forte Double Strength 1000 mg / 800 IU Chewable Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/013/003	Chewable tablet	-Calcium carbonate -Cholecalciferol concentrate (powder form)
Calcipotriol/Betamethasone 50 microgram/g + 0.5 mg/g gel	Aristo Pharma GmbH	PA1983/005/001	Gel	-Betamethasone -Calcipotriol
Calcipotriol/Betamethasone Rowex 50 microgram/g + 0.5 mg/g Ointment	Rowex Ltd	PA0711/254/001	Ointment	-Calcipotriol -Betamethasone
Calcium Acetate 500mg Tablets	Pinewood Laboratories Ltd	PA0281/063/001	Tablet	-Calcium acetate
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	-Calcium polystyrene sulphonate
Calciup D3 500 mg/440 IU chewable tablet	Rowex Ltd	PA0711/217/002	Chewable tablet	-Calcium carbonate -Cholecalciferol concentrate
Calciup D3 Forte 1000mg/880 IU Chewable Tablets	Rowex Ltd	PA0711/217/001	Chewable tablet	-Calcium carbonate -Cholecalciferol concentrate (powder form)
Calmurid HC 10%/5%/1% w/w Cream	Galderma International	PA22743/003/001	Cream	-Hydrocortisone -Urea -Lactic acid
Calquence	AstraZeneca AB	EU/1/20/1479/001-002	Capsule, hard	-Acalabrutinib
Calquence	AstraZeneca AB	EU/1/20/1479/001-004	Film-coated tablet	-Acalabrutinib maleate
Calreca 100 mmol/l, solution for infusion	Fresenius Medical Care Deutschland GmbH	PA1350/006/001	Solution for infusion	-Calcium chloride dihydrate
Caltrate 600 mg/400 IU, Film-coated Tablets	Haleon Ireland Limited	PA0678/156/001	Film-coated tablet	-Calcium carbonate -Cholecalciferol concentrate
Calvepen 250 mg/5 ml Powder for Oral Suspension	Clonmel Healthcare Ltd	PA0126/137/003	Powder for oral suspension	- PHENOXYMETHYLPE NICILLIN CALCIUM
Calvepen 333 mg Tablets	Clonmel Healthcare Ltd	PA0126/137/001	Film-coated tablet	- Phenoxyethylpenicillin calcium
Calvepen 666 mg Tablets	Clonmel Healthcare Ltd	PA0126/137/002	Film-coated tablet	- PHENOXYMETHYLPE NICILLIN CALCIUM
CALVIDIN® 600 mg/400 I.U. chewable tablets	Mylan IRE Healthcare Limited	PA2010/038/001	Chewable tablet	-Calcium carbonate -Cholecalciferol
Camcevi	Accord Healthcare S.L.U.	EU/1/22/1647/001	Prolonged-release suspension for injection	-Leuprorelin Mesilate -Leuprorelin
CAMCOLIT 250 mg film-coated tablets	Essential Pharma (M) Limited	PA22644/001/001	Film-coated tablet	-Lithium carbonate
CAMCOLIT 400 mg film-coated tablets	Essential Pharma (M) Limited	PA22644/001/002	Film-coated tablet	-Lithium carbonate
Campral EC 333 mg Gastro-resistant tablets	IMED Healthcare Ltd.	PPA1463/177/001	Gastro-resistant tablet	-Acamprosate calcium
Campral EC 333mg Gastro-resistant tablets	PCO Manufacturing Ltd.	PPA0465/504/001	Gastro-resistant tablet	-Acamprosate calcium
Campral EC 333mg Gastro-resistant tablets	Merck Serono (Ireland) Limited	PA2286/007/001	Gastro-resistant tablet	-Acamprosate calcium
CAMPTO 20 mg/mL concentrate for solution for infusion	Pfizer Healthcare Ireland	PA0822/212/001	Concentrate for solution for infusion	-Irinotecan hydrochloride trihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Camzyos	Bristol-Myers Squibb Pharma EEIG	EU/1/23/1716/001-002/009	Capsule, hard	-Mavacamten
Camzyos	Bristol-Myers Squibb Pharma EEIG	EU/1/23/1716/003-004/010	Capsule, hard	-Mavacamten
Camzyos	Bristol-Myers Squibb Pharma EEIG	EU/1/23/1716/005-006/011	Capsule, hard	-Mavacamten
Camzyos	Bristol-Myers Squibb Pharma EEIG	EU/1/23/1716/007-008/012	Capsule, hard	-Mavacamten
CANCIDAS	Merck Sharp & Dohme BV	EU/1/01/196/001	Powder for concentrate for solution for infusion	-Caspofungin
Cancidas	Merck Sharp & Dohme BV,	EU/1/01/196/002	Powder for solution for infusion	-Caspofungin
Cancidas	Merck Sharp & Dohme BV	EU/1/01/196/003	Powder for concentrate for solution for infusion	-Caspofungin
Candesartan 16 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/150/003	Tablet	-Candesartan cilexetil
Candesartan 4 mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/150/001	Tablet	-Candesartan cilexetil
Candesartan 8 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/150/002	Tablet	-Candesartan cilexetil
Candesartan Hydrochlorothiazide 16 mg/12.5 mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/151/001	Tablet	-Candesartan cilexetil -Hydrochlorothiazide
Candesartan Hydrochlorothiazide Krka 16mg/12.5mg tablets	KRKA, d.d., Novo mesto	PA1347/011/002	Tablet	-Candesartan cilexetil -Hydrochlorothiazide
Candesartan Hydrochlorothiazide Krka 32mg/12.5mg tablets	KRKA, d.d., Novo mesto	PA1347/011/003	Tablet	-Candesartan cilexetil -Hydrochlorothiazide
Candesartan Hydrochlorothiazide Krka 32mg/25mg Tablets	KRKA, d.d., Novo mesto	PA1347/011/004	Tablet	-Candesartan cilexetil -Hydrochlorothiazide
Candesartan Hydrochlorothiazide Krka 8mg/12.5mg tablets	KRKA, d.d., Novo mesto	PA1347/011/001	Tablet	-Candesartan cilexetil -Hydrochlorothiazide
Candesartan Krka 16 mg tablets	KRKA, d.d., Novo mesto	PA1347/026/003	Tablet	-Candesartan cilexetil
Candesartan Krka 32 mg Tablets	KRKA, d.d., Novo mesto	PA1347/026/004	Tablet	-Candesartan cilexetil
Candesartan Krka 4 mg tablets	KRKA, d.d., Novo mesto	PA1347/026/001	Tablet	-Candesartan cilexetil
Candesartan Krka 8 mg tablets	KRKA, d.d., Novo mesto	PA1347/026/002	Tablet	-Candesartan cilexetil
Candist 16 mg Tablets	Clonmel Healthcare Ltd	PA0126/206/003	Tablet	-Candesartan cilexetil
Candist 4 mg Tablets	Clonmel Healthcare Ltd	PA0126/206/001	Tablet	-Candesartan cilexetil
Candist 8 mg Tablets	Clonmel Healthcare Ltd	PA0126/206/002	Tablet	-Candesartan cilexetil
Candist Plus 16 mg/12.5 mg Tablets	Clonmel Healthcare Ltd	PA0126/207/002	Tablet	-Candesartan cilexetil -Hydrochlorothiazide
Caneclear 150 mg hard capsule	Phoenix Labs	PA1113/013/001	Capsule, hard	-Fluconazole
Canespor 10 mg/g cream	Bayer Limited	PA1410/083/001	Cream	-Bifonazole
Canesten 10 mg/g Cream	PCO Manufacturing Ltd.	PPA0465/048/001	Cream	-Clotrimazole
Canesten 100mg Pessary	Bayer Limited	PA1410/039/007	Pessary	-Clotrimazole

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Canesten 200mg Pessary	Bayer Limited	PA1410/039/008	Pessary	-Clotrimazole
Canesten 500 mg Pessary	Bayer Limited	PA1410/039/009	Pessary	-Clotrimazole
Canesten 500 mg Pessary.	PCO Manufacturing Ltd.	PPA0465/048/002	Pessary	-Clotrimazole
Canesten 500mg Soft Vaginal Capsule	Bayer Limited	PA1410/039/010	Vaginal capsule, soft	-Clotrimazole
Canesten Athlete's Foot Cream	Bayer Limited	PA1410/039/013	Cream	-Clotrimazole
Canesten Combi Pessary & Cream	Bayer Limited	PA1410/039/001	Cream + pessary	-Clotrimazole -Clotrimazole
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	-Clotrimazole -Clotrimazole
Canesten Cream	Bayer Limited	PA1410/039/002	Cream	-Clotrimazole
Canesten Cream Combi Internal & External Creams	Bayer Limited	PA1410/039/003	Vaginal cream	-Clotrimazole -Clotrimazole
Canesten Duopak	Bayer Limited	PA1410/039/005	Cream + pessary	-Clotrimazole -Clotrimazole
Canesten HC 1% w/w + 1% w/w Cream	Bayer Limited	PA1410/040/002	Cream	-Clotrimazole -HYDROCORTISONE ACETATE
Canesten HC Cream Clotrimazole 1.0% w/w Hydrocortisone 1.0% w/w	Bayer Limited	PA1410/040/001	Cream	-Clotrimazole -Hydrocortisone
Canesten Internal Cream	Bayer Limited	PA1410/039/006	Vaginal cream	-Clotrimazole
Canesten Thrush Cream	Bayer Limited	PA1410/039/012	Vaginal cream	-Clotrimazole
Canesten Thrush Cream	PCO Manufacturing Ltd.	PPA0465/048/004	Vaginal cream	-Clotrimazole
Canesten Thrush Cream	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/061/001	Vaginal cream	-Clotrimazole
CanOral 150mg Capsule	Bayer Limited	PA1410/041/001	Capsule, hard	-Fluconazole
Capasal Therapeutic Shampoo	Dermal Laboratories (Ireland) Limited	PA23128/008/001	Shampoo	-Salicylic acid -Coconut oil -Coal tar
Capecitabine	Accord Healthcare S.L.U.	EU/1/12/762/001-006	Film-coated tablet	-Capecitabine
Capecitabine	Accord Healthcare S.L.U.	EU/1/12/762/007-012	Film-coated tablet	-Capecitabine
Capecitabine	Accord Healthcare S.L.U.	EU/1/12/762/013-018	Film-coated tablet	-Capecitabine
Capecitabine medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/12/802/001-014	Film-coated tablet	-Capecitabine
Capecitabine medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/12/802/015-028	Film-coated tablet	-Capecitabine
Capecitabine medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/12/802/029-042	Film-coated tablet	-Capecitabine
Capecitabine Teva 150 mg film-coated tablets	Teva B.V.	EU/1/12/761/001	Film-coated tablet	-Capecitabine
Capecitabine Teva 500 mg film-coated tablets	Teva B.V.	EU/1/12/761/002	Film-coated tablet	-Capecitabine
Caprelsa	Genzyme Europe B.V.	EU/1/11/749/001	Film-coated tablet	-Vandetanib

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Caprelsa	Genzyme Europe B.V.	EU/1/11/749/002	Film-coated tablet	-Vandetanib
Carbaglu Dispersible	Recordati Rare Diseases	EU/1/02/246/1-2	Dispersible tablet	-Carglumic acid
Carbamazepine 100 mg Tablets	Azure Pharmaceuticals Ltd	PA22871/010/001	Tablet	-Carbamazepine
Carbamazepine 200 mg Tablets	Azure Pharmaceuticals Ltd	PA22871/010/002	Tablet	-Carbamazepine
Carbamazepine 400 mg Tablets	Azure Pharmaceuticals Ltd	PA22871/010/003	Tablet	-Carbamazepine
Carbamazepine Essential Pharma 125 mg Suppositories	Essential Pharma (M) Limited	PA22644/003/001	Suppository	-Carbamazepine
Carbamazepine Essential Pharma 250 mg Suppositories	Essential Pharma (M) Limited	PA22644/003/002	Suppository	-Carbamazepine
Carbidopa/Levodopa Fair-Med 10 mg/100 mg Tablets	Fairmed Healthcare GmbH	PA1789/007/002	Tablet	-Carbidopa -Levodopa
Carbidopa/Levodopa Fair-Med 12.5mg/50mg Tablets	Fairmed Healthcare GmbH	PA1789/007/001	Tablet	-Levodopa -Carbidopa
Carbidopa/Levodopa Fair-Med 25 mg/100 mg Tablets	Fairmed Healthcare GmbH	PA1789/007/003	Tablet	-Carbidopa -Levodopa
Carbidopa/Levodopa Fair-Med 25 mg/250 mg Tablets	Fairmed Healthcare GmbH	PA1789/007/004	Tablet	-Carbidopa -Levodopa
Carbidopa/Levodopa Orion 12.5 mg/50 mg tablets	Orion Corporation	PA1327/021/001	Tablet	-Carbidopa monohydrate -Levodopa
Carbidopa/Levodopa Orion 25 mg/100 mg tablets	Orion Corporation	PA1327/021/002	Tablet	-Carbidopa monohydrate -Levodopa
Carbimazole 20 mg Tablets	Essential-Healthcare Ltd.	PA2130/001/002	Tablet	-Carbimazole
Carbimazole 20 mg Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/006/002	Tablet	-Carbimazole
Carbimazole 5 mg Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/006/001	Tablet	-Carbimazole
Carbimazole 5 mg Tablets	Essential-Healthcare Ltd.	PA2130/001/001	Tablet	-Carbimazole
Carbocisteine 375mg Hard Capsules	Chanelle Medical Unlimited Company	PA0688/045/001	Capsule, hard	-Carbocisteine
Carbomix 50 g Granules for Oral Suspension	Athlone Pharmaceuticals Limited	PA1418/007/001	Granules for oral suspension	-Charcoal, activated
Carboplatin 10 mg/ml concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/032/001	Concentrate for solution for infusion	-Carboplatin
Carboplatin 10 mg/ml Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/080/001	Concentrate for solution for infusion	-Carboplatin
Carboplatin-Teva 10 mg/ml Concentrate for Solution for Infusion	Teva Pharma B.V.	PA0749/004/001	Concentrate for solution for infusion	-Carboplatin
Carbosan 2% w/w Gel	Rowa Pharmaceuticals Limited	PA0074/011/001	Gel	-CARBENOXOLONE SODIUM
Carbosylane 140mg/45mg Capsules	Laboratoires Grimberg	PA0345/001/001	Capsule	-Simeticone -Charcoal, activated
Cardicor 1.25 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/004/001	Film-coated tablet	-Bisoprolol hemifumarate
Cardicor 10 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/004/006	Film-coated tablet	-Bisoprolol hemifumarate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Cardicor 2.5 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/004/002	Film-coated tablet	-Bisoprolol hemifumarate
Cardicor 3.75 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/004/003	Film-coated tablet	-Bisoprolol hemifumarate
Cardicor 5 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/004/004	Film-coated tablet	-Bisoprolol hemifumarate
Cardicor 7.5 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/004/005	Film-coated tablet	-Bisoprolol hemifumarate
CARDURA 1mg Tablets	Viartis Healthcare Limited	PA23355/003/001	Tablet	-Doxazosin
CARDURA 2mg Tablets	Viartis Healthcare Limited	PA23355/003/002	Tablet	-Doxazosin
Cardura XL 4 mg Prolonged-release tablets	Viartis Healthcare Limited	PA23355/001/001	Prolonged-release tablet	-Doxazosin
Cardura XL 8 mg Prolonged-release tablets	Viartis Healthcare Limited	PA23355/001/002	Prolonged-release tablet	-Doxazosin
Cariban 10 mg/10 mg modified-release hard capsules	Italfarmaco S.p.A.	PA1776/002/001	Modified-release capsule, hard	-DOXYLAMINE SUCCINATE -Pyridoxine hydrochloride
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	-Carmustine
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	-Carmustine
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	-Carmustine
Carmustine medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/18/1278/001	Powder and solvent for concentrate for solution for infusion	-Carmustine
Carvedilol Krka 12.5 mg Tablets	KRKA, d.d., Novo mesto	PA1347/037/003	Tablet	-Carvedilol
Carvedilol Krka 25 mg Tablets	KRKA, d.d., Novo mesto	PA1347/037/004	Tablet	-Carvedilol
Carvedilol Krka 3.125 mg Tablets	KRKA, d.d., Novo mesto	PA1347/037/001	Tablet	-Carvedilol
Carvedilol Krka 6.25 mg tablets	KRKA, d.d., Novo mesto	PA1347/037/002	Tablet	-Carvedilol
Carvykti	Janssen Pharmaceutica NV	EU/1/22/1648/001	Dispersion for infusion	-Ciltacabtagene autoleucel
Casacol Expectorant Syrup Methoxyphenamine hydrochloride 20 mg/5 ml Guaiphenesin 100 mg/5 ml Sodium Citrate 200 mg/5 ml	Phoenix Labs	PA1113/007/001	Syrup	-Methoxyphenamine hydrochloride -Sodium citrate -Guaiphenesin
Casodex 50 mg film-coated tablets	Laboratoires Juvise Pharmaceuticals	PA23154/002/001	Film-coated tablet	-Bicalutamide
Casodex 50 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/144/001	Film-coated tablet	-Bicalutamide
Casodex 50 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/037/001	Film-coated tablet	-Bicalutamide
Casodex 50 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/107/001	Film-coated tablet	-Bicalutamide
Caspofungin 50mg powder for concentrate for solution for infusion	Flynn Pharma Limited	PA1226/013/001	Powder for concentrate for solution for infusion	-Caspofungin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Caspofungin 50mg powder for concentrate for solution for infusion	Demo S.A.	PA1989/001/001	Powder for concentrate for solution for infusion	-Caspofungin
Caspofungin 50mg powder for concentrate for solution for infusion	Pinewood Laboratories Ltd	PA0281/246/001	Powder for concentrate for solution for infusion	-Caspofungin
Caspofungin 70mg powder for concentrate for solution for infusion	Pinewood Laboratories Ltd	PA0281/246/002	Powder for concentrate for solution for infusion	-Caspofungin
Caspofungin 70mg powder for concentrate for solution for infusion	Demo S.A.	PA1989/001/002	Powder for concentrate for solution for infusion	-Caspofungin
Caspofungin 70mg powder for concentrate for solution for infusion	Flynn Pharma Limited	PA1226/013/002	Powder for concentrate for solution for infusion	-Caspofungin
Caspofungin Accord	Accord Healthcare S.L.U.	EU/1/15/1081/001	Powder for concentrate for solution for infusion	-Caspofungin acetate
Caspofungin Accord	Accord Healthcare S.L.U.	EU/1/15/1081/002	Powder for concentrate for solution for infusion	-Caspofungin acetate
Caspofungin Clonmel 50 mg powder for concentrate for solution for infusion	Clonmel Healthcare Ltd	PA0126/341/001	Powder for concentrate for solution for infusion	-Caspofungin acetate
Caspofungin Clonmel 70 mg powder for concentrate for solution for infusion	Clonmel Healthcare Ltd	PA0126/341/002	Powder for concentrate for solution for infusion	-Caspofungin acetate
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	-Caspofungin
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	-Caspofungin
Cataflam 50mg Coated Tablets	Novartis Ireland Limited	PA0896/004/001	Coated tablet	-Diclofenac potassium
Catapres Ampoules 150 micrograms in 1 ml Solution for Injection	Glenwood GmbH	PA2256/002/001	Solution for injection	-Clonidine hydrochloride
Catapres Tablets 100 micrograms	Glenwood GmbH	PA2256/003/001	Tablet	-Clonidine hydrochloride
Catasart Plus 16mg/12.5mg tablets	Rowex Ltd	PA0711/164/001	Tablet	-Candesartan cilexetil -Hydrochlorothiazide
Catephen 10 % ointment	Kora Corporation Limited trading as Kora Healthcare	PA1748/003/001	Ointment	-Green tea dry extract
Catiolanze	Santen OY	EU/1/23/1763/001-004	Eye drops, emulsion in single-dose container	-Latanoprost
Caverject 10 micrograms Powder and Solvent for Solution for Injection	Pfizer Healthcare Ireland	PA0822/115/002	Powder and solvent for solution for injection	-Alprostadil
Caverject 20 micrograms Powder and Solvent for Solution for Injection	Pfizer Healthcare Ireland	PA0822/115/003	Powder and solvent for solution for injection	-Alprostadil

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Cayston	Gilead Sciences Ireland UC	EU/1/09/543/001	Powder and solvent for nebuliser solution	-Aztreonam (as lysine salt)
Ceclova 75 mg/20 mg modified-release hard capsules	Aenova IP GmbH	PA22984/001/001	Modified-release capsule, hard	-Diclofenac sodium -Omeprazole
Cefixime 200 mg film-coated tablets	Orchid Europe Limited	PA1335/002/001	Film-coated tablet	-Cefixime
Cefixime Nectar Lifesciences 100 mg/5 ml Powder for Oral Suspension	NECLIFE PT UNIPESAL LDA	PA22914/001/001	Powder for oral suspension	-Cefixime
Cefotaxime 1 g powder for solution for injection/infusion	Noridem Enterprises Limited	PA1122/019/002	Powder for solution for injection/infusion	-Cefotaxime
Cefotaxime 1g Powder for solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/223/002	Powder for solution for injection/infusion	-Cefotaxime sodium
Cefotaxime 2 g powder for solution for injection/infusion	Noridem Enterprises Limited	PA1122/019/003	Powder for solution for injection/infusion	-Cefotaxime
Cefotaxime 500 mg powder for solution for injection/infusion	Noridem Enterprises Limited	PA1122/019/001	Powder for solution for injection/infusion	-Cefotaxime
Cefotaxime 500mg Powder for solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/223/001	Powder for solution for injection/infusion	-Cefotaxime sodium
Cefotaxime Netpharmalab 1g Powder for solution for injection or infusion	Netpharmalab Consulting Services S. L.	PA22665/001/001	Powder for solution for injection/infusion	-Cefotaxime
Ceftal 250mg coated tablets	Rowex Ltd	PA0711/101/002	Coated tablet	-Cefuroxime
Ceftal 500 mg Coated Tablets	Rowex Ltd	PA0711/101/003	Coated tablet	-Cefuroxime
Ceftazidime 1 g powder for solution for injection/infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/012/002	Powder for solution for injection/infusion	-Ceftazidime
Ceftazidime 1g Powder for solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/224/001	Powder for solution for injection/infusion	-Ceftazidime
Ceftazidime 2 g powder for solution for injection/infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/012/003	Powder for solution for injection/infusion	-Ceftazidime
Ceftazidime 2g Powder for solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/224/002	Powder for solution for injection/infusion	-Ceftazidime
Ceftazidime 500 mg powder for solution for injection	Hikma Farmacêutica (Portugal) S.A.	PA1217/012/001	Powder for solution for injection	-Ceftazidime
Ceftriaxone 1 g powder for solution for injection/infusion	AS Kalceks	PA2165/017/001	Powder for solution for injection/infusion	-Ceftriaxone sodium
Ceftriaxone 1g Powder for solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/225/001	Powder for solution for injection/infusion	-Ceftriaxone
Ceftriaxone 1g powder for solution for injection/infusion	JED Pharma Limited	PA23183/006/001	Solution for injection/infusion	-Ceftriaxone sodium
Ceftriaxone 2 g powder for solution for injection/infusion	AS Kalceks	PA2165/017/002	Powder for solution for injection/infusion	-Ceftriaxone sodium
Ceftriaxone 2g Powder for Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/225/002	Powder for solution for injection/infusion	-Ceftriaxone sodium
Cefuroxime 1.5 g Powder for Injection/Infusion	Flynn Pharma Limited	PA1226/009/002	Powder for solution for injection/infusion	-Cefuroxime Sodium

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Cefuroxime 1.5 g powder for solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/006/002	Powder for solution for injection/infusion	-Cefuroxime Sodium
Cefuroxime 1500 mg Powder for solution for injection or infusion	Stravencon Ltd	PA1947/002/003	Powder for solution for injection/infusion	-Cefuroxime Sodium
Cefuroxime 250 mg Powder for solution for injection	Stravencon Ltd	PA1947/002/001	Powder for solution for injection	-Cefuroxime Sodium
Cefuroxime 750 mg Powder for Injection/Infusion	Flynn Pharma Limited	PA1226/009/001	Powder for solution for injection/infusion	-Cefuroxime Sodium
Cefuroxime 750 mg Powder for solution for injection	Stravencon Ltd	PA1947/002/002	Powder for solution for injection	-Cefuroxime Sodium
Cefuroxime 750 mg powder for solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/006/001	Powder for solution for injection/infusion	-Cefuroxime Sodium
Cefuroxime Milpharm 250mg Film-coated tablets	Aurobindo Pharma (Malta) Limited	PA1445/022/001	Film-coated tablet	-Cefuroxime axetil (amorphous)
Cefuroxime Milpharm 500mg Film-coated tablets	Aurobindo Pharma (Malta) Limited	PA1445/022/002	Film-coated tablet	-Cefuroxime axetil (amorphous)
Celdoxome pegylated liposomal	Yes Pharmaceutical Development Services GmbH	EU/1/22/1666/001-004	Concentrate for solution for infusion	-DOXORUBICIN HYDROCHLORIDE
Celebrex 100 mg hard capsules	Upjohn EESV	PA23055/006/001	Capsule, hard	-Celecoxib
Celebrex 200 mg hard capsules	Upjohn EESV	PA23055/006/002	Capsule, hard	-Celecoxib
Celebrex 200 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/118/002	Capsule, hard	-Celecoxib
Celecoxib 100mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/228/001	Capsule, hard	-Celecoxib
Celecoxib 200mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/228/002	Capsule, hard	-Celecoxib
Celecoxib Krka 100mg capsules, hard	KRKA, d.d., Novo mesto	PA1347/033/001	Capsule, hard	-Celecoxib
Celecoxib Krka 200mg capsules, hard	KRKA, d.d., Novo mesto	PA1347/033/002	Capsule, hard	-Celecoxib
CellCept	Roche Registration GmbH	EU/1/96/005/001	Capsule, hard	-Mycophenolate mofetil
CellCept	Roche Registration GmbH	EU/1/96/005/002	Film-coated tablet	-Mycophenolate mofetil
CellCept	Roche Registration GmbH	EU/1/96/005/003	Capsule, hard	-Mycophenolate mofetil
CellCept	Roche Registration GmbH	EU/1/96/005/004	Film-coated tablet	-Mycophenolate mofetil
CellCept	Roche Registration GmbH	EU/1/96/005/005	Powder for concentrate for solution for infusion	-Mycophenolate mofetil
CellCept	Roche Registration GmbH	EU/1/96/005/006	Powder for oral suspension	-Mycophenolate mofetil
Celluvisc 0.5 %w/v eye drops solution, unit dose	AbbVie Limited	PA1824/016/002	Eye drops, solution	-Carmellose sodium
Celluvisc 1% w/v Eye drops, solution, unit dose	AbbVie Limited	PA1824/016/001	Eye drops, solution	-Carmellose sodium
Celluvisc 1.0 % w/v eye drops, solution, unit dose	PCO Manufacturing Ltd.	PPA0465/259/001	Eye drops, solution	-Carmellose sodium
Celluvisc 1.0% w/v Eye drops, solution, unit dose	IMED Healthcare Ltd.	PPA1463/147/001	Eye drops, solution	-Carmellose sodium
Celsentri	ViiV Healthcare BV	EU/1/07/418/011	Film-coated tablet	-Maraviroc

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Celsentri	ViiV Healthcare BV	EU/1/07/418/012	Film-coated tablet	-Maraviroc
Celsentri	ViiV Healthcare BV	EU/1/07/418/1-5	Film-coated tablet	-Maraviroc
Celsentri	ViiV Healthcare BV	EU/1/07/418/6-10	Film-coated tablet	-Maraviroc
Celsentri	ViiV Healthcare BV	EU/01/07/418/013	Oral solution	-Maraviroc
Celsior solution for organ preservation	Institut Georges Lopez - IGL	PA1996/001/001	Solution for organ preservation	-Glutathione -Mannitol -Lactobionic acid -Glutamic acid -Sodium hydroxide -Calcium chloride 2 h2o -Potassium chloride -Magnesium chloride 6 h2o -Histidine
Celsunax	Pinax Pharma GmbH	EU/1/21/1560/001-002	Solution for injection	-loflupane (123l)
Centrax 10mg Tablets	Pfizer Healthcare Ireland	PA0822/010/001	Tablet	-Prazepam
Centyl K 2.5 mg/573 mg modified-release tablets	KARO PHARMA AB	PA22650/002/002	Modified-release tablet	-Bendroflumethiazide -Potassium chloride
Ceplene 0.5 mg/0.5 ml solution for injection	Laboratoires DELBERT	EU/1/08/477/1	Solution for injection	-Histamine dihydrochloride
Ceprotrin	Baxter Vaccine AG	EU/1/01/190/001	Powder and solvent for solution for injection	-Protein c
Ceprotrin	Baxter Vaccine AG	EU/1/01/190/002	Powder and solvent for solution for injection	-Protein c
Cerazette 75 microgram film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/016/001	Film-coated tablet	-Desogestrel
Cerdelga	Genzyme Europe B.V.	EU/1/14/974/001-002	Capsule, hard	-Eliglustat (as tartrate)
Cerezyme	Genzyme Europe B.V.	EU/1/97/053/001	Powder for concentrate for solution for infusion	-Imiglucerase
Cerezyme	Genzyme Europe B.V.	EU/1/97/053/002	Powder for concentrate for solution for infusion	-Imiglucerase
Cerezyme	Genzyme Europe B.V.	EU/1/97/053/003	Powder for concentrate for solution for infusion	-Imiglucerase
Cerezyme	Genzyme Europe B.V.	EU/1/97/053/004	Powder for concentrate for solution for infusion	-Imiglucerase
Cerezyme	Genzyme Europe B.V.	EU/1/97/053/005	Powder for concentrate for solution for infusion	-Imiglucerase
Cernevit, Powder for Solution for Injection or Infusion	Baxter Holding B.V.	PA2299/019/001	Powder for solution for injection/infusion	-Retinol palmitate -Cholecalciferol -Dl-a-tocopherol -Ascorbic acid -Coccarboxylase tetrahydrate -Riboflavin sodium phosphate -Pyridoxine hydrochloride -Cyanocobalamin -Folic acid -Dexpanthenol -D-biotin -Nicotinamide
Certican 0.1mg Dispersible Tablets	Novartis Ireland Limited	PA0896/005/005	Dispersible tablet	-Everolimus
Certican 0.25mg Dispersible Tablets	Novartis Ireland Limited	PA0896/005/006	Dispersible tablet	-Everolimus

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Certican 0.25mg Tablets	Novartis Ireland Limited	PA0896/005/001	Tablet	-Everolimus
Certican 0.5mg Tablets	Novartis Ireland Limited	PA0896/005/002	Tablet	-Everolimus
Certican 0.75mg Tablets	Novartis Ireland Limited	PA0896/005/003	Tablet	-Everolimus
Certican 1 mg Tablets	Novartis Ireland Limited	PA0896/005/004	Tablet	-Everolimus
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	-DAUNORUBICIN HYDROCHLORIDE
Cervarix	GlaxoSmithKline Biologicals S.A.	EU/1/07/419/1-12	Suspension for injectio	-Hpv 16 I1 protein -Hpv 18 I1 protein
Cetirelief Allergy 10mg Film-coated Tablets	Phoenix Labs	PA1113/014/001	Film-coated tablet	-Cetirizine dihydrochloride
Cetirizine dihydrochloride Pinewood 10 mg film-coated Tablets	Pinewood Laboratories Ltd	PA0281/252/001	Film-coated tablet	-Cetirizine dihydrochloride
Citrine 10 mg Film-coated Tablets	Rowex Ltd	PA0711/075/001	Film-coated tablet	-Cetirizine hydrochloride
Citrine Allergy 1 mg/ml oral solution	Rowex Ltd	PA0711/075/003	Oral solution	-Cetirizine dihydrochloride
Citrine Allergy 10mg Film-coated Tablets	Rowex Ltd	PA0711/075/002	Film-coated tablet	-Cetirizine hydrochloride
Cetrix 10mg Film-coated Tablets	Teva B.V.	PA1986/114/001	Film-coated tablet	-Cetirizine hydrochloride
Cetrotide	Merck Europe B.V.	EU/1/99/100/001	Powder and solvent for solution for injection	-Cetrotirelix acetate
Cetrotide	Merck Europe B.V.	EU/1/99/100/002	Powder and solvent for solution for injection	-Cetrotirelix acetate
Cetrotide	Merck Europe B.V.	EU/1/99/100/003	Powder and solvent for solution for injection	-Cetrotirelix acetate
Cevenfacta	Laboratoire francais du Fractionnement et des Biotechnologies	EU/1/22/1664/001	Powder and solvent for solution for injection	-Eptacog beta (activated)
Cevenfacta	Laboratoire francais du Fractionnement et des Biotechnologies	EU/1/22/1664/002	Powder and solvent for solution for injection	-Eptacog beta (activated)
Cevenfacta	Laboratoire francais du Fractionnement et des Biotechnologies	EU/1/22/1664/003	Powder and solvent for solution for injection	-Eptacog beta (activated)
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	-Cetrotirelix
Champix	Pfizer Europe MA EEIG	EU/1/06/360/01	Film-coated tablet	-Varenicline tartrate
Champix	Pfizer Europe MA EEIG	EU/1/06/360/02	Film-coated tablet	-Varenicline tartrate
Chenodeoxycholic acid	Leadiant Gmbh	EU/1/16/1110/001	Capsule, hard	-Chenodeoxycholic acid
Chirocaine 1.25 mg/ml solution for infusion	AbbVie Limited	PA1824/003/005	Solution for infusion	-Levobupivacaine hydrochloride
Chirocaine 2.5 mg/ml solution for injection/concentrate for solution for infusion	AbbVie Limited	PA1824/003/001	Solution for injection/infusion	-Levobupivacaine hydrochloride
Chirocaine 5 mg/ml solution for injection/concentrate for solution for infusion	AbbVie Limited	PA1824/003/002	Solution for injection/infusion	-Levobupivacaine hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Chirocaine 7.5 mg/ml solution for injection/concentrate for solution for infusion	AbbVie Limited	PA1824/003/003	Solution for injection/infusion	-Levobupivacaine hydrochloride
ChloraPrep 2% w/v / 70% v/v impregnated cutaneous swab	Becton Dickinson France	PA2287/001/003	Impregnated cutaneous swab	-Chlorhexidine digluconate -Isopropyl alcohol
ChloraPrep 2% w/v/ 70% v/v cutaneous solution	Becton Dickinson France	PA2287/001/002	Cutaneous solution	-Chlorhexidine gluconate -Isopropyl alcohol
ChloraPrep with Tint 2% w/v / 70% v/v cutaneous solution	Becton Dickinson France	PA2287/001/001	Cutaneous solution	-Chlorhexidine gluconate -Isopropyl alcohol
Chlorhexidine acetate 0.015% w/v and Cetrimide 0.15% w/v Irrigation solution	Baxter Holding B.V.	PA2299/005/001	Irrigation solution	-Chlorhexidine acetate -Cetrimide
Chlorhexidine Acetate BP 0.05% w/v Irrigation solution	Baxter Holding B.V.	PA2299/004/001	Irrigation solution	-Chlorhexidine acetate
Chloromycetin 0.5% w/v Redidrops eye drops, solution	Amdipharm Limited	PA1142/021/001	Eye drops, solution	-Chloramphenicol
Chlorphenamine 10 mg/ml Solution for Injection	Evolan Pharma AB	PA2262/003/001	Solution for injection	-Chlorphenamine maleate
Chlorpromazine Elixir BP 25 mg/5 ml Oral Solution	Pinewood Laboratories Ltd	PA0281/124/001	Oral solution	-CHLORPROMAZINE HYDROCHLORIDE
CHOLEDIAM Kit for radiopharmaceutical preparation of technetium [99mTc] mebrofenin injection	MEDiAM	PA1229/001/001	Powder for solution for injection	-Mebrofenin
CHOLESTAGEL 625 mg FILM-COATED tablets	CHEPLAPHARM Arzneimittel GmbH	EU/1/03/268/1-3	Tablet	
Cholib	Viartis Healthcare Limited	EU/1/13/866/001-002	Film-coated tablet	-Micronized fenofibrate -Simvastatin with 0.2% butylated hydroxyanisole (bha), (E320)
Cholib	Viartis Healthcare Limited	EU/1/13/866/003-004	Film-coated tablet	-Micronized fenofibrate -Simvastatin with 0.2% butylated hydroxyanisole (bha), (E320)
Cholurso 250 mg film-coated tablets	Laboratoires Mayoly Spindler	PA1913/002/001	Film-coated tablet	-Ursodeoxycholic acid
Cholurso 500 mg film-coated tablets	Laboratoires Mayoly Spindler	PA1913/002/002	Film-coated tablet	-Ursodeoxycholic acid
Chondromel 400 mg Capsules	IBSA Farmaceutici Italia S.r.l	PA1104/003/001	Capsule, hard	-Chondroitin sulfate
Cialis	Eli Lilly Nederland B.V.	EU/1/02/237/006	Film-coated tablet	-Tadalafil
CIALIS	Eli Lilly Nederland B.V.	EU/1/02/237/1-5	Film-coated tablet	-Tadalafil
Cialis	Eli Lilly Nederland B.V.	EU/1/02/237/7-8	Film-coated tablet	-Tadalafil
Cialis for men 10 mg film-coated tablets	A. Nattermann & Cie. GmbH	PA25208/001/001	Film-coated tablet	-Tadalafil
Ciambra	Menarini International Operations Luxembourg S.A.	EU/1/15/1055/001	Powder for concentrate for solution for infusion	-Pemetrexed disodium

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
CIAMBRA	Menarini International Operations Luxembourg S.A.	EU/1/15/1055/002	Powder for concentrate for solution for infusion	-PEMETREXED -DISODIUM
Cibinqo	Pfizer Europe MA EEIG	EU/1/21/1593/001-005	Film-coated tablet	-Abrocitinib
Cibinqo	Pfizer Europe MA EEIG	EU/1/21/1593/006-010	Film-coated tablet	-Abrocitinib
Cibinqo	Pfizer Europe MA EEIG	EU/1/21/1593/011-015	Film-coated tablet	-Abrocitinib
Cifloxager 250 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/069/001	Film-coated tablet	-Ciprofloxacin
Cifloxager 500 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/069/002	Film-coated tablet	-Ciprofloxacin
Cifoban 136 mmol/l solution for infusion	Fresenius Medical Care Deutschland GmbH	PA1350/008/001	Solution for injection	-Trisodium citrate dihydrate
Cifox 250 mg Film-coated tablets	Rowex Ltd	PA0711/122/001	Film-coated tablet	-Ciprofloxacin
Cifox 500 mg Film-coated tablets	Rowex Ltd	PA0711/122/002	Film-coated tablet	-Ciprofloxacin
Cifox 750 mg Film-coated tablets	Rowex Ltd	PA0711/122/003	Film-coated tablet	-Ciprofloxacin
Cilique 250/35 micrograms tablets	Gedeon Richter Plc	PA1330/029/001	Tablet	-Norgestimate -Ethinylestradiol
Ciloxan 3 mg/ml ear drops, solution	Novartis Ireland Limited	PA0896/006/001	Ear drops, solution	-Ciprofloxacin hydrochloride
Cimeldine 400 mg Film-coated tablets	Clonmel Healthcare Ltd	PA0126/077/002	Film-coated tablet	-Cimetidine
Cimzia	UCB Pharma S.A.	EU/1/09/544/1-2	Solution for injection in pre-filled syringe	-Certolizumab pegol
Cinacalcet Accordpharma 30 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/20/1429/001-004	Film-coated tablet	-Cinacalcet hydrochloride
Cinacalcet Accordpharma 60 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/20/1429/005-008	Film-coated tablet	-Cinacalcet hydrochloride
Cinacalcet Accordpharma 90 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/20/1429/009-012	Film-coated tablet	-Cinacalcet hydrochloride
Cinacalcet Clonmel 30 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/306/001	Film-coated tablet	-Cinacalcet hydrochloride
Cinacalcet Clonmel 60 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/306/002	Film-coated tablet	-Cinacalcet hydrochloride
Cinacalcet Clonmel 90 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/306/003	Film-coated tablet	-Cinacalcet hydrochloride
Cinacalcet Mylan 30 mg film-coated tablets	Mylan Pharmaceuticals Limited	EU/1/15/1054/001-004	Film-coated tablet	-Cinacalcet hydrochloride
Cinacalcet Mylan 60 mg film-coated tablets	Mylan Pharmaceuticals Limited	EU/1/15/1054/005-007	Film-coated tablet	-Cinacalcet hydrochloride
Cinacalcet Mylan 90 mg film-coated tablets	Mylan Pharmaceuticals Limited	EU/1/15/1054/008-010	Film-coated tablet	-Cinacalcet hydrochloride
Cinacalcet Teva 30 mg film-coated tablets	Teva B.V.	PA1986/007/001	Film-coated tablet	-Cinacalcet hydrochloride -TALC PH.EUR.
Cinacalcet Teva 60 mg film-coated tablets	Teva B.V.	PA1986/007/002	Film-coated tablet	-Cinacalcet hydrochloride
Cinacalcet Teva 90 mg film-coated tablets	Teva B.V.	PA1986/007/003	Film-coated tablet	-Cinacalcet hydrochloride
Cinquaero	Teva B.V.	EU/1/16/1125/001	Concentrate for solution for infusion	-Reslizumab

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Cinryze	Takeda Manufacturing Austria AG	EU/1/11/688/001	Powder and solvent for solution for injection	-C1 inhibitor
Ciplox 250 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/100/001	Film-coated tablet	-Ciprofloxacin hydrochloride
Ciplox 500 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/100/002	Film-coated tablet	-Ciprofloxacin hydrochloride
Ciplox 750 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/100/003	Film-coated tablet	-Ciprofloxacin hydrochloride
Ciprager 10 mg Film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/047/001	Film-coated tablet	-Citalopram
Ciprager 20 mg Film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/047/002	Film-coated tablet	-Citalopram
Ciprager 40 mg Film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/047/003	Film-coated tablet	-Citalopram
Cipramil 10 mg film-coated tablets	Lundbeck (Ireland) Limited	PA0776/001/001	Film-coated tablet	-Citalopram
Cipramil 20 mg film-coated tablets	Lundbeck (Ireland) Limited	PA0776/001/002	Film-coated tablet	-Citalopram
Cipramil 40 mg/ml Oral drops, solution	Lundbeck (Ireland) Limited	PA0776/001/004	Oral drops, solution	-Citalopram
Ciprofloxacin 2 mg/ml Solution for infusion	Noridem Enterprises Limited	PA1122/005/001	Solution for infusion	-Ciprofloxacin
Ciprofloxacin Krka 250 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/035/001	Film-coated tablet	-Ciprofloxacin hydrochloride
Ciprofloxacin Krka 500 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/035/002	Film-coated tablet	-Ciprofloxacin hydrochloride
Ciprofloxacin Krka 750 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/035/003	Film-coated tablet	-Ciprofloxacin hydrochloride
Ciprofloxacin Teva 250 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/031/002	Film-coated tablet	-Ciprofloxacin
Ciprofloxacin Teva 500 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/031/003	Film-coated tablet	-Ciprofloxacin
Ciprotan 10mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/131/001	Film-coated tablet	-Citalopram
Ciprotan 20mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/131/002	Film-coated tablet	-Citalopram
Circadin	RAD Neurim Pharmaceuticals EEC SARL	EU/1/07/392/001	Prolonged-release tablet	-Melatonin
Cisatracurium 2 mg/ml solution for injection/infusion	Noridem Enterprises Limited	PA1122/017/001	Solution for injection/infusion	-Cisatracurium
Cisatracurium 2 mg/ml solution for injection/infusion	AS Kalceks	PA2165/008/001	Solution for injection/infusion	-Cisatracurium Besilate -Cisatracurium
Cisplatin 1 mg/ml Concentrate for Solution for Infusion	Pfizer Healthcare Ireland	PA0822/199/001	Concentrate for solution for infusion	-Cisplatin
Cisplatin 1mg/ml Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/081/001	Concentrate for solution for infusion	-Cisplatin
Citalopram Bluefish 10 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/018/001	Film-coated tablet	-Citalopram hydrobromide
Citalopram Bluefish 20 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/018/002	Film-coated tablet	-Citalopram hydrobromide
Citalopram Bluefish 40 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/018/003	Film-coated tablet	-Citalopram hydrobromide
Citalopram Teva 10 mg film-coated tablets	Teva Pharma B.V.	PA0749/019/001	Film-coated tablet	-Citalopram

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Citalopram Teva 20 mg film-coated tablets	Teva Pharma B.V.	PA0749/019/002	Film-coated tablet	-Citalopram
Citalopram Teva 40mg film-coated tablets	Teva Pharma B.V.	PA0749/019/003	Film-coated tablet	-Citalopram
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	-Felypressin -Prilocaine hydrochloride
Citidaron 1.5 mg tablets	Aflofarm Farmacja Polska Sp. z o.o.	PA22714/001/001	Tablet	-Cytisine
CitraFleet oral solution	Casen-Recordati S.L.	PA2028/002/002	Oral solution	-Sodium picosulfate -Magnesium oxide, light -Citric acid
CitraFleet, Powder for oral solution in sachet	Casen-Recordati S.L.	PA2028/002/001	Powder for oral solution in sachet	-Sodium picosulfate -Light magnesium oxide -Citric acid anhydrous
Citrol 10 mg Film-Coated Tablets	Rowex Ltd	PA0711/064/001	Film-coated tablet	-Citalopram hydrobromide
CITROL 20 mg Film-Coated Tablets	Rowex Ltd	PA0711/064/002	Film-coated tablet	-Citalopram hydrobromide
Citrol 30 mg Film-Coated Tablets	Rowex Ltd	PA0711/064/003	Film-coated tablet	-Citalopram hydrobromide
Claforan Powder for Solution for Injection 1g	Amdipharm Limited	PA1142/041/002	Powder for solution for injection	-Cefotaxime sodium
Claforan Powder for Solution for Injection 500mg	Amdipharm Limited	PA1142/041/001	Powder for solution for injection	-Cefotaxime sodium
Clareeze Allergy 10 mg Tablets	Phoenix Labs	PA1113/015/001	Tablet	-Loratadine
Clariscan 279.32 mg/ml solution for injection	GE Healthcare AS	PA0735/011/001	Solution for injection	-Gadoteric acid
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	-Gadoteric acid
Clarithromycin 250 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/002/001	Film-coated tablet	-Clarithromycin
Clarithromycin 250 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/197/001	Film-coated tablet	-Clarithromycin
Clarithromycin 500 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/197/002	Film-coated tablet	-Clarithromycin
Clarithromycin 500 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/002/002	Film-coated tablet	-Clarithromycin
Clarithromycin 500 mg Powder for concentrate for solution for infusion	Noridem Enterprises Limited	PA1122/025/001	Powder for concentrate for solution for infusion	-Clarithromycin lactobionate
Clarithromycin 500 mg Powder for Concentrate for Solution for Infusion	Amdipharm Limited	PA1142/022/001	Powder for concentrate for solution for infusion	-Clarithromycin
Clarithromycin 500 mg powder for concentrate for solution for infusion	hameln pharma gmbh	PA2237/003/001	Powder for concentrate for solution for infusion	-Clarithromycin
Clarithromycin Krka 250 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/068/001	Film-coated tablet	-Clarithromycin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Clarithromycin Krka 500 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/068/002	Film-coated tablet	-Clarithromycin
Clarithromycin Teva 250 mg film-coated tablets	Teva Pharma B.V.	PA0749/148/001	Film-coated tablet	-Clarithromycin
Clarithromycin Teva 500 mg film-coated tablets	Teva Pharma B.V.	PA0749/148/002	Film-coated tablet	-Clarithromycin
Clarityn 10 mg Tablets	Bayer Limited	PA1410/075/001	Tablet	-Loratadine
Clarityn 10 mg Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/060/001	Tablet	-Loratadine
Clarityn 1mg/1ml Syrup	Bayer Limited	PA1410/075/002	Syrup	-Loratadine
Clavamel Forte 500mg/125mg film- coated tablet	Clonmel Healthcare Ltd	PA0126/243/001	Film-coated tablet	-Amoxicillin -Clavulanic acid
Cleenema Ready-to- Use 21.4g / 9.4g Enema	Casen-Recordati S.L.	PA2028/001/001	Rectal solution	-Sodium dihydrogen phosphate dihydrate -Disodium phosphate dodecahydrate
Clenil Modulite 100 micrograms per metered dose Pressurised Inhalation Solution	Chiesi Farmaceutici S.p.A.	PA0584/006/002	Pressurised inhalation, solution	-Beclometasone dipropionate
Clenil Modulite 200 micrograms per metered dose Pressurised Inhalation Solution	Chiesi Farmaceutici S.p.A.	PA0584/006/003	Pressurised inhalation, solution	-Beclometasone dipropionate
Clenil Modulite 250 micrograms per metered dose Pressurised Inhalation Solution	Chiesi Farmaceutici S.p.A.	PA0584/006/004	Pressurised inhalation, solution	-Beclometasone dipropionate
Clenil Modulite 50 micrograms per metered dose Pressurised Inhalation Solution	Chiesi Farmaceutici S.p.A.	PA0584/006/001	Pressurised inhalation, solution	-Beclometasone dipropionate
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
Climara 50 micrograms/24 hours Transdermal Patch	Bayer Limited	PA1410/015/001	Transdermal patch	-Estradiol
Climara Forte 100 micrograms/24 hours Transdermal Patch	Bayer Limited	PA1410/015/002	Transdermal patch	-Estradiol
Clindamycin + Benzoyl Peroxide 10 mg/g + 50 mg/g gel	Morningside Healthcare (Malta) Limited	PA23142/015/001	Gel	-CLINDAMYCIN PHOSPHATE -Benzoyl Peroxide, Hydrus
Clindamycin 150 mg Capsule	Chanelle Medical Unlimited Company	PA0688/044/001	Capsule, hard	-Clindamycin
Clindamycin 150 mg Capsules, hard	Renata Pharmaceuticals (Ireland) Limited	PA22865/004/002	Capsule, hard	-Clindamycin hydrochloride
Clindamycin 150 mg/ml solution for injection	Fresenius Kabi Deutschland GmbH	PA2059/007/001	Solution for injection	-CLINDAMYCIN PHOSPHATE
Clindamycin 150 mg/ml Solution for injection/infusion	Noridem Enterprises Limited	PA1122/033/001	Solution for injection/infusion	-CLINDAMYCIN PHOSPHATE
Clindamycin 300 mg Capsules	EG (Eurogenerics)	PA25213/001/001	Capsule, hard	-Clindamycin hydrochloride
Clindamycin 300 mg Capsules, hard	Renata Pharmaceuticals (Ireland) Limited	PA22865/004/003	Capsule, hard	-Clindamycin hydrochloride
Clindamycin 75 mg Capsules, hard	Renata Pharmaceuticals (Ireland) Limited	PA22865/004/001	Capsule, hard	-Clindamycin hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
CLINIMIX N14G30E, solution for infusion	Baxter Holding B.V.	PA2299/020/001	Solution for infusion	-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
Clobazam Essential Pharmaceuticals 1 mg/ml oral suspension	Essential Pharmaceuticals Limited	PA22662/004/001	Oral suspension	-Clobazam
Clobazam Thame 10mg/5ml Oral Suspension	Syri Pharma Limited t/a Thame Laboratories	PA22697/006/002	Oral suspension	-Clobazam
Clobazam Thame 5mg/5ml Oral Suspension	Syri Pharma Limited t/a Thame Laboratories	PA22697/006/001	Oral suspension	-Clobazam
Clodol 75 mg film-coated tablets	Rowex Ltd	PA0711/166/001	Film-coated tablet	-Clopidogrel hydrochloride
Clomid 50 mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/020/001	Tablet	-Clomiphene citrate
Clonactil 100 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/026/002	Film-coated tablet	-CHLORPROMAZINE HYDROCHLORIDE
Clonactil 25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/026/003	Film-coated tablet	-CHLORPROMAZINE HYDROCHLORIDE
Clonactil 50 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/026/001	Film-coated tablet	-CHLORPROMAZINE HYDROCHLORIDE
Clonazepam Rosemont 0.5 mg/5 ml oral solution	Taw Pharma (Ireland) Limited	PA23081/009/001	Oral solution	-Clonazepam
Clonocid 250 mg film-coated Tablets	Clonmel Healthcare Ltd	PA0126/136/001	Film-coated tablet	-Clarithromycin
Clonocid 500 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/136/002	Film-coated tablet	-Clarithromycin
Clopidogrel Zentiva	Zentiva k.s.	EU/1/08/465/1-14	Film-coated tablet	-Clopidogrel
Clopidogrel 75mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/198/001	Film-coated tablet	-Clopidogrel hydrogensulfate
Clopidogrel BGR	Laboratoires BIOGARAN	EU/1/09/558/1-12	Film-coated tablet	-Clopidogrel
Clopidogrel Bluefish 75 mg Film-coated Tablets	Bluefish Pharmaceuticals AB	PA1436/026/001	Film-coated tablet	-Clopidogrel besilate
Clopidogrel Clonmel 75mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/279/001	Film-coated tablet	-Clopidogrel
Clopidogrel Krka	KRKA, d.d., Novo mesto	EU/1/09/556/1-9	Film-coated tablet	-Clopidogrel hydrochloride
CLOPIDOGREL KRKA D.D.	Krka, d.d., Novo mesto	EU/1/09/562/001-9	Film-coated tablet	-CLOPIDOGREL HYDROCHLORIDE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Clopidogrel MSN 75 mg film-coated tablets	MSN Labs Europe Limited	PA23250/005/001	Film-coated tablet	-Clopidogrel Hydrogen Sulfate
Clopidogrel ratiopharm	Teva B.V.	EU/1/14/975/001-017	Film-coated tablet	-Clopidogrel
CLOPIDOGREL TAD	TAD Pharma GmbH	EU/1/09/555/1-9	Film-coated tablet	-CLOPIDOGREL HYDROCHLORIDE
Clopidogrel Taw Pharma	Taw Pharma (Ireland) Ltd	EU/1/09/559/001-016	Film-coated tablet	-Clopidogrel hydrochloride
CLOPIDOGREL TEVA	Teva B.V.	EU/1/09/540/1-16	Film-coated tablet	-CLOPIDOGREL HYDROGEN SULPHATE
Clopidogrel Viatrix	Viatrix Limited	EU/1/09/568/001-020	Film-coated tablet	-Clopidogrel besylate
Clopidogrel Zentiva	Zentiva k.s.	EU/1/08/465/15-17	Film-coated tablet	-Clopidogrel
Clopidogrel/Acetylsalicylic acid Mylan	Mylan Pharmaceuticals Limited	EU/1/19/1395/001-005	Film-coated tablet	-Clopidogrel hydrogen sulphate -Acetylsalicylic acid
Clopidogrel/Acetylsalicylic acid Mylan	Mylan Pharmaceuticals Limited	EU/1/19/1395/006-010	Film-coated tablet	-Clopidogrel hydrogen sulphate -Acetylsalicylic acid
Clopidogrel/Acetylsalicylic acid Zentiva	sanofi-aventis groupe	EU/1/10/623/1-7	Film-coated tablet	-Acetylsalicylic acid -Clopidogrel hydrogen sulphate
Clopidogrel/Acetylsalicylic acid Zentiva	sanofi-aventis groupe	EU/1/10/623/8-14	Film-coated tablet	-Acetylsalicylic acid -Clopidogrel hydrogen sulphate
Clopixol 10mg Film-coated Tablets	Lundbeck (Ireland) Limited	PA0776/002/003	Film-coated tablet	-Zuclopenthixol hydrochloride
Clopixol 200 mg/ml Solution for Injection	Lundbeck (Ireland) Limited	PA0776/002/001	Solution for injection	-ZUCLOPENTHIXOL DECANOATE
Clopixol Conc. 500 mg/ml Solution for Injection	Lundbeck (Ireland) Limited	PA0776/002/002	Solution for injection	-ZUCLOPENTHIXOL DECANOATE
Clorom 250 mg Film-Coated Tablets	Rowex Ltd	PA0711/061/001	Film-coated tablet	-Clarithromycin
Clorom 500 mg film-coated tablets	Rowex Ltd	PA0711/061/002	Film-coated tablet	-Clarithromycin
Clorom XL 500 mg Prolonged-Release Tablets	Morningside Healthcare (Malta) Limited	PA23142/006/001	Prolonged-release tablet	-Clarithromycin
Clozaril 100 mg tablets	Mylan IRE Healthcare Limited	PA2010/020/002	Tablet	-Clozapine
Clozaril 25 mg Tablets	Mylan IRE Healthcare Limited	PA2010/020/001	Tablet	-Clozapine
Coagadex	BPL Bioproducts Laboratory GmbH	EU/1/16/1087/001	Powder and solvent for solution for injection	-Human coagulation factor x
Coagadex	BPL Bioproducts Laboratory GmbH	EU/1/16/1087/002	Powder and solvent for solution for injection	-Human coagulation factor x
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	-Amoxicillin -Clavulanic acid
Co-amoxiclav 1000mg/200mg Powder for Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/226/002	Powder for solution for injection/infusion	-Amoxicillin sodium -potassium clavulanate
Co-amoxiclav 1000mg/200mg powder for solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/026/001	Powder for solution for injection/infusion	-Amoxicillin -Clavulanic acid
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	-Amoxicillin -Clavulanic acid
Co-amoxiclav 250mg/125mg Film-coated tablets	Brown & Burk IR Limited	PA23148/004/001	Film-coated tablet	-Amoxicillin -Clavulanic acid

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Amoxicillin -Clavulanic acid
Co-amoxiclav 500mg/100mg Powder for Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/226/001	Powder for solution for injection/infusion	-Amoxicillin sodium -potassium clavulanate
Co-amoxiclav 500mg/125mg Film-coated tablets	Brown & Burk IR Limited	PA23148/004/002	Film-coated tablet	-Amoxicillin -Clavulanic acid
Co-amoxiclav 875mg/125mg Film-coated Tablets	Brown & Burk IR Limited	PA23148/004/003	Film-coated tablet	-Amoxicillin -Clavulanic acid
Co-amoxiclav Bluefish 500 mg/125 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/002/002	Film-coated tablet	-Amoxicillin -Clavulanic acid
Co-amoxiclav Bluefish 875 mg/125 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/002/003	Film-coated tablet	-Amoxicillin -Clavulanic acid
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	-Amoxicillin -Clavulanic acid
Co-Amoxiclav Sugar Free 400 mg/57 mg/5 ml Powder for Oral Suspension	Brown & Burk IR Limited	PA23148/005/002	Powder for oral suspension	-Amoxicillin -Clavulanic acid
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	-Amoxicillin -Clavulanic acid
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	-Amoxicillin -Clavulanic acid
CoAprovel	Sanofi Pharma Bristol-Myers Squibb SNC	EU/1/98/86/023-028	Tablet	-Irbesartan -Hydrochlorothiazide
COAPROVEL	Sanofi Pharma Bristol-Myers Squibb SNC	EU/1/98/86/23-28	Tablet	-IRBESARTAN -HYDROCHLOROTHIAZIDE
CoAprovel	Sanofi Winthrop Industrie	EU/1/98/086/001	Tablet	-Irbesartan -Hydrochlorothiazide
CoAprovel	Sanofi Winthrop Industrie	EU/1/98/086/001-003	Tablet	-Irbesartan -Hydrochlorothiazide
CoAprovel	Sanofi Winthrop Industrie	EU/1/98/086/002	Tablet	-Irbesartan -Hydrochlorothiazide
CoAprovel	Sanofi Winthrop Industrie	EU/1/98/086/003	Tablet	-Irbesartan -Hydrochlorothiazide
CoAprovel	Sanofi Winthrop Industrie	EU/1/98/086/004	Tablet	-Irbesartan -Hydrochlorothiazide
CoAprovel	Sanofi Winthrop Industrie	EU/1/98/086/004-006	Tablet	-Irbesartan -Hydrochlorothiazide
CoAprovel	Sanofi Winthrop Industrie	EU/1/98/086/005	Tablet	-Irbesartan -Hydrochlorothiazide
CoAprovel	Sanofi Winthrop Industrie	EU/1/98/086/007	Tablet	-Irbesartan -Hydrochlorothiazide
Co-codamol 15 mg/500 mg film-coated tablets	Azure Pharmaceuticals Ltd	PA22871/020/001	Film-coated tablet	-Paracetamol -Codeine phosphate hemihydrate
Cocois Ointment, coal tar 12.0% sulphur for external use 4.0%, salicylic acid 2.0%	RPH Pharmaceuticals AB	PA1638/005/001	Ointment	-Coal tar solution -Sulphur for external use -Salicylic acid

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Codant 30 mg Tablets	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/029/001	Tablet	-Codeine phosphate hemihydrate
Codinex Codeine Phosphate 15mg/5ml Oral Solution	Pinewood Laboratories Ltd	PA0281/005/001	Oral solution	-Codeine phosphate hemihydrate
Co-Diovan 160 mg/12.5 mg film-coated tablets	Novartis Ireland Limited	PA0896/007/002	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Co-Diovan 160 mg/12.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/226/002	Film-coated tablet	-Hydrochlorothiazide -Valsartan
Co-Diovan 160 mg/12.5 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/043/002	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Co-Diovan 160 mg/25 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/043/003	Film-coated tablet	-Hydrochlorothiazide -Valsartan
Co-Diovan 160 mg/25 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/046/001	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Co-Diovan 160 mg/25 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/226/003	Film-coated tablet	-Hydrochlorothiazide -Valsartan
Co-Diovan 160 mg/25 mg film-coated tablets	Novartis Ireland Limited	PA0896/007/003	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Co-Diovan 320 mg/12.5 mg film-coated tablets	Novartis Ireland Limited	PA0896/007/004	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Co-Diovan 320 mg/12.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/226/005	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Co-Diovan 320 mg/25 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/226/004	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Co-Diovan 320 mg/25 mg film-coated tablets	Novartis Ireland Limited	PA0896/007/005	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Co-Diovan 80 mg/12.5 mg film-coated tablets	Novartis Ireland Limited	PA0896/007/001	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Co-Diovan 80 mg/12.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/226/001	Film-coated tablet	-Hydrochlorothiazide -Valsartan
Co-Diovan 80 mg/12.5 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/043/001	Film-coated tablet	-Hydrochlorothiazide -Valsartan
Codipar 15 mg/ 500 mg Capsules	Amdipharm Limited	PA1142/023/002	Capsule, hard	-Paracetamol -Codeine phosphate hemihydrate
Colchicine 500 microgram Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/002/001	Tablet	-Colchicine
Colchicine Tiofarma 1000 microgram tablets	Tiofarma B.V.	PA2200/001/002	Tablet	-COLCHICINE PH. EUR.
Colchicine Tiofarma 500 microgram tablets	Tiofarma B.V.	PA2200/001/001	Tablet	-COLCHICINE PH. EUR.
Colecalciferol 30000 IU film-coated tablets	Consilient Health Limited	PA1876/008/004	Film-coated tablet	-Colecalciferol
Colecalciferol 1000 IU film-coated tablets	Consilient Health Limited	PA1876/008/002	Film-coated tablet	-Cholecalciferol -Cholecalciferol concentrate (powder form)
Colecalciferol 3000 IU/ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/007/001	Oral solution	-Colecalciferol
Colecalciferol 7000 IU film-coated tablets	Consilient Health Limited	PA1876/008/003	Film-coated tablet	-Cholecalciferol -Cholecalciferol concentrate (powder form)
Colecalciferol 800 IU capsules, soft	Strides Pharma (Cyprus) Limited	PA22639/002/001	Capsule, soft	-Colecalciferol

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Colecalciferol 800 IU film-coated tablets	Consilient Health Limited	PA1876/008/001	Film-coated tablet	-Cholecalciferol -Cholecalciferol concentrate (powder form)
Colecalciferol Aristo 20,000 IU soft capsules	Aristo Pharma GmbH	PA1983/002/001	Capsule, soft	-Colecalciferol
Colecalciferol EQL Pharma 2000 IU tablet	EQL Pharma AB	PA22981/001/002	Tablet	-Colecalciferol
Colecalciferol EQL Pharma 800 IU tablet	EQL Pharma AB	PA22981/001/001	Tablet	-Colecalciferol
Colistimethate sodium 1 million IU Powder for nebuliser solution	Noridem Enterprises Limited	PA1122/030/001	Powder for nebuliser solution	-Colistimethate sodium
Colistimethate sodium 1 million IU Powder for solution for injection/infusion	Noridem Enterprises Limited	PA1122/031/001	Powder for solution for injection/infusion	-Colistimethate sodium
Colistimethate sodium 2 million IU Powder for nebuliser solution	Noridem Enterprises Limited	PA1122/030/002	Powder for nebuliser solution	-Colistimethate sodium
Colistimethate sodium 2 million IU Powder for solution for injection/infusion	Noridem Enterprises Limited	PA1122/031/002	Powder for solution for injection/infusion	-Colistimethate sodium
Colobreathe	Teva B.V.	EU/1/11/747/001	Inhalation powder, hard capsule	-Colistimethate sodium (r inn)
Colofac 135 mg Tablets	Mylan IRE Healthcare Limited	PA2010/007/001	Coated tablet	-Mebeverine hydrochloride
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	-Colistimethate sodium
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	-Colistimethate sodium
Coloprep 1500 mg Tablets	Laboratoires Mayoly Spindler	PA1993/003/001	Tablet	-Sodium phosphate monobasic -Sodium phosphate dibasic, anhydrous
Columvi	Roche Registration GmbH	EU/1/23/1742/001	Concentrate for solution for infusion	-Glofitamab
Columvi	Roche Registration GmbH	EU/1/23/1742/002	Concentrate for solution for infusion	-Glofitamab
Combigan 2 mg/ml + 5 mg/ml eye drops, solution	AbbVie Limited	PA1824/019/001	Eye drops, solution	-Brimonidine tartrate -Timolol Maleate
Combiprasal 0.5 mg/2.5 mg per 2.5 ml nebuliser solution	Pharma Stulln GmbH	PA1815/001/001	Nebuliser solution	-Ipratropium bromide -SALBUTAMOL SULFATE
Combivir	ViiV Healthcare BV	EU/1/98/058/001	Film-coated tablet	-Zidovudine -Lamivudine
Combivir	ViiV Healthcare BV	EU/1/98/058/002	Film-coated tablet	-Zidovudine -Lamivudine
Combodart 0.5 mg/ 0.4 mg hard capsules	GlaxoSmithKline (Ireland) Limited	PA1077/118/001	Capsule, hard	-Dutasteride -Tamsulosin hydrochloride
Combodart 0.5 mg/ 0.4 mg hard capsules	IMED Healthcare Ltd.	PPA1463/068/001	Capsule, hard	-Dutasteride -Tamsulosin hydrochloride
Combodart 0.5 mg/ 0.4 mg hard capsules	Merit Pharmaceuticals Limited	PPA23080/025/001	Capsule, hard	-Dutasteride -Tamsulosin hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Combodart 0.5 mg/0.4 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/334/001	Capsule, hard	-Dutasteride -Tamsulosin hydrochloride
Combogesic 10 mg/ml Paracetamol + 3 mg/ml Ibuprofen solution for infusion	JED Pharma Ltd	PA23183/002/001	Solution for infusion	-Paracetamol -Ibuprofen sodium dihydrate
Cometriq	Ipsen Pharma	EU/1/13/890/001	Capsule, hard	-Cabozantinib (s)-malate
Cometriq	Ipsen Pharma	EU/1/13/890/002-003	Capsule, hard	-Cabozantinib (s)-malate
Comirnaty	BioNTech Manufacturing GmbH	EU/1/20/1528/001	Concentrate for dispersion for injection	-Tozinameran
Comirnaty	BioNTech Manufacturing GmbH	EU/1/20/1528/002-003	Concentrate for dispersion for injection	-Tozinameran
Comirnaty	BioNTech Manufacturing GmbH	EU/1/20/1528/004-005	Concentrate for dispersion for injection	-Tozinameran
Comirnaty	BioNTech Manufacturing GmbH	EU/1/20/1528/010	Concentrate for dispersion for injection	-Tozinameran
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1528/018	Dispersion for injection	-Tozinameran
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1528/019	Dispersion for injection	-Tozinameran
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1528/020	Dispersion for injection	-Tozinameran
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1528/021	Concentrate for dispersion for injection	-Tozinameran
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1528/022	Dispersion for injection	-Tozinameran
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1528/023	Dispersion for injection	-Tozinameran
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1528/024	Concentrate for dispersion for injection	-Tozinameran
Comirnaty Omicron XBB. 1.5	BioNTech Manufacturing GmbH	EU/1/20/1258/021	Concentrate for dispersion for injection	-Tozinameran
Comirnaty Original/Omicron BA.1	BioNTech Manufacturing GmbH	EU/1/20/1528/006-007	Concentrate for dispersion for injection	-Tozinameran
Comirnaty Original/Omicron BA.4-5	BioNTech Manufacturing GmbH	EU/1/20/1528/008-009	Dispersion for injection	-Tozinameran
Comirnaty Original/Omicron BA.4-5	BioNTech Manufacturing GmbH	EU/1/20/1528/011	Concentrate for dispersion for injection	-Tozinameran
Comirnaty Original/Omicron BA.4-5	BioNTech Manufacturing GmbH	EU/1/20/1528/012	Concentrate for dispersion for injection	-Tozinameran
Comirnaty Original/Omicron BA.4-5	BioNTech Manufacturing GmbH	EU/1/20/1528/015-016	Concentrate for dispersion for injection	-Tozinameran -Famtozinameran
Comirnaty Original/Omicron BA.4-5	BioNTech Manufacturing GmbH	EU/1/20/1528/017	Dispersion for injection	-Tozinameran -Famtozinameran
Comirnaty Original/Omicron BA.4-5	BioNTech Manufacturing GmbH	EU/1/20/1258/008-009	Dispersion for injection	-Tozinameran -COVID-19 mRNA vaccine (nucleoside-modified)
Competact	Takeda Pharma A/S	EU/1/06/354/001-009	Tablet	-METFORMIN HYDROCHLORIDE -Pioglitazone
Competact 15 mg/850 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	EU/1/06/354/001-012	Film-coated tablet	-Pioglitazone -Metformin Hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Compound Sodium Lactate Intravenous Infusion BP, Ecobag (Hartmann's Solution)	B. Braun Medical Limited	PA0179/004/008	Solution for infusion	-Sodium chloride -Potassium chloride -Sodium lactate solution -Calcium chloride dihydrate
Compound Sodium Lactate Intravenous Infusion BP, Solution for Infusion (Hartmann's Solution)	B. Braun Medical Limited	PA0179/004/003	Solution for infusion	-Sodium chloride -Potassium chloride -Sodium lactate solution -Calcium chloride dihydrate
Compound Sodium Lactate Solution for Infusion BP	Baxter Holding B.V.	PA2299/012/001	Solution for infusion	-Sodium chloride -Potassium chloride -Calcium chloride dihydrate -Sodium lactate
Comtan	Orion Corporation	EU/1/98/081/001	Tablet	-ENTACAPONE
Comtan	Orion Corporation	EU/1/98/081/002	Tablet	-ENTACAPONE
Comtan	Orion Corporation	EU/1/98/081/003	Tablet	-ENTACAPONE
Comtan	Orion Corporation	EU/1/98/081/004	Tablet	-ENTACAPONE
Comtess	Orion Corporation	EU/1/98/082/001	Tablet	-ENTACAPONE
Comtess	Orion Corporation	EU/1/98/082/002	Tablet	-ENTACAPONE
Comtess	Orion Corporation	EU/1/98/082/003	Tablet	-ENTACAPONE
Comtess	Orion Corporation	EU/1/98/082/004	Tablet	-ENTACAPONE
CONBRIZA	Pfizer Europe MA EEIG	EU/1/09/511/1-4	Film-coated tablet	-Bazedoxifene
Concerta XL 18 mg prolonged-release tablets	Janssen Sciences Ireland UC	PA22612/002/001	Prolonged-release tablet	-Methylphenidate hydrochloride -Methylphenidate hydrochloride -Methylphenidate hydrochloride
Concerta XL 27 mg prolonged-release tablets	Janssen Sciences Ireland UC	PA22612/002/004	Prolonged-release tablet	-Methylphenidate hydrochloride
Concerta XL 36 mg prolonged-release tablets	Janssen Sciences Ireland UC	PA22612/002/002	Prolonged-release tablet	-Methylphenidate hydrochloride -Methylphenidate hydrochloride -Methylphenidate hydrochloride
Condylone 5 mg/ml Cutaneous Solution	Takeda Products Ireland Ltd	PA2229/006/001	Cutaneous solution	-Podophyllotoxin
Constella	AbbVie Deutschland GmbH & Co. KG	EU/1/12/801/001-004	Capsule, hard	-Linaclotide
Controloc Control	Takeda GmbH	EU/1/09/515/001	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate
Controloc Control	Takeda GmbH	EU/1/09/515/001-004	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate
Copalia	Novartis Europharm Limited	EU/1/06/372/001-008	Film-coated tablet	-Amlodipine besilate -Valsartan
Copalia	Novartis Europharm Limited	EU/1/06/372/009-016	Film-coated tablet	-Amlodipine besilate -Valsartan
Copalia	Novartis Europharm Limited	EU/1/06/372/017-024	Film-coated tablet	-Amlodipine besilate -Valsartan
Copalia HCT	Novartis Europharm Limited	EU/1/09/575/1-12	Film-coated tablet	-Amlodipine besylate -Hydrochlorothiazide -Valsartan
Copalia HCT	Novartis Europharm Limited	EU/1/09/575/13-24	Film-coated tablet	-Hydrochlorothiazide -Valsartan -Amlodipine besylate
Copalia HCT	Novartis Europharm Limited	EU/1/09/575/25-36	Film-coated tablet	-Amlodipine besylate -Hydrochlorothiazide -Valsartan

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Copalia HCT	Novartis Europharm Limited	EU/1/09/575/37-48	Film-coated tablet	-Hydrochlorothiazide -Valsartan -Amlodipine besylate
Copalia HCT	Novartis Europharm Limited	EU/1/09/575/49-60	Film-coated tablet	-Valsartan -Hydrochlorothiazide -Amlodipine besylate
Copaxone 20 mg/ml solution for injection in pre-filled syringe	TEVA GmbH	PA22579/001/001	Solution for injection in pre-filled syringe	-Glatiramer acetate
Copaxone 40 mg/ml solution for injection in pre-filled syringe	PCO Manufacturing Ltd.	PPA0465/432/002	Solution for injection in pre-filled syringe	-Glatiramer acetate
Copaxone 40mg/ml solution for injection in pre-filled syringe	TEVA GmbH	PA22579/001/002	Solution for injection in pre-filled syringe	-Glatiramer acetate
Copiktra	Secura Bio Limited	EU/1/21/1542/001	Capsule, hard	-Duvelisib
Copiktra	Secura Bio Limited	EU/1/21/1542/002	Capsule, hard	-Duvelisib
Cordarone X 100mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/142/001	Tablet	-Amiodarone hydrochloride
Cordarone X 200 mg Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/020/002	Tablet	-Amiodarone hydrochloride
Cordarone X 200mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/142/002	Tablet	-Amiodarone hydrochloride
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	-Amiodarone hydrochloride
Corlentor	Les Laboratoires Servier	EU/1/05/317/1-7	Film-coated tablet	-Ivabradine
Corlentor	Les Laboratoires Servier	EU/1/05/317/8-14	Film-coated tablet	-Ivabradine
Corsodyl 1% w/w Dental Gel	Haleon Ireland Limited	PA0678/002/001	Dental gel	-Chlorhexidine digluconate
Cortiment 9 mg prolonged release tablets	Ferring Ireland Ltd	PA1009/026/001	Prolonged-release tablet	-Budesonide
Cortopin 1% w/w Cream	Pinewood Laboratories Ltd	PA0281/071/002	Cream	-Hydrocortisone
Cosartal Plus 100 mg/12.5 mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/190/003	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Cosartal Plus 100 mg/25 mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/190/002	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Cosartal Plus 50 mg/12.5 mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/190/001	Film-coated tablet	-Hydrochlorothiazide -Losartan potassium
Cosentyx	Novartis Europharm Limited	EU/1/14/980/001	Powder for solution for injection	-Secukinumab
Cosentyx	Novartis Europharm Limited	EU/1/14/980/002-003	Solution for injection in pre-filled syringe	-Secukinumab
Cosentyx	Novartis Europharm Limited	EU/1/14/980/004-005	Solution for injection in pre-filled pen	-Secukinumab
Cosentyx	Novartis Europharm Limited	EU/1/14/980/008-009	Solution for injection in pre-filled syringe	-Secukinumab
Cosentyx	Novartis Europharm Limited	EU/1/14/980/012-013	Solution for injection in pre-filled syringe	-Secukinumab
Cosentyx	Novartis Europharm Limited	EU/1/14/980/10-011	Solution for injection in pre-filled pen	-Secukinumab
Cosimpresl 10mg/10mg Film-Coated Tablets	Les Laboratoires Servier	PA0568/029/004	Film-coated tablet	-BISOPROLOL FUMARATE -Perindopril arginine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Cosimprel 10mg/5mg Film-Coated Tablets	Les Laboratoires Servier	PA0568/029/003	Film-coated tablet	-BISOPROLOL FUMARATE -Perindopril arginine
Cosimprel 5mg/10mg Film-Coated Tablets	Les Laboratoires Servier	PA0568/029/002	Film-coated tablet	-BISOPROLOL FUMARATE -Perindopril arginine
Cosimprel 5mg/5mg Film-Coated Tablets	Les Laboratoires Servier	PA0568/029/001	Film-coated tablet	-BISOPROLOL FUMARATE -Perindopril arginine
CosmoFer 50 mg/ml solution for infusion and injection	Originalis B.V.	PPA2306/021/001	Solution for injection/infusion	-IRON (III)
CosmoFer 50mg/ml solution for infusion and injection	Pharmacosmos A/S	PA0982/001/001	Solution for injection/infusion	-Iron (III) hydroxide dextran complex
COSOPT 20 mg/ml + 5 mg/ml eye drops, solution	IMED Healthcare Ltd.	PPA1463/060/001	Eye drops, solution	-Timolol -Dorzolamide
COSOPT 20 mg/ml + 5 mg/ml eye drops, solution	PCO Manufacturing Ltd.	PPA0465/296/001	Eye drops, solution	-Dorzolamide -Timolol
COSOPT 20mg/ml + 5mg/ml eye drops, solution	Santen OY	PA0879/005/001	Eye drops, solution	-Dorzolamide -Timolol
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	-Dorzolamide -Timolol
Cotellic	Roche Registration GmbH	EU/1/15/1048/001	Film-coated tablet	-Cobimetinib hemifumarate
Co-Tipol 500 mg/30 mg hard capsules	Clonmel Healthcare Ltd	PA0126/332/001	Capsule, hard	-Paracetamol -Codeine phosphate hemihydrate
Co-Tipol 500 mg/30 mg suppositories	Clonmel Healthcare Ltd	PA0126/332/002	Suppository	-Paracetamol -Codeine phosphate hemihydrate
Co-Tipol Max 1000 mg/60 mg suppository	Clonmel Healthcare Ltd	PA0126/332/003	Suppository	-Paracetamol -Codeine phosphate hemihydrate
Co-Vatan 160 mg/12.5 mg Film-coated Tablets	Rowex Ltd	PA0711/182/002	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Co-Vatan 160 mg/25 mg Film-coated Tablets	Rowex Ltd	PA0711/182/003	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Co-Vatan 80 mg/12.5 mg Film-coated Tablets	Rowex Ltd	PA0711/182/001	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Coverdine 10 mg/2.5 mg/10 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/022/003	Film-coated tablet	-Indapamide -Amlodipine -Perindopril arginine
Coverdine 10 mg/2.5 mg/5 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/022/002	Film-coated tablet	-Amlodipine -Indapamide -Perindopril arginine
Coverdine 10mg/2.5mg/10mg film-coated tablets	Originalis B.V.	PPA2306/028/001	Film-coated tablet	-Perindopril arginine -Indapamide -Amlodipine
Coverdine 10mg/2.5mg/10mg film-coated tablets	Les Laboratoires Servier	PA0568/024/005	Film-coated tablet	-Perindopril arginine -Indapamide -Amlodipine
Coverdine 10mg/2.5mg/5mg film-coated tablets	Les Laboratoires Servier	PA0568/024/004	Film-coated tablet	-Perindopril arginine -Indapamide -Amlodipine
Coverdine 5 mg/1.25 mg/5 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/022/001	Film-coated tablet	-Amlodipine -Perindopril arginine -Indapamide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Coverdine 5mg/1.25mg/10mg film-coated tablets	Les Laboratoires Servier	PA0568/024/003	Film-coated tablet	-Perindopril arginine -Indapamide -Amlodipine
Coverdine 5mg/1.25mg/5mg film-coated tablets	Les Laboratoires Servier	PA0568/024/002	Film-coated tablet	-Perindopril arginine -Indapamide -Amlodipine
Coversyl Arginine 10 mg film coated tablets	Les Laboratoires Servier	PA0568/002/006	Film-coated tablet	-Perindopril arginine
Coversyl Arginine 2.5 mg film-coated tablets	Les Laboratoires Servier	PA0568/002/004	Film-coated tablet	-Perindopril arginine
Coversyl Arginine 5 mg film-coated tablets	Les Laboratoires Servier	PA0568/002/005	Film-coated tablet	-Perindopril arginine
COVERSYL ARGININE PLUS	B & S Healthcare	PPA1328/122/001	Film-coated tablet	-PERINDOPRIL ARGININE -INDAPAMIDE
Coversyl Arginine Plus 10mg/2.5mg film-coated tablets	Les Laboratoires Servier	PA0568/022/002	Film-coated tablet	-Perindopril arginine -Indapamide
Coversyl Arginine Plus 2.5mg/0.625mg film-coated tablets	Les Laboratoires Servier	PA0568/008/003	Film-coated tablet	-Perindopril arginine -Indapamide
Coversyl Arginine Plus 5mg/1.25mg film-coated tablets	Les Laboratoires Servier	PA0568/016/002	Film-coated tablet	-Perindopril arginine -Indapamide
Cozaar 100 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/029/002	Film-coated tablet	-Losartan potassium
Cozaar 100 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/106/002	Film-coated tablet	-Losartan potassium
Cozaar 100 mg Film-coated Tablets	Organon Pharma (Ireland) Limited	PA23198/002/003	Film-coated tablet	-Losartan potassium
Cozaar 12.5mg Film-coated Tablets	Organon Pharma (Ireland) Limited	PA23198/002/001	Film-coated tablet	-Losartan potassium
Cozaar 50 mg Film-coated Tablets	Organon Pharma (Ireland) Limited	PA23198/002/002	Film-coated tablet	-Losartan potassium
Cozaar 50 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/106/001	Film-coated tablet	-Losartan potassium
Cozaar 50 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/029/001	Film-coated tablet	-Losartan potassium
Cozaar Comp 100 mg/12.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/109/004	Film-coated tablet	-Hydrochlorothiazide -Losartan potassium
Cozaar Comp 100 mg/12.5 mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/001/001	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Cozaar Comp 100 mg/25 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/109/002	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Cozaar Comp 100mg/25mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/001/003	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Cozaar Comp 50 mg/12.5 mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/001/002	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Cozaar Comp 50 mg/12.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/109/001	Film-coated tablet	-Hydrochlorothiazide -Losartan potassium
Cozatan 100 mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/167/002	Film-coated tablet	-Losartan potassium
Cozatan 50 mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/167/001	Film-coated tablet	-Losartan potassium
Cozatan Comp 100 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/184/002	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Cozatan Comp 50 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/184/001	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Crampex Tablets Cholecalciferol 0.02 mg Calcium Gluconate 200 mg Nicotinic Acid 20 mg	Clonmel Healthcare Ltd	PA0126/318/001	Tablet	-Cholecalciferol -Calcium gluconate -Nicotinic acid
Creon 10000 Gastro-resistant Capsules	PCO Manufacturing Ltd.	PPA0465/125/001	Gastro-resistant capsule, hard	-Pancreatin
Creon 10000 Gastro-resistant Capsules	Viartis Healthcare Limited	PA23355/006/001	Gastro-resistant capsule, hard	-Pancreas powder
Creon 10000 Gastro-Resistant Capsules	IMED Healthcare Ltd.	PPA1463/145/001	Gastro-resistant capsule, hard	-Pancreas powder
Creon 10000 Gastro-resistant Capsules	Merit Pharmaceuticals Limited	PPA23080/019/001	Gastro-resistant capsule, hard	-Lipase -Amylase -Protease
Creon 20000 Gastro-resistant Capsules, hard	Viartis Healthcare Limited	PA23355/006/004	Gastro-resistant capsule, hard	-Pancreas Powder Ph. Eur.
Creon 25000 Gastro-resistant Capsules	Viartis Healthcare Limited	PA23355/006/002	Gastro-resistant capsule, hard	-Pancreas powder
Creon 25000 Gastro-resistant Capsules	PCO Manufacturing Ltd.	PPA0465/125/002	Gastro-resistant capsule, hard	-Pancreatin
Creon 25000 Gastro-resistant capsules	IMED Healthcare Ltd.	PPA1463/033/002	Gastro-resistant capsule, hard	-Pancreatin
Creon 35000 Gastro-resistant Capsules, hard	Viartis Healthcare Limited	PA23355/006/005	Gastro-resistant capsule, hard	-Pancreas Powder Ph. Eur.
Creon for Children 5000 Gastro-resistant Granules	Viartis Healthcare Limited	PA23355/006/003	Gastro-resistant granules	-Pancreas powder
Cresemba	Basilea Pharmaceutica Deutschland GmbH	EU/1/15/1036/001	Powder for concentrate for solution for infusion	-Isavuconazonium sulfate
Cresemba	Basilea Pharmaceutica Deutschland GmbH	EU/1/15/1036/002	Powder for concentrate for solution for infusion	-Isavuconazonium sulfate
Crestor 10 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/119/002	Film-coated tablet	-Rosuvastatin
Crestor 10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/441/002	Film-coated tablet	-Rosuvastatin
Crestor 10 mg film-coated tablets	Grunenthal Pharma Ltd	PA2242/016/002	Film-coated tablet	-Rosuvastatin
Crestor 20 mg film-coated tablets	Grunenthal Pharma Ltd	PA2242/016/003	Film-coated tablet	-Rosuvastatin
Crestor 20 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/441/003	Film-coated tablet	-Rosuvastatin
Crestor 20 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/119/003	Film-coated tablet	-Rosuvastatin
Crestor 40 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/119/004	Film-coated tablet	-Rosuvastatin
Crestor 40 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/441/004	Film-coated tablet	-Rosuvastatin
Crestor 40 mg film-coated tablets	Grunenthal Pharma Ltd	PA2242/016/004	Film-coated tablet	-Rosuvastatin
Crestor 5 mg film-coated tablets	Grunenthal Pharma Ltd	PA2242/016/001	Film-coated tablet	-Rosuvastatin
Crestor 5 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/119/001	Film-coated tablet	-Rosuvastatin
Crestor 5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/441/001	Film-coated tablet	-Rosuvastatin
Crinone 8% w/w progesterone vaginal gel	PCO Manufacturing Ltd.	PPA0465/301/001	Vaginal gel	-Progesterone
Crinone 8% w/w progesterone vaginal gel	IMED Healthcare Ltd.	PPA1463/112/001	Vaginal gel	-Progesterone

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Crinone 8% w/w progesterone vaginal gel	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/031/001	Vaginal gel	-Progesterone
Crinone 8% w/w progesterone vaginal gel	Merck Serono (Ireland) Limited	PA2286/001/001	Vaginal gel	-Progesterone
Crystapen 600mg Powder for Solution for Injection or Infusion	Clonmel Healthcare Ltd	PA0126/313/001	Powder for solution for injection/infusion	-Benzylpenicillin Sodium
CRYSVITA	Kyowa Kirin Holdings B.V.	EU/1/17/1262/001	Solution for injection	-Recombinant human igg1 monoclonal antibody to fibroblast growth factor 23
CRYSVITA	Kyowa Kirin Holdings B.V.	EU/1/17/1262/002	Solution for injection	-Recombinant human igg1 monoclonal antibody to fibroblast growth factor 23
CRYSVITA	Kyowa Kirin Holdings B.V.	EU/1/17/1262/003	Solution for injection	-Recombinant human igg1 monoclonal antibody to fibroblast growth factor 23
Cubicin	Merck Sharp & Dohme BV	EU/1/05/328/001	Powder for solution for injection/infusion	-Daptomycin
Cubicin	Merck Sharp & Dohme BV	EU/1/05/328/002	Powder for solution for injection/infusion	-Daptomycin
Cufence	Univar B.V	EU/1/19/1365/001	Capsule, hard	-TRIENTINE DIHYDROCHLORIDE
Cufence	Univar B.V	EU/1/19/1365/002	Capsule, hard	-Trientine tetrahydrochloride
Cuprior 150 mg film-coated tablets	gmp-orphan SA	EU/1/17/1199/001	Film-coated tablet	-Trientine tetrahydrochloride
Cuprymina	A.C.O.M. -ADVANCED CENTER ONCOLOGY MACERATA -S.R.L.	EU/1/12/784/001	Radiopharmaceutical precursor, solution	-Copper (64 cu) chloride
Curanail 5% w/v medicated nail lacquer	Galderma International	PA22743/004/001	Medicated nail lacquer	-Amorolfine
CUROSURF 120 mg/vial Endotracheopulmonary instillation, suspension	Chiesi Farmaceutici S.p.A.	PA0584/005/001	Endotracheopulmonary instillation, suspension	-Porcine lung surfactant
CUROSURF 240 mg/vial Endotracheopulmonary instillation, suspension	Chiesi Farmaceutici S.p.A.	PA0584/005/002	Endotracheopulmonary instillation, suspension	-Porcine lung surfactant
CUTAQUIG, 165 mg/ml, solution for injection	Octapharma (IP) SPRL	PA2219/001/001	Solution for injection	-Human normal immunoglobulin
Cuvitru 200 mg/ml solution for subcutaneous injection	Baxalta Innovations GmbH	PA2004/008/001	Solution for injection	-Human normal immunoglobulin
Cyanokit	SERB S.A.,	EU/1/07/420/001	Powder for solution for infusion	-Hydroxocobalamin
Cyanokit	Merck Sante s.a.s.	EU/1/07/420/002	Powder for solution for infusion	-Hydroxocobalamin
Cyclimorph 10 solution for injection	Amdipharm Limited	PA1142/003/001	Solution for injection	-CYCLIZINE TARTRATE -Morphine tartrate
Cyclimorph 15 Solution for Injection	Amdipharm Limited	PA1142/003/002	Solution for injection	-Cyclizine -Morphine Tartrate BPC 1959
Cyclolux 279.32 mg/ml solution for injection	Sanochemia Pharmazeutika GmbH	PA23317/001/001	Solution for injection	-Gadoteric acid

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Cyklokapron 100 mg/mL solution for injection/infusion	Pfizer Healthcare Ireland	PA0822/117/001	Solution for injection/infusion	-Tranexamic acid
Cyklokapron 500 mg Film-coated Tablets	Mylan IRE Healthcare Limited	PA2010/055/001	Film-coated tablet	-TRANEXAMIC ACID PH. EUR.
Cymbalta 30 mg hard gastro-resistant capsules	Eli Lilly Nederland B.V.	EU/1/04/296/1-4	Gastro-resistant capsule, hard	-Duloxetine hydrochloride
Cymbalta 60 mg hard gastro-resistant capsules	Eli Lilly Nederland B.V.	EU/1/04/296/002-005	Gastro-resistant capsule, hard	-Duloxetine
Cymevene 500 mg powder for concentrate for solution for infusion	CHEPLAPHARM Arzneimittel GmbH	PA2239/003/001	Powder for concentrate for solution for infusion	-Ganciclovir
Cymex Cream	Teva B.V.	PA1986/112/001	Cream	-Cetrimide -Chlorocresol -Dimeticone -Urea
Cyramza	Eli Lilly Nederland B.V.	EU/1/14/957/001-003	Concentrate for solution for infusion	-Ramucirumab
Cystadane	Recordati Rare Diseases	EU/1/06/379/001	Oral powder	-Betaine anhydrous
Cystadrops	Recordati Rare Diseases	EU/1/15/1049/001	Eye drops, solution	-Mercaptamine hydrochloride
Cystagon	Recordati Rare Diseases	EU/1/97/039/001	Capsule, hard	-Mercaptamine bitartrate
Cystagon	Recordati Rare Diseases	EU/1/97/039/002	Capsule, hard	-Mercaptamine bitartrate
Cystagon	Recordati Rare Diseases	EU/1/97/039/003	Capsule, hard	-Mercaptamine bitartrate
Cystagon	Recordati Rare Diseases	EU/1/97/039/004	Capsule, hard	-Mercaptamine bitartrate
Cystopurin 3g Granules for oral solution	Bayer Limited	PA1410/042/001	Granules for oral solution	-Potassium citrate
Cytarabine 100 mg/ml Solution for Injection	Pfizer Healthcare Ireland	PA0822/200/002	Solution for injection	-Cytarabine
Cytarabine 100 mg/ml Solution for Injection or Infusion	Fresenius Kabi Deutschland GmbH	PA2059/034/001	Solution for injection/infusion	-Cytarabine
Cytarabine 100 mg/ml solution for injection or infusion	Accord Healthcare Ireland Ltd.	PA2315/082/001	Solution for injection/infusion	-Cytarabine
Cytarabine 20 mg/ml Solution for Injection or Infusion	Pfizer Healthcare Ireland	PA0822/200/001	Solution for injection/infusion	-Cytarabine
Cytarabine 20 mg/ml Solution for Injection/Infusion	Accord Healthcare Ireland Ltd.	PA2315/082/002	Solution for injection/infusion	-Cytarabine
Cytisinicline APC Pharmlog 1.5 mg film-coated tablets	APC Pharmlog Sp. z o.o.	PA2153/002/001	Film-coated tablet	-Cytisinicline
Cytotec 200 microgram Tablets	Pfizer Healthcare Ireland	PA0822/118/001	Tablet	-Misoprostol
Dabigatran Etexilate Accord	Accord Healthcare S.L.U.	EU/1/22/1665/001-006	Capsule, hard	-Dabigatran etexilate mesilate
Dabigatran Etexilate Accord	Accord Healthcare S.L.U.	EU/1/22/1665/007-016	Capsule, hard	-Dabigatran etexilate mesilate
Dabigatran Etexilate Accord	Accord Healthcare S.L.U.	EU/1/22/1665/017-027	Capsule, hard	-Dabigatran etexilate mesilate
Dabigatran etexilate Clonmel 110 mg hard capsules	Clonmel Healthcare Ltd	PA0126/340/002	Capsule, hard	-Dabigatran etexilate mesilate
Dabigatran etexilate Clonmel 150 mg hard capsules	Clonmel Healthcare Ltd	PA0126/340/003	Capsule, hard	-Dabigatran etexilate mesilate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Dabigatran etexilate Clonmel 75 mg hard capsules	Clonmel Healthcare Ltd	PA0126/340/001	Capsule, hard	-Dabigatran etexilate mesilate
Dabigatran Etexilate Krka 110 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/110/002	Capsule, hard	-Dabigatran etexilate mesilate
Dabigatran Etexilate Krka 150 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/110/003	Capsule, hard	-Dabigatran etexilate mesilate
Dabigatran Etexilate Krka 75 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/110/001	Capsule, hard	-Dabigatran etexilate mesilate
Dacarbazine Lipomed 1000 mg powder for solution for infusion	Lipomed GmbH	PA1760/001/003	Powder for solution for infusion	-Dacarbazine
Dacarbazine Lipomed 200 mg powder for solution for injection or infusion	Lipomed GmbH	PA1760/001/001	Powder for solution for injection/infusion	-Dacarbazine
Dacarbazine Lipomed 500 mg powder for solution for infusion	Lipomed GmbH	PA1760/001/002	Powder for solution for infusion	-Dacarbazine
Dacarbazine medac 1000 mg, powder for solution for infusion	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/003/004	Powder for solution for infusion	-Dacarbazine
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	-Dacarbazine
Dacarbazine medac 500 mg, powder for solution for infusion	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/003/003	Powder for solution for infusion	-Dacarbazine
Dacepton 10 mg/ml solution for injection in cartridge	EVER Valinject GmbH	PA1774/001/003	Solution for injection in cartridge	-Apomorphine hydrochloride hemihydrate
Dacepton 5 mg/ml solution for infusion	EVER Valinject GmbH	PA1774/001/002	Solution for infusion	-Apomorphine hydrochloride hemihydrate
Dacogen	Janssen-Cilag International NV	EU/1/12/792/001	Powder for concentrate for solution for infusion	-Decitabine
Dafiro	Novartis Europharm Limited	EU/1/06/371/001-008	Film-coated tablet	-Amlodipine besilate -Valsartan
Dafiro	Novartis Europharm Limited	EU/1/06/371/009-016	Film-coated tablet	-Amlodipine besilate -Valsartan
Dafiro	Novartis Europharm Limited	EU/1/06/371/017-024	Film-coated tablet	-Valsartan -Amlodipine besilate
Dafiro HCT	Novartis Europharm Limited	EU/1/09/574/1-12	Film-coated tablet	-Amlodipine besylate -Hydrochlorothiazide -Valsartan
Dafiro HCT	Novartis Europharm Limited	EU/1/09/574/13-24	Film-coated tablet	-Hydrochlorothiazide -Valsartan -Amlodipine besylate
Dafiro HCT	Novartis Europharm Limited	EU/1/09/574/25-36	Film-coated tablet	-Amlodipine besylate -Hydrochlorothiazide -Valsartan
Dafiro HCT	Novartis Europharm Limited	EU/1/09/574/37-48	Film-coated tablet	-Hydrochlorothiazide -Valsartan -Amlodipine besylate
Dafiro HCT	Novartis Europharm Limited	EU/1/09/574/49-60	Film-coated tablet	-Valsartan -Hydrochlorothiazide -Amlodipine besylate
Daktarin 2% w/w Cream	JNTL Consumer Health I (Ireland) Limited	PA23490/028/001	Cream	-Miconazole nitrate
Daktarin 2% w/w Cutaneous Powder	Johnson & Johnson (Ireland) Limited	PA0330/048/002	Cutaneous powder	-Miconazole nitrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Daktarin 20 mg/g Oral Gel	Johnson & Johnson (Ireland) Limited	PA0330/048/003	Oral gel	-Miconazole
Dalacin 100 mg Vaginal Ovule	Pfizer Healthcare Ireland	PA0822/119/001	Pessary	-CLINDAMYCIN PHOSPHATE
Dalacin 2 % Vaginal Cream	PCO Manufacturing Ltd.	PPA0465/416/001	Vaginal cream	-Clindamycin
Dalacin 2% Vaginal Cream	Pfizer Healthcare Ireland	PA0822/119/002	Vaginal cream	-CLINDAMYCIN PHOSPHATE
Dalacin C 150 mg Hard Capsules	Pfizer Healthcare Ireland	PA0822/120/001	Capsule, hard	-Clindamycin
Dalacin C 150 mg Hard Capsules	PCO Manufacturing Ltd.	PPA0465/205/001	Capsule, hard	-Clindamycin
Dalacin C 150 mg Hard Capsules	Merit Pharmaceuticals Limited	PPA23080/008/001	Capsule, hard	-Clindamycin
Dalacin C 150 mg hard capsules	IMED Healthcare Ltd.	PPA1463/150/001	Capsule, hard	-Clindamycin
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	-Clindamycin
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	-Clindamycin
Dalacin T Topical Lotion 10 mg/ml Cutaneous Emulsion	Pfizer Healthcare Ireland	PA0822/121/001	Cutaneous emulsion	-Clindamycin
Dalmane 15 mg Hard Capsules	Mylan IRE Healthcare Limited	PA2010/039/001	Capsule, hard	-FLURAZEPAM HYDROCHLORIDE
Dalmane 30 mg Hard Capsules	Mylan IRE Healthcare Limited	PA2010/039/002	Capsule, hard	-FLURAZEPAM HYDROCHLORIDE
Dancex SR 10 mg Prolonged-Release Tablets	Rowex Ltd	PA0711/143/002	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE
Dancex SR 20 mg Prolonged-Release Tablets	Rowex Ltd	PA0711/143/003	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE
Dancex SR 40 mg Prolonged-Release Tablets	Rowex Ltd	PA0711/143/004	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE
Dancex SR 5 mg Prolonged-Release Tablets	Rowex Ltd	PA0711/143/001	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE
Dancex SR 80 mg Prolonged-Release Tablets	Rowex Ltd	PA0711/143/006	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE
Dancex SR Plus 10 mg/5 mg Prolonged-release tablets	Rowex Ltd	PA0711/250/002	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE -NALOXONE HYDROCHLORIDE
Dancex SR Plus 20 mg/10 mg Prolonged-release tablets	Rowex Ltd	PA0711/250/003	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE -NALOXONE HYDROCHLORIDE
Dancex SR Plus 40 mg/20 mg Prolonged-release tablets	Rowex Ltd	PA0711/250/004	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE -NALOXONE HYDROCHLORIDE
Dancex SR Plus 5 mg/2.5 mg Prolonged-release tablets	Rowex Ltd	PA0711/250/001	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE -NALOXONE HYDROCHLORIDE
Dantrium 100 mg Capsules	Norgine B.V.	PA1336/004/002	Capsule, hard	-DANTROLENE SODIUM

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Dantrium 25 mg Capsules	Norgine B.V.	PA1336/004/001	Capsule, hard	-DANTROLENE SODIUM
Dantrium Intravenous 20 mg powder for solution for injection	Norgine B.V.	PA1336/004/003	Powder for solution for injection	-Dantrolene sodium
Dapagliflozin Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/111/002	Film-coated tablet	-Dapagliflozin
Dapagliflozin Krka 5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/111/001	Film-coated tablet	-Dapagliflozin
Dapagliflozin Viatriis	Viatriis Limited	EU/1/23/1721/001-012	Film-coated tablet	-Dapagliflozin
Dapagliflozin Viatriis	Viatriis Limited	EU/1/23/1721/013-024	Film-coated tablet	-Dapagliflozin
Daptomycin 350 mg powder for solution for injection/infusion	Reddy Holding GmbH	PA23092/004/001	Powder for solution for injection/infusion	-Daptomycin
Daptomycin 350 mg powder for solution for injection/infusion	hameln pharma gmbh	PA2237/005/001	Powder for solution for injection/infusion	-Daptomycin
Daptomycin 500 mg powder for solution for injection/infusion	hameln pharma gmbh	PA2237/005/002	Powder for solution for injection/infusion	-Daptomycin
Daptomycin 500 mg powder for solution for injection/infusion	Reddy Holding GmbH	PA23092/004/002	Powder for solution for injection/infusion	-Daptomycin
Daptomycin Accord Healthcare 350 mg powder for solution for injection/infusion	Accord Healthcare Ireland Ltd.	PA2315/258/001	Powder for solution for injection/infusion	-Daptomycin
Daptomycin Accord Healthcare 500 mg powder for solution for injection/infusion	Accord Healthcare Ireland Ltd.	PA2315/258/002	Powder for solution for injection/infusion	-Daptomycin
Daptomycin Accordpharma 350 mg powder for solution for injection/infusion	Accord Healthcare Ireland Ltd.	PA2315/237/001	Powder for solution for injection/infusion	-Daptomycin
Daptomycin Accordpharma 500 mg powder for solution for injection/infusion	Accord Healthcare Ireland Ltd.	PA2315/237/002	Powder for solution for injection/infusion	-Daptomycin
Daptomycin Hospira	Pfizer Europe MA EEIG	EU/1/17/1175/001-002	Powder for solution for injection/infusion	-Daptomycin
Daptomycin Hospira	Pfizer Europe MA EEIG	EU/1/17/1175/003-004	Powder for solution for injection/infusion	-Daptomycin
Daptomycin Noridem 350 mg Powder for solution for injection/infusion	Noridem Enterprises Limited	PA1122/021/001	Powder for solution for injection/infusion	-Daptomycin
Daptomycin Noridem 500 mg Powder for solution for injection/infusion	Noridem Enterprises Limited	PA1122/021/002	Powder for solution for injection/infusion	-Daptomycin
Daptomycin Xellia 350 mg powder for solution for injection/infusion	Xellia Pharmaceuticals ApS	PA1982/003/001	Powder for solution for injection/infusion	-Daptomycin
Daptomycin Xellia 500 mg powder for solution for injection/infusion	Xellia Pharmaceuticals ApS	PA1982/003/002	Powder for solution for injection/infusion	-Daptomycin
Darunavir Clonmel 600 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/299/002	Film-coated tablet	-Darunavir
Darunavir Clonmel 800 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/299/003	Film-coated tablet	-Darunavir
Darunavir Krka	KRKA, d.d., Novo mesto	EU/1/17/1249/001-004	Film-coated tablet	-Darunavir
Darunavir Krka	KRKA, d.d., Novo mesto	EU/1/17/1249/005-008	Film-coated tablet	-Darunavir

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Darunavir Krka	KRKA, d.d., Novo mesto	EU/1/17/1249/009-010	Film-coated tablet	-Darunavir
DARUNAVIR KRKA D.D.	Krka d.d., Novo mesto	EU/1/17/1248/001-004	Film-coated tablet	-DARUNAVIR
DARUNAVIR KRKA D.D.	Krka d.d., Novo mesto	EU/1/17/1248/005-008	Film-coated tablet	-DARUNAVIR
DARUNAVIR KRKA D.D.	Krka d.d., Novo mesto	EU/1/17/1248/009-010	Film-coated tablet	-DARUNAVIR
Darunavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1140/001-005	Film-coated tablet	-Darunavir
Darunavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1140/006-011	Film-coated tablet	-Darunavir
Darunavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1140/012-021	Film-coated tablet	-Darunavir
Darunavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1140/022-029	Film-coated tablet	-Darunavir
Darunavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1140/030-038	Film-coated tablet	-Darunavir
Darunavir Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1140/039-045	Film-coated tablet	-Darunavir
Darunavir Rowex 800 mg Film-coated tablets	Rowex Ltd	PA0711/269/004	Film-coated tablet	-Darunavir
Darzalex	Janssen-Cilag International NV	EU/1/16/1101/001-002	Concentrate for solution for infusion	-Daratumumab
Darzalex	Janssen-Cilag International NV	EU/1/16/1101/004	Solution for injection	-Daratumumab
Dasatinib Clonmel 100 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/310/004	Film-coated tablet	-Dasatinib
Dasatinib Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/310/001	Film-coated tablet	-Dasatinib
Dasatinib Clonmel 50 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/310/002	Film-coated tablet	-Dasatinib
Dasatinib Clonmel 70 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/310/003	Film-coated tablet	-Dasatinib
Dasatinib Krka 100 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/093/005	Film-coated tablet	-Dasatinib
Dasatinib Krka 140 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/093/006	Film-coated tablet	-Dasatinib
Dasatinib Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/093/001	Film-coated tablet	-Dasatinib
Dasatinib Krka 50 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/093/002	Film-coated tablet	-Dasatinib
Dasatinib Krka 70 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/093/003	Film-coated tablet	-Dasatinib
Dasatinib Krka 80 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/093/004	Film-coated tablet	-Dasatinib
Dasatinib Teva 100 mg Film-coated Tablets	Teva B.V.	PA1986/066/004	Film-coated tablet	-Dasatinib
Dasatinib Teva 20 mg Film-coated Tablets	Teva B.V.	PA1986/066/001	Film-coated tablet	-Dasatinib
Dasatinib Teva 50 mg Film-coated Tablets	Teva B.V.	PA1986/066/002	Film-coated tablet	-Dasatinib
Dasatinib Teva 70 mg Film-coated Tablets	Teva B.V.	PA1986/066/003	Film-coated tablet	-Dasatinib
Dasselta	KRKA, d.d., Novo mesto	EU/1/11/739/001-008	Film-coated tablet	-Desloratidine
DaTSCAN	GE Healthcare B.V.	EU/1/00/135/001	Solution for injection	-Ioflupane
Daurismo	Pfizer Europe MA EEIG	EU/1/20/1451/001-002	Film-coated tablet	-Glasdegib Maleate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Daurismo	Pfizer Europe MA EEIG	EU/1/20/1451/003-004	Film-coated tablet	-Glasdegib Maleate
Daxas	AstraZeneca AB	EU/1/10/636/001-007	Film-coated tablet	-Roflumilast
Daxas	AstraZeneca AB	EU/1/10/636/008	Tablet	-Roflumilast
DDAVP/Desmopressin 4 micrograms/ml Solution for Injection	Ferring Ireland Ltd	PA1009/001/002	Solution for injection	-DESMOPRESSIN ACETATE
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	-Triptorelin
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	-Triptorelin
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	-Triptorelin
Decapeptyl 3-month, 11.25 mg Powder and solvent for suspension for injection	Ipsen Pharmaceuticals Limited	PA0869/003/002	Powder and solvent for suspension for injection	-Triptorelin
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	-Triptorelin pamoate
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	-Triptorelin
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	-Triptorelin
Decapeptyl SR, 3 mg powder and solvent for suspension for injection	Ipsen Pharmaceuticals Limited	PA0869/003/001	Powder and solvent for suspension for injection	-Triptorelin
Dectova	GlaxoSmithKline Trading Services Limited	EU/1/18/1349/001	Solution for infusion	-Zanamivir
Deferasirox Accord 180 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/19/1412/005-008	Film-coated tablet	-Deferasirox
Deferasirox Accord 360 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/19/1412/009-012	Film-coated tablet	-Deferasirox
Deferasirox Accord 90 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/19/1412/001-004	Film-coated tablet	-Deferasirox
Deferasirox Mylan 180 mg film-coated tablets	Mylan Pharmaceuticals Limited	EU/1/19/1386/006-010	Film-coated tablet	-Deferasirox
Deferasirox Mylan 360 mg film-coated tablets	Mylan Pharmaceuticals Limited	EU/1/19/1386/011-016	Film-coated tablet	-Deferasirox
Deferasirox Mylan 90 mg film-coated tablets	Mylan Pharmaceuticals Limited	EU/1/19/1386/001-005	Film-coated tablet	-Deferasirox
Deferasirox Pharmathen 180 mg film-coated tablets	Pharmathen S.A.	PA1368/021/002	Film-coated tablet	-Deferasirox

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Deferasirox Pharmathen 360 mg film-coated tablets	Pharmathen S.A.	PA1368/021/003	Film-coated tablet	-Deferasirox
Deferasirox Pharmathen 90 mg film-coated tablets	Pharmathen S.A.	PA1368/021/001	Film-coated tablet	-Deferasirox
Deferiprone Lipomed	Lipomed GmbH	EU/1/18/1310/001	Film-coated tablet	-Deferiprone
Defitelio	Gentium S.p.A.	EU/01/13/878/001	Concentrate for solution for infusion	-Defibrotide
Degarelix Accord	Accord Healthcare S.L.U.	EU/1/23/1753/001-002	Powder and solvent for solution for injection	-Degarelix Acetate
Degarelix Accord	Accord Healthcare S.L.U.	EU/1/23/1753/003	Powder and solvent for solution for injection	-Degarelix Acetate
Delstrigo	Merck Sharp & Dohme BV,	EU/1/18/1333/001-002	Film-coated tablet	-Doravirine -Lamivudine -Tenofovir disoproxil fumarate
DELTACORTIL ENTERIC 2.5 mg gastro-resistant tablets	Phoenix Labs	PA1113/003/002	Gastro-resistant tablet	-Prednisolone
DELTACORTIL ENTERIC 5 mg gastro- resistant tablets	Phoenix Labs	PA1113/003/001	Gastro-resistant tablet	-Prednisolone
Deltyba	Otsuka Novel Products GmbH	EU/1/13/875/001-003	Film-coated tablet	-Delamanid
Deltyba	Otsuka Novel Products GmbH	EU/1/13/875/005	Dispersible tablet	-Delamanid
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda	Takeda GmbH	EU/1/22/1699/001	Powder and solvent for solution for injection	-Dengue virus serotype 1# (live, attenuated) -Dengue virus, serotype 2, live, attenuated -Dengue virus serotype 3# (live, attenuated) -Dengue virus serotype 4# (live, attenuated)
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda	Takeda GmbH	EU/1/22/1699/002	Powder and solvent for solution for injection	-Dengue virus serotype 1# (live, attenuated) -Dengue virus, serotype 2, live, attenuated -Dengue virus serotype 3# (live, attenuated) -Dengue virus serotype 4# (live, attenuated)
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda	Takeda GmbH	EU/1/22/1699/003	Powder and solvent for solution for injection	-Dengue virus serotype 1# (live, attenuated) -Dengue virus, serotype 2, live, attenuated -Dengue virus serotype 3# (live, attenuated) -Dengue virus serotype 4# (live, attenuated)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Dengue Tetravalent Vaccine (Live, Attenuated) Takeda	Takeda GmbH	EU/1/22/1699/004	Powder and solvent for solution for injection	-Dengue virus serotype 1# (live, attenuated) -Dengue virus, serotype 2, live, attenuated -Dengue virus serotype 3# (live, attenuated) -Dengue virus serotype 4# (live, attenuated)
Dengvaxia	Sanofi Pasteur	EU/1/18/1338/001-000	Powder and solvent for suspension for injection	-Live, attenuated, chimeric dengue virus
Denzapine 100 mg Tablets	Clonmel Healthcare Ltd	PA0126/235/002	Tablet	-Clozapine
Denzapine 200 mg Tablets	Clonmel Healthcare Ltd	PA0126/235/004	Tablet	-Clozapine
Denzapine 25 mg Tablets	Clonmel Healthcare Ltd	PA0126/235/001	Tablet	-Clozapine
Denzapine 50 mg Tablets	Clonmel Healthcare Ltd	PA0126/235/003	Tablet	-Clozapine
Denzapine 50 mg/ml Oral Suspension	Clonmel Healthcare Ltd	PA0126/235/005	Oral suspension	-Clozapine
Depixol 20mg/ml Solution for Injection	Lundbeck (Ireland) Limited	PA0776/003/001	Solution for injection	-FLUPENTIXOL DECANOATE
Depixol Conc. 100mg/ml Solution for Injection	Lundbeck (Ireland) Limited	PA0776/003/002	Solution for injection	-FLUPENTIXOL DECANOATE
Depo-Medrone 40 mg/ml Suspension for Injection 1 ml vial	Pfizer Healthcare Ireland	PA0822/122/001	Suspension for injectio	-Methylprednisolone acetate
Depo-Medrone 40 mg/ml Suspension for Injection 2 ml vial	Pfizer Healthcare Ireland	PA0822/122/002	Suspension for injectio	-Methylprednisolone acetate
Depo-Medrone 40 mg/ml Suspension for Injection 3 ml vial	Pfizer Healthcare Ireland	PA0822/122/003	Suspension for injectio	-Methylprednisolone acetate
Depo-Medrone 40mg/ml with Lidocaine 10mg/ml Suspension for Injection, 2ml vial	Pfizer Healthcare Ireland	PA0822/123/002	Suspension for injectio	-Methylprednisolone acetate -Lidocaine hydrochloride
Depo-Provera 150 mg/ml Suspension for Injection	Pfizer Healthcare Ireland	PA0822/124/001	Suspension for injectio	-Medroxyprogesterone acetate
Depreger 100 mg film-coated tablet	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/067/002	Film-coated tablet	-Sertraline
Depreger 50 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/067/001	Film-coated tablet	-Sertraline
Derbac M Liquid 0.5% w/w cutaneous emulsion	LanesHealth (Ireland) Limited	PA22702/001/001	Cutaneous emulsion	-Malathion
DERMATRANS 10 mg/24 h transdermal patch	Rottapharm Ltd	PA0868/006/002	Transdermal patch	-Glyceryl trinitrate
DERMATRANS 15 mg/24 h transdermal patch	Rottapharm Ltd	PA0868/006/003	Transdermal patch	-Glyceryl trinitrate
DERMATRANS 5 mg/24 h transdermal patch	Rottapharm Ltd	PA0868/006/001	Transdermal patch	-Glyceryl trinitrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Dermovate 0.05 % w/w Ointment	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/005/001	Ointment	-Clobetasol propionate
Dermovate 0.05% w/w Cream	GlaxoSmithKline (Ireland) Limited	PA1077/005/001	Cream	-Clobetasol propionate
Dermovate 0.05% w/w Ointment	GlaxoSmithKline (Ireland) Limited	PA1077/005/002	Ointment	-Clobetasol propionate
Dermovate Scalp Application 0.05% w/v Cutaneous Solution	GlaxoSmithKline (Ireland) Limited	PA1077/005/003	Cutaneous solution	-Clobetasol propionate
Dermovate Scalp Application 0.05% w/v cutaneous solution	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/005/002	Cutaneous solution	-Clobetasol propionate
Descovy	Gilead Sciences Ireland UC	EU/1/16/1099/001-002	Film-coated tablet	-Emtricitabine -Tenofovir alafenamide
Descovy	Gilead Sciences Ireland UC	EU/1/16/1099/003-004	Film-coated tablet	-Emtricitabine -Tenofovir alafenamide
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	-Deferoxamine mesilate
Deslor 0.5 mg/ml Oral Solution	Rowex Ltd	PA0711/202/002	Oral solution	-Desloratidine
Deslor 5 mg Film-Coated Tablets	Rowex Ltd	PA0711/202/001	Film-coated tablet	-Desloratidine
Desloratidine	Actavis Group hf	EU/1/11/745/001-009	Film-coated tablet	-Desloratidine
DESLORATADINE	Ratiopharm GmbH	EU/1/11/746/001-012	Film Coated Tablet	-DESLORATIDINE
Desloratidine 5mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/016/001	Film-coated tablet	-Desloratidine
Desloratidine Glenmark 5 mg Tablets	Glenmark Arzneimittel GmbH	PA22645/004/001	Tablet	-Desloratidine
Desloratidine ratiopharm	Ratiopharm GmbH	EU/1/11/746/001-011	Film-coated tablet	-DESLORATADINE
Desloratidine Teva	Teva B.V.	EU/1/11/732/001-013	Film-coated tablet	-Desloratidine
Desmospray, Desmopressin Nasal Spray	Ferring Ireland Ltd	PA1009/005/001	Nasal spray, solution	-DESMOPRESSIN ACETATE
Desmotabs Melt 120 micrograms oral lyophilisate	Ferring Ireland Ltd	PA1009/007/003	Oral lyophilisate	-DESMOPRESSIN ACETATE
Desmotabs Melt 120 micrograms oral lyophilisate	IMED Healthcare Ltd.	PPA1463/174/001	Oral lyophilisate	-DESMOPRESSIN ACETATE
Desmotabs Melt 120 micrograms oral lyophilisate	PCO Manufacturing Ltd.	PPA0465/260/001	Oral lyophilisate	-Desmopressin
Desmotabs Melt 240 micrograms oral lyophilisate	Ferring Ireland Ltd	PA1009/007/004	Oral lyophilisate	-DESMOPRESSIN ACETATE
Desmotabs Melt 60 micrograms oral lyophilisate	Ferring Ireland Ltd	PA1009/007/002	Oral lyophilisate	-DESMOPRESSIN ACETATE
Desogestrel Rowex 75 microgram Film-coated Tablets	Rowex Ltd	PA0711/243/001	Film-coated tablet	-Desogestrel
Desunin 10 000 IU soft capsules	Viartis Limited	PA23266/005/001	Capsule, soft	-Colecalciferol
Desunin 1000 IU Tablets	Viartis Healthcare Limited	PA23355/009/002	Tablet	-Colecalciferol
Desunin 2000 IU Tablets	Viartis Healthcare Limited	PA23355/009/003	Tablet	-Colecalciferol
Desunin 25,000 IU soft capsules	Viartis Limited	PA23266/005/002	Capsule, soft	-Colecalciferol

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Desunin 4000 IU Tablets	Viartis Healthcare Limited	PA23355/009/004	Tablet	-Colecalciferol concentrate
Desunin 800 IU Tablets	Viartis Healthcare Limited	PA23355/009/001	Tablet	-Colecalciferol
Detrunorm 15 mg Film-coated Tablets	Apogepha Arzneimittel GmbH	PA0803/004/001	Film-coated tablet	-Propiverine hydrochloride
Detrunorm XL 30 mg Modified-Release Capsules	Consilient Health Limited	PA1876/009/001	Modified-release capsule, hard	-Propiverine hydrochloride
Detrunorm XL 45 mg Modified-Release Capsules	Consilient Health Limited	PA1876/009/002	Modified-release capsule, hard	-Propiverine hydrochloride
Detrusitol 1 mg film-coated tablets	Upjohn EESV	PA23055/014/001	Film-coated tablet	-Tolterodine tartrate
Detrusitol 2 mg film-coated tablets	Upjohn EESV	PA23055/014/002	Film-coated tablet	-Tolterodine tartrate
Detrusitol SR 2 mg, prolonged-release capsules, hard	Upjohn EESV	PA23055/007/001	Prolonged-release capsule, hard	-Tolterodine tartrate
Detrusitol SR 4 mg, prolonged-release capsules, hard	Upjohn EESV	PA23055/007/002	Prolonged-release capsule, hard	-Tolterodine tartrate
Dexafree 1 mg/ml eye drops, solution in single dose container	IMED Healthcare Ltd.	PPA1463/193/001	Eye drops, solution	-DEXAMETHASONE PHOSPHATE
Dexafree 1mg/ml eye drops, solution in single dose container	Laboratoires Thea	PA1107/005/001	Eye drops, solution in single-dose container	-DEXAMETHASONE PHOSPHATE
Dexamethasone 10mg/5ml Oral Solution	Taw Pharma (Ireland) Limited	PA23081/007/001	Oral solution	-Dexamethasone sodium phosphate
Dexamethasone 2mg Tablets	Aspen Pharma Trading Limited	PA1691/014/001	Tablet	-Dexamethasone
Dexamethasone Activase 0.5 mg Tablets	Activase Pharmaceuticals Limited	PA1567/002/001	Tablet	-Dexamethasone
Dexamethasone Activase 2 mg Tablets	Activase Pharmaceuticals Limited	PA1567/002/002	Tablet	-Dexamethasone
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	-DEXAMETHASONE PHOSPHATE
Dexamethasone phosphate 4 mg/ml solution for injection	Fresenius Kabi Deutschland GmbH	PA2059/077/001	Solution for injection	-Dexamethasone sodium phosphate
Dexamethasone Phosphate 4 mg/ml solution for injection	hameln pharma gmbh	PA2237/004/001	Solution for injection	-Dexamethasone sodium phosphate
Dexamethasone phosphate 4 mg/ml solution for injection/infusion	AS Kalceks	PA2165/014/001	Solution for injection/infusion	-Dexamethasone sodium phosphate
Dexamethasone phosphate 4mg/ml Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/237/002	Solution for injection/infusion	-Dexamethasone sodium phosphate
Dexamethasone Phosphate Krka 4 mg/ml solution for injection/infusion	KRKA, d.d., Novo mesto	PA1347/091/001	Solution for injection/infusion	-Dexamethasone sodium phosphate
Dexamethasone phosphate Noridem 4 mg/mL Solution for injection	Noridem Enterprises Limited	PA1122/020/001	Solution for injection	-Dexamethasone sodium phosphate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Dexamethasone phosphate Teva 4 mg/ml solution for injection	Teva B.V.	PA1986/105/001	Solution for injection	-Dexamethasone sodium phosphate
Dexdor	Orion Corporation	EU/1/11/718/001-006	Concentrate for solution for infusion	-Dexmedetomidine hydrochloride
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	-DEXAMETHASONE PHOSPHATE
Deximune 100 mg Soft Capsules	Dexcel Pharma GmbH	PA2261/001/003	Capsule, soft	-Ciclosporin
Deximune 25 mg Soft Capsules	Dexcel Pharma GmbH	PA2261/001/001	Capsule, soft	-Ciclosporin
Deximune 50 mg soft capsules	Dexcel Pharma GmbH	PA2261/001/002	Capsule, soft	-Ciclosporin
Dexliq 4 mg/ml Oral Solution	Laboratoires CTRS	PA2137/001/001	Oral solution	-Dexamethasone sodium phosphate
Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion	AS Kalceks	PA2165/010/001	Concentrate for solution for infusion	-Dexmedetomidine
Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion	Baxter Holding B.V.	PA2299/050/001	Concentrate for solution for infusion	-Dexmedetomidine hydrochloride
Dexmedetomidine Accord	Accord Healthcare S.L.U.	EU/1/19/1418/001-010	Concentrate for solution for infusion	-Dexmedetomidine hydrochloride -Dexmedetomidine
Dexmedetomidine B. Braun 100 micrograms/ml concentrate for solution for infusion	B. Braun Melsungen AG	PA0736/042/001	Concentrate for solution for infusion	-Dexmedetomidine
Dexmedetomidine EVER Pharma 100 micrograms/ml concentrate for solution for infusion	EVER Valinject GmbH	PA1774/002/001	Concentrate for solution for infusion	-Dexmedetomidine hydrochloride
Dexmedetomidine Kabi 100 micrograms/mL concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/076/001	Concentrate for solution for infusion	-Dexmedetomidine hydrochloride
Dexsol 2 mg/ 5 ml Oral Solution	Taw Pharma (Ireland) Limited	PA23081/006/001	Oral solution	-Dexamethasone sodium phosphate
Diabact UBT 50 mg tablets	Laboratoires Mayoly Spindler	PA1993/004/001	Tablet	-13c-urea
Diabrezide 80 mg tablets	L. Molteni & C. dei F.lli Alitti	PA0925/001/001	Tablet	-Gliclazide
Diaclide MR 30 mg modified-release tablet	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/030/002	Modified-release tablet	-Gliclazide
Diaclide MR 60 mg modified-release tablet	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/030/003	Modified-release tablet	-Gliclazide
Diacomit	Biocodex	EU/1/06/367/001-3	Capsule, hard	-Stiripentol
Diacomit	Biocodex	EU/1/06/367/013	Capsule, hard	-Stiripentol
Diacomit	Biocodex	EU/1/06/367/10-12	Powder for oral suspension in sachet	-Stiripentol
Diacomit	Biocodex	EU/1/06/367/4-6	Capsule, hard	-Stiripentol
Diacomit	Biocodex	EU/1/06/367/7-9	Powder for oral suspension in sachet	-Stiripentol
Diacronal MR 30 mg modified-release tablet	KRKA, d.d., Novo mesto	PA1347/024/002	Modified-release tablet	-Gliclazide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Diacronal MR 60 mg modified-release tablet	KRKA, d.d., Novo mesto	PA1347/024/001	Modified-release tablet	-Gliclazide
Diafer 50 mg/ml solution for injection	Pharmacosmos A/S	PA0982/004/001	Solution for injection	-IRON (III)
Diaglyc 30 mg modified-release tablet	Teva Pharma B.V.	PA0749/076/001	Modified-release tablet	-Gliclazide
Diamicon MR 30 mg modified-release tablet	Les Laboratoires Servier	PA0568/013/001	Modified-release tablet	-Gliclazide
DIAMICRON MR 60 mg modified-release tablet	Les Laboratoires Servier	PA0568/013/002	Modified-release tablet	-Gliclazide
Diamox 250 mg Tablets	Amdipharm Limited	PA1142/020/003	Tablet	-Acetazolamide
Diamox SR 250mg Modified Release Hard Capsules	Amdipharm Limited	PA1142/020/001	Modified-release capsule, hard	-Acetazolamide
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	-Sodium chloride -Sodium lactate -Calcium chloride dihydrate ph. eur. -Magnesium chloride hexahydrate -Glucose anhydrous -Glucose monohydrate
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	-Sodium chloride -Sodium lactate -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Glucose anhydrous -Glucose monohydrate
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	-Glucose anhydrous -Glucose monohydrate -Sodium chloride -Sodium lactate -Calcium chloride dihydrate -Magnesium chloride hexahydrate
Dianette 2 mg/35 microgram coated tablets	PCO Manufacturing Ltd.	PPA0465/050/001	Coated tablet	-Cyproterone acetate -Ethinylestradiol
Dianette 2 mg/35 microgram coated tablets	IMED Healthcare Ltd.	PPA1463/164/001	Coated tablet	-Cyproterone acetate -Ethinylestradiol
Dianette 2 mg/35 microgram coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/033/001	Coated tablet	-Cyproterone acetate -Ethinylestradiol
Dianette 2mg/35 microgram coated tablets	Bayer Limited	PA1410/003/001	Coated tablet	-Cyproterone acetate -Ethinylestradiol ph.eur.
Diazemuls Emulsion for Injection 5 mg/ml	Accord Healthcare Ireland Ltd.	PA2315/098/001	Emulsion for injection	-Diazepam
Diazepam 10mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/199/002	Tablet	-Diazepam
Diazepam 5mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/199/001	Tablet	-Diazepam
Diclac 1% w/w Gel	Rowex Ltd	PA0711/009/002	Gel	-Diclofenac sodium
Diclac 100mg Suppositories	Rowex Ltd	PA0711/009/009	Suppository	-Diclofenac sodium
Diclac 25 mg/ml Solution for Injection 3 ml Ampoule	Rowex Ltd	PA0711/009/010	Solution for injection	-Diclofenac sodium

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Diclac 50 mg Gastro-resistant Tablets	Rowex Ltd	PA0711/009/008	Gastro-resistant tablet	-Diclofenac sodium
Diclac 75 mg Prolonged-release Tablet	Rowex Ltd	PA0711/009/003	Prolonged-release tablet	-Diclofenac sodium
Diclac Retard 100 mg Prolonged-release Tablets	Rowex Ltd	PA0711/009/006	Prolonged-release tablet	-Diclofenac sodium
Diclo 75mg prolonged release tablets	Pinewood Laboratories Ltd	PA0281/106/001	Prolonged-release tablet	-Diclofenac sodium
Diclofenac 140 mg medicated plaster	IBSA Farmaceutici Italia S.r.l	PA1104/005/001	Medicated plaster	-Diclofenac epolamine
Diclofenac Liderlens 40 mg/ml cutaneous spray solution	Nutra Essential Otc S.L.	PA23205/001/001	Cutaneous spray, solution	-Diclofenac sodium
Diclomel Max Strength 2% w/w gel	Clonmel Healthcare Ltd	PA0126/372/001	Gel	-Diclofenac sodium
Dicycloverine hydrochloride 10mg/5ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/008/001	Oral solution	-Dicycloverine hydrochloride
Dienogest Stragen 2 mg film-coated tablets	G&G Pharmaceutical (Netherlands) B.V.	PA23029/001/001	Film-coated tablet	-Dienogest
Difene 1% w/w Gel	Glenwood GmbH	PA2256/001/005	Gel	-Diclofenac sodium
Difene 100 mg Dual Release Capsules	Glenwood GmbH	PA2256/001/004	Modified-release capsule, hard	-Diclofenac sodium
Difene 100mg Suppositories	Glenwood GmbH	PA2256/001/006	Suppository	-Diclofenac sodium
Difene 25mg Capsules	Glenwood GmbH	PA2256/001/001	Gastro-resistant capsule, hard	-Diclofenac sodium
Difene 50mg Capsules	Glenwood GmbH	PA2256/001/002	Gastro-resistant capsule, hard	-Diclofenac sodium
Difene 75 mg Dual Release Capsules	Glenwood GmbH	PA2256/001/003	Modified-release capsule, hard	-Diclofenac sodium
Difene Spray Gel 4% w/w Cutaneous Spray, Solution	Glenwood GmbH	PA2256/001/007	Cutaneous spray, solution	-Diclofenac sodium
Differin 0.1% w/w Cream	Galderma International	PA22743/005/001	Cream	-Adapalene
Differin 0.1% w/w Cream	PCO Manufacturing Ltd.	PPA0465/437/002	Cream	-Adapalene
Differin 0.1% w/w cream	IMED Healthcare Ltd.	PPA1463/120/001	Cream	-Adapalene
Differin 0.1% w/w gel	IMED Healthcare Ltd.	PPA1463/120/002	Gel	-Adapalene
Differin 0.1% w/w gel	PCO Manufacturing Ltd.	PPA0465/437/001	Gel	-Adapalene
Differin 0.1% w/w Gel	Galderma International	PA22743/005/002	Gel	-Adapalene
Diffiam Oral Rinse 0.15% w/v, gargle	Mylan IRE Healthcare Limited	PA2010/030/002	Gargle	-BENZYLAMINE HYDROCHLORIDE
Diffiam Spray, 0.15% w/v, Oromucosal Spray	Mylan IRE Healthcare Limited	PA2010/030/003	Oromucosal spray	-BENZYLAMINE HYDROCHLORIDE
Difclir	Tillotts Pharma GmbH	EU/1/11/733/001-004	Film-coated tablet	-Fidaxomicin
Difclir	Tillotts Pharma GmbH	EU/1/11/733/005	Granules for oral suspension	-Fidaxomicin
Diflucan 10 mg/ml powder for oral suspension	Pfizer Healthcare Ireland	PA0822/211/006	Powder for oral suspension	-Fluconazole
Diflucan 150 mg hard capsules	Pfizer Healthcare Ireland	PA0822/211/002	Capsule, hard	-Fluconazole
Diflucan 2 mg/ml solution for infusion	Pfizer Healthcare Ireland	PA0822/211/004	Solution for infusion	-Fluconazole
Diflucan 2 mg/ml solution for infusion	Pfizer Healthcare Ireland	PA0822/211/005	Solution for infusion	-Fluconazole

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Diflucan 200 mg hard capsules	Pfizer Healthcare Ireland	PA0822/211/003	Capsule, hard	-Fluconazole
Diflucan 40 mg/ml powder for oral suspension	Pfizer Healthcare Ireland	PA0822/211/007	Powder for oral suspension	-Fluconazole
Diflucan 50 mg hard capsules	Pfizer Healthcare Ireland	PA0822/211/001	Capsule, hard	-Fluconazole
Dilacort 2.5 mg gastro-resistant tablets	Crescent Pharma International Limited	PA22699/001/001	Gastro-resistant tablet	-Prednisolone
Dilacort 5 mg gastro-resistant tablets	Crescent Pharma International Limited	PA22699/001/002	Gastro-resistant tablet	-Prednisolone
Dimethyl fumarate Accord	Accord Healthcare S.L.U.	EU/1/22/1711/001	Gastro-resistant capsule, hard	-Dimethyl Fumarate
Dimethyl fumarate Accord	Accord Healthcare S.L.U.	EU/1/22/1711/002-003	Gastro-resistant capsule, hard	-Dimethyl Fumarate
Dimethyl Fumarate Mylan	Mylan IRE Healthcare Limited	EU/1/22/1634/001-000	Gastro-resistant capsule, hard	-Dimethyl Fumarate
Dimethyl Fumarate Mylan	Mylan IRE Healthcare Limited	EU/1/22/1634/005-010	Gastro-resistant capsule, hard	-Dimethyl Fumarate
Dimethyl Fumarate Polpharma	Zakłady Farmaceutyczne POLPHARMA S.A.	EU/1/22/1635/001-002	Gastro-resistant capsule, hard	-Dimethyl Fumarate
Dimethyl Fumarate Polpharma	Zakłady Farmaceutyczne POLPHARMA S.A.	EU/1/22/1635/003-004	Gastro-resistant capsule, hard	-Dimethyl Fumarate
Dimethyl fumarate Teva	TEVA GmbH	EU/1/22/1702/001-003	Gastro-resistant capsule, hard	-Dimethyl Fumarate
Dimethyl fumarate Teva	TEVA GmbH	EU/1/22/1702/004-008	Gastro-resistant capsule, hard	-Dimethyl Fumarate
Dimethyl Fumarate Neuraxpharm	Laboratorios Lesvi, S.L.	EU/1/22/1637/001-002	Gastro-resistant capsule, hard	-Dimethyl Fumarate
Dimethyl Fumarate Neuraxpharm	Laboratorios Lesvi, S.L.	EU/1/22/1637/003-005	Gastro-resistant capsule, hard	-Dimethyl Fumarate
Dioralyte Blackcurrant Powder for Oral Solution	Phoenix Labs	PA1113/025/001	Powder for oral solution	-Sodium chloride -Potassium chloride -Glucose -Disodium hydrogen citrate
Dioralyte Citrus Powder for Oral Solution	Phoenix Labs	PA1113/025/002	Powder for oral solution	-Glucose -Sodium chloride -Disodium hydrogen citrate -Potassium chloride
Dioralyte Natural, Powder for oral solution	Phoenix Labs	PA1113/026/001	Powder for oral solution	-Glucose -Sodium chloride -Potassium chloride -Disodium hydrogen citrate
Dioralyte Rebalance Blackcurrant Powder for Oral Solution	Phoenix Labs	PA1113/028/001	Powder for oral solution	-Sodium chloride -Potassium chloride -Glucose -Disodium hydrogen citrate
Dioralyte Rebalance Citrus Powder for Oral Solution	Phoenix Labs	PA1113/028/002	Powder for oral solution	-Sodium chloride -Potassium chloride -Glucose -Disodium hydrogen citrate
Dioralyte Rebalance Natural Powder for Oral Solution	Phoenix Labs	PA1113/028/003	Powder for oral solution	-Sodium chloride -Potassium chloride -Glucose -Disodium hydrogen citrate
Diovan 160 mg film-coated tablets	Novartis Ireland Limited	PA0896/009/002	Film-coated tablet	-Valsartan
Diovan 160 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/461/001	Film-coated tablet	-Valsartan

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Diovan 320 mg film-coated tablets	Novartis Ireland Limited	PA0896/009/004	Film-coated tablet	-Valsartan
Diovan 3mg/ml oral solution	Novartis Ireland Limited	PA0896/009/005	Oral solution	-Valsartan
Diovan 40 mg film-coated tablets	Novartis Ireland Limited	PA0896/009/003	Film-coated tablet	-Valsartan
Diovan 80 mg film-coated tablets	Novartis Ireland Limited	PA0896/009/001	Film-coated tablet	-Valsartan
Diovan 80 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/461/002	Film-coated tablet	-Valsartan
Dipentum 250mg hard Capsules	Atnahs Pharma Netherlands B.V.	PA22657/001/001	Capsule, hard	-Olsalazine sodium
Dipentum 500mg Tablets	Atnahs Pharma Netherlands B.V.	PA22657/001/002	Tablet	-Olsalazine sodium
Dipeptiven, concentrate for solution for infusion	Fresenius AG	PA0697/002/001	Concentrate for solution for infusion	-L-alanyl-l glutamine
Diprivan 1% w/v Emulsion for Injection or Infusion, Pre-filled Syringe	Aspen Pharma Trading Limited	PA1691/022/001	Emulsion for injection/infusion	-Propofol
Diprobase Cream	Phoenix Labs	PA1113/030/001	Cream	
DiproSalic 0.05% w/w + 2% w/w Scalp Application	PCO Manufacturing Ltd.	PPA0465/487/001	Cutaneous solution	-BETAMETHASONE DIPROPIONATE -Salicylic acid
DiproSalic 0.05% w/w + 2% w/w scalp application	IMED Healthcare Ltd.	PPA1463/206/001	Cutaneous solution	-Betamethasone dipropionate -Salicylic acid
DiproSalic 0.05% w/w + 2% w/w scalp application	Organon Pharma (Ireland) Limited	PA23198/009/001	Cutaneous solution	-Betamethasone dipropionate -Salicylic acid
Dipyridamole 200mg/5ml Oral Suspension	Syri Pharma Limited t/a Thame Laboratories	PA22697/009/001	Oral suspension	-Dipyridamole
Distaclor 125mg/5ml Granules for Oral Suspension	Flynn Pharma Limited	PA1226/001/002	Granules for oral suspension	-Cefaclor
Distaclor 250mg/5ml Granules for Oral Suspension	Flynn Pharma Limited	PA1226/001/003	Granules for oral suspension	-Cefaclor
Distaclor LA 375 mg Prolonged Release Tablets	Flynn Pharma Limited	PA1226/001/004	Prolonged-release tablet	-Cefaclor monohydrate
Distaclor LA Forte 500 mg prolonged release tablets	Flynn Pharma Limited	PA1226/001/005	Prolonged-release tablet	-Cefaclor monohydrate
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	-Diphtheria toxoid -Tetanus toxoid
Divigel 0.1% w/w Gel, 1 mg/dose	Orion Corporation	PA1327/002/001	Gel	-Estradiol
Divigel 0.1% w/w Gel, 1 mg/dose	Merit Pharmaceuticals Limited	PPA23080/026/001	Gel	-Estradiol
Dnord 255 microgram soft capsules	Nordic Pharma Limited	PA23343/001/001	Capsule, soft	-Calcifediol monohydrate
Dobutamine 12.5mg/ml Concentrate for Solution for Infusion	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/137/001	Concentrate for solution for infusion	-DOBUTAMINE HYDROCHLORIDE
Docetaxel 20mg/ml concentrate for solution for infusion	Seacross Pharma (Europe) Limited	PA22766/001/001	Concentrate for solution for infusion	-Docetaxel anhydrous

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Docetaxel Accord	Accord Healthcare S.L.U.	EU/1/12/769/001	Concentrate for solution for infusion	-Docetaxel
Docetaxel Accord	Accord Healthcare S.L.U.	EU/1/12/769/003	Concentrate for solution for infusion	-Docetaxel
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	-Docetaxel
Docetaxel Kabi	Fresenius Kabi Deutschland GmbH	EU/1/12/770/001	Concentrate for solution for infusion	-Docetaxel
DOCETAXEL KABI	Fresenius Kabi Deutschland GmbH	EU/1/12/770/002	Concentrate for solution for infusion	-DOCETAXEL
DOCETAXEL KABI	Fresenius Kabi Deutschland GmbH	EU/1/12/770/003	Concentrate for solution for infusion	-DOCETAXEL
DOCETAXEL KABI	Fresenius Kabi Deutschland GmbH	EU/1/12/770/004	Concentrate for solution for infusion	-DOCETAXEL
Docetaxel Mylan	Mylan S.A.S.	EU/1/11/748/001-006	Concentrate for solution for infusion	-Anhydrous docetaxel
Docetaxel Pfizer 10 mg/mL concentrate for solution for infusion	Pfizer Healthcare Ireland	PA0822/146/001	Concentrate for solution for infusion	-Docetaxel
Dolenio 1500mg Film-coated tablets	Blue Bio Pharmaceuticals Ltd	PA1516/001/001	Film-coated tablet	-Glucosamine sulfate
Dolmatil 200mg Tablets	Neuraxpharm Ireland Limited	PA23229/010/001	Tablet	-Sulpiride
Dolocopin 40mg/g Cream	Ferndale Laboratories Limited	PA22869/001/001	Cream	-Lidocaine
Domerid 10mg tablets	Rowex Ltd	PA0711/046/001	Tablet	-Domperidone
Domerid Relief 10mg tablets	Rowex Ltd	PA0711/046/002	Tablet	-Domperidone
Dona 1500 mg powder for oral solution	PCO Manufacturing Ltd.	PPA0465/401/001	Powder for oral solution	-Glucosamine sulfate sodium chloride
Dona 1500 mg Powder for oral solution	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/035/001	Powder for oral solution	-Glucosamine sulfate
Dona 1500 mg Powder for oral solution	Mylan IRE Healthcare Limited	PA2010/022/002	Powder for oral solution	-Glucosamine sulfate -Sodium chloride -Glucosamine sulfate sodium chloride
Dona 500mg Capsules	Mylan IRE Healthcare Limited	PA2010/022/001	Capsule, hard	-Glucosamine sulfate sodium chloride -GLUCOSAMINE SULPHATE
Donepezil 10mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/033/002	Film-coated tablet	-Donepezil hydrochloride
Donepezil 5mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/033/001	Film-coated tablet	-Donepezil hydrochloride
Donepezil Hydrochloride 10mg Film-coated Tablets	Brillpharma (Ireland) Limited	PA22749/004/002	Film-coated tablet	-Donepezil hydrochloride
Donepezil Hydrochloride 5mg Film-coated Tablets	Brillpharma (Ireland) Limited	PA22749/004/001	Film-coated tablet	-Donepezil hydrochloride
Donepezil Hydrochloride Bluefish 10mg Film-coated Tablet	Bluefish Pharmaceuticals AB	PA1436/015/002	Film-coated tablet	-Donepezil hydrochloride
Donepezil Hydrochloride Bluefish 5mg Film-coated Tablet	Bluefish Pharmaceuticals AB	PA1436/015/001	Film-coated tablet	-Donepezil hydrochloride
Donepezil Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/014/004	Film-coated tablet	-Donepezil hydrochloride
Donepezil Krka 5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/014/003	Film-coated tablet	-Donepezil hydrochloride
Donepezil Teva 10 mg film-coated tablets	Teva Pharma B.V.	PA0749/194/002	Film-coated tablet	-Donepezil hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Donepezil Teva 5 mg film-coated tablets	Teva Pharma B.V.	PA0749/194/001	Film-coated tablet	-Donepezil hydrochloride
Donesyn 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/183/002	Film-coated tablet	-Donepezil hydrochloride
Donesyn 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/183/001	Film-coated tablet	-Donepezil hydrochloride
Donopa, 50 %/50 % v/v, medicinal gas, compressed	SOL S.p.A.	PA1848/003/001	Medicinal gas, compressed	-Oxygen -Nitrous oxide
Dopamine Hydrochloride 40 mg/ml Sterile Concentrate	Pfizer Healthcare Ireland	PA0822/202/001	Concentrate for solution for infusion	-DOPAMINE HYDROCHLORIDE
Doptelet	Swedish Orphan Biovitrum AB(publ)	EU/1/19/1373/001-002	Film-coated tablet	-Avatrombopag maleate
Dorzolamide + Timolol PharmaSwiss 20 mg/ml + 5 mg/ml, eye drops solution	Bausch + Lomb Ireland Limited	PA23259/003/001	Eye drops, solution	-Dorzolamide hydrochloride -Timolol Maleate
Dorzolamide PharmaSwiss 20 mg/ml eye drops solution	Bausch + Lomb Ireland Limited	PA23259/002/001	Eye drops, solution	-Dorzolamide
Dostinex 500 microgram Tablets	PCO Manufacturing Ltd.	PPA0465/338/001	Tablet	-Cabergoline
Dostinex 500 microgram tablets	IMED Healthcare Ltd.	PPA1463/162/001	Tablet	-Cabergoline
Dostinex 500 microgram tablets	Pfizer Healthcare Ireland	PA0822/126/001	Tablet	-Cabergoline
Dosulepin Hydrochloride 25 mg Hard Capsules	Azure Pharmaceuticals Ltd	PA22871/013/001	Capsule, hard	-Dosulepin hydrochloride
Dosulepin Hydrochloride Azure 75 mg Coated Tablets	Azure Pharmaceuticals Ltd	PA22871/025/001	Coated tablet	-Dosulepin hydrochloride
Dotagraf 279.32 mg/ml solution for injection	Bayer Limited	PA1410/082/001	Solution for injection	-Gadolinium oxide -DOTA ACID -Meglumine -Gadoteric acid
Dotagraf 279.32 mg/ml solution for injection	Bayer Limited	PA1410/082/002	Solution for injection	-Gadolinium oxide -DOTA ACID -Meglumine
Dotarem 279.32 mg/ml solution for injection	Guerbet	PA0686/003/002	Solution for injection	-Gadoteric acid
Dotarem 279.32 mg/ml solution for injection in pre-filled syringe	Guerbet	PA0686/003/005	Solution for injection in pre-filled syringe	-Gadoteric acid
DOVATO	ViiV Healthcare BV	EU/1/19/1370/001-002	Film-coated tablet	-Dolutegravir sodium -Lamivudine
Dovobet 50 microgram/g + 0.5 mg/g gel	LEO Pharma A/S	PA1025/001/002	Gel	-Calcipotriol -Betamethasone
Dovobet 50 microgram/g + 0.5 mg/g gel	PCO Manufacturing Ltd.	PPA0465/213/002	Gel	-Calcipotriol -Betamethasone
Dovobet 50 microgram/g + 0.5 mg/g Ointment	B & S Healthcare	PPA1328/066/001	Ointment	-Calcipotriol -Betametasone dipropionate
Dovobet® 50 microgram/g + 0.5 mg/g ointment	LEO Pharma A/S	PA1025/001/001	Ointment	-Calcipotriol -Betamethasone
Dovonex 50 microgram/g Ointment	Leo Laboratories Limited	PA0046/061/001	Ointment	-Calcipotriol, anhydrous
Dovonex 50 micrograms/g Cream	Leo Laboratories Limited	PA0046/061/002	Cream	-Calcipotriol hydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Doxacar 4 mg Prolonged release Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/076/001	Prolonged-release tablet	-Doxazosin mesilate
Doxane XL 4 mg prolonged-release tablets	Rowex Ltd	PA0711/103/001	Prolonged-release tablet	-Doxazosin mesilate
Doxapram Hydrochloride 20mg/ml Solution for Injection	MercuryPharm Ltd	PA0857/003/002	Solution for injection	-Doxapram hydrochloride
Doxapram Hydrochloride 2mg/ml Solution for Infusion	MercuryPharm Ltd	PA0857/003/001	Solution for infusion	-Doxapram hydrochloride
Doxatan 1mg tablets	Clonmel Healthcare Ltd	PA0126/202/001	Tablet	-Doxazosin mesilate
Doxatan 2mg tablets	Clonmel Healthcare Ltd	PA0126/202/002	Tablet	-Doxazosin mesilate
Doxatan 4mg tablets	Clonmel Healthcare Ltd	PA0126/202/003	Tablet	-Doxazosin
Doxatan XL 4 mg Prolonged-release Tablets	Clonmel Healthcare Ltd	PA0126/202/004	Prolonged-release tablet	-Doxazosin
Doxorubicin 2 mg/ml Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/083/001	Concentrate for solution for infusion	-DOXORUBICIN HYDROCHLORIDE
Doxorubicin 2mg/ml Concentrate for Solution for Infusion	Seacross Pharma (Europe) Limited	PA22766/004/001	Concentrate for solution for infusion	-DOXORUBICIN HYDROCHLORIDE
Doxorubicin Rivopharm 2 mg/ml concentrate for solution for infusion	Rivopharm Limited	PA2318/002/001	Concentrate for solution for infusion	-DOXORUBICIN HYDROCHLORIDE
Doxorubicin Teva 2 mg/ml Concentrate for Solution for Infusion	Teva Pharma B.V.	PA0749/083/001	Concentrate for solution for infusion	-DOXORUBICIN HYDROCHLORIDE
Doxpirexel 20 mg/ 20 mg modified-release tablets	Exeltis healthcare S.L.	PA22998/004/001	Modified-release tablet	-Pyridoxine hydrochloride -Doxylamine hydrogen succinate
Doxycycline Bluefish 100 mg Capsules	Bluefish Pharmaceuticals AB	PA1436/030/001	Capsule, hard	-Doxycycline
Doxycycline Pinewood 100 mg Capsules	Pinewood Laboratories Ltd	PA0281/161/001	Capsule, hard	-Doxycycline
Doxycycline Teva 100mg Hard Capsules	Teva B.V.	PA1986/081/001	Capsule, hard	-Doxycycline hydrochloride
Doxylamine/Pyridoxine Exeltis 10 mg/10 mg gastro-resistant tablets	Exeltis healthcare S.L.	PA22998/001/001	Gastro-resistant tablet	-Doxylamine -Pyridoxine hydrochloride
Doxylamine/Pyridoxine Exeltis Healthcare 20mg/ 20mg modified-release tablets	Exeltis healthcare S.L.	PA22998/005/001	Modified-release tablet	-Doxylamine hydrogen succinate -Pyridoxine hydrochloride
Dozept 10 mg film-coated-tablets	Rowex Ltd	PA0711/141/002	Film-coated tablet	-Donepezil hydrochloride
Dozept 5 mg film-coated tablets	Rowex Ltd	PA0711/141/001	Film-coated tablet	-Donepezil hydrochloride
Dozol Oral Solution Paracetamol 120 mg/5 ml Diphenhydramine Hydrochloride 12.5 mg/5 ml	Phoenix Healthcare Ltd	PA1721/005/001	Oral solution	-Diphenhydramine hydrochloride -Paracetamol
Drapolene Cream Benzalkonium chloride 0.01% w/w Cetrimide 0.2% w/w	Ravira Limited	PA2034/001/001	Cream	-Benzalkonium chloride solution -Cetrimide
Dretine 0.03 mg/3 mg Film-coated Tablets	Theramex Ireland Limited	PA22668/007/001	Film-coated tablet	-Ethinylestradiol -Drospirenone

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Dretinelle 0.02 mg/3 mg Film-coated Tablets	Theramex Ireland Limited	PA22668/006/001	Film-coated tablet	-Ethinylestradiol -Drospirenone
Droperidol 0.5 mg/ml solution for injection	Sintetica GmbH	PA22835/005/001	Solution for injection	-Droperidol
Dropizol 10 mg/ml Oral Drops Solution	Atnahs Pharma Nordics A/S	PA2245/001/001	Oral drops, solution	-OPIUM TINCTURE
Drovelis	Chemical Works Of Gedeon Richter PLC	EU/1/21/1547/001-004	Film-coated tablet	-Drospirenone -Estetrol -Estetrol monohydrate
Drynol 10 mg orodispersible tablet	Menarini International Operations Luxembourg S.A.	PA0865/018/002	Orodispersible tablet	-Bilastine
Drynol 2.5 mg/ml oral solution	Menarini International Operations Luxembourg S.A.	PA0865/018/003	Oral solution	-Bilastine
Drynol 20 mg orodispersible tablets	Menarini International Operations Luxembourg S.A.	PA0865/018/004	Orodispersible tablet	-Bilastine
Drynol 20 mg Tablets	Menarini International Operations Luxembourg S.A.	PA0865/018/001	Tablet	-Bilastine
Drynol 20mg Tablets	PCO Manufacturing Ltd.	PPA0465/424/001	Tablet	-Bilastine
Drynol 6 mg/mL eye drops, solution	Menarini International Operations Luxembourg S.A.	PA0865/018/005	Eye drops, solution	-Bilastine
Duac Once Daily 10mg/g + 50mg/g Gel	GlaxoSmithKline (Ireland) Limited	PA1077/120/001	Gel	-CLINDAMYCIN PHOSPHATE -Benzoyl peroxide hydrous
Duaklir Genuair	Covis Pharma Europe B.V.	EU/1/14/964/001-002	Inhalation powder	-Micronized acridinium bromide -Micronized formoterol fumarate dihydrate
Duavive	Pfizer Europe MA EEIG	EU/1/14/960/001	Modified-release tablet	-Conjugated estrogens (ce) -Bazedoxifene acetate
Duressa 1 mg/ml + 5 mg/ml, eye drops, solution	Santen OY	PA0879/009/001	Eye drops, solution	-Levofloxacin -Dexamethasone
DUKORAL	Crucell Sweden AB	EU/1/03/263/1-3	Suspension and effervescent granules for oral suspension	-Cholera vaccine
Dulcolax 10mg Suppositories	Opella Healthcare France SAS T/A Sanofi	PA23180/018/002	Suppository	-Bisacodyl
Dulcolax 5mg Gastro-resistant Tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/018/003	Gastro-resistant tablet	-Bisacodyl
Dulcolax Pico Liquid 5 mg/5 ml oral solution	Opella Healthcare France SAS T/A Sanofi	PA23180/017/001	Oral solution	-Sodium picosulfate
Duloxetine Accord 30 mg hard gastro-resistant capsules	Accord Healthcare Ireland Ltd.	PA2315/268/001	Gastro-resistant capsule, hard	-Duloxetine hydrochloride
Duloxetine Accord 60 mg hard gastro-resistant capsules	Accord Healthcare Ireland Ltd.	PA2315/268/002	Gastro-resistant capsule, hard	-Duloxetine hydrochloride
Duloxetine Clonmel 30 mg gastro resistant capsules, hard	Clonmel Healthcare Ltd	PA0126/269/002	Gastro-resistant capsule, hard	-Duloxetine
Duloxetine Clonmel 60 mg gastro-resistant capsules, hard	Clonmel Healthcare Ltd	PA0126/269/004	Gastro-resistant capsule, hard	-Duloxetine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Duloxetine Krka 30 mg hard gastro-resistant capsules	KRKA, d.d., Novo mesto	PA1347/051/002	Gastro-resistant capsule, hard	-Duloxetine
Duloxetine Krka 60 mg hard gastro-resistant capsules	KRKA, d.d., Novo mesto	PA1347/051/004	Gastro-resistant capsule, hard	-Duloxetine
Duloxetine Lilly 30 mg hard gastro-resistant capsules	Eli Lilly Nederland B.V.	EU/1/14/972/001-003	Gastro-resistant capsule, hard	-Duloxetine hydrochloride
Duloxetine Lilly 60 mg hard gastro-resistant capsules	Eli Lilly Nederland B.V.	EU/1/14/972/005-009	Gastro-resistant capsule, hard	-Duloxetine hydrochloride
Duloxetine Mylan 30 mg hard gastro-resistant capsules	Mylan Pharmaceuticals Limited	EU/1/15/1010/01-010	Gastro-resistant capsule, hard	-Duloxetine hydrochloride
Duloxetine Mylan 60 mg hard gastro-resistant capsules	Mylan Pharmaceuticals Limited	EU/1/15/1010/011-020	Gastro-resistant capsule, hard	-Duloxetine hydrochloride
Duloxetine Pinewood 30 mg hard gastro-resistant capsules	Pinewood Laboratories Ltd	PA0281/270/001	Gastro-resistant capsule, hard	-Duloxetine hydrochloride
Duloxetine Pinewood 60 mg hard gastro-resistant capsules	Pinewood Laboratories Ltd	PA0281/270/002	Gastro-resistant capsule, hard	-Duloxetine hydrochloride
Duloxetine Zentiva 30 mg hard gastro-resistant capsules	Zentiva k.s.	EU/1/15/1028/001-003	Gastro-resistant capsule, hard	-Duloxetine
Duloxetine Zentiva 60 mg hard gastro-resistant capsules	Zentiva k.s.	EU/1/15/1028/004-007	Gastro-resistant capsule, hard	-Duloxetine
Duodopa 20 mg/ml + 5 mg/ml intestinal gel	AbbVie Limited	PA1824/002/001	Intestinal gel	-Levodopa -Carbidopa
DuoPlavin	Sanofi-Aventis Groupe	EU/1/10/619/002-007	Film-coated tablet	-Acetylsalicylic acid -Clopidogrel hydrogen sulphate
DuoPlavin	Sanofi Winthrop Industrie	EU/1/10/619/008-014	Film-coated tablet	-Acetylsalicylic acid -Clopidogrel hydrogensulfate
DuoPlavin	Sanofi Winthrop Industrie	EU/1/10/619/01-07	Film-coated tablet	-Acetylsalicylic acid -Clopidogrel hydrogensulfate
DuoResp Spiromax	Teva Pharma B.V.	EU/1/14/920 /001-003	Inhalation powder	-Budesonide -Formoterol fumarate dihydrate
DuoResp Spiromax	Teva Pharma B.V.	EU/1/14/920 /004-006	Inhalation powder	-Budesonide -Formoterol fumarate dihydrate
DuoResp Spiromax Teva	Teva Pharma B.V.	EU/1/14/921/001-003	Inhalation powder	-Budesonide -Formoterol fumarate dihydrate
DuoResp Spiromax Teva	Teva Pharma B.V.	EU/1/14/921/004-006	Inhalation powder	-Budesonide -Formoterol fumarate dihydrate
Duotrav (Extravan)	Novartis Europharm Limited	EU/1/06/338/001-003	Eye drops, solution	-Travopost -Timolol -Timolol Maleate
Duphalac 3.335 g/5 ml Oral Solution	Mylan IRE Healthcare Limited	PA2010/009/001	Oral solution	-Lactulose
Duphaston 10 mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/010/001	Film-coated tablet	-Dydrogesterone
Dupixent	Sanofi Winthrop Industrie	EU/1/17/1229/001-008	Solution for injection in pre-filled syringe	-Dupilumab
Dupixent	Sanofi Winthrop Industrie	EU/1/17/1229/009-001	Solution for injection	-Dupilumab
Dupixent	Sanofi Winthrop Industrie	EU/1/17/1229/021-022	Solution for injection	-Dupilumab

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Dupixent	Sanofi Winthrop Industrie	EU/1/17/1229/023-025	Solution for injection	-Dupilumab
Dupixent	Sanofi Winthrop Industrie	EU/1/17/1229/026-028	Solution for injection	-Dupilumab
Duraphat 5000 ppm Fluoride Toothpaste	Colgate-Palmolive A/S	PA22581/001/001	Toothpaste	-Sodium fluoride
Durogesic DTrans 100 micrograms/hour transdermal patch	Janssen Sciences Ireland UC	PA22612/004/004	Transdermal patch	-Fentanyl
Durogesic DTrans 100 micrograms/hour Transdermal Patch	PCO Manufacturing Ltd.	PPA0465/314/004	Transdermal patch	-Fentanyl
Durogesic DTrans 12 micrograms/hour Transdermal Patch	PCO Manufacturing Ltd.	PPA0465/314/005	Transdermal patch	-Fentanyl
Durogesic DTrans 12 micrograms/hour Transdermal Patch	Janssen Sciences Ireland UC	PA22612/004/005	Transdermal patch	-Fentanyl
Durogesic DTrans 25 micrograms/hour transdermal patch	Janssen Sciences Ireland UC	PA22612/004/001	Transdermal patch	-Fentanyl
Durogesic DTrans 25 micrograms/hour Transdermal Patch	PCO Manufacturing Ltd.	PPA0465/314/001	Transdermal patch	-Fentanyl
Durogesic DTrans 50 micrograms/hour Transdermal Patch	PCO Manufacturing Ltd.	PPA0465/314/002	Transdermal patch	-Fentanyl
Durogesic DTrans 50 micrograms/hour Transdermal Patch	Janssen Sciences Ireland UC	PA22612/004/002	Transdermal patch	-Fentanyl
Durogesic DTrans 75 micrograms/hour Transdermal Patch	Janssen Sciences Ireland UC	PA22612/004/003	Transdermal patch	-Fentanyl
Durogesic DTrans 75 micrograms/hour Transdermal Patch	PCO Manufacturing Ltd.	PPA0465/314/003	Transdermal patch	-Fentanyl
Dutasteride Krka 0.5 mg capsules, soft	KRKA, d.d., Novo mesto	PA1347/069/001	Capsule, soft	-Dutasteride
Dutasteride Rowa 0.5 mg soft capsules	Rowa Pharmaceuticals Limited	PA0074/076/002	Capsule, soft	-Dutasteride
Dutasteride Teva 0.5 mg soft capsules	Teva Pharma B.V.	PA0749/167/001	Capsule, soft	-Dutasteride
Dutasteride/Tamsulosin hydrochloride 0.5 mg /0.4 mg hard capsules	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/230/001	Capsule, hard	-Dutasteride -Tamsulosin hydrochloride
Dutasteride/Tamsulosin Hydrochloride 0.5 mg/0.4 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/222/001	Capsule, hard	-Dutasteride -Tamsulosin hydrochloride
Dutasteride/Tamsulosin hydrochloride Pinewood 0.5 mg/0.4 mg hard capsules	Pinewood Laboratories Ltd	PA0281/216/001	Capsule, hard	-Dutasteride -Tamsulosin hydrochloride
Dutasteride/Tamsulosin Rowa 0.5 mg/0.4 mg hard capsules.	Rowa Pharmaceuticals Limited	PA0074/076/001	Capsule, hard	-Tamsulosin hydrochloride -Dutasteride
Dymista 137 micrograms / 50 micrograms per actuation, Nasal Spray Suspension	Viartis Healthcare Limited	PA23355/010/001	Nasal spray, suspension	-Azelastine hydrochloride -Fluticasone propionate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Dymista 137 micrograms / 50 micrograms per actuation, Nasal Spray Suspension	Merit Pharmaceuticals Limited	PPA23080/018/001	Nasal spray, suspension	-Fluticasone propionate -Azelastine hydrochloride
Dymista 137 micrograms / 50 micrograms per actuation, Nasal Spray Suspension	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/024/001	Nasal spray, suspension	-Fluticasone propionate -Azelastine hydrochloride
Dymista 137 micrograms/50 micrograms per actuation nasal spray, suspension	IMED Healthcare Ltd.	PPA1463/151/001	Nasal spray, suspension	-Azelastine hydrochloride -Fluticasone propionate
Dymista 137 micrograms/50 micrograms per actuation nasal spray, suspension	PCO Manufacturing Ltd.	PPA0465/422/001	Nasal spray, suspension	-Azelastine hydrochloride -Fluticasone propionate
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/001	Powder for solution for injection	-Parecoxib Sodium
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/002	Powder and solvent for solution for injection	-Parecoxib Sodium
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/003	Powder and solvent for solution for injection	-Parecoxib Sodium
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/004	Powder and solvent for solution for injection	-Parecoxib Sodium
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/005	Powder for solution for injection	-Parecoxib Sodium
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/006	Powder and solvent for solution for injection	-Parecoxib Sodium
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/007	Powder and solvent for solution for injection	-Parecoxib Sodium
Dynastat	Pfizer Europe MA EEIG	EU/1/02/209/008	Powder and solvent for solution for injection	-Parecoxib Sodium
Dysport 500 units Powder for solution for injection	Ipsen Pharma	PA1613/002/001	Powder for solution for injection	-Clostridium botulinum toxin type a haemagglutinin complex
Dzuevo	Laboratoire AGUETTANT	EU/1/18/1284/001-002	Sublingual tablet	-SUFENTANIL CITRATE
Easofen 200mg Film-Coated Tablets	Clonmel Healthcare Ltd	PA0126/060/001	Film-coated tablet	-Ibuprofen
Easofen for Children Six Plus Strawberry 200mg/5ml Oral Suspension	Clonmel Healthcare Ltd	PA0126/060/004	Oral suspension	-Ibuprofen
Easofen for Children Strawberry 100mg/5ml Oral Suspension	Clonmel Healthcare Ltd	PA0126/060/003	Oral suspension	-Ibuprofen
Easofen Max Strength 400 mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/060/002	Film-coated tablet	-Ibuprofen
Easofen Rapid Relief Max Strength 400 mg soft capsules	Clonmel Healthcare Ltd	PA0126/343/001	Capsule, soft	-Ibuprofen
Easolief Duo 500mg/150mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/294/001	Film-coated tablet	-Paracetamol -Ibuprofen

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Ebglyss	Almirall, S.A.	EU/1/23/1765/001-006	Solution for injection in pre-filled syringe	-Lebrikizumab
Ebglyss	Almirall, S.A.	EU/1/23/1765/007-012	Solution for injection in pre-filled pen	-Lebrikizumab
Ebilfumini	Actavis Group PTC ehf	EU/1/14/915/001-002	Capsule, hard	-Osetamivir phosphate
EBILFUMIN	Actavis Group PTC ehf	EU/1/14/915/003-004	Capsule, hard	-OSELTAMIVIR PHOSPHATE
EBILFUMIN	Actavis Group PTC ehf	EU/1/14/915/005-006	Capsule, hard	-OSELTAMIVIR PHOSPHATE
EBIXA	H. Lundbeck A/S	EU/1/02/219/001-003	Film-coated tablet	-Memantine
Ebixa	H. Lundbeck A/S	EU/1/02/219/005-006	Oral solution	-MEMANTINE HYDROCHLORIDE
Ebixa	H. Lundbeck A/S	EU/1/02/219/022	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
Ebixa	H. Lundbeck A/S	EU/1/02/219/023-035	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
Ebvallo	Pierre Fabre Medicament	EU/1/22/1700/001	Dispersion for injection	-Tabelecleucel
Ebymect	AstraZeneca AB	EU/1/15/1051/001-006	Film-coated tablet	-Metformin Hydrochloride -Dapagliflozin propanediol monohydrate
Ebymect	AstraZeneca AB	EU/1/15/1051/007-012	Film-coated tablet	-Metformin Hydrochloride -Dapagliflozin propanediol monohydrate
Ecalta	Pfizer Europe MA EEIG	EU/1/07/416/001	Powder and solvent for concentrate for solution for infusion	-Anidulafungin
Ecalta	Pfizer Europe MA EEIG	EU/1/07/416/002	Powder for concentrate for solution for infusion	-Anidulafungin
Ecansya	KRKA, d.d., Novo mesto	EU/1/12/763/001-006	Film-coated tablet	-Capecitabine
Ecansya	KRKA, d.d., Novo mesto	EU/1/12/763/007-012	Film-coated tablet	-Capecitabine
Ecansya	KRKA, d.d., Novo mesto	EU/1/12/763/013-018	Film-coated tablet	-Capecitabine
Eczibet 20 mg/g + 1 mg/g cream	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/196/001	Cream	-Betamethasone -Fusidic acid
Edarbi	Takeda Pharma A/S	EU/1/11/734/001-004	Tablet	-Azilsartan medoxomil
Edarbi	Takeda Pharma A/S	EU/1/11/734/005-008	Tablet	-Azilsartan medoxomil
Edarbi	Takeda Pharma A/S	EU/1/11/734/009-011	Tablet	-Azilsartan medoxomil
Edicis 2mg kit for radiopharmaceutical preparation	CIS bio International	PA0677/021/001	Kit for radiopharmaceutical preparation	-N'n'-ethylene-(l,l) -dicysteine
Edistride	AstraZeneca AB	EU/1/15/1052/001-005	Film-coated tablet	-Dapagliflozin propanediol monohydrate
Edistride	AstraZeneca AB	EU/1/15/1052/006-010	Film-coated tablet	-Dapagliflozin propanediol monohydrate
Edluar 10 mg sublingual tablets	Mylan IRE Healthcare Limited	PA2010/050/002	Sublingual tablet	-Zolpidem tartrate
Edluar 5 mg sublingual tablets	Mylan IRE Healthcare Limited	PA2010/050/001	Sublingual tablet	-Zolpidem tartrate
Edronax 4 mg tablets	Pfizer Healthcare Ireland	PA0822/127/001	Tablet	-Reboxetine
EDURANT	Janssen-Cilag International NV	EU/1/11/736/001	Film-coated tablet	-Rilpivirine (as hydrochloride)
Efavirenz Teva	Teva B.V.	EU/1/11/742/001-010	Film-coated tablet	-Efavirenz

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Efavirenz/Emtricitabine /Tenofovir Disoproxil Clonmel 600 mg/200 mg/245 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/301/001	Film-coated tablet	-Efavirenz -Emtricitabine -Tenofovir disoproxil
Efavirenz/Emtricitabine /Tenofovir disoproxil Krka	KRKA, d.d., Novo mesto	EU/1/17/1263/001-002	Film-coated tablet	-Tenofovir disoproxil succinate -Efavirenz -Emtricitabine
Efavirenz/Emtricitabine /Tenofovir disoproxil Mylan	Mylan Pharmaceuticals Limited	EU/1/17/1222/001-002	Film-coated tablet	-Efavirenz -Tenofovir disoproxil maleate -Emtricitabine
Efavirenz/Emtricitabine /Tenofovir disoproxil Teva 600 mg/200 mg/245 mg Film-coated Tablets	Teva B.V.	PA1986/033/001	Film-coated tablet	-Efavirenz -Emtricitabine -Tenofovir disoproxil
Efavirenz/Emtricitabine /Tenofovir disoproxil Zentiva	Zentiva k.s.	EU/1/17/1210/001	Film-coated tablet	-Tenofovir disoproxil phosphate -Efavirenz -Emtricitabine
Efexor XL 150 mg prolonged-release capsules, hard	Viartis Healthcare Limited	PA23355/002/003	Prolonged-release capsule, hard	-Venlafaxine hydrochloride
Efexor XL 37.5 mg prolonged-release capsules, hard	Viartis Healthcare Limited	PA23355/002/001	Prolonged-release capsule, hard	-Venlafaxine hydrochloride
Efexor XL 75 mg prolonged-release capsules, hard	Viartis Healthcare Limited	PA23355/002/002	Prolonged-release capsule, hard	-Venlafaxine hydrochloride
Efexor XL 75 mg prolonged-release capsules, hard	PCO Manufacturing Ltd.	PPA0465/085/003	Prolonged-release capsule, hard	-Venlafaxine
Efexor XL 75 mg prolonged-release capsules, hard	IMED Healthcare Ltd.	PPA1463/209/001	Prolonged-release capsule, hard	-Venlafaxine
Effentora	Teva B.V.	EU/1/08/441/1-2	Buccal tablet	-FENTANYL CITRATE
Effentora	Teva B.V.	EU/1/08/441/3-4	Buccal tablet	-FENTANYL CITRATE
Effentora	Teva B.V.	EU/1/08/441/5-6	Buccal tablet	-FENTANYL CITRATE
Effentora	Teva B.V.	EU/1/08/441/7-8	Buccal tablet	-FENTANYL CITRATE
Effentora	Teva B.V.	EU/1/08/441/9-10	Buccal tablet	-FENTANYL CITRATE
Efficib	Merck Sharp & Dohme BV,	EU/1/08/457/1-7	Film-coated tablet	-Sitagliptin phosphate -Metformin Hydrochloride
Efficib	Merck Sharp & Dohme BV	EU/1/08/457/8-14	Film-coated tablet	-Sitagliptin phosphate -Metformin Hydrochloride
Efient	Substipharm	EU/1/08/503/1-7	Film-coated tablet	-Prasugrel hydrochloride
Efient	Substipharm	EU/1/08/503/8-14	Film-coated tablet	-Prasugrel hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Efluelda Tetra, suspension for injection in pre-filled syringe	Sanofi Pasteur	PA2131/015/001	Suspension for injection in pre-filled syringe	-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)
Efmody	Diurnal Europe B.V.	EU/1/21/1549/001	Modified-release capsule, hard	-Hydrocortisone
Efmody	Diurnal Europe B.V.	EU/1/21/1549/002	Modified-release capsule, hard	-Hydrocortisone
Efmody	Diurnal Europe B.V.	EU/1/21/1549/003	Modified-release capsule, hard	-Hydrocortisone
EFRACEA 40 mg modified-release hard capsules	Galderma International	PA22743/006/001	Modified-release capsule, hard	-Doxycycline
Efudix 5 % w/w Cream	Mylan IRE Healthcare Limited	PA2010/049/001	Cream	-Fluorouracil
Egostar 22400 IU film-coated tablets	Jaba Recordati S.A.	PA23312/001/001	Film-coated tablet	-Cholecalciferol concentrate
Eklira Genuair	Covis Pharma Europe B.V.	EU/1/12/778/001-003	Inhalation powder	-Micronized acclidinium bromide
Eladynos	Theramex Ireland Limited	EU/1/22/1706/001	Solution for injection in pre-filled syringe	-Abaloparatide
Elantan 20 mg Tablets	Merus Labs Luxco II S.à.R.L.	PA2118/002/003	Tablet	-Isosorbid-5-mononitrat
Elantan LA 25mg Prolonged Release Capsules	Merus Labs Luxco II S.à.R.L.	PA2118/002/005	Prolonged-release capsule, hard	-ISOSORBIDE MONONITRATE
Elantan LA 50 mg Prolonged Release Capsules, hard	Merus Labs Luxco II S.à.R.L.	PA2118/002/004	Prolonged-release capsule, hard	-ISOSORBIDE MONONITRATE
Elaprased	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/06/365/1-3	Concentrate for solution for infusion	-Idursulfase
Eldepryl 5 mg Tablets	Orion Corporation	PA1327/003/001	Tablet	-Selegiline hydrochloride
Elebrato Ellipta	GlaxoSmithKline Trading Services Limited	EU/1/17/1237/001-003	Inhalation powder, pre-dispensed	-Fluticasone furoate -Umeclidinium bromide -Vilanterol trifenate
Eletriptan 20mg Film-coated tablet	Chanelle Medical Unlimited Company	PA0688/048/001	Film-coated tablet	-ELETRIPTAN
Eletriptan 40mg Film-coated tablet	Chanelle Medical Unlimited Company	PA0688/048/002	Film-coated tablet	-ELETRIPTAN
Elfabrio	Chiesi Farmaceutici S.p.A.	EU/1/23/1724/001-003	Concentrate for solution for infusion	-Pegunigalsidase Alfa
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	-Leuprorelin acetate
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	-Leuprorelin acetate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Leuprorelin acetate
Eliquis 2.5 mg film-coated tablets	Bristol-Myers Squibb Pharma EEIG	EU/1/11/691/001-005, 013	Film-coated tablet	-Apixaban
Eliquis 5 mg film-coated tablets	Bristol-Myers Squibb Pharma EEIG	EU/1/11/691/006-012	Film-coated tablet	-Apixaban
ELLAONE	Laboratoire HRA Pharma	EU/1/09/552/003	Film-coated tablet	-ULIPRISTAL ACETATE
Ellaone	Laboratoire HRA Pharma	EU/1/09/522/001	Tablet	-ULIPRISTAL (INN)
Ellura hard capsules	Laboratoire Pharmaceutique Pharmatoka SAS	TR22953/001/001	Capsule, hard	-Cranberry fruit juice refined dry extract
Elmiron (previously called Pentosan)	bene-Arzneimittel GmbH	EU/1/17/1189/001-002	Capsule, hard	-Pentosan polysulfate sodium
Elocon 0.1% w/w Cream	Organon Pharma (Ireland) Limited	PA23198/010/001	Cream	-Mometasone furoate
Elocon 0.1% w/w Cream	PCO Manufacturing Ltd.	PPA0465/268/001	Cream	-Mometasone furoate
Elocon 0.1% w/w Ointment	PCO Manufacturing Ltd.	PPA0465/268/003	Ointment	-Mometasone furoate
Elocon 0.1% w/w Ointment	Organon Pharma (Ireland) Limited	PA23198/010/002	Ointment	-Mometasone furoate
Elocon 0.1% w/w Scalp Lotion, Cutaneous Solution	Organon Pharma (Ireland) Limited	PA23198/010/003	Cutaneous solution	-Mometasone furoate
ELOCTA	Swedish Orphan Biovitrum AB	EU/1/15/1046/001	Powder and solvent for solution for injection	-Efmoroctocog alfa
ELOCTA	Swedish Orphan Biovitrum AB	EU/1/15/1046/002	Powder and solvent for solution for injection	-Efmoroctocog alfa
ELOCTA	Swedish Orphan Biovitrum AB	EU/1/15/1046/003	Powder and solvent for solution for injection	-Efmoroctocog alfa
ELOCTA	Swedish Orphan Biovitrum AB	EU/1/15/1046/004	Powder and solvent for solution for injection	-Efmoroctocog alfa
ELOCTA	Swedish Orphan Biovitrum AB	EU/1/15/1046/005	Powder and solvent for solution for injection	-Efmoroctocog alfa
ELOCTA	Swedish Orphan Biovitrum AB	EU/1/15/1046/006	Powder and solvent for solution for injection	-Efmoroctocog alfa
ELOCTA	Swedish Orphan Biovitrum AB	EU/1/15/1046/007	Powder and solvent for solution for injection	-Efmoroctocog alfa
Elocta	Swedish Orphan Biovitrum AB(publ)	EU/1/15/1046/008	Powder and solvent for solution for injection	-Efmoroctocog alfa
Elocta	Swedish Orphan Biovitrum AB(publ)	EU/1/15/1046/009	Powder and solvent for solution for injection	-Efmoroctocog alfa
Elocta	Swedish Orphan Biovitrum AB(publ)	EU/1/15/1046/010	Powder and solvent for solution for injection	-Efmoroctocog alfa
Elonva	N.V. Organon	EU/1/09/609/001	Solution for injection	-Corifollitropin alfa
Elonva	N.V. Organon	EU/1/09/609/002	Solution for injection	-Corifollitropin alfa
ELREXFIO	Pfizer Europe MA EEIG	EU/1/23/1770/001-002	Solution for injection	-Elranatamab
Eltroxin 100 microgram Tablets	Amdipharm Limited	PA1142/028/002	Tablet	-Levothyroxine sodium
Eltroxin 25 microgram Tablets	Amdipharm Limited	PA1142/029/001	Tablet	-Levothyroxine sodium

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Eltroxin 50 microgram Tablets	Amdipharm Limited	PA1142/028/001	Tablet	-Levothyroxine sodium
Elucirem	Guerbet	EU/1/23/1772/001-010	Solution for injection	-Gadopiclenol
Elvina 0.03mg/3mg film-coated tablets	Gedeon Richter Plc	PA1330/007/001	Film-coated tablet	-Drospirenone -Ethinylestradiol
Elvinette 0.02mg/3mg film-coated tablets	Gedeon Richter Plc	PA1330/008/001	Film-coated tablet	-Drospirenone -Ethinylestradiol
Elymbus 0.1 mg/g eye gel in single-dose container	Laboratoires Thea	PA1107/019/001	Eye gel in single-dose container	-Bimatoprost
Elzonris	TMC Pharma (EU) Limited	EU/1/20/1504/001	Concentrate for solution for infusion	-Tagraxofusp
Emadine	Immedica Pharma AB	EU/1/98/095/001	Eye drops, solution	-Emedastine difumarate
Emadine	Immedica Pharma AB	EU/1/98/095/002	Eye drops, solution	-Emedastine difumarate
Emadine	Immedica Pharma AB	EU/1/98/095/003	Eye drops, solution	-Emedastine difumarate
Emadine	Immedica Pharma AB	EU/1/98/095/004	Eye drops, solution	-Emedastine difumarate
Emazole 20 mg gastro-resistant tablets	Rowex Ltd	PA0711/158/001	Gastro-resistant tablet	-Esomeprazole magnesium dihydrate
Emazole 40 mg gastro-resistant tablets	Rowex Ltd	PA0711/158/002	Gastro-resistant tablet	-Esomeprazole magnesium dihydrate
Emazole Control 20 mg gastro-resistant tablets	IQ Pharmatek Ltd	PA22777/001/001	Gastro-resistant tablet	-Esomeprazole magnesium dihydrate
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	-Argipressin
Emend	Merck Sharp & Dohme BV,	EU/1/03/262/009-010	Capsule, hard	-Aprepitant
Emend	Merck Sharp & Dohme BV,	EU/1/03/262/011	Powder for oral suspension	-Aprepitant
EMEND	Merck Sharp and Dohme Limited	EU/1/03/262/1-6	Capsule, hard	-Aprepitant
Emend	Merck Sharp & Dohme BV,	EU/1/03/262/7-8	Capsule, hard	-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	-Adrenaline
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	-Adrenaline
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	-Adrenaline
Emgality	Eli Lilly Nederland B.V.	EU/1/18/1330/001-004	Solution for injection	-GALCANEZUMAB
Emizof 4 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/083/003	Film-coated tablet	-Ondansetron
Emizof 8 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/083/002	Film-coated tablet	-Ondansetron
EMLA 5% w/w Cream	Aspen Pharma Trading Limited	PA1691/023/001	Cream	-Lidocaine -Prilocaine
Empliciti	Bristol-Myers Squibb Pharma EEIG	EU/1/16/1088/001	Powder for concentrate for solution for infusion	-Elotuzumab
Empliciti	Bristol-Myers Squibb Pharma EEIG	EU/1/16/1088/002	Powder for concentrate for solution for infusion	-Elotuzumab

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
EMSELEX	zr pharma& GmbH	EU/1/04/294/1-12	Prolonged-release tablet	-Darifenacin hydrobromide
Emtricitabine/Tenofovir disoproxil Accordpharma 200 mg/245 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/200/002	Film-coated tablet	-Emtricitabine -Tenofovir disoproxil
Emtricitabine/Tenofovir disoproxil Clonmel 200 mg/245 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/289/001	Film-coated tablet	-Emtricitabine -Tenofovir disoproxil
Emtricitabine/Tenofovir disoproxil Krka 200 mg/245 mg film-coated tablets	KRKA, d.d., Novo mesto	EU/1/16/1151/001-004	Film-coated tablet	-Emtricitabine -Tenofovir disoproxil
Emtricitabine/Tenofovir disoproxil Krka d.d 200 mg/245 mg film-coated tablets	KRKA, d.d., Novo mesto	EU/1/17/1182/001-004	Film-coated tablet	-Tenofovir disoproxil -Emtricitabine
Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film-coated tablets	Mylan Pharmaceuticals Limited	EU/1/16/1133/001-006	Film-coated tablet	-Emtricitabine -Tenofovir disoproxil
Emtricitabine/Tenofovir disoproxil Teva 200 mg/245 mg film-coated tablets	Teva B.V.	PA1986/016/001	Film-coated tablet	-Emtricitabine -Tenofovir disoproxil
Emtricitabine/Tenofovir disoproxil Tillomed 200 mg/245 mg film-coated tablets	Tillomed Pharma GmbH	PA22720/008/001	Film-coated tablet	-Emtricitabine -Tenofovir disoproxil fumarate
Emtricitabine/Tenofovir disoproxil Zentiva 200 mg/245 mg film-coated tablets	Zentiva k.s.	EU/1/16/1148/001-002	Film-coated tablet	-Tenofovir disoproxil -Emtricitabine
Emtriva	Gilead Sciences Ireland UC	EU/1/03/261/1-3	Capsule, hard	-Emtricitabine
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	-Isopropyl myristate -Liquid paraffin -Benzalkonium chloride
Enalapril maleate Accord 10mg tablets	Accord Healthcare Ireland Ltd.	PA2315/241/002	Tablet	-Enalapril maleate
Enalapril maleate Accord 20mg tablets	Accord Healthcare Ireland Ltd.	PA2315/241/003	Tablet	-Enalapril maleate
Enalapril maleate Accord 5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/241/001	Tablet	-Enalapril maleate
Enalapril/Lercanidipine Krka 10mg/10mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/029/001	Film-coated tablet	-Enalapril maleate -Lercanidipine
Enalapril/Lercanidipine Krka 20mg/10mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/029/002	Film-coated tablet	-Enalapril maleate -Lercanidipine
ENAP 10mg Tablets	Rowex Ltd	PA0711/028/002	Tablet	-Enalapril maleate
ENAP 20mg Tablets	Rowex Ltd	PA0711/028/003	Tablet	-Enalapril maleate
ENAP 5mg Tablets	Rowex Ltd	PA0711/028/001	Tablet	-Enalapril maleate
ENBREL	Pfizer Europe MA EEIG	EU/1/99/126/001-003	Powder for solution for injection	-Etanercept
Enbrel	Pfizer Europe MA EEIG	EU/1/99/126/002	Powder for solution for injection	-Etanercept
Enbrel	Pfizer Europe MA EEIG	EU/1/99/126/013-015	Solution for injection in pre-filled syringe	-Etanercept

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Enbrel	Pfizer Europe MA EEIG	EU/1/99/126/016-021	Solution for injection in pre-filled syringe	-Etanercept
Enbrel	Pfizer Europe MA EEIG	EU/1/99/126/022	Powder and solvent for solution for injection	-Etanercept
Enbrel	Pfizer Europe MA EEIG	EU/1/99/126/023-025	Solution for injection in pre-filled pen	-Etanercept
EndolucinBeta	ITM Medical Isotopes GmbH	EU/1/16/1105/001-002	Radiopharmaceutical precursor, solution	-Lutetium (177lu) chloride
Endoxana Coated Tablets 50 mg	Baxter Holding B.V.	PA2299/027/003	Coated tablet	-Cyclophosphamide monohydrate
Endoxana Injection 1000 mg Powder for Solution for Injection	Baxter Holding B.V.	PA2299/027/002	Powder for solution for injection	-Cyclophosphamide
Endoxana Injection 500 mg Powder for Solution for Injection	Baxter Holding B.V.	PA2299/027/001	Powder for solution for injection	-Cyclophosphamide
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	-Indacaterol acetate -Glycopyrronium bromide -Mometasone furoate
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	-Hepatitis b surface antigen, recominant
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	-Hepatitis b surface antigen, recominant
Enhertu	Daiichi Sankyo Europe GmbH	EU/1/20/1508/001	Powder for concentrate for solution for infusion	-Trastuzumab Deruxtecan
Enjaymo	Genzyme Europe B.V.	EU/1/22/1687/001-002	Solution for infusion	-Sutimlimab
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
Enrylaze	Jazz Pharmaceuticals Ireland Limited	EU/1/23/1747/001	Solution for injection/infusion	-Crisantaspase

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Enspryng	Roche Registration GmbH	EU/1/21/1559/001	Solution for injection in pre-filled syringe	-Satralizumab
Enstilar 50 micrograms/g + 0.5 mg/g cutaneous foam	LEO Pharma A/S	PA1025/005/001	Cutaneous foam	-Calcipotriol -Betamethasone
Entacapone	Orion Corporation	EU/1/11/708/001-004	Film-coated tablet	-Entacapone
ENTACAPONE TEVA	Teva B.V.	EU/1/10/665/001-004	Film-coated tablet	-ENTACAPONE
Entecavir Accord	Accord Healthcare S.L.U.	EU/1/17/1211/001-003	Film-coated tablet	-Entecavir
Entecavir Accord	Accord Healthcare S.L.U.	EU/1/17/1211/004-006	Film-coated tablet	-Entecavir
Entecavir Mylan	Mylan Pharmaceuticals Limited	EU/1/17/1227/001-005	Film-coated tablet	-Entecavir
Entecavir Mylan	Mylan Pharmaceuticals Limited	EU/1/17/1227/006-010	Film-coated tablet	-Entecavir
Entecavir Rowex 0.5 mg Film-coated tablets	Rowex Ltd	PA0711/274/001	Film-coated tablet	-ENTECAVIR MONOHYDRATE
Entocort CR 3 mg Gastro-resistant Capsule, Hard	IMED Healthcare Ltd.	PPA1463/178/001	Gastro-resistant capsule, hard	-Budesonide
Entocort CR 3 mg Gastro-resistant Capsule, Hard	PCO Manufacturing Ltd.	PPA0465/467/001	Gastro-resistant capsule, hard	-Budesonide
Entocort® CR 3 mg Gastro-resistant Capsule, Hard	Tillotts Pharma GmbH	PA2018/003/001	Gastro-resistant capsule, hard	-Budesonide
Entonox	BOC Gases Ireland Ltd	PA0208/005/001	Medicinal gas, compressed	-Oxygen -Nitrous oxide
Entresto	Novartis Europharm Limited	EU/1/15/1058/001	Film-coated tablet	-Sacubitril valsartan
Entresto	Novartis Europharm Limited	EU/1/15/1058/002-004	Film-coated tablet	-Sacubitril valsartan
Entresto	Novartis Europharm Limited	EU/1/15/1058/005-007	Film-coated tablet	-Sacubitril valsartan
Entresto	Novartis Europharm Limited	EU/1/15/1058/023	Granules	-Sacubitril -Valsartan
ENTYVIO	Takeda Pharma A/S	EU/1/14/923/001	Powder for concentrate for solution for infusion	-Vedolizumab
Entyvio	Takeda Pharma A/S	EU/1/14/923/002-004	Solution for injection in pre-filled syringe	-Vedolizumab
Entyvio	Takeda Pharma A/S	EU/1/14/923/005-007	Solution for injection in pre-filled pen	-Vedolizumab
Enurev Breezhaler	Novartis Europharm Limited	EU/1/12/789/001-006	Inhalation powder, hard capsule	-Glycopyrronium bromide
Envarsus	Chiesi Farmaceutici S.p.A.	EU/1/14/35/001-003	Prolonged-release tablet	-Tacrolimus monohydrate
Envarsus	Chiesi Farmaceutici S.p.A.	EU/1/14/35/004-006	Prolonged-release tablet	-Tacrolimus monohydrate
Envarsus	Chiesi Farmaceutici S.p.A.	EU/1/14/35/007-009	Prolonged-release tablet	-Tacrolimus monohydrate
ENYGLID	Krka d.d., Novo mesto	EU/1/09/580/13-18	Tablet	-REPAGLINIDE
ENYGLID	Krka d.d., Novo mesto	EU/1/09/580/1-6	Tablet	-REPAGLINIDE
ENYGLID	Krka d.d., Novo mesto	EU/1/09/580/7-12	Tablet	-REPAGLINIDE
Enzalutamide Rowex 40 mg film-coated tablets	Rowex Ltd	PA0711/332/001	Film-coated tablet	-Enzalutamide
Enzalutamide Rowex 80 mg film-coated tablets	Rowex Ltd	PA0711/332/002	Film-coated tablet	-Enzalutamide
Epaclob 1 mg/ml Oral Suspension	Ethypharm	PA0549/026/001	Oral suspension	-Clobazam
Epaclob 2 mg/ml Oral Suspension	Ethypharm	PA0549/026/002	Oral suspension	-Clobazam

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Epanutin 100 mg Hard Capsules	PCO Manufacturing Ltd.	PPA0465/244/001	Capsule, hard	-PHENYTOIN SODIUM
Epanutin 100 mg Hard Capsules	Upjohn EESV	PA23055/003/003	Capsule, hard	-PHENYTOIN SODIUM
Epanutin 25 mg Hard Capsules	Upjohn EESV	PA23055/003/001	Capsule, hard	-PHENYTOIN SODIUM
Epanutin 30 mg/5ml Oral Suspension	Upjohn EESV	PA23055/003/007	Oral suspension	-Phenytoin
Epanutin 300 mg Hard Capsules	Upjohn EESV	PA23055/003/004	Capsule, hard	-PHENYTOIN SODIUM
Epanutin 50 mg Hard Capsules	Upjohn EESV	PA23055/003/002	Capsule, hard	-PHENYTOIN SODIUM
Epanutin Infatabs 50mg Chewable Tablets	Upjohn EESV	PA23055/003/005	Chewable tablet	-Phenytoin
Epanutin Ready Mixed Parenteral 250mg/5ml Solution for Injection or Infusion	Upjohn EESV	PA23055/003/006	Solution for injection/infusion	-PHENYTOIN SODIUM
Epclusa	Gilead Sciences Ireland UC	EU/1/16/1116/001	Film-coated tablet	-Sofosbuvir -Velpatasvir
Epclusa	Gilead Sciences Ireland UC	EU/1/16/1116/002	Film-coated tablet	-Sofosbuvir
Epclusa	Gilead Sciences Ireland UC	EU/1/16/1116/003	Coated granules	-Sofosbuvir -Velpatasvir
Epclusa	Gilead Sciences Ireland UC	EU/1/16/1116/004	Coated granules	-Sofosbuvir -Velpatasvir
Ephedrine Hydrochloride 3 mg/ml solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/011/001	Solution for injection in pre-filled syringe	-Ephedrine hydrochloride
Ephedrine Hydrochloride 30mg in 1ml Solution for Injection	Ethypharm	PA0549/027/001	Solution for injection	-Ephedrine hydrochloride
Epiduo 0.1%/2.5% gel	Galderma International	PA22743/007/001	Gel	-Adapalene -Benzoyl Peroxide
Epiduo 0.3 %/2.5 % gel	Galderma International	PA22743/007/002	Gel	-Adapalene -Benzoyl Peroxide
Epidyolex	Jazz Pharmaceuticals Ireland Limited	EU/1/19/1389/001	Oral solution	-CANNABIDIOL
Epilim 100 mg Crushable Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/001	Tablet	-Sodium valproate
Epilim Chrono 200mg Prolonged Release Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/010	Prolonged-release tablet	-Sodium valproate -Valproic acid
Epilim Chrono 300mg Prolonged Release Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/011	Prolonged-release tablet	-Sodium valproate -Valproic acid
Epilim Chrono 500mg Prolonged Release Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/012	Prolonged-release tablet	-Sodium valproate -Valproic acid
Epilim Chronosphere 100mg prolonged-release granules	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/005	Prolonged-release granules	-Sodium valproate -Valproic acid
Epilim Chronosphere 250mg prolonged-release granules	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/006	Prolonged-release granules	-Sodium valproate -Valproic acid
Epilim Chronosphere 500mg prolonged-release granules	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/007	Prolonged-release granules	-Sodium valproate -Valproic acid
Epilim Enteric 200 mg gastro-resistant coated tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/002	Gastro-resistant tablet	-Sodium valproate
Epilim Enteric 500mg Gastro-resistant Coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/003	Gastro-resistant tablet	-Sodium valproate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Sodium valproate
Epilim Liquid 200 mg/5ml Oral Solution	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/014	Oral solution	-Sodium valproate
Epilim Syrup 200mg/5ml Oral Solution	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/150/015	Oral solution	-Sodium valproate
EPINITRIL 10 mg/24 h transdermal patch	Rottapharm Ltd	PA0868/003/002	Transdermal patch	-Glyceryl trinitrate
EPINITRIL 15 mg/24 h transdermal patch	Rottapharm Ltd	PA0868/003/003	Transdermal patch	-Glyceryl trinitrate
EPINITRIL 5 mg/24 h transdermal patch	Rottapharm Ltd	PA0868/003/001	Transdermal patch	-Glyceryl trinitrate
EpiPen 300 micrograms solution for injection in pre-filled pen	Viartis Healthcare Limited	PA23355/011/002	Solution for injection in pre-filled pen	-Adrenaline
EpiPen Junior 150 micrograms solution for injection in pre-filled pen	Viartis Healthcare Limited	PA23355/011/001	Solution for injection in pre-filled pen	-Adrenaline
Epirubicin 2 mg/ml Solution for Injection	Seacross Pharma (Europe) Limited	PA22766/003/001	Solution for injection	-Epirubicin hydrochloride
Epirubicin Hydrochloride 2 mg/ml solution for injection or infusion	Accord Healthcare Ireland Ltd.	PA2315/034/001	Solution for injection/infusion	-Epirubicin hydrochloride
Epistatus 10 mg oromucosal solution	SERB S.A.,	PA20595/002/001	Oromucosal solution	-Midazolam
Epistatus 2.5 mg oromucosal solution	SERB S.A.,	PA20595/002/002	Oromucosal solution	-Midazolam
Epistatus 5 mg oromucosal solution	SERB S.A.,	PA20595/002/003	Oromucosal solution	-Midazolam
Epistatus 7.5 mg oromucosal solution	SERB S.A.,	PA20595/002/004	Oromucosal solution	-Midazolam
Epivir	ViiV Healthcare BV	EU/1/96/015/001	Coated tablet	-Lamivudine
Epivir	ViiV Healthcare BV	EU/1/96/015/002	Oral solution	-Lamivudine
Epivir	ViiV Healthcare BV	EU/1/96/015/003	Film-coated tablet	-Lamivudine
Eplerenone 25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/085/001	Film-coated tablet	-Eplerenone
Eplerenone 50 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/085/002	Film-coated tablet	-Eplerenone
Eplerenone Bluefish 25 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/022/001	Film-coated tablet	-Eplerenone
Eplerenone Bluefish 50 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/022/002	Film-coated tablet	-Eplerenone
Eplerenone Krka 25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/078/001	Film-coated tablet	-Eplerenone
Eplerenone Krka 50 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/078/002	Film-coated tablet	-Eplerenone
Eplerenone Mylan 25 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/168/001	Film-coated tablet	-Eplerenone
Eplerenone Rowex 25 mg film-coated tablets	Rowex Ltd	PA0711/235/001	Film-coated tablet	-Eplerenone
Eplerenone Rowex 50 mg film-coated tablets	Rowex Ltd	PA0711/235/002	Film-coated tablet	-Eplerenone
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/11-12	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/1-2	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/13-14	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/15-16	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/21-22	Solution for injection in pre-filled syringe	-Epoetin alfa
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/23-24	Solution for injection in pre-filled syringe	-Epoetin alfa
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/25-26	Solution for injection in pre-filled syringe	-Epoetin alfa
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/3-4	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/5-6	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/7-8	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Epoetin alfa Hexal	Hexal AG	EU/1/07/411/9-10	Solution for injection in pre-filled syringe	-Recombinant human erythropoietin alfa
Eporatio	Ratiopharm GmbH	EU/1/09/573/11-16	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Eporatio	Ratiopharm GmbH	EU/1/09/573/1-2	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Eporatio	Ratiopharm GmbH	EU/1/09/573/17-22	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Eporatio	Ratiopharm GmbH	EU/1/09/573/23-28	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Eporatio	Ratiopharm GmbH	EU/1/09/573/3-4	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Eporatio	Ratiopharm GmbH	EU/1/09/573/5-6	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Eporatio	Ratiopharm GmbH	EU/1/09/573/7-8	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Eporatio	Ratiopharm GmbH	EU/1/09/573/9-10	Solution for injection in pre-filled syringe	-Xm01 drug substance epoetin theta
Eptifibatide Accord 0.75 mg/ml solution for infusion	Accord Healthcare S.L.U.	EU/1/15/1065/001	Solution for infusion	-Eptifibatide
Eptifibatide Accord 2 mg/ml solution for injection	Accord Healthcare S.L.U.	EU/1/15/1065/002	Solution for injection	-Eptifibatide
Epysqli	Samsung Bioepis NL B.V.	EU/1/23/1735/001	Concentrate for solution for infusion	-Eculizumab
Equasym XL 10 mg modified-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/001/001	Modified-release capsule, hard	-Methylphenidate hydrochloride
Equasym XL 20 mg modified-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/001/002	Modified-release capsule, hard	-Methylphenidate hydrochloride
Equasym XL 30 mg modified-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/001/003	Modified-release capsule, hard	-Methylphenidate hydrochloride
Equasym XL 40 mg modified-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/001/004	Modified-release capsule, hard	-Methylphenidate hydrochloride
Equasym XL 50 mg modified-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/001/005	Modified-release capsule, hard	-Methylphenidate hydrochloride
Equasym XL 60 mg modified-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/001/006	Modified-release capsule, hard	-Methylphenidate hydrochloride
Erbitux	Merck Europe B.V.	EU/1/04/281/001	Solution for infusion	-Cetuximab

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Erbix	Merck Europe B.V.	EU/1/04/281/2-5	Solution for infusion	-Cetuximab, chimeric antibody
Erdotin 300 mg capsules	Galen Pharma Ireland Limited	PA22680/004/001	Capsule, hard	-Erdosteine
Erelzi (Formely known: Etanercept Sandoz)	Sandoz GmbH	EU/1/17/1195/001-004	Solution for injection in pre-filled syringe	-Etanercept
Erelzi (Formely known: Etanercept Sandoz)	Sandoz GmbH	EU/1/17/1195/005-012	Solution for injection	-Etanercept
Eribulin Advanz Pharma 0.44 mg/ml solution for injection	Advanz Pharma Limite	PA23450/001/001	Solution for injection	-Eribulin mesylate
Erivedge	Roche Registration GmbH	EU/1/13/848/001	Capsule, hard	-Vismodegib
Erleada	Janssen-Cilag International NV	EU/1/18/1342/001-003	Film-coated tablet	-APALUTAMIDE
Erleada	Janssen-Cilag International NV	EU/1/18/1342/004-006	Film-coated tablet	-APALUTAMIDE
Ertapenem SUN	Sun Pharmaceutical Industries Europe B.V.	EU/1/22/1656/001-002	Powder for concentrate for solution for infusion	-Ertapenem sodium
ERtracER Solution for Injection	Curium Pharma Ireland Limited	PA1125/002/001	Solution for injection	-Fludeoxyglucose [18F]
Ervebo	Merck Sharp & Dohme BV,	EU/1/19/1392/001	Solution for injection	-Recombinant Vesicular Stomatitis Virus - Zaire Ebola virus Vaccine (Live Attenuated)
Erwinase 10 000 U powder for solution for injection/infusion	Porton Biopharma Limited	PA23208/001/001	Powder for solution for injection/infusion	-Crisantaspase
Erythrocin 250 mg Tablets	Amdipharm Limited	PA1142/008/002	Film-coated tablet	-Erythromycin
Erythrocin 500 mg Tablets	Amdipharm Limited	PA1142/008/003	Film-coated tablet	-Erythromycin
Erythrocin IV Lactobionate 1 g Powder for Concentrate for Solution for Infusion	Amdipharm Limited	PA1142/008/001	Powder for concentrate for solution for infusion	-Erythromycin
Erythroped Adult 500mg Film-coated Tablets	Amdipharm Limited	PA1142/006/004	Film-coated tablet	-Erythromycin
Erythroped PI SF 125mg/5ml granules for oral suspension	Amdipharm Limited	PA1142/006/002	Granules for oral suspension	-Erythromycin
Erythroped SF 250mg/5ml granules for oral suspension	Amdipharm Limited	PA1142/006/001	Granules for oral suspension	-Erythromycin
Esbriet	Roche Registration GmbH	EU/1/11/667/005-008	Film-coated tablet	-Pirfenidone
Esbriet 267 mg film-coated tablets	Roche Registration GmbH	EU/1/11/667/007-008	Film-coated tablet	-Pirfenidone
Esbriet 267 mg hard capsules	Roche Registration GmbH	EU/1/11/667/001-003	Capsule, hard	-Pirfenidone
Esbriet 534 mg film-coated tablets	Roche Registration GmbH	EU/1/11/667/009-010	Film-coated tablet	-Pirfenidone
Esbriet 801 mg film-coated tablets	Roche Registration GmbH	EU/1/11/667/011	Film-coated tablet	-Pirfenidone
Esciprex 10 mg film-coated tablets	Rowex Ltd	PA0711/194/002	Film-coated tablet	-Escitalopram
Esciprex 15 mg film-coated tablets	Rowex Ltd	PA0711/194/003	Film-coated tablet	-Escitalopram
Esciprex 20 mg film-coated tablets	Rowex Ltd	PA0711/194/004	Film-coated tablet	-Escitalopram

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Esciprex 5 mg film-coated tablets	Rowex Ltd	PA0711/194/001	Film-coated tablet	-Escitalopram
Escitalopram 10 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/008/002	Film-coated tablet	-Escitalopram
Escitalopram 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/086/002	Film-coated tablet	-Escitalopram
Escitalopram 15 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/008/003	Film-coated tablet	-Escitalopram
Escitalopram 20 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/008/004	Film-coated tablet	-Escitalopram
Escitalopram 20 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/086/003	Film-coated tablet	-Escitalopram
Escitalopram 20mg/ml Oral drops, solution	Chanelle Medical Unlimited Company	PA0688/041/001	Oral drops, solution	-Escitalopram
Escitalopram 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/086/001	Film-coated tablet	-Escitalopram
Escitalopram 5 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/008/001	Film-coated tablet	-Escitalopram
Escitalopram Bluefish 10 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/023/002	Film-coated tablet	-Escitalopram oxalate
Escitalopram Bluefish 15 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/023/003	Film-coated tablet	-Escitalopram oxalate
Escitalopram Bluefish 20 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/023/004	Film-coated tablet	-Escitalopram oxalate
Escitalopram Bluefish 5 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/023/001	Film-coated tablet	-Escitalopram oxalate
Escitalopram Glenmark 10 mg film-coated tablets	Glenmark Arzneimittel GmbH	PA22645/005/002	Film-coated tablet	-Escitalopram
Escitalopram Glenmark 15 mg film-coated tablets	Glenmark Arzneimittel GmbH	PA22645/005/003	Film-coated tablet	-Escitalopram
Escitalopram Glenmark 20 mg film-coated tablets	Glenmark Arzneimittel GmbH	PA22645/005/004	Film-coated tablet	-Escitalopram
Escitalopram Glenmark 5 mg film-coated tablet	Glenmark Arzneimittel GmbH	PA22645/005/001	Film-coated tablet	-Escitalopram
Escitalopram Grindeks 10 mg film-coated tablets	AS Grindeks	PA22992/007/002	Film-coated tablet	-Escitalopram oxalate
Escitalopram Grindeks 20 mg film-coated tablets	AS Grindeks	PA22992/007/003	Film-coated tablet	-Escitalopram oxalate
Escitalopram Grindeks 5 mg film-coated tablet	AS Grindeks	PA22992/007/001	Film-coated tablet	-Escitalopram oxalate
Escitalopram Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/046/002	Film-coated tablet	-Escitalopram
Escitalopram Krka 15 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/046/003	Film-coated tablet	-Escitalopram
Escitalopram Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/046/004	Film-coated tablet	-Escitalopram
Escitalopram Krka 5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/046/001	Film-coated tablet	-Escitalopram
Escitalopram Pinewood 10 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/262/002	Film-coated tablet	-Escitalopram oxalate
Escitalopram Pinewood 15 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/262/003	Film-coated tablet	-Escitalopram oxalate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Escitalopram Pinewood 20 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/262/004	Film-coated tablet	-Escitalopram oxalate
Escitalopram Pinewood 5 mg film-coated tablet	Pinewood Laboratories Ltd	PA0281/262/001	Film-coated tablet	-Escitalopram oxalate
Escitalopram Teva 10 mg film-coated tablets	Teva Pharma B.V.	PA0749/111/002	Film-coated tablet	-Escitalopram
Escitalopram Teva 15 mg film-coated tablets	Teva Pharma B.V.	PA0749/111/003	Film-coated tablet	-Escitalopram
Escitalopram Teva 20 mg film-coated tablets	Teva Pharma B.V.	PA0749/111/004	Film-coated tablet	-Escitalopram oxalate
Escitalopram Teva 5 mg film-coated tablets	Teva Pharma B.V.	PA0749/111/001	Film-coated tablet	-Escitalopram oxalate
Escitalpro 10 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/108/002	Film-coated tablet	-Escitalopram oxalate
Escitalpro 15 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/108/003	Film-coated tablet	-Escitalopram oxalate
Escitalpro 20 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/108/004	Film-coated tablet	-Escitalopram oxalate
Escitalpro 5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/108/001	Film-coated tablet	-Escitalopram oxalate
Esketamine Sintetica 25 mg/ml solution for injection/infusion	Sintetica GmbH	PA22835/002/002	Solution for injection/infusion	-ESKETAMINE HYDROCHLORIDE
Esketamine Sintetica 5 mg/ml solution for injection/infusion	Sintetica GmbH	PA22835/002/001	Solution for injection/infusion	-ESKETAMINE HYDROCHLORIDE
Esmeron 10 mg/ml solution for injection/infusion	Merck Sharp & Dohme Ireland (Human Health) Limited	PA1286/058/001	Solution for injection/infusion	-Rocuronium bromide
Esmya	Gedeon Richter Plc	EU/1/12/750/001	Tablet	-Ulipristal acetate
Esomeprazole 20 mg gastro-resistant tablets	Brillpharma (Ireland) Limited	PA22749/023/001	Gastro-resistant tablet	-Esomeprazole
Esomeprazole 20 mg gastro-resistant tablets	Brillpharma (Ireland) Limited	PA22749/007/001	Gastro-resistant tablet	-Esomeprazole magnesium dihydrate
Esomeprazole 20 mg gastro-resistant tablets	Accord Healthcare Ireland Ltd.	PA2315/127/003	Gastro-resistant tablet	-Esomeprazole magnesium dihydrate
Esomeprazole 20 mg hard gastro-resistant capsules	Chefaro Ireland DAC	PA1186/027/001	Gastro-resistant capsule, hard	-Esomeprazole
Esomeprazole 40 mg gastro-resistant tablets	Accord Healthcare Ireland Ltd.	PA2315/127/004	Gastro-resistant tablet	-Esomeprazole
Esomeprazole 40 mg gastro-resistant tablets	Brillpharma (Ireland) Limited	PA22749/007/002	Gastro-resistant tablet	-Esomeprazole
Esomeprazole 40 mg Powder for Solution for Injection/Infusion	Accord Healthcare Ireland Ltd.	PA2315/160/001	Powder for solution for injection/infusion	-Esomeprazole sodium
Esomeprazole 40 mg powder for solution injection/infusion	Accord Healthcare Ireland Ltd.	PA2315/132/005	Powder for solution for injection/infusion	-Esomeprazole
Esomeprazole Aristo 20 mg gastro-resistant capsules, hard	Aristo Pharma GmbH	PA1983/001/001	Gastro-resistant capsule, hard	-Esomeprazole magnesium dihydrate
Esomeprazole Aristo 40 mg gastro-resistant capsules, hard	Aristo Pharma GmbH	PA1983/001/002	Gastro-resistant capsule, hard	-Esomeprazole magnesium dihydrate
Esomeprazole Clonmel 20 mg gastro-resistant capsules, hard	Clonmel Healthcare Ltd	PA0126/208/001	Gastro-resistant capsule, hard	-Esomeprazole

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Esomeprazole Clonmel 40 mg gastro-resistant capsules, hard	Clonmel Healthcare Ltd	PA0126/208/002	Gastro-resistant capsule, hard	-Esomeprazole
Esomeprazole Krka 20 mg hard gastro-resistant capsules	KRKA, d.d., Novo mesto	PA1347/017/001	Gastro-resistant capsule, hard	-Esomeprazole
Esomeprazole Krka 40 mg hard gastro-resistant capsules	KRKA, d.d., Novo mesto	PA1347/017/002	Gastro-resistant capsule, hard	-Esomeprazole
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	-Esomeprazole
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	-Esomeprazole
Esperoct	Novo Nordisk A/S	EU/1/19/1374/001	Powder and solvent for solution for injection	-TUROCTOCOG ALFA PEGOL
Esperoct	Novo Nordisk A/S	EU/1/19/1374/002	Powder and solvent for solution for injection	-TUROCTOCOG ALFA PEGOL
Esperoct	Novo Nordisk A/S	EU/1/19/1374/003	Powder and solvent for solution for injection	-TUROCTOCOG ALFA PEGOL
Esperoct	Novo Nordisk A/S	EU/1/19/1374/004	Powder and solvent for solution for injection	-TUROCTOCOG ALFA PEGOL
Esperoct	Novo Nordisk A/S	EU/1/19/1374/005	Powder and solvent for solution for injection	-TUROCTOCOG ALFA PEGOL
Espestesin 40 mg/ml + 5 microgram/ml solution for injection	Pierrel S.p.A.	PA25244/001/002	Solution for injection	-Articaine hydrochloride -Epinephrine
Espestesin Forte 40 mg/ml + 10 microgram/ml solution for injection	Pierrel S.p.A.	PA25244/001/001	Solution for injection	-Articaine hydrochloride -Epinephrine
Espranor 2 mg Oral Lyophilisate	Ethypharm	PA0549/024/001	Oral lyophilisate	-Buprenorphine
Espranor 8 mg Oral Lyophilisate	Ethypharm	PA0549/024/002	Oral lyophilisate	-Buprenorphine
Estradiol SUN 10 micrograms vaginal tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/006/001	Vaginal tablet	-Estradiol
Estradot 100 micrograms/24 hours, transdermal patch	Novartis Ireland Limited	PA0896/010/004	Transdermal patch	-Estradiol hemihydrate
Estradot 25 micrograms/24 hours, transdermal patch	Novartis Ireland Limited	PA0896/010/005	Transdermal patch	-Estradiol hemihydrate
Estradot 37.5 micrograms/24 hours, transdermal patch	Novartis Ireland Limited	PA0896/010/001	Transdermal patch	-Estradiol hemihydrate
Estradot 50 micrograms/24 hours, transdermal patch	Novartis Ireland Limited	PA0896/010/002	Transdermal patch	-Estradiol hemihydrate
Estradot 75 micrograms/24 hours, transdermal patch	Novartis Ireland Limited	PA0896/010/003	Transdermal patch	-Estradiol hemihydrate
Estrofem 2 mg film-coated tablets	Novo Nordisk A/S	PA0218/050/001	Film-coated tablet	-Estradiol
Etalopro 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/212/002	Film-coated tablet	-Escitalopram

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Etalopro 15 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/212/003	Film-coated tablet	-Escitalopram
Etalopro 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/212/004	Film-coated tablet	-Escitalopram
Etalopro 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/212/001	Film-coated tablet	-Escitalopram
Ethambutol Hydrochloride 100mg film-coated tablets	Morningside Healthcare (Malta) Limited	PA23142/004/001	Film-coated tablet	-Ethambutol hydrochloride
Ethambutol Hydrochloride 400mg film-coated tablets	Morningside Healthcare (Malta) Limited	PA23142/004/002	Film-coated tablet	-Ethambutol hydrochloride
Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.02 mg/ 3 mg Film-coated Tablets	Laboratorios Leon Farma, S.A.	PA1474/008/001	Film-coated tablet	-Drospirenone -Ethinylestradiol
Ethinylestradiol / Drospirenone Leon Farma & Placebo 0.03 mg/ 3 mg Film-coated Tablets	Laboratorios Leon Farma, S.A.	PA1474/008/002	Film-coated tablet	-Drospirenone -Ethinylestradiol
Ethinylestradiol / Drospirenone Leon Farma 0.02mg/3 mg Film-coated Tablets	Laboratorios Leon Farma, S.A.	PA1474/004/001	Film-coated tablet	-Drospirenone -Ethinylestradiol
Ethinylestradiol / Drospirenone Leon Farma 0.03mg/3 mg Film-coated Tablets	Laboratorios Leon Farma, S.A.	PA1474/004/002	Film-coated tablet	-Drospirenone -Ethinylestradiol
Ethylex 50 mg film-coated tablets	Aop Orphan Pharmaceuticals GmbH	PA0934/002/001	Film-coated tablet	-Naltrexone hydrochloride
Etoflam 5% w/w Gel	Phoenix Labs	PA1113/002/001	Gel	-Etofenamate
Etonogestrel/Ethinylestradiol 0.120 mg/0.015 mg per 24 hours vaginal delivery system	Laboratorios Leon Farma, S.A.	PA1474/014/001	Vaginal delivery system	-Etonogestrel -Ethinylestradiol ph.eur.
Etoposide 20 mg/ml concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/036/001	Concentrate for solution for infusion	-Etoposide
Etoposide 20mg/ml Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/201/001	Concentrate for solution for infusion	-Etoposide
Etoposide-Teva 20 mg/ml Concentrate for Solution for Infusion	Teva Pharma B.V.	PA0749/002/001	Concentrate for solution for infusion	-Etoposide
Etoricoxib 120 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/018/004	Film-coated tablet	-Etoricoxib
Etoricoxib 120 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/018/004	Film-coated tablet	-Etoricoxib
Etoricoxib 120 mg film-coated tablets	Chanelle Medical Unlimited Company	PA0688/032/004	Film-coated tablet	-Etoricoxib
Etoricoxib 120 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/210/004	Film-coated tablet	-Etoricoxib
Etoricoxib 120 mg film-coated tablets	Rowex Ltd	PA0711/232/004	Film-coated tablet	-Etoricoxib
Etoricoxib 30 mg film-coated tablets	Rowex Ltd	PA0711/232/001	Film-coated tablet	-Etoricoxib
Etoricoxib 30 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/210/001	Film-coated tablet	-Etoricoxib
Etoricoxib 30 mg film-coated tablets	Chanelle Medical Unlimited Company	PA0688/032/001	Film-coated tablet	-Etoricoxib

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Etoricoxib 30 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/018/001	Film-coated tablet	-Etoricoxib
Etoricoxib 30 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/018/001	Film-coated tablet	-Etoricoxib
Etoricoxib 60 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/018/002	Film-coated tablet	-Etoricoxib
Etoricoxib 60 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/018/002	Film-coated tablet	-Etoricoxib
Etoricoxib 60 mg film-coated tablets	Chanelle Medical Unlimited Company	PA0688/032/002	Film-coated tablet	-Etoricoxib
Etoricoxib 60 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/210/002	Film-coated tablet	-Etoricoxib
Etoricoxib 60 mg film-coated tablets	Rowex Ltd	PA0711/232/002	Film-coated tablet	-Etoricoxib
Etoricoxib 90 mg film-coated tablets	Rowex Ltd	PA0711/232/003	Film-coated tablet	-Etoricoxib
Etoricoxib 90 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/210/003	Film-coated tablet	-Etoricoxib
Etoricoxib 90 mg film-coated tablets	Chanelle Medical Unlimited Company	PA0688/032/003	Film-coated tablet	-Etoricoxib
Etoricoxib 90 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/018/003	Film-coated tablet	-Etoricoxib
Etoricoxib 90 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/018/003	Film-coated tablet	-Etoricoxib
Etoricoxib Krka 120 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/064/004	Film-coated tablet	-Etoricoxib
Etoricoxib Krka 30 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/064/001	Film-coated tablet	-Etoricoxib
Etoricoxib Krka 60 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/064/002	Film-coated tablet	-Etoricoxib
Etoricoxib Krka 90 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/064/003	Film-coated tablet	-Etoricoxib
Etoricoxib Teva 120 mg film-coated tablets	Teva B.V.	PA1986/002/004	Film-coated tablet	-Etoricoxib
Etoricoxib Teva 30 mg film-coated tablets	Teva B.V.	PA1986/002/001	Film-coated tablet	-Etoricoxib
Etoricoxib Teva 60 mg film-coated tablets	Teva B.V.	PA1986/002/002	Film-coated tablet	-Etoricoxib
Etoricoxib Teva 90 mg film-coated tablets	Teva B.V.	PA1986/002/003	Film-coated tablet	-Etoricoxib
Etrivex 500 micrograms/g shampoo	Galderma International	PA22743/008/001	Shampoo	-Clobetasol propionate
Eucardic 12.5 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/001/002	Tablet	-Carvedilol
Eucardic 25 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/001/003	Tablet	-Carvedilol
Eucardic 6.25 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/001/001	Tablet	-Carvedilol
Eucreas	Novartis Europharm Limited	EU/1/07/425/13-15	Film-coated tablet	-Vildagliptin -Metformin hci
Eucreas	Novartis Europharm Limited	EU/1/07/425/1-6	Film-coated tablet	-Metformin hci -Vildagliptin
Eucreas	Novartis Europharm Limited	EU/1/07/425/16-18	Film-coated tablet	-Vildagliptin -Metformin hci
Eucreas	Novartis Europharm Limited	EU/1/07/425/7-12	Film-coated tablet	-Metformin hci -Vildagliptin
Eumovate Cream 0.05% w/w	GlaxoSmithKline (Ireland) Limited	PA1077/006/001	Cream	-CLOBETASONE BUTYRATE
Eurartesim	Alfasigma S.p.A	EU/1/11/716/001-004	Film-coated tablet	-Piperazine phosphate -Dihydroartemisinin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Eurartesim	Sigma-Tau Industrie Farmaceutiche Riunite SpA	EU/1/11/716/005	Film-coated tablet	-Dihydroartemisinin -Piperazine phosphate
Eurax 10% w/w Cream	Clonmel Healthcare Ltd	PA0126/325/001	Cream	-Crotamiton
Evenity	UCB Pharma S.A.	EU/1/19/1411/001-002	Solution for injection in pre-filled pen	-ROMOSOZUMAB
Evenity	UCB Pharma S.A.	EU/1/19/1411/003-004	Solution for injection in pre-filled syringe	-ROMOSOZUMAB
Everolimus TAD 10 mg tablets	TAD Pharma GmbH	PA0876/009/003	Tablet	-Everolimus
Everolimus TAD 2.5 mg tablets	TAD Pharma GmbH	PA0876/009/001	Tablet	-Everolimus
Everolimus TAD 5 mg tablets	TAD Pharma GmbH	PA0876/009/002	Tablet	-Everolimus
Evicel	Omrix Biopharmaceuticals S.A.	EU/1/08/473/1-3	Solution for sealant	-Human fibrinogen -Human thrombin
Eviplera	Gilead Sciences Ireland UC	EU/1/11/737/001-002	Film-coated tablet	-Rilpivirine hydrochloride -Tenofovir disoproxil fumarate (tdf) -Emtricitabine
Evista	Substipharm	EU/1/98/073/001	Film-coated tablet	-Raloxifene
Evista	Substipharm	EU/1/98/073/002	Film-coated tablet	-Raloxifene
Evista	Substipharm	EU/1/98/073/003	Film-coated tablet	-Raloxifene
Evista	Substipharm	EU/1/98/073/004	Film-coated tablet	-Raloxifene
Evkeeza	Ultragenyx Germany GmbH	EU/1/21/1551/001-002	Concentrate for solution for infusion	-Evinacumab
Evoltra	Sanofi B.V.	EU/1/06/334/01	Concentrate for solution for infusion	-Clofarabine
Evorel 50 micrograms per 24 hours Transdermal Patch	Theramex Ireland Limited	PA22668/008/001	Transdermal patch	-Estradiol hemihydrate
Evorel Conti 50/170 micrograms per 24 hours Transdermal Patch	Theramex Ireland Limited	PA22668/009/001	Transdermal patch	-Estradiol hemihydrate -Norethisterone acetate
Evorel Conti 50/170 micrograms per 24 hours transdermal patch	PCO Manufacturing Ltd.	PPA0465/489/001	Transdermal patch	-Estradiol -Norethisterone acetate
Evotaz	Bristol-Myers Squibb Pharma EEIG	EU/1/15/1025/001-002	Film-coated tablet	-Atazanavir -Cobicistat
EVRA	Gedeon Richter Plc	EU/1/02/223/001	Transdermal patch	-Norelgestromin -Ethinylestradiol
Evra	Gedeon Richter Plc	EU/1/02/223/002	Transdermal patch	-Norelgestromin -Ethinylestradiol
Evra	Gedeon Richter Plc	EU/1/02/223/003	Transdermal patch	-Norelgestromin -Ethinylestradiol
Evrenzo	Astellas Pharma Europe B.V.	EU/1/21/1574/001	Film-coated tablet	-Roxadustat
Evrenzo	Astellas Pharma Europe B.V.	EU/1/21/1574/002	Film-coated tablet	-Roxadustat
Evrenzo	Astellas Pharma Europe B.V.	EU/1/21/1574/003	Film-coated tablet	-Roxadustat
Evrenzo	Astellas Pharma Europe B.V.	EU/1/21/1574/004	Film-coated tablet	-Roxadustat
Evrenzo	Astellas Pharma Europe B.V.	EU/1/21/1574/005	Film-coated tablet	-Roxadustat
Evrysdi	Roche Registration GmbH	EU/1/21/1531/001	Powder for oral solution	-Risdiplam
EVUSHELD	AstraZeneca AB	EU/1/22/1651/001	Solution for injection	-Tixagevimab -Cilgavimab
EXALIEF	BIAL - Portela & C ^a , S.A.	EU/1/09/520/1-6	Tablet	-ESLICARBAZEPINE ACETATE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Excedrin 250 mg/ 250 mg/ 65 mg film coated tablets	Haleon Ireland Limited	PA0678/122/001	Film-coated tablet	-Acetylsalicylic acid -Paracetamol -Caffeine
EXELON	Novartis Europharm Limited	EU/1/98/066/001	Capsule, hard	-Rivastigmine hydrogen tartrate
Exelon	Novartis Europharm Limited	EU/1/98/066/002	Capsule, hard	-Rivastigmine hydrogen tartrate
Exelon	Novartis Europharm Limited	EU/1/98/066/003	Capsule, hard	-Rivastigmine hydrogen tartrate
Exelon	Novartis Europharm Limited	EU/1/98/066/004	Capsule, hard	-Rivastigmine hydrogen tartrate
Exelon	Novartis Europharm Limited	EU/1/98/066/005	Capsule, hard	-Rivastigmine hydrogen tartrate
Exelon	Novartis Europharm Limited	EU/1/98/066/006	Capsule, hard	-Rivastigmine hydrogen tartrate
Exelon	Novartis Europharm Limited	EU/1/98/066/007	Capsule, hard	-Rivastigmine hydrogen tartrate
Exelon	Novartis Europharm Limited	EU/1/98/066/008	Capsule, hard	-Rivastigmine hydrogen tartrate
Exelon	Novartis Europharm Limited	EU/1/98/066/009	Capsule, hard	-Rivastigmine hydrogen tartrate
Exelon	Novartis Europharm Limited	EU/1/98/066/010	Capsule, hard	-Rivastigmine hydrogen tartrate
Exelon	Novartis Europharm Limited	EU/1/98/066/011	Capsule, hard	-Rivastigmine hydrogen tartrate
Exelon	Novartis Europharm Limited	EU/1/98/066/012	Capsule, hard	-Rivastigmine hydrogen tartrate
Exelon	Novartis Europharm Limited	EU/1/98/066/013	Oral solution	-Rivastigmine hydrogen tartrate
Exelon	Novartis Europharm Limited	EU/1/98/066/027-030	Transdermal patch	-Rivastigmine
Exelon	Novartis Europharm Limited	EU/1/98/066/19-22	Transdermal patch	-Rivastigmine base
Exelon	Novartis Europharm Limited	EU/1/98/066/23-26	Transdermal patch	-Rivastigmine base
Exemestane 25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/087/001	Film-coated tablet	-Exemestane
Exemestane Teva 25 mg film-coated tablets	Teva B.V.	PA1986/115/001	Film-coated tablet	-Exemestane
Exforge	Novartis Europharm Limited	EU/1/06/370/001-008	Film-coated tablet	-Amlodipine besilate -Valsartan
Exforge	Novartis Europharm Limited	EU/1/06/370/009-016	Film-coated tablet	-Amlodipine besilate -Valsartan
Exforge	Novartis Europharm Limited	EU/1/06/370/017-024	Film-coated tablet	-Valsartan -Amlodipine besilate
Exforge HCT	Novartis Europharm Limited	EU/1/09/569/1-12	Film-coated tablet	-Amlodipine besylate -Hydrochlorothiazide -Valsartan
Exforge HCT	Novartis Europharm Limited	EU/1/09/569/13-24	Film-coated tablet	-Hydrochlorothiazide -Valsartan -Amlodipine besylate
Exforge HCT	Novartis Europharm Limited	EU/1/09/569/25-36	Film-coated tablet	-Amlodipine besylate -Hydrochlorothiazide -Valsartan
Exforge HCT	Novartis Europharm Limited	EU/1/09/569/37-48	Film-coated tablet	-Hydrochlorothiazide -Valsartan -Amlodipine besylate
Exforge HCT	Novartis Europharm Limited	EU/1/09/569/49-60	Film-coated tablet	-Valsartan -Hydrochlorothiazide -Amlodipine besylate
Exjade	Novartis Europharm Limited	EU/1/06/356/020	Granules	-Deferasirox
Exjade	Novartis Europharm Limited	EU/1/06/356/021	Granules	-Deferasirox
Exjade	Novartis Europharm Limited	EU/1/06/356/022	Granules	-Deferasirox

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Exjade 180 mg film-coated tablets	Novartis Europharm Limited	EU/1/06/356/014-016	Film-coated tablet	-Deferasirox
Exjade 360 mg film-coated tablets	Novartis Europharm Limited	EU/1/06/356/017-019	Film-coated tablet	-Deferasirox
Exjade 90 mg film-coated tablets	Novartis Europharm Limited	EU/1/06/356/011-013	Film-coated tablet	-Deferasirox
Exjade Dispersible	Novartis Europharm Limited	EU/1/06/356/001-009	Dispersible tablet	-Deferasirox
EXOCIN (Ofloxacin) 0.3% w/v Eye Drops Solution	AbbVie Limited	PA1824/014/001	Eye drops, solution	-Ofloxacin
Exorex Lotion 5% v/w Cutaneous Emulsion	Teva B.V.	PA1986/078/001	Cutaneous emulsion	-Coal tar solution
EXPAREL liposomal	Pacira Ireland Limited	EU/1/20/1489/001-004	Prolonged-release dispersion for injection	-Bupivacaine
Expudyne 250mg/5ml oral solution	JED Pharma Limited	PA23183/003/001	Oral solution	-Carbocisteine
Expudyne Rx 750 mg/5 ml oral solution	JED Pharma Limited	PA23183/005/001	Oral solution	-Carbocisteine
Exputex 250mg / 5ml Oral Solution	Phoenix Labs	PA1113/010/001	Oral solution	-Carbocisteine
Extavia	Novartis Europharm Limited	EU/1/08/454/1,2,5	Powder and solvent for solution for injection	-Interferon beta-1b
Exterol 5% w/w Ear Drops, Solution	Dermal Laboratories (Ireland) Limited	PA23128/006/001	Ear drops, solution	-Urea hydrogen peroxide
EXTRANEAL Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/017/001	Solution for peritoneal dialysis	-Icodextrin -Sodium chloride -Sodium (S) - lactate -Calcium chloride -Magnesium chloride
Exviera	AbbVie Deutschland GmbH & Co. KG	EU/1/14/983/001	Film-coated tablet	-Dasabuvir sodium
Eylea	Bayer AG	EU/1/12/797/001-002	Solution for injection	-Aflibercept
Eylea	Bayer AG	EU/1/12/797/003	Solution for injection	-Aflibercept
Eyreida 0.3 mg/ml eye drops, solution	Morningside Healthcare (Malta) Limited	PA23142/014/001	Eye drops, solution	-Bimatoprost
Eyzeetan 0.3 mg/ml + 5 mg/ml eye drops, solution	Morningside Healthcare (Malta) Limited	PA23142/013/001	Eye drops, solution	-Bimatoprost -Timolol Maleate
Ezetimibe 10 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/088/001	Tablet	-Ezetimibe
Ezetimibe 10 mg tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/198/001	Tablet	-Ezetimibe
Ezetimibe Krka 10 mg tablets	KRKA, d.d., Novo mesto	PA1347/066/001	Tablet	-Ezetimibe
Ezetimibe Rowa 10 mg tablets	Rowa Pharmaceuticals Limited	PA0074/074/001	Tablet	-Ezetimibe
Ezetimibe Teva 10 mg tablets	Teva B.V.	PA1986/012/001	Tablet	-Ezetimibe
Ezetimibe/ Atorvastatin Zentiva 10 mg/10 mg film-coated tablets	Zentiva k.s.	PA1701/009/001	Film-coated tablet	-Ezetimibe -Atorvastatin
Ezetimibe/ Atorvastatin Zentiva 10 mg/20 mg film-coated tablets	Zentiva k.s.	PA1701/009/002	Film-coated tablet	-Ezetimibe -Atorvastatin calcium trihydrate
Ezetimibe/ Atorvastatin Zentiva 10 mg/40 mg film-coated tablets	Zentiva k.s.	PA1701/009/003	Film-coated tablet	-Ezetimibe -Atorvastatin calcium trihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Ezetimibe/ Atorvastatin Zentiva 10 mg/80 mg film-coated tablets	Zentiva k.s.	PA1701/009/004	Film-coated tablet	-Ezetimibe -Atorvastatin calcium trihydrate
Ezetimibe/Simvastatin 10 mg/40 mg tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/180/002	Tablet	-Ezetimibe -Simvastatin
Ezetimibe/Simvastatin 10mg/20mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/180/001	Tablet	-Ezetimibe -Simvastatin
Ezetimibe/Simvastatin 10mg/80mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/180/003	Tablet	-Ezetimibe -Simvastatin
Ezetimibe/Simvastatin Accord 10mg/20mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/225/001	Tablet	-Ezetimibe -Simvastatin
Ezetimibe/Simvastatin Accord 10mg/40mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/225/002	Tablet	-Ezetimibe -Simvastatin
Ezetimibe/Simvastatin Accord 10mg/80mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/225/003	Tablet	-Ezetimibe -Simvastatin
Ezetimibe/Simvastatin Clonmel 10 mg/10 mg tablets	Clonmel Healthcare Ltd	PA0126/281/001	Tablet	-Ezetimibe -Simvastatin
Ezetimibe/Simvastatin Clonmel 10 mg/20 mg tablets	Clonmel Healthcare Ltd	PA0126/281/002	Tablet	-Ezetimibe -Simvastatin
Ezetimibe/Simvastatin Clonmel 10 mg/40 mg tablets	Clonmel Healthcare Ltd	PA0126/281/003	Tablet	-Ezetimibe -Simvastatin
Ezetimibe/Simvastatin Clonmel 10 mg/80 mg tablets	Clonmel Healthcare Ltd	PA0126/281/004	Tablet	-Ezetimibe -Simvastatin
Ezetimibe/Simvastatin Krka 10 mg/10 mg tablets	KRKA, d.d., Novo mesto	PA1347/067/001	Tablet	-Ezetimibe -Simvastatin
Ezetimibe/Simvastatin Krka 10 mg/20 mg tablets	KRKA, d.d., Novo mesto	PA1347/067/002	Tablet	-Ezetimibe -Simvastatin
Ezetimibe/Simvastatin Krka 10 mg/40 mg tablets	KRKA, d.d., Novo mesto	PA1347/067/003	Tablet	-Ezetimibe -Simvastatin
Ezetimibe/Simvastatin Teva Pharma 10 mg/20 mg tablets	Teva B.V.	PA1986/067/001	Tablet	-Ezetimibe -Simvastatin
Ezetimibe/Simvastatin Teva Pharma 10 mg/40 mg tablets	Teva B.V.	PA1986/067/002	Tablet	-Ezetimibe -Simvastatin
Ezetimibe/Simvastatin Teva Pharma 10 mg/80 mg tablets	Teva B.V.	PA1986/067/003	Tablet	-Ezetimibe -Simvastatin
Ezetrol 10 mg tablets	Organon Pharma (Ireland) Limited	PA23198/023/001	Tablet	-Ezetimibe
Ezetrol 10 mg tablets	PCO Manufacturing Ltd.	PPA0465/227/001	Tablet	-Ezetimibe
Ezetrol 10 mg tablets	IMED Healthcare Ltd.	PPA1463/187/001	Tablet	-Ezetimibe
Fabrazyme	Genzyme Europe B.V.	EU/1/01/188/001-002	Powder for concentrate for solution for infusion	-Protein c agalsidase beta (recombinant human-a-galactoside a)
Fabrazyme	Genzyme Europe B.V.	EU/1/01/188/001-003	Powder for concentrate for solution for infusion	-Agalsidase Beta

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Fabrazyme	Genzyme Europe B.V.	EU/1/01/188/003	Powder for concentrate for solution for infusion	-Protein c agalsidase beta (recombinant human-a-galactoside a)
Fabrazyme	Genzyme Europe B.V.	EU/1/01/188/004-006	Powder for concentrate for solution for infusion	-Protein c agalsidase beta (recombinant human-a-galactoside a)
Famciclovir 500 mg Film-Coated Tablets	Medinutrix Ltd.	PA2030/001/001	Film-coated tablet	-Famciclovir
Famciclovir Teva 250 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/025/002	Film-coated tablet	-Famciclovir
Famotidine Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/344/001	Film-coated tablet	-Famotidine
Famotidine Clonmel 40 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/344/002	Film-coated tablet	-Famotidine
Fampridine Accord	Accord Healthcare S.L.U.	EU/1/20/1477/001-002	Prolonged-release tablet	-Fampridine
Fampridine Rowa 10 mg prolonged-release tablets	Rowa Pharmaceuticals Limited	PA0074/087/001	Prolonged-release tablet	-Fampridine
Fampyra	Biogen Netherlands B.V.	EU/1/11/699/001-002	Prolonged-release tablet	-Fampridine (4-aminopyridine)
Famvir 125 mg film-coated tablets	Phoenix Labs	PA1113/018/001	Film-coated tablet	-Famciclovir
Famvir 250 mg film-coated tablets	Phoenix Labs	PA1113/018/002	Film-coated tablet	-Famciclovir
Famvir 250 mg Film-Coated Tablets	IMED Healthcare Ltd.	PPA1463/166/001	Film-coated tablet	-Famciclovir
Famvir 250 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/212/001	Film-coated tablet	-Famciclovir
Famvir 500 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/212/002	Film-coated tablet	-Famciclovir
Famvir 500 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/166/002	Film-coated tablet	-Famciclovir
Famvir 500 mg film-coated tablets	Phoenix Labs	PA1113/018/003	Film-coated tablet	-Famciclovir
Fanhdi 1000 IU powder and solvent for solution for injection	Instituto Grifols S.A.	PA0849/001/003	Powder and solvent for solution for injection	-Human coagulation factor viii
Fanhdi 250 IU powder and solvent for solution for injection	Instituto Grifols S.A.	PA0849/001/001	Powder and solvent for solution for injection	-Human coagulation factor viii
Fanhdi 500 IU powder and solvent for solution for injection	Instituto Grifols S.A.	PA0849/001/002	Powder and solvent for solution for injection	-Human coagulation factor viii
Fareston	Orion Corporation	EU/1/96/004/001	Tablet	-Toremifene citrate
Fareston	Orion Corporation	EU/1/96/004/002	Tablet	-Toremifene
Farydak	zr pharma& GmbH	EU/1/15/1023/001-003	Capsule, hard	-Panobinostat
Farydak	zr pharma& GmbH	EU/1/15/1023/004-006	Capsule, hard	-Panobinostat
Farydak	zr pharma& GmbH	EU/1/15/1023/007-009	Capsule, hard	-Panobinostat
Fasenra	AstraZeneca AB	EU/1/17/1252/001-002	Solution for injection in pre-filled syringe	-Benralizumab
Faslodex 250 mg Solution for injection	AstraZeneca AB	EU/1/03/269/001-002	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	-Ketoprofen
Fastum 2.5% w/w Gel	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/025/001	Gel	-Ketoprofen

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Fasturtec	Sanofi Winthrop Industrie	EU/1/00/170/001-002	Powder and solvent for concentrate for solution for infusion	-Rasburicase
Faverin 100 mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/031/002	Film-coated tablet	-Fluvoxamine maleate
Faverin 50 mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/031/001	Film-coated tablet	-Fluvoxamine maleate
Febuxostat Accord 120mg Film Coated Tablet	Accord Healthcare Ireland Ltd.	PA2315/023/002	Film-coated tablet	-Febuxostat
Febuxostat Accord 80mg Film Coated Tablet	Accord Healthcare Ireland Ltd.	PA2315/023/001	Film-coated tablet	-Febuxostat
Febuxostat Clonmel 120 mg Film-coated tablets	Clonmel Healthcare Ltd	PA0126/295/002	Film-coated tablet	-Febuxostat
Febuxostat Clonmel 80 mg Film-coated tablets	Clonmel Healthcare Ltd	PA0126/295/001	Film-coated tablet	-Febuxostat
Febuxostat Krka	KRKA, d.d., Novo mesto	EU/1/18/1347/001-004	Film-coated tablet	-Febuxostat
Febuxostat Krka	KRKA, d.d., Novo mesto	EU/1/18/1347/005-008	Film-coated tablet	-Febuxostat
Febuxostat Mylan	Mylan Pharmaceuticals Limited	EU/1/17/1194/001-008	Film-coated tablet	-Febuxostat
Febuxostat Mylan	Mylan Pharmaceuticals Limited	EU/1/17/1194/009-016	Film-coated tablet	-Febuxostat
Febuxostat Pinewood 120 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/160/002	Film-coated tablet	-Febuxostat
Febuxostat Pinewood 80 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/160/001	Film-coated tablet	-Febuxostat
Febuxostat Rowa 120 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/085/002	Film-coated tablet	-Febuxostat
Febuxostat Rowa 80 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/085/001	Film-coated tablet	-Febuxostat
Febuxostat Rowex 120 mg Film-coated Tablets	Rowex Ltd	PA0711/273/002	Film-coated tablet	-Febuxostat
Febuxostat Rowex 80 mg Film-coated Tablets	Rowex Ltd	PA0711/273/001	Film-coated tablet	-Febuxostat
Febuxostat Tillomed 120 mg film-coated tablets	Laboratorios Tillomed Spain, S.L.U.	PA2321/004/002	Film-coated tablet	-Febuxostat
Febuxostat Tillomed 80 mg film-coated tablets	Laboratorios Tillomed Spain, S.L.U.	PA2321/004/001	Film-coated tablet	-Febuxostat
Fefol Spansule 150 mg/0.5 mg Modified Release Capsules	Intapharm Labs Ltd	PA23101/001/001	Modified-release capsule, hard	-Dried ferrous sulphate -Folic acid
FEIBA 50 U/ml powder and solvent for solution for infusion	Baxalta Innovations GmbH	PA2004/001/002	Powder and solvent for solution for infusion	-Feiba
Feldene 5mg/g Gel	Pfizer Healthcare Ireland	PA0822/194/003	Gel	-Piroxicam
Femara 2.5 mg film-coated tablets	Novartis Ireland Limited	PA0896/012/001	Film-coated tablet	-Letrozole
Femara 2.5 mg film-coated tablets	Originalis B.V.	PPA2306/001/001	Film-coated tablet	-Letrozole
Fematab 1mg film-coated tablet	Mylan IRE Healthcare Limited	PA2010/011/001	Film-coated tablet	-Estradiol hemihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Fematab 2mg Film-coated tablet	Mylan IRE Healthcare Limited	PA2010/011/002	Film-coated tablet	-Estradiol hemihydrate
Femoston 1/10mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/012/001	Film-coated tablet	-Estradiol hemihydrate -Dydrogesterone
Femoston 2/10mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/012/002	Film-coated tablet	-Estradiol hemihydrate -Dydrogesterone
Femoston-conti 0.5 mg/2.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/464/002	Film-coated tablet	-Estradiol -Dydrogesterone
Femoston-conti 0.5mg/2.5mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/012/003	Film-coated tablet	-Estradiol -Dydrogesterone
Femoston-conti 1 mg/5 mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/012/004	Film-coated tablet	-Estradiol -Dydrogesterone
Femoston-conti 1 mg/5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/464/001	Film-coated tablet	-Dydrogesterone -Estradiol
Femoston-conti 1 mg/5 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/189/001	Film-coated tablet	-Estradiol -Dydrogesterone
FENDRIX	GlaxoSmithKline Biologicals S.A.	EU/1/04/0299/001-003	Suspension for injectio	-Hepatitis b vaccine
Penopine 100mg/5ml Oral Suspension	Pinewood Laboratories Ltd	PA0281/088/004	Oral suspension	-Ibuprofen
Penopine 200 mg/5 ml Oral Suspension	Pinewood Laboratories Ltd	PA0281/088/005	Oral suspension	-Ibuprofen ph. eur.
Penopine for Children Six Plus Strawberry 200mg/5ml Oral Suspension	Pinewood Laboratories Ltd	PA0281/088/006	Oral suspension	-Ibuprofen
Fentadur 100 micrograms/hour Transdermal Patch	Lavipharm S.A.	PA1676/002/004	Transdermal patch	-Fentanyl
Fentadur 12 micrograms/hour transdermal patch	Lavipharm S.A.	PA1676/002/005	Transdermal patch	-Fentanyl
Fentadur 25 micrograms/hour Transdermal Patch	Lavipharm S.A.	PA1676/002/001	Transdermal patch	-Fentanyl
Fentadur 50 micrograms/hour Transdermal Patch	Lavipharm S.A.	PA1676/002/002	Transdermal patch	-Fentanyl
Fentadur 75 micrograms/hour Transdermal Patch	Lavipharm S.A.	PA1676/002/003	Transdermal patch	-Fentanyl
Fental Matrix 100 micrograms/hour transdermal patch	Rowex Ltd	PA0711/146/004	Transdermal patch	-Fentanyl
Fental Matrix 25 micrograms/hour transdermal patch	Rowex Ltd	PA0711/146/001	Transdermal patch	-Fentanyl
Fental Matrix 50 micrograms/hour transdermal patch	Rowex Ltd	PA0711/146/002	Transdermal patch	-Fentanyl
Fental Matrix 75 micrograms/hour transdermal patch	Rowex Ltd	PA0711/146/003	Transdermal patch	-Fentanyl
Fentanyl 100 micrograms in 2 ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/122/001	Solution for injection	-FENTANYL CITRATE
Fentanyl 50 micrograms/ml solution for injection	AS Kalceks	PA2165/011/001	Solution for injection	-Fentanyl
Fentanyl 500 micrograms in 10 ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/122/002	Solution for injection	-FENTANYL CITRATE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Feraccru	Norgine B.V.	EU/1/15/1075/001	Capsule, hard	-Ferric maltol
Ferinject 50 mg iron/mL dispersion for injection/infusion	Vifor France	PA0949/004/001	Dispersion for injection/infusion	-IRON CARBOXYMALTOSE
Ferric carboxymaltose 50 mg iron/ml solution for injection/infusion	Rowex Ltd	PA0711/315/001	Solution for injection/infusion	-Ferric carboxymaltose
FERRIPROX	Chiesi Farmaceutici S.p.A.	EU/1/99/108/001	Film-coated tablet	-Deferiprone
Ferriprox	Chiesi Farmaceutici S.p.A.	EU/1/99/108/002-003	Oral solution	-Deferiprone
Ferriprox	Chiesi Farmaceutici S.p.A.	EU/1/99/108/004-006	Film-coated tablet	-Deferiprone
Ferrograd 325mg Prolonged release Tablets	Teofarma S.R.L.	PA1235/001/001	Prolonged-release tablet	-Ferrous sulphate
Ferrograd C 325mg/500mg Prolonged release Tablets	Teofarma S.R.L.	PA1235/002/001	Prolonged-release tablet	-Ferrous sulfate -Sodium ascorbate
Ferrograd Folic 325mg/0.35mg Prolonged release Tablets	Teofarma S.R.L.	PA1235/003/001	Prolonged-release tablet	-Ferrous sulfate -Folic acid
Fesoterodine Accord 4 mg prolonged-release tablets	Accord Healthcare Ireland Ltd.	PA2315/243/002	Prolonged-release tablet	-Fesoterodine fumarate
Fesoterodine Accord 8 mg prolonged-release tablets	Accord Healthcare Ireland Ltd.	PA2315/243/001	Prolonged-release tablet	-Fesoterodine fumarate
Fesoterodine Aristo 4 mg prolonged-release tablets	Aristo Pharma GmbH	PA1983/007/001	Prolonged-release tablet	-Fesoterodine fumarate
Fesoterodine Aristo 8 mg prolonged-release tablets	Aristo Pharma GmbH	PA1983/007/002	Prolonged-release tablet	-Fesoterodine fumarate
Fesoterodine Clonmel 4 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/335/001	Prolonged-release tablet	-Fesoterodine fumarate
Fesoterodine Clonmel 8 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/335/002	Prolonged-release tablet	-Fesoterodine fumarate
Fesoterodine Doc 4 mg prolonged-release tablets	DOC Generici S.r.l.	PA2244/002/001	Prolonged-release tablet	-Fesoterodine fumarate
Fesoterodine Doc 8 mg prolonged-release tablets	DOC Generici S.r.l.	PA2244/002/002	Prolonged-release tablet	-Fesoterodine fumarate
Fesoterodine Pinewood 4 mg prolonged-release tablets	Pinewood Laboratories Ltd	PA0281/215/001	Prolonged-release tablet	-Fesoterodine fumarate
Fesoterodine Pinewood 8 mg prolonged-release tablets	Pinewood Laboratories Ltd	PA0281/215/002	Prolonged-release tablet	-Fesoterodine fumarate
Fesoterodine Rowa 4 mg prolonged-release tablets	Rowa Pharmaceuticals Limited	PA0074/091/001	Prolonged-release tablet	-Fesoterodine fumarate
Fesoterodine Rowa 8 mg prolonged-release tablets	Rowa Pharmaceuticals Limited	PA0074/091/002	Prolonged-release tablet	-Fesoterodine fumarate
Fetcroja	Shionogi B.V.	EU/1/20/1434/001	Powder for concentrate for solution for infusion	-Cefiderocol Sulfate Tosilate
Fexeric	Akebia Europe Limited	EU/1/15/1039/001	Film-coated tablet	-Ferric citrate coordination complex

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Fexo Allergy Relief 120 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/096/001	Film-coated tablet	-Fexofenadine hydrochloride
Fexofast 180 mg Film-coated Tablets	Cipla Europe NV	PA1963/014/002	Film-coated tablet	-Fexofenadine hydrochloride
Fexofenadine Hydrochloride 120 mg Film-coated tablets	Azure Pharmaceuticals Ltd	PA22871/004/002	Film-coated tablet	-Fexofenadine hydrochloride
Fexofenadine hydrochloride 120 mg Film-coated tablets	Chanelle Medical Unlimited Company	PA0688/017/001	Film-coated tablet	-Fexofenadine hydrochloride
Fexofenadine hydrochloride 180 mg Film-coated Tablets	Chanelle Medical Unlimited Company	PA0688/017/002	Film-coated tablet	-Fexofenadine hydrochloride
Fiasp	Novo Nordisk A/S	EU/1/16/1160/001-011	Solution for injection	-Insulin aspart
Fiasp	Novo Nordisk A/S	EU/1/16/1160/001-013	Solution for injection	-Insulin aspart
Fibrovein 0.2% Solution for Injection	STD Pharmaceutical (Ireland) Limited	PA22778/002/001	Solution for injection	-Sodium tetradecyl sulfate
Fibrovein 0.5% Solution for Injection	STD Pharmaceutical (Ireland) Limited	PA22778/002/002	Solution for injection	-Sodium tetradecyl sulfate
Fibrovein 1% Solution for Injection	STD Pharmaceutical (Ireland) Limited	PA22778/002/003	Solution for injection	-Sodium tetradecyl sulfate
Fibrovein 3% Solution for Injection	STD Pharmaceutical (Ireland) Limited	PA22778/002/004	Solution for injection	-Sodium tetradecyl sulfate
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	-Human fibrinogen
Filgrastim HEXAL	Hexal AG	EU/1/08/496/1-4	Solution for injection in pre-filled syringe	-Ep2006 (recombinant human granulocyte-colony stimulating factor)
Filgrastim Hexal	Hexal AG	EU/1/08/496/5-8	Solution for injection in pre-filled syringe	-Ep2006 (recombinant human granulocyte-colony stimulating factor)
Filsuvez	Amryt Pharmaceuticals DAC,	EU/1/22/1652/001-002	Gel	-BETULAE CORTEX DRY EXTRACT (5-10 : 1); EXTRACTION SOLVENT: N-HEPTANE 95% (W/W)
Finasteride 1mg film-coated tablets	Careforsons Ireland Limited	PA22753/002/001	Film-coated tablet	-Finasteride
Finasteride 5 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/089/001	Film-coated tablet	-Finasteride
Fingolimod 0.5 mg hard capsules	Rowa Pharmaceuticals Limited	PA0074/086/001	Capsule, hard	-Fingolimod
Fingolimod Accord	Accord Healthcare S.L.U.	EU/1/20/1450/001-006	Capsule, hard	-FINGOLIMOD HYDROCHLORIDE
Fingolimod Bluefish 0.5 mg hard capsules	Bluefish Pharmaceuticals AB	PA1436/035/001	Capsule, hard	-FINGOLIMOD HYDROCHLORIDE
Fingolimod Clonmel 0.5 mg hard capsules	Clonmel Healthcare Ltd	PA0126/319/001	Capsule, hard	-Fingolimod
Fingolimod Krka 0.5 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/101/001	Capsule, hard	-FINGOLIMOD HYDROCHLORIDE
Fingolimod MSN 0.5 mg hard capsules	MSN Labs Europe Limited	PA23250/007/001	Capsule, hard	-Fingolimod
Fingolimod Mylan	Mylan IRE Healthcare Limited	EU/1/21/1573/001-024	Capsule, hard	-FINGOLIMOD HYDROCHLORIDE
Fingolimod Pharmathen 0.5 mg hard capsules	Pharmathen S.A.	PA1368/019/001	Capsule, hard	-Fingolimod
Fingolimod Teva 0.5 mg hard capsules	Norton Waterford	PA0436/047/001	Capsule, hard	-Fingolimod
Fingolimod Tillomed 0.5 mg hard capsules	Tillomed Pharma GmbH	PA23169/001/001	Capsule, hard	-Fingolimod

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Finlee	Novartis Europharm Limited	EU/1/23/1767/001-002	Dispersible tablet	-Dabrafenib Mesylate
Finomel Emulsion for Infusion	Baxter Holding B.V.	PA2299/044/002	Emulsion for infusion	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Finomel Peri Emulsion for Infusion	Baxter Holding B.V.	PA2299/044/001	Emulsion for infusion	-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
Finovare 20 mg/g Cream	Citrine Healthcare Limited	PA23214/001/001	Cream	-Fusidic acid
Fintepla	UCB Pharma S.A.	EU/1/20/1491/001-004	Oral solution	-Fenfluramine hydrochloride
Fintrid 5 mg film-coated tablets	Aurobindo Pharma (Malta) Limited	PA1445/019/001	Film-coated tablet	-Finasteride
Firazyr	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/08/461/001-002	Solution for injection in pre-filled syringe	-Icatibant
Firdapse	SERB S.A.,	EU/1/09/601/001	Tablet	-3,4-diaminopyridine phosphate
Firmagon	Ferring Pharmaceuticals A/S	EU/1/08/504/001	Powder and solvent for solution for injection	-Degarelix (as acetate)
Firmagon	Ferring Pharmaceuticals A/S	EU/1/08/504/002	Powder and solvent for solution for injection	-Degarelix (as acetate)
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	-Timolol -Latanoprost
Flagyl 400mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/100/008	Film-coated tablet	-Metronidazole
Flagyl-S 200mg/5ml Oral Suspension	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/100/001	Oral suspension	-Metronidazole
Flebogamma	Instituto Grifols S.A.	EU/1/07/404/1-5	Solution for infusion	-Human normal immunoglobulin
Flebogamma DIF	Instituto Grifols S.A.	EU/1/07/404/006-008	Solution for infusion	-Human normal immunoglobulin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Flecainide 100mg Tablets	Teva B.V.	PA1986/050/002	Tablet	-Flecainide acetate
Flecainide 50mg Tablets	Teva B.V.	PA1986/050/001	Tablet	-Flecainide acetate
Flector Tissugel 140 mg medicated plaster	IBSA Farmaceutici Italia S.r.l	PA1104/004/001	Medicated plaster	-Diclofenac epolamine
Flexbumin 200 g/l solution for infusion	Baxalta Innovations GmbH	PA2004/002/001	Solution for infusion	-Human plasma protein
Flixabi	Samsung Bioepis NL B.V.	EU/1/16/1106/001	Powder for concentrate for solution for infusion	-Infliximab
Flixonase Allergy Relief 50 micrograms per dose Nasal Spray	Haleon Ireland Limited	PA0678/095/001	Nasal spray, suspension	-Fluticasone propionate
Flixotide Diskus 100 micrograms, Inhalation Powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/044/010	Inhalation powder, pre-dispensed	-Fluticasone propionate
Flixotide Diskus 250 micrograms, Inhalation Powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/044/011	Inhalation powder, pre-dispensed	-Fluticasone propionate
Flixotide Diskus 50 micrograms, Inhalation Powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/044/009	Inhalation powder, pre-dispensed	-Fluticasone propionate
Flixotide Diskus 500 micrograms, Inhalation Powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/044/012	Inhalation powder, pre-dispensed	-Fluticasone propionate
Flixotide Evohaler	GlaxoSmithKline (Ireland) Limited	PA1077/044/014	Pressurised inhalation, suspension	-Fluticasone propionate
Flixotide Evohaler 125 micrograms per metered dose pressurised inhalation, suspension	PCO Manufacturing Ltd.	PPA0465/073/001	Pressurised inhalation, suspension	-FLUTICASONE PROPIONATE
Flixotide Evohaler 125 micrograms per metered dose Pressurised Inhalation, Suspension	IMED Healthcare Ltd.	PPA1463/156/001	Pressurised inhalation, suspension	-Fluticasone propionate
Flixotide Evohaler 250 micrograms per metered dose Pressurised Inhalation, Suspension	IMED Healthcare Ltd.	PPA1463/156/002	Pressurised inhalation, suspension	-Fluticasone propionate
Flixotide Evohaler 250 micrograms per metered dose Pressurised Inhalation, Suspension	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/019/002	Pressurised inhalation, suspension	-FLUTICASONE PROPIONATE
Flixotide Evohaler 250 micrograms per metered dose pressurised inhalation, suspension	PCO Manufacturing Ltd.	PPA0465/073/002	Pressurised inhalation, suspension	-FLUTICASONE PROPIONATE
Flixotide Evohaler 250 micrograms per metered dose Pressurised Inhalation, Suspension	GlaxoSmithKline (Ireland) Limited	PA1077/044/015	Pressurised inhalation, suspension	-Fluticasone propionate
Flixotide Evohaler 50 micrograms per metered dose pressurised inhalation, suspension	PCO Manufacturing Ltd.	PPA0465/073/005	Pressurised inhalation, suspension	-FLUTICASONE PROPIONATE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Flixotide Evohaler 50 micrograms per metered dose, Pressurised Inhalation Suspension	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/019/001	Pressurised inhalation, suspension	-Fluticasone propionate
Flixotide Evohaler 50 micrograms per metered dose, Pressurised Inhalation Suspension	IMED Healthcare Ltd.	PPA1463/156/003	Pressurised inhalation, suspension	-Fluticasone propionate
Flixotide Evohaler 50 micrograms per metered dose, Pressurised Inhalation Suspension	GlaxoSmithKline (Ireland) Limited	PA1077/044/013	Pressurised inhalation, suspension	-Fluticasone propionate
Flolan 0.5 mg powder and solvent for solution for infusion	GlaxoSmithKline (Ireland) Limited	PA1077/058/002	Powder and solvent for solution for infusion	-Epoprostenol
Flolan 1.5 mg powder and solvent for solution for infusion	GlaxoSmithKline (Ireland) Limited	PA1077/058/001	Powder and solvent for solution for infusion	-Epoprostenol
Floxapen 1000 mg powder for solution for injection or infusion	Teva B.V.	PA1986/111/003	Powder for solution for injection/infusion	-Flucloxacillin
Floxapen 2000 mg powder for solution for injection or infusion	Teva B.V.	PA1986/111/004	Powder for solution for injection/infusion	-Flucloxacillin
Floxapen 250mg Powder for solution for Injection or Infusion	Teva B.V.	PA1986/111/001	Powder for solution for injection/infusion	-Flucloxacillin
Floxapen 500 mg Powder for Solution for Injection or Infusion	Teva B.V.	PA1986/111/002	Powder for solution for injection/infusion	-Flucloxacillin
Fluad Tetra	Seqirus Netherlands B.V.	EU/1/20/1433/001-004	Suspension for injection in pre-filled syringe	-A/(H1N1)-LIKE VIRUS ANTIGEN -A/(H3N2)-LIKE VIRUS ANTIGEN -B (Victoria Lineage) - Like Virus Antigen -B (Yamagata Lineage)-Like Virus Antigen
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	-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)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Flucelvax Tetra	Seqirus Netherlands B.V.	EU/1/18/1326/001	Suspension for injection in pre-filled syringe	-A/(H3N2)-LIKE VIRUS ANTIGEN -A/(H1N1)-LIKE VIRUS ANTIGEN -INFLUENZA B VIRUS INACTIVATED HAEMAGGLUTININ
Flucillin – Flucloxacillin Capsules 250 mg	Pinewood Laboratories Ltd	PA0281/031/004	Capsule, hard	-Flucloxacillin
Flucillin – Flucloxacillin capsules 500 mg	Pinewood Laboratories Ltd	PA0281/031/005	Capsule, hard	-Flucloxacillin
Flucloxacillin 1000 mg Film-coated Tablets	Azure Pharmaceuticals Ltd	PA22871/026/002	Film-coated tablet	-FLUCLOXACILLIN SODIUM
Flucloxacillin 1000 mg powder for solution for injection or infusion	Esteve Pharmaceuticals GmbH	PA22709/001/002	Powder for solution for injection/infusion	-FLUCLOXACILLIN SODIUM
Flucloxacillin 1000 mg Powder for solution for injection/infusion	Ibigen Srl	PA1862/003/003	Powder for solution for injection/infusion	-FLUCLOXACILLIN SODIUM
Flucloxacillin 1000 mg powder for solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/069/002	Powder for solution for injection/infusion	-FLUCLOXACILLIN SODIUM
Flucloxacillin 125 mg/5 ml Powder for Oral Solution, Sugar Free	Brillpharma (Ireland) Limited	PA22749/024/001	Powder for oral solution	-FLUCLOXACILLIN SODIUM
Flucloxacillin 125mg/5ml Oral Solution	Athlone Pharmaceuticals Limited	PA1418/016/003	Powder for oral solution	-FLUCLOXACILLIN SODIUM
Flucloxacillin 125mg/5ml Oral Solution BP	Athlone Pharmaceuticals Limited	PA1418/015/001	Powder for oral solution	-FLUCLOXACILLIN SODIUM
Flucloxacillin 1g Powder for Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/228/003	Powder for solution for injection/infusion	-Flucloxacillin sodium monohydrate
Flucloxacillin 2000 mg powder for solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/069/003	Powder for solution for injection/infusion	-FLUCLOXACILLIN SODIUM
Flucloxacillin 2000 mg powder for solution for injection/infusion	Ibigen Srl	PA1862/003/004	Powder for solution for injection/infusion	-FLUCLOXACILLIN SODIUM
Flucloxacillin 250 mg Capsules	Athlone Pharmaceuticals Limited	PA1418/016/001	Capsule, hard	-Flucloxacillin
Flucloxacillin 250 mg Capsules	Athlone Laboratories Ltd	PA0298/016/001	Capsule, hard	-Flucloxacillin
Flucloxacillin 250 mg Powder for solution for injection/infusion	Ibigen Srl	PA1862/003/001	Powder for solution for injection/infusion	-FLUCLOXACILLIN SODIUM
Flucloxacillin 250 mg/5 ml Powder for Oral Solution, Sugar Free	Brillpharma (Ireland) Limited	PA22749/024/002	Powder for oral solution	-FLUCLOXACILLIN SODIUM
Flucloxacillin 250mg Powder for Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/228/001	Powder for solution for injection/infusion	-Flucloxacillin sodium monohydrate
Flucloxacillin 250mg/5ml Oral Solution	Athlone Pharmaceuticals Limited	PA1418/016/004	Oral solution	-Flucloxacillin
Flucloxacillin 500 mg capsules	Athlone Pharmaceuticals Limited	PA1418/016/002	Capsule, hard	-Flucloxacillin
Flucloxacillin 500 mg capsules	Athlone Laboratories Ltd	PA0298/016/002	Capsule, hard	-FLUCLOXACILLIN SODIUM
Flucloxacillin 500 mg film-coated tablets	Azure Pharmaceuticals Ltd	PA22871/026/001	Film-coated tablet	-FLUCLOXACILLIN SODIUM
Flucloxacillin 500 mg powder for solution for injection or infusion	Esteve Pharmaceuticals GmbH	PA22709/001/001	Powder for solution for injection/infusion	-FLUCLOXACILLIN SODIUM

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Flucloxacillin 500 mg Powder for solution for injection/infusion	Ibigen Srl	PA1862/003/002	Powder for solution for injection/infusion	-FLUCLOXACILLIN SODIUM
Flucloxacillin 500 mg powder for solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/069/001	Powder for solution for injection/infusion	-FLUCLOXACILLIN SODIUM
Flucloxacillin 500mg Powder for Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/228/002	Powder for solution for injection/infusion	-Flucloxacillin sodium monohydrate
Flucol 150 mg Hard capsules	Rowex Ltd	PA0711/057/003	Capsule, hard	-Fluconazole
Flucol 200 mg Hard capsules	Rowex Ltd	PA0711/057/004	Capsule, hard	-Fluconazole
Flucol 50 mg Hard capsules	Rowex Ltd	PA0711/057/001	Capsule, hard	-Fluconazole
Fluconazole 150 mg hard capsule	Accord Healthcare Ireland Ltd.	PA2315/090/002	Capsule, hard	-Fluconazole
Fluconazole 2 mg / mL Solution for infusion	Noridem Enterprises Limited	PA1122/006/001	Solution for infusion	-Fluconazole
Fluconazole 2 mg/ml solution for infusion	B. Braun Melsungen AG	PA0736/030/001	Solution for infusion	-Fluconazole
Fluconazole 2 mg/ml solution for infusion	Baxter Holding B.V.	PA2299/033/001	Solution for infusion	-Fluconazole
Fluconazole 200 mg hard capsule	Accord Healthcare Ireland Ltd.	PA2315/090/003	Capsule, hard	-Fluconazole
Fluconazole 2mg/ml Solution for Infusion, non-PVC bag	Baxter Holding B.V.	PA2299/033/002	Solution for infusion	-Fluconazole
Fluconazole 50 mg hard capsule	Accord Healthcare Ireland Ltd.	PA2315/090/001	Capsule, hard	-Fluconazole
Fludara 10 mg film-coated tablets	Genzyme Europe B.V.	PA0611/004/002	Film-coated tablet	-Fludarabine phosphate
Fludarabine Phosphate 25mg/ml Concentrate for Solution for Injection or Infusion	Accord Healthcare Ireland Ltd.	PA2315/035/001	Concentrate for solution for injection/infusion	-Fludarabine phosphate
Fludrocortisone acetate 0.1 mg tablets	Mylan IRE Healthcare Limited	PA2010/064/001	Tablet	-Fludrocortisone acetate
Fludrocortisone Acetate Renata 0.1 mg tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/007/001	Tablet	-Fludrocortisone acetate
Fluenz Tetra	AstraZeneca AB	EU/1/13/887/003-004	Nasal spray, suspension	-Influenza virus, type a, h1n1 -Influenza virus, type a, h3n2 -Influenza virus, type b (yamagata lineage) -Influenza virus, type b (victoria lineage)
Fluimucil 200 mg granules for oral solution	Zambon S.p.A.	PA1441/001/001	Granules for oral solution	-Acetylcysteine
Flumazenil 0.1 mg/ml solution for injection	Fresenius Kabi Deutschland GmbH	PA2059/037/001	Solution for injection	-Flumazenil
Fluorescein 100 mg/ml Solution for injection	Pharmargus Limited	PA2273/001/001	Solution for injection	-Fluorescein sodium
Fluorouracil 25 mg/ml Solution for Injection or Infusion	Pfizer Healthcare Ireland	PA0822/223/001	Solution for injection/infusion	-Fluorouracil sodium
Fluorouracil 50 mg/ml solution for injection or infusion	Accord Healthcare Ireland Ltd.	PA2315/091/001	Solution for injection/infusion	-Fluorouracil
Fluoxetine 20 mg/ 5 ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/010/001	Oral solution	-FLUOXETINE HYDROCHLORIDE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Fluoxetine 20mg Hard Capsules	Brillpharma (Ireland) Limited	PA22749/002/001	Capsule, hard	-Fluoxetine
Fluoxetine 60 mg Hard Capsules	Brillpharma (Ireland) Limited	PA22749/002/002	Capsule, hard	-Fluoxetine
Fluticasone propionate 50 micrograms/actuation, nasal spray, suspension	Haleon Ireland Limited	PA0678/118/001	Nasal spray, suspension	-Fluticasone propionate (micronised)
Flutiform 125 microgram/5 microgram per metered dose pressurised inhalation, suspension	IMED Healthcare Ltd.	PPA1463/138/002	Pressurised inhalation, suspension	-FLUTICASONE PROPIONATE -Formoterol fumarate
Flutiform 125 microgram/5 microgram per metered dose pressurised inhalation, suspension	Mundipharma Pharmaceuticals Limited	PA1688/013/002	Pressurised inhalation, suspension	-Fluticasone propionate -Formoterol fumarate dihydrate
Flutiform 250 microgram/10 microgram per metered dose pressurised inhalation, suspension	Mundipharma Pharmaceuticals Limited	PA1688/013/003	Pressurised inhalation, suspension	-Fluticasone propionate -Formoterol fumarate dihydrate
Flutiform 250 microgram/10 microgram per metered dose pressurised inhalation, suspension	IMED Healthcare Ltd.	PPA1463/138/001	Pressurised inhalation, suspension	-FLUTICASONE PROPIONATE -Formoterol fumarate
Flutiform 50 microgram/5 microgram per metered dose pressurised inhalation, suspension	Mundipharma Pharmaceuticals Limited	PA1688/013/001	Pressurised inhalation, suspension	-Fluticasone propionate -Formoterol fumarate dihydrate
Fluzac 20mg Capsules	Rowex Ltd	PA0711/110/001	Capsule, hard	-FLUOXETINE HYDROCHLORIDE
FML Liquifilm 0.1% w/v Sterile Eye Drops Suspension	AbbVie Limited	PA1824/008/001	Eye drops, suspension	-Fluorometholone
Foclivia	Seqirus S.r.l.	EU/1/09/577/1-4	Suspension for injectio	-A/vietnam/1194/2004 (h5n1) virus surface inactivated antigen
Folic Acid 5mg Tablets	Clonmel Healthcare Ltd	PA0126/057/001	Tablet	-Folic acid
Folinic acid (as calcium folinate) 10 mg/ml solution for injection/infusion	AS Kalceks	PA2165/024/001	Solution for injection/infusion	-Calcium folinate
Folinic acid (as calcium folinate) 10mg/ml solution for injection or infusion	Fresenius Kabi Deutschland GmbH	PA2059/001/001	Solution for injection/infusion	-Folinic acid
Folinic Acid (as Calcium Folate) 15mg Tablets	Pfizer Healthcare Ireland	PA0822/198/001	Tablet	-Folinic acid
Fomepizole SERB 5 mg/mL, concentrate for solution for infusion.	SERB S.A.,	PA20595/001/001	Concentrate for solution for infusion	-Fomepizole sulphate
Fomicyt 40mg/ml Powder for solution for infusion	InfectoPharm Arzneimittel und Consilium GmbH	PA1972/001/001	Powder for solution for infusion	-FOSFOMYCIN SODIUM

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Fondaparinux sodium
Fondaparinux sodium Aspen 10 mg/0.8 ml solution for injection, pre-filled syringe.	Aspen Pharma Trading Limited	PA1691/034/005	Solution for injection	-Fondaparinux sodium
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	-Fondaparinux sodium
Fondaparinux sodium Aspen 5 mg/0.4 ml solution for injection, pre-filled syringe.	Aspen Pharma Trading Limited	PA1691/034/003	Solution for injection	-Fondaparinux sodium
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	-Fondaparinux sodium
Formoterol 12 micrograms inhalation powder, hard capsule	Laboratorios LICONSA, S.A.	PA1239/001/001	Inhalation powder, hard capsule	-Formoterol fumarate
Forsteo	Eli Lilly Nederland B.V.	EU/1/03/247/01-2	Solution for injection	-Teriparatide
Fortacin	Recordati Ireland Limited	EU/1/13/381/001	Cutaneous spray, solution	-Lidocaine -Prilocaine
Fortum 1 g powder for solution for injection or infusion	Sandoz Pharmaceuticals d.d.	PA23311/001/002	Powder for solution for injection/infusion	-Ceftazidime
Fortum 2 g powder for solution for injection or infusion	Sandoz Pharmaceuticals d.d.	PA23311/001/003	Powder for solution for injection/infusion	-Ceftazidime
Fortum 500 mg powder for solution for injection	Sandoz Pharmaceuticals d.d.	PA23311/001/001	Powder for solution for injection	-Ceftazidime
Forxiga	AstraZeneca AB	EU/1/12/795/001-005	Film-coated tablet	-Dapagliflozin propanediol monohydrate equivalent to 5mg dapagliflozin
Forxiga	AstraZeneca AB	EU/1/12/795/006-010	Film-coated tablet	-Dapagliflozin propanediol monohydrate equivalent to 10mg dapagliflozin
FOSAMAX Once Weekly 70 mg tablets	Organon Pharma (Ireland) Limited	PA23198/003/001	Tablet	-Alendronic acid
Fosavance 70 mg/2800 IU tablets	N.V. Organon	EU/1/05/310/1-4	Tablet	-Vitamin d3 -Alendronic acid
Fosavance 70 mg/5600 IU tablets	N.V. Organon	EU/1/05/310/6-8	Tablet	-Vitamin d3 -Alendronic acid
Foscan	Biolitec Pharma Limited	EU/1/01/197/001	Solution for injection	-Temoporfin
Foscan	Biolitec Pharma Limited	EU/1/01/197/002	Solution for injection	-Temoporfin
Foscarnet sodium hexahydrate Tillomed 24 mg/ml solution for infusion	Tillomed Pharma GmbH	PA22720/009/001	Solution for infusion	-Foscarnet Sodium Hexahydrate
Fostair 100 microgram/6 microgram per actuation pressurised inhalation solution	Chiesi Farmaceutici S.p.A.	PA0584/008/001	Pressurised inhalation, solution	-Beclometasone dipropionate -Formoterol fumarate dihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Fostair 200 microgram/6 microgram per actuation pressurised inhalation solution	Chiesi Farmaceutici S.p.A.	PA0584/008/003	Pressurised inhalation, solution	-Beclometasone dipropionate -Formoterol fumarate dihydrate
Fostair Nexthaler 100 micrograms/6 micrograms per metered dose inhalation powder	Chiesi Farmaceutici S.p.A.	PA0584/008/002	Inhalation powder	-Beclometasone dipropionate -Formoterol fumarate dihydrate
Fostair Nexthaler 200 micrograms/12 micrograms per metered dose inhalation powder	Chiesi Farmaceutici S.p.A.	PA0584/008/005	Inhalation powder	-Beclometasone dipropionate -Formoterol fumarate dihydrate
Fostair Nexthaler 200 micrograms/6 micrograms per metered dose inhalation powder	Chiesi Farmaceutici S.p.A.	PA0584/008/004	Inhalation powder	-Beclometasone dipropionate -Formoterol fumarate dihydrate
Fosteop Once Weekly 70mg tablets	Viatrix Limited	PA23266/018/001	Tablet	-Alendronic acid
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	-Urofollitropin
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	-Urofollitropin
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	-Urofollitropin
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	-Urofollitropin
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	-Urofollitropin
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	-Urofollitropin
Fotivda	EUSA Pharma (Netherlands) B.V.	EU/1/17/1215/001	Capsule, hard	-Tivozanib
Fotivda	EUSA Pharma (Netherlands) B.V.	EU/1/17/1215/002	Capsule, hard	-Tivozanib
Foznol 1000 mg Chewable Tablets	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/002/004	Chewable tablet	-Lanthanum carbonate hydrate
Foznol 1000 mg Chewable Tablets	PCO Manufacturing Ltd.	PPA0465/495/001	Chewable tablet	-Lanthanum
Foznol 1000 mg Oral Powder	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/002/006	Oral powder	-Lanthanum carbonate hydrate
Foznol 250 mg Chewable Tablets	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/002/001	Chewable tablet	-Lanthanum carbonate hydrate
Foznol 500 mg Chewable Tablets	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/002/002	Chewable tablet	-Lanthanum carbonate hydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Foznol 750 mg Chewable Tablets	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/002/003	Chewable tablet	-Lanthanum carbonate hydrate
Foznol 750 mg Oral Powder	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/002/005	Oral powder	-Lanthanum carbonate hydrate
Freedo 0.03mg/3mg film-coated tablets	Rowex Ltd	PA0711/218/001	Film-coated tablet	-Drospirenone -Ethinylestradiol
Freedonel 0.02 mg/3 mg film-coated tablets	Rowex Ltd	PA0711/208/001	Film-coated tablet	-Ethinylestradiol -Drospirenone
Fresenius Propoven 2 % emulsion for injection or infusion, vial	Fresenius Kabi Deutschland GmbH	PA2059/017/003	Emulsion for injection/infusion	-Propofol
Frisium 10mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/043/001	Tablet	-Clobazam
Frovatriptan 2.5mg Film-coated Tablets	Chanelle Medical Unlimited Company	PA0688/027/001	Film-coated tablet	-Frovatriptan succinate monohydrate
FROVEX 2.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/009/001	Film-coated tablet	-FROVATRIPTAN
FROVEX 2.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/321/001	Film-coated tablet	-Frovatriptan succinate monohydrate
Frumil 40mg/5mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/101/002	Tablet	-Furosemide -AMILORIDE HYDROCHLORIDE
Fucibet 20 mg/g + 1 mg/g cream	Leo Laboratories Limited	PA0046/040/001	Cream	-Fusidic acid -Betamethasone
Fucibet Lipid 20 mg/g + 1 mg/g cream	PCO Manufacturing Ltd.	PPA0465/231/002	Cream	-Betamethasone -Fusidic acid
Fucibet Lipid 20mg/g + 1mg/g cream	IMED Healthcare Ltd.	PPA1463/197/001	Cream	-Fusidic acid -Betamethasone
Fucibet Lipid 20mg/g + 1mg/g cream	Leo Laboratories Limited	PA0046/040/002	Cream	-Fusidic acid -Betamethasone
Fucidin 20 mg/g cream	Leo Laboratories Limited	PA0046/004/012	Cream	-Fusidic acid hemihydrate
Fucidin 20 mg/g Cream	IMED Healthcare Ltd.	PPA1463/083/001	Cream	-Fusidic acid
Fucidin 20 mg/g ointment	Leo Laboratories Limited	PA0046/004/008	Ointment	-Sodium fusidate
Fucidin 250mg Tablets	Leo Laboratories Limited	PA0046/004/014	Tablet	-Sodium fusidate
Fucidin H 20mg/g + 10mg/g Cream	Leo Laboratories Limited	PA0046/005/005	Cream	-Fusidic acid anhydrous -HYDROCORTISONE ACETATE
Fucithalmic 10mg/g Viscous Eye Drops, suspension	Amdipharm Limited	PA1142/016/001	Eye drops, suspension	-Fusidic acid anhydrous
Fulphila	Biosimilar Collaborations Ireland Limited	EU/1/18/1329/001-002	Solution for injection in pre-filled syringe	-Pegfilgrastim
Fulvestrant 250 mg Solution for injection in pre-filled syringe	Accord Healthcare Ireland Ltd.	PA2315/046/001	Solution for injection in pre-filled syringe	-Fulvestrant
Fulvestrant 250 mg solution for injection in pre-filled syringe	Reddy Holding GmbH	PA23092/001/001	Solution for injection in pre-filled syringe	-Fulvestrant
Fulvestrant EVER Pharma 250 mg solution for injection in pre-filled syringe	EVER Valinject GmbH	PA1774/006/001	Solution for injection in pre-filled syringe	-Fulvestrant

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Fulvestrant Mylan 250 mg solution for injection in pre-filled syringe	Mylan Pharmaceuticals Limited	EU/1/17/1253/001-002	Solution for injection in pre-filled syringe	-Fulvestrant
Fulvestrant Rowex 250 mg/5 ml solution for injection in pre-filled syringe	Rowex Ltd	PA0711/245/001	Solution for injection in pre-filled syringe	-Fulvestrant
Fulvestrant Teva 250 mg Solution for Injection in Pre-filled Syringe	Teva B.V.	PA1986/011/001	Solution for injection in pre-filled syringe	-Fulvestrant
Fungasil 250mg Tablets	Clonmel Healthcare Ltd	PA0126/141/001	Tablet	-Terbinafine
Fungizone 50 mg Powder for sterile concentrate	CHEPLAPHARM Arzneimittel GmbH	PA2239/004/001	Powder for concentrate for solution for infusion	-Amphotericin
Furosemide 10 mg/ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/011/003	Oral solution	-Furosemide
Furosemide 10 mg/ml solution for injection	hameln pharma gmbh	PA2237/002/001	Solution for injection	-Furosemide
Furosemide 10 mg/ml Solution for Injection	Baxter Holding B.V.	PA2299/036/001	Solution for injection	-Furosemide
Furosemide 10 mg/ml Solution for Injection or Infusion	Accord Healthcare Ireland Ltd.	PA2315/163/001	Solution for injection/infusion	-Furosemide
Furosemide 20 mg Tablets	Clonmel Healthcare Ltd	PA0126/008/001	Tablet	-Furosemide
Furosemide 20 mg/2 ml solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/038/001	Solution for injection	-Furosemide
Furosemide 20mg in 2ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/059/004	Solution for injection	-Furosemide
Furosemide 250mg in 25ml Solution for Injection/Infusion	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/059/006	Solution for injection/infusion	-Furosemide
Furosemide 4 mg/ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/011/001	Oral solution	-Furosemide
Furosemide 40 mg Tablets	Clonmel Healthcare Ltd	PA0126/008/002	Tablet	-Furosemide
Furosemide 50mg in 5ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/059/005	Solution for injection	-Furosemide
Furosemide 8 mg/ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/011/002	Oral solution	-Furosemide
Furosemide Bristol 20 mg Tablets	Brillpharma (Ireland) Limited	PA22749/001/001	Tablet	-Furosemide
Furosemide Bristol 40 mg Tablets	Brillpharma (Ireland) Limited	PA22749/001/002	Tablet	-Furosemide
Furosemide Pinewood 20 mg Tablets	Pinewood Laboratories Ltd	PA0281/263/001	Tablet	-Furosemide
Furosemide Pinewood 40 mg Tablets	Pinewood Laboratories Ltd	PA0281/263/002	Tablet	-Furosemide
Fuzeon	Roche Registration GmbH	EU/1/03/252/001	Powder and solvent for solution for injection	-Enfuvirtide
Fybogel Citrus 3.5 g Granules	Reckitt Benckiser Ireland Ltd	PA0979/009/001	Granules	-Ispaghula husks
Fybogel Mebeverine Granules for Oral Suspension Ispaghula Husk 3.5g Mebeverine Hydrochloride 135mg	Reckitt Benckiser Ireland Ltd	PA0979/010/001	Granules for oral suspension	-Mebeverine hydrochloride -Ispaghula husks

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Fycompa	Eisai GmbH	EU/1/12/776/001	Film-coated tablet	-Perampanel
Fycompa	Eisai GmbH	EU/1/12/776/002-004	Film-coated tablet	-Perampanel
Fycompa	Eisai GmbH	EU/1/12/776/005-007	Film-coated tablet	-Perampanel
Fycompa	Eisai GmbH	EU/1/12/776/008-010	Film-coated tablet	-Perampanel
Fycompa	Eisai GmbH	EU/1/12/776/011-013	Film-coated tablet	-Perampanel
Fycompa	Eisai GmbH	EU/1/12/776/014-016	Film-coated tablet	-Perampanel
Fycompa	Eisai GmbH	EU/1/12/776/024	Oral suspension	-Perampanel
Fydrane 0.2 mg/ml + 3.1 mg/ml + 10 mg/ml, solution for injection	Laboratoires Thea	PA1107/012/001	Solution for injection	-Tropicamide -Phenylephrine hydrochloride -Lidocaine Hydrochloride Monohydrate
Gabapentin 100 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/164/003	Capsule, hard	-Gabapentin
Gabapentin 300 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/164/004	Capsule, hard	-Gabapentin
Gabapentin 400 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/164/005	Capsule, hard	-Gabapentin
Gabapentin 600 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/164/001	Film-coated tablet	-Gabapentin
Gabapentin 800 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/164/002	Film-coated tablet	-Gabapentin
Gabapentin Auro 300 mg hard capsules	Aurobindo Pharma (Malta) Limited	PA1445/026/002	Capsule, hard	-Gabapentin
Gabapentin Auro 400 mg hard capsules	Aurobindo Pharma (Malta) Limited	PA1445/026/003	Capsule, hard	-Gabapentin
Gabapentin Auro 100 mg hard capsules	Aurobindo Pharma (Malta) Limited	PA1445/026/001	Capsule, hard	-Gabapentin
Gabapentin Aurobindo 100 mg capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/025/001	Capsule, hard	-Gabapentin
Gabapentin Aurobindo 300 mg capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/025/002	Capsule, hard	-Gabapentin
Gabapentin Aurobindo 400 mg capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/025/003	Capsule, hard	-Gabapentin
Gabapentin Rosemont 50mg/ml Oral Solution	Taw Pharma (Ireland) Limited	PA23081/010/001	Oral solution	-Gabapentin
Gabin 100 mg capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/020/001	Capsule, hard	-Gabapentin
Gabin 300 mg capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/020/002	Capsule, hard	-Gabapentin
Gabin 400 mg capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/020/003	Capsule, hard	-Gabapentin
Gabitril 10 mg film-coated tablets	Teva Pharma B.V.	PA0749/199/002	Film-coated tablet	-Tiagabine
Gabitril 15 mg film-coated tablets	Teva Pharma B.V.	PA0749/199/003	Film-coated tablet	-Tiagabine
Gabitril 5 mg, film-coated tablet	Teva Pharma B.V.	PA0749/199/001	Film-coated tablet	-Tiagabine anhydrous
Gadovist 1.0 mmol/ml solution for injection	Bayer Limited	PA1410/018/003	Solution for injection	-Gadobutrol
Gadovist 1.0 mmol/ml solution for injection	Bayer Limited	PA1410/018/001	Solution for injection	-Gadobutrol
Gadovist 1.0 mmol/ml solution for injection in pre-filled cartridge	Bayer Limited	PA1410/018/004	Solution for injection in cartridge	-Gadobutrol
Gadovist 1.0 mmol/ml solution for injection in pre-filled syringe	Bayer Limited	PA1410/018/002	Solution for injection in pre-filled syringe	-Gadobutrol
Galafold	Amicus Therapeutics Europe Limited	EU/1/15/1082/001	Capsule, hard	-Migalastat hydrochloride
Galfer 140 mg/5ml Oral Suspension	Clonmel Healthcare Ltd	PA0126/314/002	Oral suspension	-Ferrous fumarate Ph.Eur.
Galfer 305 mg Hard Capsules	Clonmel Healthcare Ltd	PA0126/314/001	Capsule, hard	-Ferrous fumarate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Galfer FA 305 mg / 0.35 mg Hard Capsules	Clonmel Healthcare Ltd	PA0126/317/001	Capsule, hard	-Ferrous fumarate -Folic acid
GalliaPharm 0.74 – 1.85 GBq radionuclide generator	Eckert & Ziegler Radiopharma GmbH	PA2192/001/001	Radionuclide generator	-GERMANIUM (68GE) CHLORIDE -Gallium (68Ga) Chloride
Gallium (Ga67) Citrate injection	Curium Netherlands B.V.	PA0690/003/001	Solution for injection	-Gallium (67 ga) citrate
Galsya SR 16 mg prolonged-release capsules, hard	KRKA, d.d., Novo mesto	PA1347/015/002	Prolonged-release capsule, hard	-Galantamine
Galsya SR 24 mg prolonged-release capsules, hard	KRKA, d.d., Novo mesto	PA1347/015/003	Prolonged-release capsule, hard	-Galantamine
Galsya SR 8 mg prolonged-release capsules, hard	KRKA, d.d., Novo mesto	PA1347/015/001	Prolonged-release capsule, hard	-Galantamine
Galtasa 1000 mg gastro-resistant tablets	Faes Farma S.A.	PA0864/001/003	Gastro-resistant tablet	-Mesalazine
Galtasa 500 mg gastro-resistant tablets	Faes Farma S.A.	PA0864/001/001	Gastro-resistant tablet	-Mesalazine
Galtasa 500 mg suppositories	Faes Farma S.A.	PA0864/001/002	Suppository	-Mesalazine
Galvus	Novartis Europharm Limited	EU/1/07/414/1-10	Tablet	-Vildagliptin
Galvus	Novartis Europharm Limited	EU/1/07/414/11-17	Tablet	-Vildagliptin
Gamanil 70mg film-coated tablets	Zentiva k.s.	PA1701/004/001	Film-coated tablet	-Lofepamine hydrochloride
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	-HUMAN PLASMA PROTEIN >90% GAMMA GLOBULIN
Gammanorm, 165 mg/mL, solution for injection	Octapharma (IP) SPRL	PA2219/006/001	Solution for injection	-Human normal immunoglobulin
Gamunex® 10%, 100 mg/ml, solution for infusion	Grifols Deutschland GmbH	PA1405/001/001	Solution for infusion	-Immunoglobulin human normal
Ganfort	AbbVie Deutschland GmbH & Co. KG	EU/1/06/340/001-002	Eye drops, solution	-Bimatoprost -Timolol
Ganirelix Gedeon Richter	Chemical Works Of Gedeon Richter PLC	EU/1/22/1658/001-002	Solution for injection in pre-filled syringe	-Ganirelix Acetate
Gardasil	Merck Sharp & Dohme BV,	EU/1/06/357/01-21	Suspension for injectio	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Gardasil 9	Merck Sharp & Dohme BV,	EU/1/15/1007/001-003	Suspension for injectio	-Hpv type 6 I1 protein -Hpv type 11 I1 protein -Hpv 16 I1 protein -Hpv 18 I1 protein -Hpv type 31 I1 protein -Hpv type 33 I1 protein -Hpv type 45 I1 protein -Hpv type 52 I1 protein -Hpv type 58 I1 protein
Gastrografin, 660mg/ml and 100mg/ml Oral and Rectal Solution	Bayer Limited	PA1410/004/001	Oral/rectal solution	-Sodium amidotrizoate -Amidotrizoate meglumine -AMIDOTRIZOIC ACID -Meglumine
Gastromiro 612.4mg/ml oral or rectal solution	Bracco Imaging spa	PA1826/005/001	Oral/rectal solution	-Iopamidol
Gaviscon Advance Chewable Tablets Sodium alginate 500 mg, Potassium hydrogen carbonate 100 mg.	Reckitt Benckiser Ireland Ltd	PA0979/011/008	Chewable tablet	-Potassium bicarbonate -Sodium alginate
Gaviscon Advance Oral Suspension Sodium alginate 500 mg, Potassium hydrogen carbonate 100 mg.	Reckitt Benckiser Ireland Ltd	PA0979/011/001	Oral suspension	-Potassium hydrogen carbonate -Sodium alginate
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	-Sodium alginate -Potassium hydrogen carbonate
Gaviscon Advance Peppermint Oral Suspension Sodium alginate 500 mg, Potassium hydrogen carbonate 100 mg.	Reckitt Benckiser Ireland Ltd	PA0979/011/007	Oral suspension	-Sodium alginate -Potassium hydrogen carbonate
Gaviscon Infant, Powder for Oral Suspension	Reckitt Benckiser Ireland Ltd	PA0979/012/001	Powder for oral suspension	-Sodium alginate -Magnesium alginate
Gaviscon Oral Suspension 500mg/10ml Sodium Alginate 267mg/10ml Sodium Bicarbonate 160mg/10ml Calcium Carbonate	Reckitt Benckiser Ireland Ltd	PA0979/015/001	Oral suspension	-Sodium bicarbonate -Calcium carbonate -Sodium alginate
Gavreto	Roche Registration GmbH	EU/1/21/1555/001-003	Capsule, hard	-Pralsetinib
Gazyvaro	Roche Registration GmbH	EU/1/14/937/001	Concentrate for solution for infusion	-Obinutuzumab
Gedarel 20/150 microgram film-coated tablets	Gedeon Richter Plc	PA1330/006/001	Film-coated tablet	-Ethinylestradiol -Desogestrel
Gedarel extra 30/150 micrograms Film Coated Tablets	Gedeon Richter Plc	PA1330/005/001	Film-coated tablet	-Ethinylestradiol -Desogestrel
Gefitinib Mylan	Mylan Pharmaceuticals Limited	EU/1/18/1321/001-002	Film-coated tablet	-Gefitinib

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Gelaspan Solution for Infusion	B. Braun Melsungen AG	PA0736/034/001	Solution for infusion	-Succinylated gelatine (= modified fluid gelatine) -Sodium chloride -Sodium acetate trihydrate -Potassium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate
Gelofusine 40mg/ml Solution for Infusion	B. Braun Melsungen AG	PA0736/011/001	Solution for infusion	-Succinylated gelatine (= modified fluid gelatine) -Sodium chloride -Sodium hydroxide
Geloplasma Solution for Infusion (Polyolefine/Freeflex Bag)	Fresenius Kabi Deutschland GmbH	PA2059/008/002	Solution for infusion	-Modified liquid gelatine -Sodium chloride -Magnesium chloride hexahydrate -Potassium chloride -Sodium (s)-lactate solution
Geloplasma, Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/008/001	Solution for infusion	-Modified liquid gelatine -Sodium chloride -Magnesium chloride hexahydrate -Potassium chloride -Sodium lactate solution
Geltears 0.2 % w/w carbomer eye gel	Bausch + Lomb Ireland Limited	PA23259/006/001	Eye gel	-Carbomer
Gemcitabine 1 g Powder for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/092/002	Powder for solution for infusion	-Gemcitabine
Gemcitabine 1 g powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/039/002	Powder for solution for infusion	-Gemcitabine
Gemcitabine 100 mg/ml Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/092/004	Concentrate for solution for infusion	-Gemcitabine
Gemcitabine 2 g powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/039/003	Powder for solution for infusion	-Gemcitabine
Gemcitabine 200 mg powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/039/001	Powder for solution for infusion	-Gemcitabine
Gemcitabine 200 mg Powder for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/092/001	Powder for solution for infusion	-Gemcitabine
Gemcitabine 2g Powder for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/092/003	Powder for solution for infusion	-Gemcitabine hydrochloride
Gemcitabine 38 mg/ml Concentrate for Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/039/005	Concentrate for solution for infusion	-Gemcitabine hydrochloride
Gemcitabine Teva 40mg/ml Concentrate for Solution for Infusion	Teva B.V.	PA1986/122/001	Concentrate for solution for infusion	-Gemcitabine
Gecebok	Gennisium Pharma	EU/1/20/1465/001	Solution for infusion	-Caffeine -Caffeine citrate
GENOTROPIN	Pfizer Healthcare Ireland	PA0822/128/001	Powder and solvent for solution for injection	-Somatropin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
GENOTROPIN	Pfizer Healthcare Ireland	PA0822/128/002	Powder and solvent for solution for injection	-Somatropin
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/003	Powder and solvent for solution for injection	-Somatropin -Somatropin
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/004	Powder and solvent for solution for injection	-Somatropin -Somatropin
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/005	Powder and solvent for solution for injection	-Somatropin
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/006	Powder and solvent for solution for injection	-Somatropin
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/007	Powder and solvent for solution for injection	-Somatropin -Somatropin
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/008	Powder and solvent for solution for injection	-Somatropin
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/009	Powder and solvent for solution for injection	-Somatropin -Somatropin
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/010	Powder and solvent for solution for injection	-Somatropin -Somatropin
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/011	Powder and solvent for solution for injection	-Somatropin -Somatropin
GENOTROPIN MINIQUICK	Pfizer Healthcare Ireland	PA0822/128/012	Powder and solvent for solution for injection	-Somatropin -Somatropin
Gentamicin 10 mg/ml solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/242/001	Solution for injection/infusion	-Gentamicin
Gentamicin 20 mg/mL Solution for injection/infusion	Noridem Enterprises Limited	PA1122/023/001	Solution for injection/infusion	-Gentamicin
Gentamicin 40 mg/ml solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/242/002	Solution for injection/infusion	-Gentamicin
Gentamicin 40 mg/mL Solution for injection/infusion	Noridem Enterprises Limited	PA1122/023/002	Solution for injection/infusion	-Gentamicin
Gentamicin 80 mg/mL Solution for injection/infusion	Noridem Enterprises Limited	PA1122/023/003	Solution for injection/infusion	-Gentamicin
Gentamicin Panpharma 40 mg/ml solution for injection/infusion	Panpharma	PA2272/002/001	Solution for injection/infusion	-Gentamicin sulfate
Genticin 0.3% w/v Eye/Ear Drops, Solution	Amdipharm Limited	PA1142/013/002	Ear/eye drops, solution	-Gentamicin sulfate
Genticin 80mg/2ml Solution for Injection	Amdipharm Limited	PA1142/013/001	Solution for injection	-Gentamicin sulfate
Gentisone HC 0.3% w/v & 1.0% w/v Ear Drops, Suspension	Amdipharm Limited	PA1142/014/001	Ear drops, suspension	-Gentamicin sulfate -HYDROCORTISONE ACETATE
Genvoya	Gilead Sciences Ireland UC	EU/1/15/1061/001-002	Film-coated tablet	-Elvitegravir -Cobicistat -Emtricitabine -Tenofovir alafenamide fumarate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Genvoya	Gilead Sciences Ireland UC	EU/1/15/1061/003-004	Film-coated tablet	-Elvitegravir -Cobicistat -Emtricitabine -Tenofovir alafenamide -Tenofovir alafenamide fumarate
Geodon 20mg capsules, hard	Upjohn EESV	PA23055/015/001	Capsule, hard	-Ziprasidone hydrochloride monohydrate
Geodon 40mg capsules, hard	Upjohn EESV	PA23055/015/002	Capsule, hard	-Ziprasidone
Geodon 60mg capsules, hard	Upjohn EESV	PA23055/015/003	Capsule, hard	-Ziprasidone
Geodon 80mg capsules, hard	Upjohn EESV	PA23055/015/004	Capsule, hard	-Ziprasidone
Gerax 1 mg Tablets	Aurobindo Pharma (Malta) Limited	PA1445/024/003	Tablet	-Alprazolam
Gerax 250 microgram Tablets	Aurobindo Pharma (Malta) Limited	PA1445/024/001	Tablet	-Alprazolam
Gerax 500 microgram Tablets	Aurobindo Pharma (Malta) Limited	PA1445/024/002	Tablet	-Alprazolam
Germentin 125 mg/31.25 mg per 5 ml Powder for Oral Suspension	Viartis Limited	PA23266/015/002	Powder for oral suspension	-Clavulanic acid -Amoxicillin
Germentin 250 mg/125 mg Film-coated Tablets	Viartis Limited	PA23266/015/003	Film-coated tablet	-potassium clavulanate -Amoxicillin trihydrate
Germentin 500 mg/125 mg film coated tablets	Viartis Limited	PA23266/015/001	Film-coated tablet	-Amoxicillin trihydrate -potassium clavulanate
Geroquel 100 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/090/002	Film-coated tablet	-Quetiapine fumarate
Geroquel 200 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/090/003	Film-coated tablet	-Quetiapine fumarate
Geroquel 25 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/090/001	Film-coated tablet	-Quetiapine fumarate
Gerozac 60 mg Capsules, Hard	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/071/001	Capsule, hard	-FLUOXETINE HYDROCHLORIDE
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Enoxaparin sodium
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	-Enoxaparin sodium
GHRYVELIN	Atrahs Pharma Netherlands B.V.	EU/1/18/1337/001	Granules for oral solution in sachet	-MACIMORELIN ACETATE
Giapreza	Paion Deutschland GmbH	EU/1/19/1384/001-002	Concentrate for solution for infusion	
GILENYA	Novartis Europharm Limited	EU/1/11/677/001-004	Capsule, hard	-Fingolimod
Gilenya	Novartis Europharm Limited	EU/1/11/677/007-008	Capsule, hard	-FINGOLIMOD HYDROCHLORIDE
Ginkgo-Biloba Pharma Nord film-coated tablets	Pharma Nord ApS	TR1242/001/001	Film-coated tablet	-GINKGO BILOBA EXTRACT
Giotrif	Boehringer Ingelheim International GmbH	EU/1/13/879/001-003	Film-coated tablet	-Afatinib-dimaleate
Giotrif	Boehringer Ingelheim International GmbH	EU/1/13/879/004-006	Film-coated tablet	-Afatinib-dimaleate
Giotrif	Boehringer Ingelheim International GmbH	EU/1/13/879/007-009	Film-coated tablet	-Afatinib-dimaleate
Giotrif	Boehringer Ingelheim International GmbH	EU/1/13/879/010-012	Film-coated tablet	-Afatinib-dimaleate
Givlaari	Alnylam Netherlands B.V.	EU/1/20/1428/001	Solution for injection	-Givosiran Sodium
Gliadel 7.7 mg Implant	MGI Pharma GmbH	PA22740/001/001	Implant	-Carmustine
Gliclazide MR 30 mg prolonged-release tablets	Brillpharma (Ireland) Limited	PA22749/006/001	Prolonged-release tablet	-Gliclazide
Gliolan	Photonamic GmbH & Co. KG	EU/1/07/413/1-3	Powder for oral solution	-5-aminolevulinic acid hydrochloride
Glivec	Novartis Europharm Limited	EU/1/01/198/001	Capsule, hard	-Imatinib mesilate
Glivec	Novartis Europharm Limited	EU/1/01/198/002	Capsule, hard	-Imatinib mesilate
Glivec	Novartis Europharm Limited	EU/1/01/198/003	Capsule, hard	-Imatinib mesilate
Glivec	Novartis Europharm Limited	EU/1/01/198/004	Capsule, hard	-Imatinib mesilate
Glivec	Novartis Europharm Limited	EU/1/01/198/005	Capsule, hard	-Imatinib mesilate
Glivec	Novartis Europharm Limited	EU/1/01/198/006	Capsule, hard	-Imatinib mesilate
Glivec	Novartis Europharm Limited	EU/1/01/198/007	Film-coated tablet	-Imatinib mesilate
Glivec	Novartis Europharm Limited	EU/1/01/198/008	Film-coated tablet	-Imatinib mesilate
Glivec	Novartis Europharm Limited	EU/1/01/198/009	Film-coated tablet	-Imatinib mesilate
Glivec	Novartis Europharm Limited	EU/1/01/198/010	Film-coated tablet	-Imatinib mesilate
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	-GLUCAGON
GlucaGen Hypokit 1 mg powder and solvent for solution for injection	PCO Manufacturing Ltd.	PPA0465/331/001	Powder and solvent for solution for injection	-Glucagon hydrochloride
Glucophage 1000 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/005/003	Film-coated tablet	-Metformin Hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Glucophage 500 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/005/001	Film-coated tablet	-Metformin Hydrochloride
Glucophage 850 mg film-coated tablets	Merck Serono (Ireland) Limited	PA2286/005/002	Film-coated tablet	-Metformin Hydrochloride
Glucosamine Pharma Nord 400 mg Capsules	Pharma Nord ApS	PA1242/001/001	Capsule, hard	-Glucosamine
Glucose 10 % w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/005	Solution for infusion	-Glucose anhydrous
Glucose 10 % w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/006	Solution for infusion	-Glucose anhydrous
Glucose 10 % w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/007	Solution for infusion	-Glucose anhydrous
Glucose 10 % w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/008	Solution for infusion	-Glucose anhydrous
Glucose 10 % w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/010	Solution for infusion	-Glucose anhydrous
Glucose 10% w/v Solution for Infusion	Baxter Holding B.V.	PA2299/003/002	Solution for infusion	-Glucose
Glucose 5 % w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/009	Solution for infusion	-Glucose anhydrous
Glucose 5% w/v Intravenous Infusion BP, polyolefin/polyamide bag	Baxter Holding B.V.	PA2299/003/001	Solution for infusion	-Glucose
Glucose 5% w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/003	Solution for infusion	-Glucose anhydrous
Glucose 5% w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/004	Solution for infusion	-Glucose anhydrous
Glucose 5% w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/001	Solution for infusion	-Glucose anhydrous
Glucose 5% w/v, Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/040/002	Solution for infusion	-Glucose anhydrous
Glucose 50% w/v sterile concentrate, concentrate solution for infusion	B. Braun Medical Limited	PA0179/001/039	Concentrate for solution for infusion	-Anhydrous glucose
Glucose Intravenous Infusion BP 10% w/v, solution for infusion	B. Braun Medical Limited	PA0179/001/028	Solution for infusion	-Anhydrous glucose
Glucose Intravenous Infusion BP 5% w/v solution for infusion	B. Braun Medical Limited	PA0179/001/003	Solution for infusion	-Glucose
Glycerol 1g Suppositories	Ethypharm	PA0549/028/001	Suppository	-Glycerol
Glycerol Suppositories BP for Adults	Ethypharm	PA0549/028/003	Suppository	-Glycerol
Glyceryl Trinitrate 5 mg/ml Sterile Concentrate	Pfizer Healthcare Ireland	PA0822/204/001	Concentrate for solution for infusion	-Glyceryl trinitrate
Glycopyrronium Bromide 200 micrograms/ml Solution for Injection	MercuryPharm Ltd	PA0857/001/001	Solution for injection	-Glycopyrronium bromide
Glycopyrronium bromide 200 micrograms/ml Solution for injection	Ethypharm	PA0549/029/001	Solution for injection	-Glycopyrronium bromide
Glycopyrronium Bromide and Neostigmine Metilsulfate 0.5mg / 2.5mg per ml Solution for Injection	MercuryPharm Ltd	PA0857/002/001	Solution for injection	-Glycopyrronium bromide -Neostigmine Metilsulfate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
GLYPRESSIN 1 mg Powder and Solvent for Solution for Injection	Ferring Ireland Ltd	PA1009/004/001	Powder and solvent for solution for injection	-Terlipressin acetate
Glypressin 1 mg/ 8.5 ml solution for injection	Ferring Ireland Ltd	PA1009/004/002	Solution for injection	-Terlipressin acetate
Glytrin 400 micrograms per metered dose Sublingual Spray	Ayrton Saunders (Ireland) Limited	PA22906/002/001	Sublingual spray, solution	-Glyceryl trinitrate
Glyxambi	Boehringer Ingelheim International GmbH	EU/1/16/1146/001-009	Film-coated tablet	-Empagliflozin -Linagliptin
Glyxambi	Boehringer Ingelheim International GmbH	EU/1/16/1146/010-018	Film-coated tablet	-Empagliflozin -Linagliptin
Golden Eye 0.1% w/v Eye drops, solution	Cambridge Healthcare Ireland Limited	PA22695/001/001	Eye drops, solution	-Propamidine isetionate
Golden Eye 0.15% w/w Eye Ointment	Cambridge Healthcare Ireland Limited	PA22695/001/002	Eye ointment	-Dibromopropamidine isethionate
Golpimec 0.5 mg hard capsules	Neuraxpharm Ireland Limited	PA23229/003/001	Capsule, hard	-Fingolimod
Gonal-F	Merck Europe B.V.	EU/1/95/001/005	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Merck Europe B.V.	EU/1/95/001/012	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Merck Europe B.V.	EU/1/95/001/013	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Merck Europe B.V.	EU/1/95/001/014	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Merck Europe B.V.	EU/1/95/001/015	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Merck Europe B.V.	EU/1/95/001/017	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Merck Europe B.V.	EU/1/95/001/018	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Merck Europe B.V.	EU/1/95/001/019	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Merck Europe B.V.	EU/1/95/001/020	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Merck Europe B.V.	EU/1/95/001/021	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Merck Europe B.V.	EU/1/95/001/022	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Serono Limited	EU/1/95/001/023	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Serono Limited	EU/1/95/001/024	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Merck Europe B.V.	EU/1/95/001/025	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Merck Europe B.V.	EU/1/95/001/026	Powder and solvent for solution for injection	-Follitropin alfa

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Gonal-F	Merck Europe B.V.	EU/1/95/001/027	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Serono Limited	EU/1/95/001/028	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Serono Limited	EU/1/95/001/029	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Merck Europe B.V.	EU/1/95/001/031	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F	Merck Europe B.V.	EU/1/95/001/032	Powder and solvent for solution for injection	-Follitropin alfa
GONAL-F	Merck Europe B.V.	EU/1/95/001/033	Solution for injection in pre-filled pen	-Follitropin alfa
Gonal-F	Merck Europe B.V.	EU/1/95/001/034	Solution for injection	-Follitropin alfa
Gonal-F - Ampoule	Merck Europe B.V.	EU/1/95/001/004	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F - Ampoule	Merck Europe B.V.	EU/1/95/001/001	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F - Ampoule	Merck Europe B.V.	EU/1/95/001/002	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F Ampoule	Merck Europe B.V.	EU/1/95/001/003	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F Ampoule	Merck Europe B.V.	EU/1/95/001/010	Powder for solution for injection	-Follitropin alfa
Gonal-F Vial	Merck Europe B.V.	EU/1/95/001/006	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F Vials	Merck Europe B.V.	EU/1/95/001/008	Powder and solvent for solution for injection	-Follitropin alfa
Gonal-F Vials	Merck Europe B.V.	EU/1/95/001/016	Powder and solvent for solution for injection	-Follitropin alfa
GoResp Digihaler	Teva Pharma B.V.	EU/1/19/1403/001-003	Inhalation powder	-Budesonide -Formoterol fumarate dihydrate
GoResp Digihaler	Teva Pharma B.V.	EU/1/19/1403/004-005	Inhalation powder	-Budesonide -Formoterol fumarate dihydrate
Grafalon 20 mg/ml concentrate for solution for infusion	Neovii Biotech GmbH	PA1015/001/001	Concentrate for solution for infusion	-Anti-human t-lymphocyte immunoglobulin from rabbits
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	-Lenograstim
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	-Lenograstim
Granpidam	Accord Healthcare S.L.U.	EU/1/16/1137/001-005	Film-coated tablet	-Sildenafil base (as citrate)
GRANUPAS	Eurocept International BV	EU/1/13/896/001	Gastro-resistant granules	-Para-aminosalicylic acid

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Grastofil	Accord Healthcare S.L.U.	EU/1/13/877/001-002	Solution for injection/infusion in pre-filled syringe	-Filgrastim
Grastofil	Accord Healthcare S.L.U.	EU/1/13/877/003-004	Solution for injection/infusion in pre-filled syringe	-Filgrastim
Grasustek	Juta Pharma GmbH	EU/1/19/1375/001	Solution for injection	
GRAZAX 75,000 SQ-T sublingual lyophilisate	ALK-Abello A/S	PA1255/004/001	Sublingual lyophilisate	-Grass pollen extract (phleum pratense)
GREPID	Pharmathen S.A.	EU/1/09/535/1-16	Film-coated tablet	-CLOPIDOGREL BESYLATE
Griseofulvin 500 mg film-coated tablets	Brown & Burk IR Limited	PA23148/006/001	Film-coated tablet	-Griseofulvin
Guaifenesin 200 mg syrup in sachet	Johnson & Johnson (Ireland) Limited	PA0330/059/001	Syrup in sachet	-Guaifenesin
Gyno-Pevaryl Once 150 mg Vaginal Pessary	Karo Pharma AB	PA22650/006/001	Pessary	-ECONAZOLE NITRATE
Gynoxin 200 mg Vaginal Capsules	Recordati Industria Chimica e Farmaceutica SpA	PA0812/004/001	Vaginal capsule, soft	-Fenticonazole nitrate
Gynoxin 600 mg Vaginal Capsules	Recordati Industria Chimica e Farmaceutica SpA	PA0812/004/002	Vaginal capsule, soft	-Fenticonazole nitrate
Halaven	Eisai GmbH	EU/1/11/678/001-002	Solution for injection	-Eribulin mesylate
Halcion 125 micrograms Tablets	Pfizer Healthcare Ireland	PA0822/129/002	Tablet	-Triazolam
Halcion 250 microgram Tablets	Pfizer Healthcare Ireland	PA0822/129/001	Tablet	-Triazolam
Haldol Decanoate 100mg/ml Solution for Injection	Essential Pharma Limited	PA22587/003/002	Solution for injection	-Haloperidol
Haldol Decanoate 50mg/ml Solution for Injection	Essential Pharma Limited	PA22587/003/001	Solution for injection	-Haloperidol
Half Beta-Propranolol 80 mg Prolonged-Release Capsules	Tillomed Pharma GmbH	PA22720/002/002	Prolonged-release capsule, hard	-Propranolol hydrochloride
Half Sinemet CR 25mg/100mg Prolonged-Release Tablets	Organon Pharma (Ireland) Limited	PA23198/004/006	Prolonged-release tablet	-Levodopa -Carbidopa
Haloperidol 5mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/101/001	Solution for injection	-Haloperidol
Hartmann's Solution for Infusion, glass bottle	Fresenius Kabi Deutschland GmbH	PA2059/057/004	Solution for infusion	-Sodium chloride -Potassium chloride -Calciumchloride dihydrate -Sodium lactate (as 50% solution)
Hartmann's Solution for Infusion, PPC PSEB bag	Fresenius Kabi Deutschland GmbH	PA2059/057/003	Solution for infusion	-Sodium chloride -Potassium chloride -Calcium chloride dihydrate -Sodium lactate (as 50% solution)
Hartmann's Solution for Infusion, PSEB bag	Fresenius Kabi Deutschland GmbH	PA2059/057/002	Solution for infusion	-Sodium chloride -Potassium chloride -Calcium chloride dihydrate -Sodium lactate (as 50% solution)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Hartmann's Solution for Infusion, PVC bag	Fresenius Kabi Deutschland GmbH	PA2059/057/001	Solution for infusion	-Sodium chloride -Potassium chloride -Calcium chloride dihydrate -Sodium lactate (as 50% solution)
Hartmann's Solution Compound Sodium Lactate Intravenous Infusion BP	Laboratoire AGUETTANT	PA1968/020/001	Solution for infusion	-Sodium chloride -Calcium chloride dihydrate -Potassium chloride -Sodium lactate solution 60%
Hartmann's Solution for Infusion, PE bottle	Fresenius Kabi Deutschland GmbH	PA2059/057/005	Solution for infusion	-Sodium chloride -Potassium chloride -Calcium chloride dihydrate -Sodium lactate (as 50% solution)
Harvoni	Gilead Sciences Ireland UC	EU/1/14/958/001-002	Film-coated tablet	-Sofosbuvir -Ledipasvir
Harvoni	Gilead Sciences Ireland UC	EU/1/14/958/003	Film-coated tablet	-Ledipasvir -Sofosbuvir
Harvoni	Gilead Sciences Ireland UC	EU/1/14/958/004	Granules	-Ledipasvir -Sofosbuvir
Harvoni	Gilead Sciences Ireland UC	EU/1/14/958/005	Granules	-Ledipasvir -Sofosbuvir
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	-Aluminium -Hepatitis A antigen
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	-Aluminium -Hepatitis A antigen
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/001	Suspension for injectio	-Hepatitis b vaccine
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/002	Suspension for injectio	-Hepatitis b vaccine
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/003	Suspension for injectio	-Hepatitis b vaccine
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/004	Suspension for injection in pre-filled syringe	-Hepatitis b vaccine
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/005	Suspension for injection in pre-filled syringe	-Hepatitis b vaccine
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/006	Suspension for injectio	-Hepatitis b vaccine
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/007	Suspension for injectio	-Hepatitis b vaccine
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/008	Suspension for injectio	-Hepatitis b vaccine
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/009	Suspension for injectio	-Hepatitis b vaccine
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/010	Suspension for injectio	-Hepatitis b vaccine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/011	Suspension for injection in pre-filled syringe	-Hepatitis b vaccine
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/012	Suspension for injectio	-Hepatitis b vaccine
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/013	Suspension for injection in pre-filled syringe	-Hepatitis b vaccine
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/014	Suspension for injectio	-Hepatitis b vaccine
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/015	Suspension for injectio	-Hepatitis b vaccine
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/018-025	Suspension for injectio	-Hepatitis b vaccine
HBVAXPRO	Sanofi Pasteur MSD Ltd	EU/1/01/183/018-025,30-31	Suspension for injectio	-Hepatitis b vaccine
HBVAXPRO	Merck Sharp & Dohme BV,	EU/1/01/183/026-029	Suspension for injection in pre-filled syringe	-Hepatitis b vaccine
HBVAXPRO	Sanofi Pasteur MSD Ltd	EU/1/01/183/026-029,32	Suspension for injectio	-Hepatitis b vaccine
HC45 Hydrocortisone Acetate Cream (Hydrocortisone Acetate 1% w/w)	KARO PHARMA AB	PA22650/008/001	Cream	-HYDROCORTISONE ACETATE
Hefiya	Sandoz GmbH	EU/1/18/1287/001-003	Solution for injection in pre-filled syringe	-Adalimumab
Hefiya	Sandoz GmbH	EU/1/18/1287/004-006	Solution for injection in pre-filled pen	-Adalimumab
HELIOBACTER Test INFAL	INFAL Institut fur biomedizinisch	EU/1/97/045/001	Powder for oral solution	-13c-urea
Heliobacter Test INFAL	INFAL Institut fur biomedizinisch	EU/1/97/045/003	Powder for oral solution	-13c-urea
Hemangirol	Pierre Fabre Dermatologie	EU/1/14/919/001	Oral solution	-PROPRANOLOL HYDROCHLORIDE
Hemgenix	CSL Behring GmbH	EU/1/22/1715/001	Concentrate for solution for infusion	-Etranacogene dezaparvovec
Hemlibra	Roche Registration GmbH	EU/1/18/1271/001	Solution for injection	-Emicizumab
Hemlibra	Roche Registration GmbH	EU/1/18/1271/002-004	Solution for injection	-Emicizumab
Hemosol B0 solution for haemodialysis/haemofiltration	Baxter Holding B.V.	PA2299/051/002	Solution for haemodialysis/haemofiltration	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Hemosol B0 solution for haemodialysis/haemofiltration	Baxter Holding B.V.	PA2299/051/001	Solution for haemodialysis/haemofiltration	-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
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	-Heparin sodium
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	-Heparin sodium
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	-Heparin sodium
Heparin Sodium 10 I.U./ml flushing solution for maintenance of patency of intravenous devices	Pinewood Laboratories Ltd	PA0281/230/001	Irrigation solution	-Heparin sodium
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	-Heparin sodium
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	-Heparin sodium
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	-Heparin sodium -Sodium chloride -Disodium phosphate dodecahydrate -Citric acid monohydrate
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	-Heparin sodium -Sodium chloride -Disodium phosphate dodecahydrate -Citric acid monohydrate
Hepatect CP 50 IU/ml; solution for infusion	Biotest Pharma GmbH	PA0592/005/004	Solution for infusion	-Human plasma protein -Hbs antibodies

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Hepcludex	Gilead Sciences Ireland UC	EU/1/20/1446/001	Powder for solution for injection	-Bulevirtide
Hepilisav B	Dynavax GmbH	EU/1/20/1503/001	Solution for injection in pre-filled syringe	-Hepatitis b surface antigen
Herceptin	Roche Registration GmbH	EU/1/00/145/001	Powder for concentrate for solution for infusion	-Trastuzumab
Herceptin	Roche Registration GmbH	EU/1/00/145/002	Solution for injection	-Trastuzumab
Herwenda	Sandoz GmbH	EU/1/23/1762/001	Powder for concentrate for solution for infusion	-Trastuzumab
Herzuma	Celltrion Healthcare Hungary Kft.	EU/1/17/1257/001	Powder for concentrate for solution for infusion	-Trastuzumab
Hetlioz	Vanda Pharmaceuticals Netherlands B.V.	EU/1/15/1008/001	Capsule, hard	-Tasimelteon
Hexacima	Sanofi Pasteur SA	EU/1/13/828/001-007	Suspension for injectio	-Haemophilus influenzae type b capsular polysaccharide -Pertussis toxoid -(polyribosylribitol phosphate) conjugated to tetanus protein -Filamentous haemagglutinin -Type 1 (mahoney) -Diphtheria toxoid -Type 2 (mef-1) -Tetanus toxoid -Type 3 (saukett) -Hepatitis b surface antigen
Hexiprep 2.0% w/v / 70.0% w/v Impregnated Pad	GAMA Healthcare Ireland Ltd	PA23120/001/001	Impregnated pad	-Chlorhexidine digluconate solution -Isopropyl alcohol
Hexvix 85 mg, powder and solvent for intravesical solution	Photocure ASA	PA1024/003/001	Powder and solvent for intravesical solution	-Hexaminolevulinate hydrochloride
Hexyon	Sanofi Pasteur	EU/1/13/829/001-007	Suspension for injectio	-(polyribosylribitol phosphate) conjugated to tetanus 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
Hezkue 12.5 mg/actuation, oral suspension	Aspargo Labs Ireland Limited	PA25240/001/001	Oral suspension	-Sildenafil citrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Haemophilus influenzae type b polysaccharide -Conjugate of haemophilus influenzae type b capsular polysaccharide (prp) and tetanus toxoid
Hidrasec 100 mg hard capsules	Bioproject Europe Ltd	PA1714/001/001	Capsule, hard	-Racecadotril
Hidrasec Children 30mg Granules for Oral Suspension	Bioproject Europe Ltd	PA1714/001/003	Granules for oral suspension	-Racecadotril
Hidrasec Infants 10mg Granules for Oral Suspension	Bioproject Europe Ltd	PA1714/001/002	Granules for oral suspension	-Racecadotril
Hidrasec Infants and Children 4 mg/mL Oral Suspension	Bioprojet Pharma	PA22580/002/001	Oral suspension	-Racecadotril
Hirobriz Breezhaler	Novartis Europharm Limited	EU/1/09/594/1-5	Inhalation powder, hard capsule	-Indacaterol maleate
Hirobriz Breezhaler	Novartis Europharm Limited	EU/1/09/594/6-10	Inhalation powder, hard capsule	-Indacaterol maleate
Histaclar 10mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/046/001	Film-coated tablet	-Loratadine
Hizentra	CSL Behring GmbH	EU/1/11/687/001-12	Solution for injection	-Human normal immunoglobulin
Holland & Barrett Hypericum Hard Capsules	Holland & Barrett Limited	TR23157/003/001	Capsule, hard	
Holoclar	Holostem S.r.l.	EU/1/14/987/001	Living tissue equivalent	-Ex vivo expanded autologous corneal epithelial cells containing stem cells
Hukyndra	Stada Arzneimittel AG	EU/1/21/1589/001-006	Solution for injection in pre-filled syringe	-Adalimumab
Hulio	Biosimilar Collaborations Ireland Limited	EU/1/18/1319/001-007	Solution for injection	-Adalimumab
Hulio	Biosimilar Collaborations Ireland Limited	EU/1/18/1319/009-010	Solution for injection in pre-filled syringe	-Adalimumab
Humalog	Eli Lilly Nederland B.V.	EU/1/96/007/019	Solution for injection	-Insulin lispro
Humalog	Eli Lilly and Company Limited	EU/1/96/007/039-042	Solution for injection	
Humalog 3ml	Eli Lilly Nederland B.V.	EU/1/96/007/004	Solution for injection in cartridge	-Insulin lispro
Humalog Mix25	Eli Lilly Nederland B.V.	EU/1/96/007/005	Suspension for injectio	-Insulin lispro
Humalog Mix25	Eli Lilly Nederland B.V.	EU/1/96/007/008	Suspension for injectio	-Insulin lispro
Humalog Mix50	Eli Lilly Nederland B.V.	EU/1/96/007/006	Suspension for injectio	-Insulin lispro
Humalog NPL	Eli Lilly Nederland B.V.	EU/1/96/007/010	Suspension for injectio	-Insulin lispro
Humalog Vials	Eli Lilly Nederland B.V.	EU/1/96/007/002	Solution for injection	-Insulin lispro
Human Albumin Baxalta 200 g/l Solution for Infusion	Baxalta Innovations GmbH	PA2004/004/002	Solution for infusion	-Plasma protein containing at least 95% human albumin
Human Albumin Baxalta 50 g/l Solution for Infusion	Baxalta Innovations GmbH	PA2004/004/001	Solution for infusion	-Plasma protein containing at least 95% human albumin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Human Albumin CSL Behring, 200 g/l, solution for infusion	CSL Behring GmbH	PA0800/012/001	Solution for infusion	-Human albumin solution
Humira	AbbVie Deutschland GmbH & Co. KG	EU/1/03/256/020	Solution for injection in pre-filled syringe	-Adalimumab
Humira	AbbVie Deutschland GmbH & Co. KG	EU/1/03/256/022	Solution for injection in pre-filled syringe	-Adalimumab
HUMIRA	AbbVie Deutschland GmbH & Co. KG	EU/1/03/256/1-10	Solution for injection	-Adalimumab
Humulin I (Isophane) 100 IU/ml Suspension for Injection in cartridge	Eli Lilly Nederland B.V.	PA2276/002/004	Suspension for injection in cartridge	-Human insulin (recombinant dna origin)
Humulin I (Isophane) 100 IU/ml Suspension for Injection in vial	Eli Lilly Nederland B.V.	PA2276/002/003	Suspension for injectio	-Human insulin (recombinant dna origin)
Humulin I KwikPen (Isophane) 100 IU/ml Suspension for Injection	Eli Lilly Nederland B.V.	PA2276/005/002	Suspension for injectio	-Human insulin (recombinant dna origin)
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	-Human insulin (recombinant dna origin)
Humulin M3 (Mixture 3) 100 IU/ml Suspension for Injection in vial	Eli Lilly Nederland B.V.	PA2276/003/003	Suspension for injectio	-Human insulin (recombinant dna origin)
Humulin M3 KwikPen (mixture 3) 100 IU/ml Suspension for Injection	Eli Lilly Nederland B.V.	PA2276/006/002	Suspension for injectio	-Human insulin (recombinant dna origin)
Humulin M3 KwikPen (mixture 3) 100 IU/ml Suspension for Injection	PCO Manufacturing Ltd.	PPA0465/501/001	Suspension for injectio	-Human insulin (recombinant dna origin)
Humulin S (Soluble) 100 IU/ml Solution for Injection in vial	Eli Lilly Nederland B.V.	PA2276/001/003	Solution for injection in vial	-Human insulin (recombinant dna origin)
Humulin S (Soluble), 100 IU/ml Solution for Injection in cartridge	Eli Lilly Nederland B.V.	PA2276/001/004	Solution for injection in cartridge	-Human insulin (recombinant dna origin)
Hyaluronidase 1500 I.U. Powder for Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/231/001	Powder for solution for injection/infusion	-Hyaluronidase
Hycamtin	Sandoz Pharmaceuticals d.d.	EU/1/96/027/001	Powder for concentrate for solution for infusion	-Topotecan hydrochloride
Hycamtin	Sandoz Pharmaceuticals d.d.	EU/1/96/027/003	Powder for concentrate for solution for infusion	-Topotecan hydrochloride
Hycamtin	Sandoz Pharmaceuticals d.d.	EU/1/96/027/004	Powder for concentrate for solution for infusion	-Topotecan (as hydrochloride)
Hycamtin	Sandoz Pharmaceuticals d.d.	EU/1/96/027/005	Powder for concentrate for solution for infusion	-Topotecan (as hydrochloride)
Hycamtin	Sandoz Pharmaceuticals d.d.	EU/1/96/027/006	Capsule, hard	-Topotecan hydrochloride
Hycamtin	Sandoz Pharmaceuticals d.d.	EU/1/96/027/007	Capsule, hard	-Topotecan hydrochloride
Hydrea 500 mg Hard Capsules	CHEPLAPHARM Arzneimittel GmbH	PA2239/021/001	Capsule, hard	-Hydroxycarbamide
Hydrex Surgical Scrub 4.0% w/v Cutaneous Solution	Ecolab Deutschland GmbH	PA1843/001/001	Cutaneous solution	-Chlorhexidine gluconate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Hydrocortisone 1 % w/w Cream	Ovelle Limited	PA0206/030/001	Cream	-Hydrocortisone
Hydrocortisone 10 mg Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/003/001	Tablet	-Hydrocortisone
Hydrocortisone 20 mg Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/003/002	Tablet	-Hydrocortisone
Hydrocortisone 5 mg Tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/003/003	Tablet	-Hydrocortisone
Hydrocortone 10 mg Tablets	Teva B.V.	PA1986/054/001	Tablet	-Hydrocortisone
Hydromorphone Hydrochloride 20 mg/ml Solution for Injection / Concentrate for Solution for Infusion	Ethypharm	PA0549/030/001	Solution for injection/infusion	-Hydromorphone hydrochloride
Hydromorphone hydrochloride 20 mg/ml solution for injection/infusion	AS Kalceks	PA2165/023/001	Solution for injection/infusion	-Hydromorphone hydrochloride
Hydromorphone Hydrochloride 50 mg/ml Solution for Injection / Concentrate for Solution for Infusion	Ethypharm	PA0549/030/002	Solution for injection/infusion	-Hydromorphone hydrochloride
Hydromorphone hydrochloride 50 mg/ml solution for injection/infusion	AS Kalceks	PA2165/023/002	Solution for injection/infusion	-Hydromorphone hydrochloride
Hydroxocobalamin 1 mg/ml solution for injection	G.L. Pharma GmbH	PA1770/002/001	Solution for injection	-Hydroxocobalamin
Hydroxocobalamin Basi 1000 microgram/mL solution for injection	Laboratorios Basi Industria Farmaceutica S.A.	PA23303/001/001	Solution for injection	-Hydroxocobalamin chloride
Hydroxychloroquine sulfate Accord 200 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/223/001	Film-coated tablet	-Hydroxychloroquine sulfate
Hydroxyzine hydrochloride 25 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/025/001	Film-coated tablet	-Hydroxyzine hydrochloride
Hyftor	Plusultra Pharma GmbH	EU/1/23/1723/001	Gel	-Sirolimus
Hyoscine Hydrobromide Martindale Pharma 600 micrograms/ml Solution for Injection	Ethypharm	PA0549/031/002	Solution for injection	-Hyoscine hydrobromide
Hypnovel 10 mg/2 ml Solution for Injection	CHEPLAPHARM Arzneimittel GmbH	PA2239/007/001	Solution for injection	-Midazolam hydrochloride
Hypnovel 10 mg/5 ml Solution for Injection	CHEPLAPHARM Arzneimittel GmbH	PA2239/007/002	Solution for injection	-Midazolam hydrochloride
Hypoloc 5 mg tablets	Menarini International Operations Luxembourg S.A.	PA0865/010/001	Tablet	-Nebivolol
Hypoloc Plus 5 mg/12.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/016/001	Film-coated tablet	-Nebivolol -Hydrochlorothiazide
Hypoloc Plus 5 mg/25 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/016/002	Film-coated tablet	-Nebivolol -Hydrochlorothiazide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Hypovase 0.5mg Tablets	Pfizer Healthcare Ireland	PA0822/195/001	Tablet	-Prazosin
HyQvia	Baxalta Innovations GmbH	EU/1/13/840/001-006	Solution for infusion	-Human normal immunoglobulin
Hyrimoz	Sandoz GmbH	EU/1/18/1286/001-003	Solution for injection in pre-filled syringe	-Adalimumab
Hyrimoz	Sandoz GmbH	EU/1/18/1286/004-006	Solution for injection in pre-filled pen	-Adalimumab
Hyrimoz	Sandoz GmbH	EU/1/18/1286/007	Solution for injection in pre-filled syringe	-Adalimumab
Hytrin 10mg Tablets	Amdipharm Limited	PA1142/005/004	Tablet	-Terazosin
Hytrin 1mg and 2mg Tablets (Starter Pack)	Amdipharm Limited	PA1142/005/001	Tablet	-Terazosin -Terazosin
Hytrin 2mg Tablets	Amdipharm Limited	PA1142/005/002	Tablet	-Terazosin
Hytrin 5mg Tablets	Amdipharm Limited	PA1142/005/003	Tablet	-Terazosin
IASIBON	Pharmathen S.A.	EU/1/10/659/003	Concentrate for solution for infusion	-IBANDRONIC ACID
IASIBON	Pharmathen S.A.	EU/1/10/659/004	Concentrate for solution for infusion	-IBANDRONIC ACID
IASIBON	Pharmathen S.A.	EU/1/10/659/005-007	Concentrate for solution for infusion	-IBANDRONIC ACID
lasibon 50 mg film-coated tablets	Pharmathen S.A.	EU/1/10/659/001-002&8-10	Film-coated tablet	-Ibandronic acid
Ibandronic Acid 150 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/184/001	Film-coated tablet	-Ibandronate sodium monohydrate
Ibandronic Acid 6 mg Concentrate for Solution for Infusion	Noridem Enterprises Limited	PA1122/018/001	Concentrate for solution for infusion	-Ibandronate sodium monohydrate
Ibandronic acid Accord	Accord Healthcare S.L.U.	EU/1/12/798/001	Concentrate for solution for infusion	-Ibandronate sodium monohydrate
Ibandronic acid Accord	Accord Healthcare S.L.U.	EU/1/12/798/002-004	Concentrate for solution for infusion	-Ibandronate sodium monohydrate
Ibandronic acid Accord	Accord Healthcare S.L.U.	EU/1/12/798/005-006	Solution for injection in pre-filled syringe	-Ibandronic acid -Ibandronate sodium monohydrate -Ibandronate sodium
Ibandronic Acid Clonmel 150 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/240/001	Film-coated tablet	-Ibandronic acid
Ibandronic Acid Mylan 150 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/111/001	Film-coated tablet	-Ibandronic sodium monohydrate
Ibandronic Acid Sandoz 50 mg film-coated tablets	Sandoz GmbH	EU/1/11/685/001-005	Film-coated tablet	-Ibandronic acid
Ibandronic Acid Teva 150 mg film-coated tablets	Teva Pharma B.V.	EU/1/10/642/003-004	Film-coated tablet	-Ibandronic acid
Ibandronic Acid Teva 50 mg film-coated tablets	Teva Pharma B.V.	EU/1/10/642/001-002	Film-coated tablet	-Ibandronic acid
Ibrance	Pfizer Europe MA EEIG	EU/1/16/1147/001-002	Capsule, hard	-Palbociclib
Ibrance	Pfizer Europe MA EEIG	EU/1/16/1147/0012-01	Film-coated tablet	-Palbociclib
Ibrance	Pfizer Europe MA EEIG	EU/1/16/1147/003-004	Capsule, hard	-Palbociclib
Ibrance	Pfizer Europe MA EEIG	EU/1/16/1147/005-006	Capsule, hard	-Palbociclib
Ibrance	Pfizer Europe MA EEIG	EU/1/16/1147/010-011	Film-coated tablet	-Palbociclib
Ibrance	Pfizer Europe MA EEIG	EU/1/16/1147/014-015	Film-coated tablet	-Palbociclib
Ibugel 5% w/w Gel	Dermal Laboratories (Ireland) Limited	PA23128/011/001	Gel	-Ibuprofen

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Ibuprofen 200 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/165/001	Film-coated tablet	-Ibuprofen
Ibuprofen 200 mg soft capsules	Brillpharma (Ireland) Limited	PA22749/022/004	Capsule, soft	-Ibuprofen ph. eur.
Ibuprofen 200mg Coated Tablets	Chefaro Ireland DAC	PA1186/022/001	Coated tablet	-Ibuprofen
Ibuprofen 400 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/165/002	Film-coated tablet	-Ibuprofen
Ibuprofen 600 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/165/003	Film-coated tablet	-Ibuprofen
Ibuprofen B. Braun 200 mg solution for infusion	B. Braun Melsungen AG	PA0736/041/003	Solution for infusion	-Ibuprofen
Ibuprofen B. Braun 400 mg solution for infusion	B. Braun Melsungen AG	PA0736/041/001	Solution for infusion	-Ibuprofen
Ibuprofen B. Braun 600 mg solution for infusion	B. Braun Melsungen AG	PA0736/041/002	Solution for infusion	-Ibuprofen
Ibuprofen Banner 100 mg soft chewable capsules	Patheon Softgels B.V.	PA22773/001/001	Chewable capsule, soft	-Ibuprofen
Ibuprofen Farmalider 200 mg film-coated tablets	Farmalider, S.A.	PA2090/002/001	Film-coated tablet	-Ibuprofen ph. eur.
Ibuprofen Max 400mg Film-coated Tablets	Chefaro Ireland DAC	PA1186/022/002	Film-coated tablet	-Ibuprofen
Ibuprofen/Paracetamol Hialeon 200 mg/500 mg film-coated tablets	Hialeon Ireland Limited	PA0678/160/001	Film-coated tablet	-Ibuprofen -Paracetamol
ICANDRA	Novartis Europharm Limited	EU/1/08/484/1-6, 13-15	Film Coated Tablet	
Icandra	Novartis Europharm Limited	EU/1/08/484/7-12, 16-18	Film-coated tablet	
Icatibant 30 mg solution for injection in pre-filled syringe	Fresenius Kabi Deutschland GmbH	PA2059/075/001	Solution for injection in pre-filled syringe	-Icatibant Acetate
Icatibant Accord	Accord Healthcare S.L.U.	EU/1/21/1567/001-002	Solution for infusion in pre-filled syringe	-Icatibant
Icatibant Aguettant 30 mg solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/014/001	Solution for injection in pre-filled syringe	-Icatibant Acetate
Iclusig	Incyte Biosciences Distribution B.V.	EU/1/13/839/001-002	Film-coated tablet	-Ponatinib hci
Iclusig	Incyte Biosciences Distribution B.V.	EU/1/13/839/003-004	Film-coated tablet	-Ponatinib hci
Iclusig	Incyte Biosciences Distribution B.V.	EU/1/13/839/006	Film-coated tablet	-Ponatinib hci
Icorvida SR 1.5mg Prolonged-release Tablets	KRKA, d.d., Novo mesto	PA1347/022/001	Prolonged-release tablet	-Indapamide
IDACIO	Fresenius Kabi Deutschland GmbH	EU/1/19/1356/001	Solution for injection	-Adalimumab
IDACIO	Fresenius Kabi Deutschland GmbH	EU/1/19/1356/002	Solution for injection in pre-filled syringe	-Adalimumab
IDACIO	Fresenius Kabi Deutschland GmbH	EU/1/19/1356/003	Solution for injection in pre-filled pen	-Adalimumab
Idefirix	Hansa Biopharma AB	EU/1/20/1471/001-002	Powder for concentrate for solution for infusion	-Imlifidase
IDELVION	CSL Behring GmbH	EU/1/16/1095/001	Powder and solvent for solution for injection	-Rix-fp
IDELVION	CSL Behring GmbH	EU/1/16/1095/002	Powder and solvent for solution for injection	-Rix-fp

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
IDELVION	CSL Behring GmbH	EU/1/16/1095/003	Powder and solvent for solution for injection	-Rix-fp
IDELVION	CSL Behring GmbH	EU/1/16/1095/004	Powder and solvent for solution for injection	-Rix-fp
Idelvion	CSL Behring GmbH	EU/1/16/1095/009	Powder and solvent for solution for injection	-Albutrepenonacog Alfa
Ideos 500 mg/400 IU Chewable Tablets	Primecrown 2010 Limited	PPA1633/033/001	Chewable tablet	-Cholecalciferol -Calcium carbonate
IDEOS 500mg/400 IU Chewable Tablets	Laboratoire Innotech International	PA1033/001/001	Chewable tablet	-Cholecalciferol -Calcium carbonate
Idrolax 10g, powder for oral solution in a sachet	IPSEN Consumer HealthCare	PA22808/001/001	Powder for oral solution in sachet	-Macrogol 4000
IELMAG3 0.2 mg kit for radiopharmaceutical preparation	ROTOP Pharmaka GmbH	PA2226/001/001	Kit for radiopharmaceutical preparation	-Mertiatide
Ifirmacombi	KRKA, d.d., Novo mesto	EU/1/11/673/001-008	Film-coated tablet	-Irbesartan hydrochloride -Hydrochlorothiazide
IFIRMACOMBI	Krka d.d., Novo mesto	EU/1/11/673/009-016	Film-coated tablet	-IRBESARTAN HYDROCHLORIDE -HYDROCHLOROTHIAZIDE
Ifirmacombi	KRKA, d.d., Novo mesto	EU/1/11/673/017-024	Film-coated tablet	-Irbesartan hydrochloride -Hydrochlorothiazide
Ifirmasta	KRKA, d.d., Novo mesto	EU/1/08/480/13-18	Film-coated tablet	-Irbesartan hydrochloride
Ifirmasta	KRKA, d.d., Novo mesto	EU/1/08/480/1-6	Film-coated tablet	-Irbesartan hydrochloride
Ifirmasta	KRKA, d.d., Novo mesto	EU/1/08/480/7-12	Film-coated tablet	-Irbesartan hydrochloride
Ikervis	Santen OY	EU/1/15/990/001-002	Eye drops, emulsion	-Ciclosporin
Ilaris	Novartis Europharm Limited	EU/1/09/564/004	Solution for injection	-Canakinumab
Ilaris	Novartis Europharm Limited	EU/1/09/564/1-2	Powder for solution for injection	-Canakinumab
Illuzyce	Billev Pharma ApS	EU/1/22/1680/001-006	Radiopharmaceutical precursor, solution	-Lutetium (177Lu) chloride
Ilumetri	Almirall, S.A.	EU/1/18/1323/001	Solution for injection in pre-filled syringe	-Tildrakizumab
Ilumetri	Almirall S.A.	EU/1/18/1323/003	Solution for injection	-Tildrakizumab
ILUVIEN 190 micrograms intravitreal implant in applicator	Alimera Sciences Europe Limited,	PA22620/001/001	Intravitreal implant in applicator	-Fluocinolone acetonide
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	-Paracetamol -BROMPHENIRAMINE MALEATE -Caffeine
Imatinib	Accord Healthcare S.L.U.	EU/1/13/845/001-008	Film-coated tablet	-Imatinib mesylate
Imatinib	Accord Healthcare S.L.U.	EU/1/13/845/009-014	Film-coated tablet	-Imatinib mesylate
Imatinib Krka d.d 100 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/054/001	Film-coated tablet	-Imatinib mesilate
Imatinib Krka d.d. 400 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/054/002	Film-coated tablet	-Imatinib mesilate
Imatinib Rowex 100mg Film-coated tablets	Rowex Ltd	PA0711/248/001	Film-coated tablet	-Imatinib mesilate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Imatinib Rowex 400mg Film-coated tablets	Rowex Ltd	PA0711/248/002	Film-coated tablet	-Imatinib mesilate
IMATINIB TEVA	Teva B.V.	EU/1/12/808/001-012	Film-coated tablet	-IMATINIB MESILATE
IMATINIB TEVA	Teva B.V.	EU/1/12/808/013-020	Film-coated tablet	-IMATINIB MESILATE
IMATINIB TEVA	Teva B.V.	EU/1/12/808/021-032	Capsule, hard	-IMATINIB MESILATE
IMATINIB TEVA	Teva B.V.	EU/1/12/808/033-040	Capsule, hard	-IMATINIB MESILATE
Imbruvica	Janssen-Cilag International NV	EU/1/14/945/001-002	Capsule, hard	-Ibrutinib
Imbruvica	Janssen-Cilag International NV	EU/1/14/945/005	Film-coated tablet	-Ibrutinib
Imbruvica	Janssen-Cilag International NV	EU/1/14/945/006	Film-coated tablet	-Ibrutinib
Imbruvica	Janssen-Cilag International NV	EU/1/14/945/007-008	Film-coated tablet	-Ibrutinib
Imbruvica	Janssen-Cilag International NV	EU/1/14/945/009-010	Film-coated tablet	-Ibrutinib
Imcivree	Rhythm Pharmaceuticals Netherlands B.V	EU/1/21/1564/001	Solution for injection	-Setmelanotide
Imdur 60 mg Prolonged-release Film-coated Tablets	Topridge Pharma (Ireland) Limited	PA2129/001/001	Prolonged-release tablet	-ISOSORBIDE MONONITRATE
Imfinzi	AstraZeneca AB	EU/1/18/1322/001-002	Concentrate for solution for infusion	-Durvalumab
Imigran 10 mg Nasal Spray, Solution	GlaxoSmithKline (Ireland) Limited	PA1077/008/003	Nasal spray, solution	-Sumatriptan
Imigran 20 mg nasal spray, solution	GlaxoSmithKline (Ireland) Limited	PA1077/008/004	Nasal spray, solution	-Sumatriptan
Imigran 20 mg nasal spray, solution	IMED Healthcare Ltd.	PPA1463/211/001	Nasal spray, solution	-Sumatriptan
Imigran 20 mg nasal spray, solution	PCO Manufacturing Ltd.	PPA0465/070/005	Nasal spray, solution	-Sumatriptan
Imigran Ftab 100 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/070/004	Film-coated tablet	-Sumatriptan
Imigran Ftab 100 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/032/002	Film-coated tablet	-Sumatriptan
Imigran Ftab 100 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/008/007	Film-coated tablet	-Sumatriptan succinate
Imigran Ftab 50 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/008/006	Film-coated tablet	-Sumatriptan succinate
Imigran Ftab 50 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/032/001	Film-coated tablet	-Sumatriptan
Imigran Ftab 50 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/070/003	Film-coated tablet	-Sumatriptan
Imipenem/Cilastatin 250 mg/250 mg powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/074/001	Powder for solution for infusion	-Imipenem -Cilastatin
Imipenem/Cilastatin 500 mg/500 mg powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/074/002	Powder for solution for infusion	-Imipenem -Cilastatin
Imipenem/Cilastatin 500 mg/500 mg powder for solution for infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/005/001	Powder for solution for infusion	-Imipenem -Cilastatin
Imjudo	AstraZeneca AB	EU/1/22/1713/001-002	Concentrate for solution for infusion	-Tremelimumab
Imlygic	Amgen Europe B.V.	EU/1/15/1064/001	Solution for injection	-Tolimogene laherparepvec
Imlygic	Amgen Europe B.V.	EU/1/15/1064/002	Solution for injection	-Tolimogene laherparepvec

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Imnovid	Bristol-Myers Squibb Pharma EEIG	EU/1/13/850/001	Capsule, hard	-Pomalidomide
Imnovid	Bristol-Myers Squibb Pharma EEIG	EU/1/13/850/002	Capsule, hard	-Pomalidomide
Imnovid	Bristol-Myers Squibb Pharma EEIG	EU/1/13/850/003	Capsule, hard	-Pomalidomide
Imnovid	Bristol-Myers Squibb Pharma EEIG	EU/1/13/850/004	Capsule, hard	-Pomalidomide
Imodium 2 mg Capsules	JNTL Consumer Health I (Ireland) Limited	PA23490/025/002	Capsule, hard	-Loperamide hydrochloride
Imodium Instants 2 mg Orodispersible Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/025/001	Orodispersible tablet	-Loperamide hydrochloride
Imodium Instants 2 mg Orodispersible Tablets	PCO Manufacturing Ltd.	PPA0465/001/002	Orodispersible tablet	-Loperamide hydrochloride
Imodium Instants 2 mg Orodispersible Tablets	IMED Healthcare Ltd.	PPA1463/207/001	Orodispersible tablet	-Loperamide hydrochloride
Imodium LiquiRelief 2mg Soft Capsules	JNTL Consumer Health I (Ireland) Limited	PA23490/025/003	Capsule, soft	-Loperamide hydrochloride
Imodium Plus 2 mg/125 mg Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/030/001	Tablet	-Loperamide hydrochloride -Simeticone
Imolieve 2 mg orodispersible tablets	Clonmel Healthcare Ltd	PA0126/305/001	Orodispersible tablet	-Loperamide hydrochloride
Implanon NXT, 68 mg implant for subdermal use	PCO Manufacturing Ltd.	PPA0465/250/001	Implant	-Etonogestrel
Implanon NXT, 68 mg implant for subdermal use	Organon Pharma (Ireland) Limited	PA23198/017/001	Implant	-Etonogestrel
Implanon NXT, 68 mg implant for subdermal use	IMED Healthcare Ltd.	PPA1463/171/001	Implant	-Etonogestrel
Implanon NXT, 68 mg implant for subdermal use	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/002/001	Implant	-Etonogestrel
Imraldi	Samsung Bioepis NL B.V.	EU/1/17/1216/001-004	Solution for injection in pre-filled syringe	-Adalimumab
Imraldi	Samsung Bioepis NL B.V.	EU/1/17/1216/005-008	Solution for injection in pre-filled pen	-Adalimumab
Imraldi	Samsung Bioepis NL B.V.	EU/1/17/1216/009	Solution for injection	-Adalimumab
Imuger 25 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/032/001	Film-coated tablet	-Azathioprine
Imuger 50 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/032/002	Film-coated tablet	-Azathioprine
Imunovir 500 mg tablets	Kora Corporation Limited trading as Kora Healthcare	PA1748/001/001	Tablet	-Inosine acedoben dimepranol
Imuran 25 mg Film-coated Tablets	Aspen Pharma Trading Limited	PA1691/003/002	Film-coated tablet	-Azathioprine
Imuran 25 mg Film-coated Tablets	IMED Healthcare Ltd.	PPA1463/196/002	Film-coated tablet	-Azathioprine
Imuran 25 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/077/001	Film-coated tablet	-Azathioprine
Imuran 50 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/077/002	Film-coated tablet	-Azathioprine
Imuran 50 mg Film-coated Tablets	IMED Healthcare Ltd.	PPA1463/196/001	Film-coated tablet	-Azathioprine
Imuran 50 mg Film-coated Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/041/001	Film-coated tablet	-Azathioprine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Imuran 50 mg Film-coated Tablets	Aspen Pharma Trading Limited	PA1691/003/003	Film-coated tablet	-Azathioprine
Imuran 50 mg Powder for Solution for Injection or Infusion	Aspen Pharma Trading Limited	PA1691/003/001	Powder for solution for injection/infusion	-Azathioprine sodium
IMVAGGIS 0.03 mg pessary	Laboratoires Besins International	PA1054/005/001	Pessary	-Estriol
Imvanex	Bavarian Nordic A/S	EU/1/13/855/001	Suspension for injectio	-Mva-bn virus
Inaqovi	Otsuka Pharmaceutical Netherlands B.V.	EU/1/23/1756/001	Film-coated tablet	-Decitabine -Cedazuridine
Inbrija	Acorda Therapeutics Ireland Limited	EU/1/19/1390/001-002	Inhalation powder, hard capsule	-Levodopa
Increlex	Ipsen Pharma	EU/1/07/402/001	Solution for injection	-Mecasermin
Incesync	Takeda Pharma A/S	EU/1/13/842/010-018	Film-coated tablet	-Alogliptin (as benzoate) -Pioglitazone (as hydrochloride)
Incesync	Takeda Pharma A/S	EU/1/13/842/01-09	Film-coated tablet	-Alogliptin (as benzoate) -Pioglitazone (as hydrochloride)
Incesync	Takeda Pharma A/S	EU/1/13/842/019-027	Film-coated tablet	-Pioglitazone (as hydrochloride) -Alogliptin (as benzoate)
Incesync	Takeda Pharma A/S	EU/1/13/842/028-036	Film-coated tablet	-Pioglitazone (as hydrochloride) -Alogliptin (as benzoate)
Incruse Ellipta	GlaxoSmithKline (Ireland) Limited	EU/1/14/922/001-003	Inhalation powder, pre-dispensed	-Umeclidinium bromide
Indium (111In) DTPA 37MBq/ml Solution for Injection	Curium Netherlands B.V.	PA0690/009/001	Solution for injection	-Indium (111 in) -PENTETIC ACID
Indium (In111) Chloride 370MBq/ml radiopharmaceutical precursor	Curium Netherlands B.V.	PA0690/008/001	Radiopharmaceutical precursor, solution	-Indium (111 in)
Indivina 1 mg/2.5 mg tablets	Orion Corporation	PA1327/005/001	Tablet	-Estradiol valerate -Medroxyprogesterone acetate
Indivina 1 mg/5 mg tablets	Orion Corporation	PA1327/005/002	Tablet	-Estradiol valerate -Medroxyprogesterone acetate
Indivina 2 mg/5 mg tablets	Orion Corporation	PA1327/005/003	Tablet	-Medroxyprogesterone acetate -Estradiol valerate
Indoramin 20 mg Film-coated Tablets	Chemidex Pharma Limited	PA22643/004/001	Film-coated tablet	-Indoramin base
InductOs	Medtronic BioPharma B.V.	EU/1/02/226/001	Powder, solvent and matrix for implantation matrix	-Dibotermis alfa
Inegy 10 mg / 20 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/024/002	Tablet	-Ezetimibe -Simvastatin
Inegy 10 mg / 80 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/024/004	Tablet	-Ezetimibe -Simvastatin
Inegy 10 mg/40 mg tablets	Organon Pharma (Ireland) Limited	PA23198/024/003	Tablet	-Ezetimibe -Simvastatin
Inegy 10mg / 10mg Tablets	Organon Pharma (Ireland) Limited	PA23198/024/001	Tablet	-Ezetimibe -Simvastatin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/001	Powder and suspension for injection	-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 injection	-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 injectio	-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 injectio	-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 injection	-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 injection	-Filamentous haemagglutinin (fha) -Polysaccharide-k -Diphtheria toxoid -Haemophilus influenzae -Tetanus toxoid -Pertactin -Pertussis toxoid -Hbs ag

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/007	Suspension for injectio	-Haemophilus influenzae -Pertactin -Diphtheria toxoid -Polysaccharide-k -Tetanus toxoid -Filamentous haemagglutinin (fha) -Hbs ag -Pertussis toxoid
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/008	Suspension for injectio	-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 injectio	-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 injectio	-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 injectio	-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 injectio	-Haemophilus influenzae -Pertactin -Diphtheria toxoid -Polysaccharide-k -Tetanus toxoid -Filamentous haemagglutinin (fha) -Hbs ag -Pertussis toxoid

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/013	Suspension for injectio	-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	-Haemophilus influenzae -Pertactin -Diphtheria toxoid -Polysaccharide-k -Tetanus toxoid -Filamentous haemagglutinin (fha) -Hbs ag -Pertussis toxoid
Infanrix hexa	GlaxoSmithKline Biologicals S.A.	EU/1/00/152/015	Suspension for injectio	-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	-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	-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)
Inflectra	Pfizer Europe MA EEIG	EU/1/13/854/001-005	Powder for concentrate for solution for infusion	-Ct-p13 (infliximab)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Influvac Tetra, suspension for injection in pre-filled syringe (influenza vaccine, surface antigen, inactivated)	Viartis Healthcare Limited	PA23355/016/001	Suspension for injection in pre-filled syringe	-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)
Infutrage concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/083/001	Concentrate for solution for infusion	-Copper chloride dihydrate -Manganese chloride tetrahydrate -Potassium iodide -Sodium selenite anhydrous -Zinc chloride
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/001-002	Solution for injection in pre-filled syringe	-Enoxaparin sodium
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/003-004	Solution for injection in pre-filled syringe	-Enoxaparin sodium
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/005-006	Solution for injection in pre-filled syringe	-Enoxaparin sodium
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/007-008	Solution for injection in pre-filled syringe	-Enoxaparin sodium
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/009-010	Solution for injection in pre-filled syringe	-Enoxaparin sodium
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/069	Solution for injection in pre-filled syringe	-Enoxaparin sodium
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/070	Solution for injection in pre-filled syringe	-Enoxaparin sodium
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/071	Solution for injection in multidose container	-Enoxaparin sodium -Enoxaparin sodium
Inhixa	Techdow Pharma Netherlands B.V	EU/1/16/1132/072	Solution for injection in multidose container	-Enoxaparin sodium -Enoxaparin sodium
Inlyta	Pfizer Europe MA EEIG	EU/1/12/777/001-003	Film-coated tablet	-Axitinib
Inlyta	Pfizer Europe MA EEIG	EU/1/12/777/004-006	Film-coated tablet	-Axitinib
Inlyta	Pfizer Europe MA EEIG	EU/1/12/777/007-009	Film-coated tablet	-Axitinib
Inlyta	Pfizer Europe MA EEIG	EU/1/12/777/010-012	Film-coated tablet	-Axitinib
innohep 10,000 IU in 0.5 ml, solution for injection	Leo Laboratories Limited	PA0046/060/010	Solution for injection	-Tinzaparin sodium
innohep 10,000 IU in 0.5 ml, solution for injection	PCO Manufacturing Ltd.	PPA0465/499/003	Solution for injection	-Tinzaparin sodium
innohep 10,000 IU/ml solution for injection	Leo Laboratories Limited	PA0046/060/002	Solution for injection	-Tinzaparin sodium
innohep 12,000 IU in 0.6 ml, Solution for injection	Leo Laboratories Limited	PA0046/060/013	Solution for injection	-Tinzaparin sodium
innohep 14,000 IU in 0.7 ml, solution for injection	Leo Laboratories Limited	PA0046/060/011	Solution for injection	-Tinzaparin sodium

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
innohep 14,000 IU in 0.7 ml, solution for injection	PCO Manufacturing Ltd.	PPA0465/499/004	Solution for injection	-Tinzaparin sodium
innohep 16,000 IU in 0.8 ml, Solution for injection	Leo Laboratories Limited	PA0046/060/014	Solution for injection	-Tinzaparin sodium
innohep 18,000 IU in 0.9 ml, solution for injection	Leo Laboratories Limited	PA0046/060/004	Solution for injection	-Tinzaparin sodium
innohep 18,000 IU in 0.9 ml, solution for injection	PCO Manufacturing Ltd.	PPA0465/499/005	Solution for injection	-Tinzaparin sodium
innohep 2,500 IU, solution for injection	Leo Laboratories Limited	PA0046/060/008	Solution for injection	-Tinzaparin sodium
innohep 20,000 IU/ml Solution for Injection	Leo Laboratories Limited	PA0046/060/003	Solution for injection	-Tinzaparin sodium
innohep 3,500 IU, solution for injection	Leo Laboratories Limited	PA0046/060/009	Solution for injection	-Tinzaparin sodium
innohep 3,500 IU, solution for injection	PCO Manufacturing Ltd.	PPA0465/499/002	Solution for injection	-Tinzaparin sodium
innohep 4,500 IU, solution for injection	PCO Manufacturing Ltd.	PPA0465/499/001	Solution for injection	-Tinzaparin sodium
innohep 4,500 IU, solution for injection	Leo Laboratories Limited	PA0046/060/007	Solution for injection	-Tinzaparin sodium
innohep 8,000 IU in 0.4 ml, Solution for injectio	Leo Laboratories Limited	PA0046/060/012	Solution for injection	-Tinzaparin sodium
Innovace 10 mg Tablets	PCO Manufacturing Ltd.	PPA0465/462/001	Tablet	-Enalapril maleate
Innovace 10 mg Tablets	IMED Healthcare Ltd.	PPA1463/208/001	Tablet	-Enalapril maleate
Innovace 10 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/005/003	Tablet	-Enalapril maleate
Innovace 2.5 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/005/001	Tablet	-Enalapril maleate
Innovace 20 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/005/004	Tablet	-Enalapril maleate
Innovace 20 mg Tablets	IMED Healthcare Ltd.	PPA1463/208/002	Tablet	-Enalapril maleate
Innovace 5 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/005/002	Tablet	-Enalapril maleate
Innozide 20 mg/12.5 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/006/001	Tablet	-Enalapril maleate -Hydrochlorothiazide
INOmax	AGA AB	EU/1/01/194/001	Medicinal gas, compressed	-Nitric oxide
INOmax	INO Therapeutics AB	EU/1/01/194/003-004	Medicinal gas, compressed	-Nitric oxide
Inovelon	Eisai GmbH	EU/1/06/378/017	Oral suspension	-Rufinamide
Inovelon	Eisai GmbH	EU/1/06/378/1-16	Film-coated tablet	-Rufinamide
Inrebic	Bristol-Myers Squibb Pharmaceuticals uc	EU/1/20/1514/001	Capsule, hard	-Fedratinib dihydrochloride monohydrate -Fedratinib
Insomniger 10 mg tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/225/001	Tablet	-Temazepam
Insomniger 20 mg tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/225/002	Tablet	-Temazepam
INSPRA	B & S Healthcare	DPR1328/016/002	Tablet	-EPLERENONE
INSPRA 25 mg film-coated tablets	Upjohn EESV	PA23055/005/001	Film-coated tablet	-Eplerenone
INSPRA 50 mg film-coated tablets	Upjohn EESV	PA23055/005/002	Film-coated tablet	-Eplerenone
Instanyl	Takeda Danmark A/S	EU/1/09/531/010-013	Nasal spray, solution	-FENTANYL CITRATE
Instanyl	Takeda Danmark A/S	EU/1/09/531/014-017	Nasal spray, solution	-FENTANYL CITRATE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Instanyl	Takeda Danmark A/S	EU/1/09/531/018-021	Nasal spray, solution	-FENTANYL CITRATE
Instanyl	Takeda Danmark A/S	EU/1/09/531/1-3	Nasal spray, solution	-FENTANYL CITRATE
Instanyl	Takeda Danmark A/S	EU/1/09/531/4-6	Nasal spray, solution	-FENTANYL CITRATE
Instanyl	Takeda Danmark A/S	EU/1/09/531/7-9	Nasal spray, solution	-FENTANYL CITRATE
Instillagel 6 ml Urethral, vaginal, rectal and oropharyngeal gel	Farco-Pharma GmbH	PA0328/001/001	Gel	-Lidocaine hydrochloride -Chlorhexidine digluconate (as chlorhexidine digluconate solution (20% w/v) ph.eur. -Methyl parahydroxybenzoate -Propyl parahydroxybenzoate
Instillagel® 11 ml Urethral, vaginal, rectal and oropharyngeal gel	Farco-Pharma GmbH	PA0328/001/002	Gel	-Lidocaine hydrochloride -Chlorhexidine digluconate (as chlorhexidine digluconate solution (20% w/v) ph.eur. -Methyl parahydroxybenzoate -Propyl parahydroxybenzoate
Insulatard	Novo Nordisk A/S	EU/1/02/233/1-15	Suspension for injectio	-Insulin human
Insulatard	Novo Nordisk A/S	EU/1/02/233/003-004	Suspension for injectio	-Insulin human
Insulatard FlexPen	Novo Nordisk A/S	EU/1/02/233/013	Suspension for injectio	-Insulin human
Insulatard InnoLet	Novo Nordisk A/S	EU/1/02/233/010-012	Suspension for injectio	-Insulin human
Insulatard Penfill	Novo Nordisk A/S	EU/1/02/233/005-007	Suspension for injectio	-Insulin human
Insulin aspart Sanofi	Sanofi Winthrop Industrie	EU/1/20/1447/001-005	Solution for injection	-Insulin aspart
Insulin aspart Sanofi	Sanofi Winthrop Industrie	EU/1/20/1447/001-007	Solution for injection	-Insulin aspart
Insulin lispro Sanofi (previously Admelog)	Sanofi Winthrop Industrie	EU/1/17/1203/001-008	Solution for injection	-Insulin lispro
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/037	Suspension for injectio	-Insulin human
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/029	Suspension for injectio	-Insulin human
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/057	Suspension for injectio	-Insulin human
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/058	Suspension for injectio	-Insulin human
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/069	Solution for injection	-Insulin human
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/070	Suspension for injectio	-Insulin human
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/071	Suspension for injectio	-Insulin human
Insuman Basal	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/072	Suspension for injectio	-Insulin human
Insuman Basal 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/033	Suspension for injectio	-Insulin human
Insuman Basal 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/034	Suspension for injectio	-Insulin human
Insuman Basal 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/035	Suspension for injectio	-Insulin human
Insuman Basal 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/036	Suspension for injectio	-Insulin human

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Insuman Comb 15	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/059	Suspension for injectio	-Insulin human
Insuman Comb 15	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/060	Suspension for injectio	-Insulin human
Insuman Comb 15	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/073	Suspension for injectio	-Insulin human
Insuman Comb 15	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/074	Suspension for injectio	-Insulin human
Insuman Comb 15	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/075	Suspension for injectio	-Insulin human
Insuman Comb 15	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/076	Suspension for injectio	-Insulin human
Insuman Comb 15 100 IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/038	Suspension for injectio	-Insulin human
Insuman Comb 15 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/039	Suspension for injectio	-Insulin human
Insuman Comb 15 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/040	Suspension for injectio	-Insulin human
Insuman Comb 15 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/041	Suspension for injectio	-Insulin human
Insuman Comb 15 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/042	Suspension for injectio	-Insulin human
Insuman Comb 25	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/077	Suspension for injectio	-Insulin human
Insuman Comb 25	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/078	Suspension for injectio	-Insulin human
Insuman Comb 25	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/079	Suspension for injectio	-Insulin human
Insuman Comb 25	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/080	Suspension for injectio	-Insulin human
Insuman Comb 25	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/061	Suspension for injectio	-Insulin human
Insuman Comb 25	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/062	Suspension for injectio	-Insulin human
Insuman Comb 25 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/043	Suspension for injectio	-Insulin human
Insuman Comb 25 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/044	Suspension for injectio	-Insulin human
Insuman Comb 25 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/045	Suspension for injectio	-Insulin human
Insuman Comb 25 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/046	Suspension for injectio	-Insulin human
Insuman Comb 25 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/047	Suspension for injectio	-Insulin human
Insuman Comb 30	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/170-189	Suspension for injectio	-Insulin human hr1799
Insuman Comb 50	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/063	Suspension for injectio	-Insulin human
Insuman Comb 50	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/064	Suspension for injectio	-Insulin human
Insuman Comb 50	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/081	Suspension for injectio	-Insulin human
Insuman Comb 50	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/082	Suspension for injectio	-Insulin human
Insuman Comb 50	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/083	Suspension for injectio	-Insulin human
Insuman Comb 50	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/084	Suspension for injectio	-Insulin human
Insuman Comb 50 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/048	Suspension for injectio	-Insulin human
Insuman Comb 50 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/049	Suspension for injectio	-Insulin human
Insuman Comb 50 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/050	Suspension for injectio	-Insulin human
Insuman Comb 50 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/051	Suspension for injectio	-Insulin human

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Insuman Comb 50 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/052	Suspension for injectio	-Insulin human
Insuman Implantable	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/202-203	Solution for infusion	-Insulin human
Insuman Infusat 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/053	Solution for injection	-Insulin human
Insuman Infusat 100IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/054	Solution for injection in cartridge	-Insulin human
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/055	Solution for injection in cartridge	-Insulin human
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/056	Solution for injection in cartridge	-Insulin human
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/065	Solution for injection	-Insulin human
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/066	Solution for injection	-Insulin human
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/067	Solution for injection	-Insulin human
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/068	Solution for injection	-Insulin human
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/030	Solution for injection in cartridge	-Insulin human
Insuman Rapid	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/031	Solution for injection	-Insulin human
INSUMAN RAPID	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/028	Solution for injection	-Insulin human
Insuman Rapid 40IU/ml	Sanofi-Aventis Deutschland GmbH	EU/1/97/030/032	Solution for injection	-Insulin human
Integrilin	GlaxoSmithKline (Ireland) Limited	EU/1/99/109/001	Solution for infusion	-Eptifibatide
Integrilin	GlaxoSmithKline (Ireland) Limited	EU/1/99/109/002	Solution for injection	-Eptifibatide
Intelence	Janssen-Cilag International NV	EU/1/08/468/002	Tablet	-Etravirine
Intelence	Janssen-Cilag International NV	EU/1/08/468/003	Tablet	-Etravirine
Intelence	Janssen-Cilag International NV	EU/1/08/468/1	Tablet	-Etravirine
Intralipid 20 % w/v Emulsion for Infusion Biofine bag	Fresenius Kabi Deutschland GmbH	PA2059/041/005	Emulsion for infusion	-Soya bean oil, refined
Intralipid 20% w/v Emulsion for Infusion, Glass Bottle	Fresenius Kabi Deutschland GmbH	PA2059/041/001	Emulsion for infusion	-Soya bean oil
Intrarosa	Endoceutics S.A.	EU/1/17/1255/001	Pessary	-Prasterone
Intratect 100 g/L, solution for infusion	Biotest Pharma GmbH	PA0592/007/002	Solution for infusion	-Human plasma protein
Intratect 50 g/L, solution for infusion	Biotest Pharma GmbH	PA0592/007/001	Solution for infusion	-Human plasma protein >96% immunoglobulins
IntronA	Schering Plough Europe	EU/1/99/127/001	Powder and solvent for solution for injection	-Interferon alfa-2b
INTRONA	Schering Plough Europe	EU/1/99/127/036	Solution for Injection	-INTERFERON ALFA- 2B
INTRONA	Schering Plough Europe	EU/1/99/127/038	Solution for Injection	-INTERFERON ALFA- 2B
Intuniv	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/15/1040/001-002	Prolonged-release tablet	-GUANFACINE HYDROCHLORIDE
Intuniv	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/15/1040/003-005	Prolonged-release tablet	-GUANFACINE HYDROCHLORIDE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Intuniv	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/15/1040/006-007	Prolonged-release tablet	-GUANFACINE HYDROCHLORIDE
Intuniv	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/15/1040/008-009	Prolonged-release tablet	-GUANFACINE HYDROCHLORIDE
Invanz	Merck Sharp & Dohme BV,	EU/1/02/216/001	Concentrate for solution for infusion	-Ertapenem sodium
INVEGA 12 mg prolonged-release tablets	Janssen-Cilag International NV	EU/1/07/395/16-20	Prolonged-release tablet	-Paliperidone
INVEGA 3 mg prolonged-release tablets	Janssen-Cilag International NV	EU/1/07/395/1-5	Prolonged-release tablet	-Paliperidone
INVEGA 6 mg prolonged-release tablets	Janssen-Cilag International NV	EU/1/07/395/6-10	Prolonged-release tablet	-Paliperidone
INVEGA 9 mg prolonged-release tablets	Janssen-Cilag International NV	EU/1/07/395/11-15	Prolonged-release tablet	-Paliperidone
Invokana	Janssen-Cilag International NV	EU/1/13/884/001-004	Film-coated tablet	-Canagliflozin
Invokana	Janssen-Cilag International NV	EU/1/13/884/005-008	Film-coated tablet	-Canagliflozin
Iodine Liniment Strong, Cutaneous Solution Iodine 10% w/v Potassium Iodide 6% w/v	Ovelle Limited	PA0206/026/001	Cutaneous solution	-Potassium iodide -Iodine
Iodine Tincture (Alcoholic Iodine Solution BP), Cutaneous Solution Iodine 2.5% w/v Potassium Iodide 2.5% w/v	Ovelle Limited	PA0206/025/001	Cutaneous solution	-Potassium iodide -Iodine
lomepron 150 mg/ml Solution for Injection	Bracco Imaging spa	PA1826/006/001	Solution for injection	-lomepron
lomepron 200 mg/ml Solution for Injection	Bracco Imaging spa	PA1826/006/002	Solution for injection	-lomepron
lomepron 250 mg/ml Solution for Injection	Bracco Imaging spa	PA1826/006/003	Solution for injection	-lomepron
lomepron 300 mg/ml Solution for Injection	Bracco Imaging spa	PA1826/006/004	Solution for injection	-lomepron
lomepron 350 mg/ml Solution for Injection	Bracco Imaging spa	PA1826/006/005	Solution for injection	-lomepron
lomepron 400 mg/ml Solution for Injection	Bracco Imaging spa	PA1826/006/006	Solution for injection	-lomepron
Ionolyte solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/042/001	Solution for infusion	-Sodium acetate trihydrate -Sodium chloride -Potassium chloride -Magnesium chloride hexahydrate -Sodium hydroxide
IOPIDINE 1%w/v Eye Drops, Solution	Essential Pharma Limited	PA22587/002/002	Eye drops, solution	-Apraclonidine hydrochloride
Iopidine 5 mg/ml Eye Drops, Solution	Essential Pharma Limited	PA22587/002/001	Eye drops, solution	-Apraclonidine hydrochloride
Ipramol Steri-Neb 0.5 mg/2.5 mg per 2.5 ml nebuliser solution	Teva B.V.	PA1986/082/001	Nebuliser solution	-Ipratropium bromide -SALBUTAMOL SULFATE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Ipratropium bromide/Salbutamol Neutec 0.5/2.5 mg per 2.5 ml nebuliser solution	Neutec Inhaler Ireland Limited	PA23030/003/001	Nebuliser solution	-Ipratropium bromide monohydrate -SALBUTAMOL SULFATE
Ipratropium Steri-Neb 250 micrograms/ml Nebuliser solution	Teva B.V.	PA1986/083/001	Nebuliser solution	-Ipratropium bromide
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	-Pertussis toxoid -Filamentous haemagglutinin -Pertactin -Diphtheria toxoid -Tetanus toxoid -Polio virus type 1 inactivated -Polio virus type 2 inactivated -Polio virus type 3 inactivated
IPV-Boostrix– Suspension for injection in a pre-filled syringe Diphtheria, 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	-Diphtheria toxoid -Tetanus toxoid -Pertussis toxoid -Filamentous haemagglutinin -Pertactin -Type 1 (mahoney) -Type 2 (mef-1) -Type 3 (saukett)
Irbesartan Accord 150 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/037/002	Film-coated tablet	-Irbesartan
Irbesartan Accord 300 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/037/003	Film-coated tablet	-Irbesartan
Irbesartan Accord 75 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/037/001	Film-coated tablet	-Irbesartan
Irbesartan Clonmel 150mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/205/002	Film-coated tablet	-Irbesartan
Irbesartan Clonmel 300mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/205/003	Film-coated tablet	-Irbesartan
Irbesartan Clonmel 75mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/205/001	Film-coated tablet	-Irbesartan
Irbesartan HCT Winthrop	Zentiva k.s.	EU/1/06/377/23-28	Tablet	-Irbesartan -Hydrochlorothiazide
Irbesartan HCT Winthrop	Zentiva k.s.	EU/1/06/377/6-10,17-22	Tablet	-Irbesartan -Hydrochlorothiazide
Irbesartan HCT Winthrop	Zentiva k.s.	EU/1/06/377/006-010	Tablet	-Irbesartan -Hydrochlorothiazide
Irbesartan HCT Zentiva	Zentiva k.s.	EU/1/06/377/1-5,11-16	Tablet	-Hydrochlorothiazide -Irbesartan
Irbesartan HCT Zentiva	Zentiva k.s.	EU/1/06/377/001-005	Tablet	-Hydrochlorothiazide -Irbesartan
IRBESARTAN PHARMATHEN	Pharmathen S.A.	EU/1/12/765/001-002	Film-coated tablet	-IRBESARTAN
IRBESARTAN PHARMATHEN	Pharmathen S.A.	EU/1/12/765/003-004	Film-coated tablet	-IRBESARTAN
IRBESARTAN PHARMATHEN	Pharmathen S.A.	EU/1/12/765/005-006	Film-coated tablet	-IRBESARTAN
Irbesartan Rowa 150 mg tablets	Rowa Pharmaceuticals Limited	PA0074/080/002	Tablet	-Irbesartan

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Irbesartan Rowa 300 mg tablets	Rowa Pharmaceuticals Limited	PA0074/080/003	Tablet	-Irbesartan
Irbesartan Rowa 75 mg tablets	Rowa Pharmaceuticals Limited	PA0074/080/001	Tablet	-Irbesartan
IRBESARTAN TEVA	Teva B.V.	EU/1/09/576/1-13	Film-coated tablet	-IRBESARTAN
IRBESARTAN TEVA	Teva B.V.	EU/1/09/576/14-26	Film-coated tablet	-IRBESARTAN
IRBESARTAN TEVA	Teva B.V.	EU/1/09/576/27-39	Film-coated tablet	-IRBESARTAN
Irbesartan Winthrop	Zentiva k.s.	EU/1/06/376/001-005	Tablet	-Irbesartan
Irbesartan Winthrop	Zentiva k.s.	EU/1/06/376/11-15	Tablet	-Irbesartan
Irbesartan Winthrop	Zentiva k.s.	EU/1/06/376/1-5	Tablet	-Irbesartan
Irbesartan Winthrop	Zentiva k.s.	EU/1/06/376/1-5-16-21	Film-coated tablet	-Irbesartan
Irbesartan Winthrop	Zentiva k.s.	EU/1/06/376/16-21	Film-coated tablet	-Irbesartan
Irbesartan Winthrop	Zentiva k.s.	EU/1/06/376/22-27	Film-coated tablet	-Irbesartan
Irbesartan Winthrop	Zentiva k.s.	EU/1/06/376/28-33	Film-coated tablet	-Irbesartan
Irbesartan Winthrop	Zentiva k.s.	EU/1/06/376/6-10	Tablet	-Irbesartan
IRBESARTAN/HYDROCHLOROTHIAZIDE TEVA	Teva B.V.	EU/1/09/583/1-24	Film-coated tablet	-IRBESARTAN - HYDROCHLOROTHIAZIDE, MICRONISED
IRBESARTAN/HYDROCHLOROTHIAZIDE TEVA	Teva B.V.	EU/1/09/583/25-48	Film-coated tablet	-IRBESARTAN - HYDROCHLOROTHIAZIDE, MICRONISED
IRBESARTAN/HYDROCHLOROTHIAZIDE TEVA	Teva B.V.	EU/1/09/583/49-72	Film-coated tablet	-IRBESARTAN - HYDROCHLOROTHIAZIDE, MICRONISED
Iressa	AstraZeneca AB	EU/1/09/526/001-002	Film-coated tablet	-Gefitinib
Ireven 150mg prolonged-release capsules, hard	Pharmathen S.A.	PA1368/002/002	Prolonged-release capsule, hard	-Venlafaxine hydrochloride
Ireven 75 mg prolonged-release capsules, hard	Pharmathen S.A.	PA1368/002/001	Prolonged-release capsule, hard	-Venlafaxine hydrochloride
Iricryn 0.3 mg/ml eye drops, solution	Farmaprojects S.A.	PA1391/006/001	Eye drops, solution	-Bimatoprost
Irinotecan 20 mg/ml Concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/044/001	Concentrate for solution for infusion	-Irinotecan
Irinotecan Hydrochloride 20 mg/mL concentrate for solution for infusion	Teva B.V.	PA1986/068/001	Concentrate for solution for infusion	-Irinotecan hydrochloride trihydrate
Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/108/001	Concentrate for solution for infusion	-Irinotecan hydrochloride trihydrate
Irujol Mono 1.2U/g Ointment	Smith & Nephew GmbH	PA22696/001/001	Ointment	-Protease -Clostridiopeptidase a
Iscover	Sanofi Winthrop Industrie	EU/1/98/070/001	Film-coated tablet	-Clopidogrel hydrogensulfate
Iscover	Sanofi Winthrop Industrie	EU/1/98/070/8-10	Film-coated tablet	-Clopidogrel hydrogensulfate
Isentress	Merck Sharp & Dohme BV,	EU/1/07/436/003	Chewable tablet	-Raltegravir
Isentress	Merck Sharp & Dohme BV	EU/1/07/436/004	Chewable tablet	-Raltegravir
Isentress	Merck Sharp & Dohme BV	EU/1/07/436/005	Granules for oral suspension	-Raltegravir
Isentress	Merck Sharp & Dohme BV	EU/1/07/436/006	Film-coated tablet	-Raltegravir
Isentress	Merck Sharp & Dohme BV,	EU/1/07/436/1-2	Film-coated tablet	-Raltegravir potassium

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Isosorbide dinitrate
Isomel SR	Dexcel Pharma GmbH	PA2261/002/001	Prolonged-release tablet	-Isosorbid-5-mononitrat
Isomonit Retard 60 mg Prolonged-release tablets	Rowex Ltd	PA0711/023/001	Prolonged-release tablet	-ISOSORBIDE MONONITRATE
Isoprenaline hydrochloride Macure 0.2 mg/ml concentrate for solution for infusion	Macure Pharma ApS	PA23199/001/001	Concentrate for solution for infusion	-ISOPRENALINE HYDROCHLORIDE
Isoptin 2.5mg/ml Solution for Injection or Infusion	Mylan IRE Healthcare Limited	PA2010/003/004	Solution for injection/infusion	-Verapamil hydrochloride
Isoptin 40 mg film- coated tablets	Mylan IRE Healthcare Limited	PA2010/003/001	Film-coated tablet	-Verapamil hydrochloride
Isoptin 80 mg film- coated tablets	Mylan IRE Healthcare Limited	PA2010/003/002	Film-coated tablet	-Verapamil hydrochloride
Isoptin SR 240 mg Prolonged-Release Tablets	Mylan IRE Healthcare Limited	PA2010/003/005	Prolonged-release tablet	-Verapamil hydrochloride
Isotretinoin 10 mg soft capsules	Rowex Ltd	PA0711/312/002	Capsule, soft	-Isotretinoin
Isotretinoin 20 mg soft capsules	Rowex Ltd	PA0711/312/003	Capsule, soft	-Isotretinoin
Isotretinoin GAP 10 mg capsule, soft	Gap S.A.	PA22735/002/001	Capsule, soft	-Isotretinoin
Isotretinoin GAP 20 mg capsule, soft	Gap S.A.	PA22735/002/002	Capsule, soft	-Isotretinoin
Isotretinoin SUN 10 mg soft capsules	Sun Pharmaceutical Industries Europe B.V.	PA2050/007/001	Capsule, soft	-Isotretinoin
Isotretinoin SUN 20 mg soft capsules	Sun Pharmaceutical Industries Europe B.V.	PA2050/007/002	Capsule, soft	-Isotretinoin
Istin 10 mg hard capsule	Upjohn EESV	PA23055/012/004	Capsule, hard	-Amlodipine besilate
Istin 10 mg tablets	Upjohn EESV	PA23055/012/002	Tablet	-Amlodipine
Istin 10 mg tablets	PCO Manufacturing Ltd.	PPA0465/065/002	Tablet	-Amlodipine
Istin 5 mg hard capsule	Upjohn EESV	PA23055/012/003	Capsule, hard	-Amlodipine besilate
Istin 5 mg tablets	Upjohn EESV	PA23055/012/001	Tablet	-Amlodipine
Istin 5 mg tablets	PCO Manufacturing Ltd.	PPA0465/065/001	Tablet	-Amlodipine
Isturis	Recordati Rare Diseases	EU/1/19/1407/001	Film-coated tablet	-Osilodrostat
Isturis	Recordati Rare Diseases	EU/1/19/1407/002	Film-coated tablet	-Osilodrostat
Isturis	Recordati Rare Diseases	EU/1/19/1407/003	Film-coated tablet	-Osilodrostat
Itami 140 mg medicated plaster	Fidia Farmaceutici S.p.A.	PA0814/002/001	Medicated plaster	-Diclofenac sodium
Itoco 20 mg/ml eye drops, solution	Farmaprojects S.A.	PA1391/003/001	Eye drops, solution	-Dorzolamide hydrochloride
Itraconazole 10mg/ml oral solution	Athlone Pharmaceuticals Limited	PA1418/004/001	Oral solution	-Itraconazole
ITULAZAX 12 SQ-Bet sublingual lyophilisate	ALK-Abello A/S	PA1255/007/001	Oral lyophilisate	-Betula verrucosa
Ivabradine Accord	Accord Healthcare S.L.U.	EU/1/17/1190/001-007	Film-coated tablet	-Ivabradine hydrochloride
Ivabradine Accord	Accord Healthcare S.L.U.	EU/1/17/1190/008-014	Film-coated tablet	-Ivabradine hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Ivabradine Anpharm	Anpharm Przedsiębiorstwo Farmaceutyczne S.A	EU/1/15/1041/001-007	Film-coated tablet	-Ivabradine hydrochloride
Ivabradine Anpharm	Anpharm Przedsiębiorstwo Farmaceutyczne S.A	EU/1/15/1041/008-014	Film-coated tablet	-Ivabradine hydrochloride
Ivabradine Krka 5 mg Film-coated Tablets	KRKA, d.d., Novo mesto	PA1347/065/001	Film-coated tablet	-Ivabradine
Ivabradine Krka 7.5 mg Film-coated Tablets	KRKA, d.d., Novo mesto	PA1347/065/002	Film-coated tablet	-Ivabradine
Ivabradine Rowex 5 mg Film-coated Tablets	Rowex Ltd	PA0711/265/001	Film-coated tablet	-Ivabradine
Ivabradine Rowex 7.5 mg Film-coated Tablets	Rowex Ltd	PA0711/265/002	Film-coated tablet	-Ivabradine
Ivabradine Zentiva	Zentiva k.s.	EU/1/16/1144/001-007	Film-coated tablet	-Ivabradine hydrochloride
IVABRADINE ZENTIVA	Zentiva k.s.	EU/1/16/1144/008-014	Film-coated tablet	-IVABRADINE HYDROCHLORIDE
IVEMEND	Merck Sharp & Dohme BV,	EU/1/07/437/001-2	Powder for solution for infusion	-Fosaprepitant dimeglumine
Ivemend	Merck Sharp & Dohme BV,	EU/1/07/437/003-004	Powder for solution for infusion	-Fosaprepitant dimeglumine
Ivozall	Aenova Holding GmbH	EU/1/19/1396/001	Concentrate for solution for infusion	-Clofarabine
Ixiaro	Intercell Austria AG	EU/1/08/501/1-2	Suspension for injectio	-Inactivated je virus
IXPRIM 37.5 mg/325 mg, film coated-tablets	Grunenthal Pharma Ltd	PA2242/006/001	Film-coated tablet	-Tramadol hydrochloride -Paracetamol
IXPRIM effervescent 37.5 mg/325 mg effervescent tablets	Grunenthal Pharma Ltd	PA2242/006/002	Effervescent tablet	-Paracetamol -Tramadol hydrochloride
Izba	Novartis Europharm Limited	EU/1/13/905/001-002	Eye drops, solution	-Travoprost
Jakavi	Novartis Europharm Limited	EU/1/12/773/001	Tablet	-Ruxolitinib
Jakavi	Novartis Europharm Limited	EU/1/12/773/002	Tablet	-Ruxolitinib
Jakavi	Novartis Europharm Limited	EU/1/12/773/003	Tablet	-Ruxolitinib
Jakavi	Novartis Europharm Limited	EU/1/12/773/013-016	Tablet	-Ruxolitinib
Jalra	Novartis Europharm Limited	EU/1/08/485/1-11	Tablet	-Vildagliptin
Janumet	Merck Sharp & Dohme BV	EU/1/08/455/008-014	Film-coated tablet	-Sitagliptin phosphate -Metformin Hydrochloride
Janumet	Merck Sharp & Dohme BV,	EU/1/08/455/1-7	Film-coated tablet	-Sitagliptin phosphate -Metformin Hydrochloride
Janumet	Merck Sharp & Dohme BV	EU/1/08/455/8-14	Film-coated tablet	-Sitagliptin phosphate -Metformin Hydrochloride
Januvia 100 mg film- coated tablets	Merck Sharp & Dohme BV	EU/1/07/383/13-18	Film-coated tablet	-Sitagliptin phosphate monohydrate
Januvia 25 mg film- coated tablets	Merck Sharp & Dohme BV,	EU/1/07/383/1-6	Film-coated tablet	-Sitagliptin phosphate monohydrate
Januvia 50 mg film- coated tablets	Merck Sharp & Dohme BV	EU/1/07/383/7-12	Film-coated tablet	-Sitagliptin phosphate monohydrate
Jardiance	Boehringer Ingelheim International GmbH	EU/1/14/930/001-009	Film-coated tablet	-Empagliflozin
Jardiance	Boehringer Ingelheim International GmbH	EU/1/14/930/010-018	Film-coated tablet	-Empagliflozin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Javlor	Pierre Fabre Medicament	EU/1/09/550/1-12	Concentrate for solution for infusion	-Vinflunine ditartrate
Jaydess 13.5 mg intrauterine delivery system	Bayer Limited	PA1410/068/001	Intrauterine delivery system	-Levonorgestrel, micronized
Jayempi	Nova Laboratories Ireland Limited	EU/1/21/1557/001	Oral suspension	-Azathioprine
Jaypirca	Eli Lilly Nederland B.V.	EU/1/23/1738/001-003	Film-coated tablet	-Pirtobrutinib
Jaypirca	Eli Lilly Nederland B.V.	EU/1/23/1738/004-009	Film-coated tablet	-Pirtobrutinib
Jcovden	Janssen-Cilag International NV	EU/1/20/1525/001	Suspension for injectio	-Adenovirus serotype 26 vector encoding SARS-CoV-2 spike protein
Jemperli	GlaxoSmithKline (Ireland) Limited	EU/1/21/1538/001	Concentrate for solution for infusion	-Dostarlimab
Jentaduetto	Boehringer Ingelheim International GmbH	EU/1/12/780/001-014	Film-coated tablet	-Linagliptin -Metformin
Jentaduetto	Boehringer Ingelheim International GmbH	EU/1/12/780/015-028	Film-coated tablet	-Metformin -Linagliptin
Jevtana	Sanofi Winthrop Industrie	EU/1/11/676/001	Concentrate and solvent for solution for infusion	-Cabazitaxel
Jext 150 micrograms solution for injection in pre-filled pen	ALK-Abello A/S	PA1255/006/001	Solution for injection in pre-filled pen	-Adrenaline
Jext 300 micrograms solution for injection in pre-filled pen	ALK-Abello A/S	PA1255/006/002	Solution for injection in pre-filled pen	-Adrenaline
Jinarc	Otsuka Pharmaceutical Netherlands B.V.	EU/1/15/1000/001-002	Tablet	-Tolvaptan
Jinarc	Otsuka Pharmaceutical Netherlands B.V.	EU/1/15/1000/003-004	Tablet	-Tolvaptan
Jinarc	Otsuka Pharmaceutical Netherlands B.V.	EU/1/15/1000/005-007	Tablet	-Tolvaptan
Jinarc	Otsuka Pharmaceutical Netherlands B.V.	EU/1/15/1000/008-010	Tablet	-Tolvaptan
Jinarc	Otsuka Pharmaceutical Netherlands B.V.	EU/1/15/1000/011-013	Tablet	-Tolvaptan
Jivi	Bayer AG	EU/1/18/1324/001	Powder and solvent for solution for injection	-DAMOCTOCOG ALFA PEGOL
Jivi	Bayer AG	EU/1/18/1324/002	Powder and solvent for solution for injection	-DAMOCTOCOG ALFA PEGOL
Jivi	Bayer AG	EU/1/18/1324/003	Powder and solvent for solution for injection	-DAMOCTOCOG ALFA PEGOL
Jivi	Bayer AG	EU/1/18/1324/004	Powder and solvent for solution for injection	-DAMOCTOCOG ALFA PEGOL
Jivi	Bayer AG	EU/1/18/1324/005	Powder and solvent for solution for injection	-DAMOCTOCOG ALFA PEGOL
Jorveza	Dr. Falk Pharma GmbH	EU/1/17/1254/001-005	Orodispersible tablet	-Budesonide
Jorveza	Dr. Falk Pharma GmbH	EU/1/17/1254/007-011	Orodispersible tablet	-Budesonide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Juluca	ViiV Healthcare BV	EU/1/18/1282/001-002	Film-coated tablet	-Dolutegravir -Rilpivirine hydrochloride -Sodium starch glycolate ep -Iron oxide yellow (E172)
Junior Parapaed Paracetamol Oral Suspension 120 mg/5 ml	Pinewood Laboratories Ltd	PA0281/002/001	Oral suspension	-Paracetamol
Junyelt, Concentrate for solution for infusion	Laboratoire AGUETTANT	PA1968/006/001	Concentrate for solution for infusion	-Zinc gluconate -Copper gluconate -Manganese Gluconate -Potassium iodide -Sodium selenite
Jylamvo	Therakind (Europe) Limited	EU/1/17/1172/001	Oral solution	-Methotrexate
Jyseleca	Galapagos NV	EU/1/20/1480/001-002	Film-coated tablet	-Filgotinib maleate
Jyseleca	Galapagos NV	EU/1/20/1480/003-004	Film-coated tablet	-Filgotinib maleate
Kabiven emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/045/003	Emulsion for infusion	-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 H2O -Amino acids -Nitrogen -Fat -Glucose -Glucose (dextrose) -Sodium -Potassium -Magnesium -Calcium -Phosphate -Sulphate -Chloride -Acetate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Kabiven Peripheral emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/045/004	Emulsion for infusion	-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
Kadcyla	Roche Registration GmbH	EU/1/13/885/001	Powder for concentrate for solution for infusion	-Trastuzumab emtansine
Kadcyla	Roche Registration GmbH	EU/1/13/885/002	Powder for concentrate for solution for infusion	-Trastuzumab emtansine
Kaftrio	Vertex Pharmaceuticals (Ireland) Limited	EU/1/20/1468/001	Film-coated tablet	-TEZACAFITOR -Ivacaftor -VX-445
Kaftrio	Vertex Pharmaceuticals (Ireland) Limited	EU/1/20/1468/002	Film-coated tablet	-Ivacaftor -TEZACAFITOR -Elexacaftor
Kalcipos-D forte 500 mg/800 IU chewable tablets	Viartis Healthcare Limited	PA23355/015/002	Chewable tablet	-Calcium -Cholecalciferol
Kalcipos-D forte 500 mg/800 IU film-coated tablets	Viartis Healthcare Limited	PA23355/015/001	Film-coated tablet	-Calcium -Cholecalciferol
Kaletra	AbbVie Deutschland GmbH & Co. KG	EU/1/01/172/003	Oral solution	-Ritonavir -Lopinavir
Kaletra	AbbVie Deutschland GmbH & Co. KG	EU/1/01/172/006	Film-coated tablet	-Ritonavir -Lopinavir
Kaletra	AbbVie Deutschland GmbH & Co. KG	EU/1/01/172/4-5,7-8	Film-coated tablet	-Lopinavir -Ritonavir
Kalydeco	Vertex Pharmaceuticals (Ireland) Limited	EU/1/12/782/001-002	Film-coated tablet	-Ivacaftor
Kalydeco	Vertex Pharmaceuticals (Ireland) Limited	EU/1/12/782/003	Granules in sachet	-Ivacaftor
Kalydeco	Vertex Pharmaceuticals (Ireland) Limited	EU/1/12/782/004	Granules in sachet	-Ivacaftor
Kalydeco	Vertex Pharmaceuticals (Ireland) Limited	EU/1/12/782/005	Film-coated tablet	-Ivacaftor
Kalydeco	Vertex Pharmaceuticals (Ireland) Limited	EU/1/12/782/007	Film-coated tablet	-Ivacaftor

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Kalydeco	Vertex Pharmaceuticals (Ireland) Limited	EU/1/12/782/008	Granules	-Ivacaftor
Kamiren 4 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/038/001	Prolonged-release tablet	-Doxazosin
Kanjinti	Amgen Europe B.V.	EU/1/18/1281/001	Powder for concentrate for solution for infusion	-Trastuzumab
Kanjinti	Amgen Europe B.V.	EU/1/18/1281/002	Powder for concentrate for solution for infusion	-Trastuzumab
KANUMA	Alexion Europe SAS	EU/1/15/1033/001	Concentrate for solution for infusion	-Sebelipase alfa
Kapake 15mg/500mg Tablets	Galen Pharma Ireland Limited	PA22680/002/001	Tablet	-Paracetamol -Codeine phosphate hemihydrate
Kapake 30mg/500mg Tablets	Galen Pharma Ireland Limited	PA22680/002/002	Tablet	-Paracetamol -Codeine phosphate
Kapruvia	Vifor France	EU/1/22/1643/001-002	Solution for injection	-Difelikefalin Acetate
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/001	Tablet	-Irbesartan
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/001-003	Tablet	-Irbesartan
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/002	Tablet	-Irbesartan
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/003	Tablet	-Irbesartan
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/004	Tablet	-Irbesartan
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/004-006	Tablet	-Irbesartan
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/005	Tablet	-Irbesartan
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/006	Tablet	-Irbesartan
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/007	Tablet	-Irbesartan
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/007-009	Tablet	-Irbesartan
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/008	Tablet	-Irbesartan
Karvea	Sanofi Winthrop Industrie	EU/1/97/049/009	Tablet	-Irbesartan
Karvezide	Sanofi Winthrop Industrie	EU/1/98/085/001	Tablet	-Irbesartan -Hydrochlorothiazide
Karvezide	Sanofi Winthrop Industrie	EU/1/98/085/001-003	Tablet	-Irbesartan -Hydrochlorothiazide
Karvezide	Sanofi Winthrop Industrie	EU/1/98/085/002	Tablet	-Irbesartan -Hydrochlorothiazide
Karvezide	Sanofi Winthrop Industrie	EU/1/98/085/003	Tablet	-Irbesartan -Hydrochlorothiazide
Karvezide	Sanofi Winthrop Industrie	EU/1/98/085/004	Tablet	-Irbesartan -Hydrochlorothiazide
Karvezide	Sanofi Winthrop Industrie	EU/1/98/085/004-006	Tablet	-Irbesartan -Hydrochlorothiazide
Karvezide	Sanofi Winthrop Industrie	EU/1/98/085/005	Tablet	-Irbesartan -Hydrochlorothiazide
Karvezide	Sanofi Winthrop Industrie	EU/1/98/085/006	Tablet	-Irbesartan -Hydrochlorothiazide
Karvezide	Sanofi Winthrop Industrie	EU/1/98/085/023-028	Film-coated tablet	-Irbesartan -Hydrochlorothiazide
KARVEZIDE	sanofi-aventis groupe	EU/1/98/85/23-28	Tablets	-IRBESARTAN -HYDROCHLOROTHIAZIDE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Kauliv	Strides Pharma (Cyprus) Limited	EU/1/22/1710/001-002	Solution for injection in cartridge	-Teriparatide
Kay-Cee-L Syrup 7.5% w/v	Elara Pharmaservices Europe Limited	PA22637/004/001	Oral solution	-Potassium chloride
Keflex 125 mg/5 ml Powder for Oral Suspension	Flynn Pharma Limited	PA1226/002/002	Powder for oral suspension	-Cephalexin monohydrate
Keflex 250 mg Hard Capsules	Flynn Pharma Limited	PA1226/002/001	Capsule, hard	-Cefalexin Anhydrous
Keflex 250 mg/5 ml Powder for Oral Suspension	Flynn Pharma Limited	PA1226/002/003	Powder for oral suspension	-Cefalexin
Keflex 500 mg Film-Coated Tablets	Flynn Pharma Limited	PA1226/002/004	Film-coated tablet	-Cefalexin
Kemadrin 5 mg Tablets	Aspen Pharma Trading Limited	PA1691/005/001	Tablet	-Procyclidine hydrochloride
Kemadrin 5 mg tablets	PCO Manufacturing Ltd.	PPA0465/494/001	Tablet	-Procyclidine hydrochloride
Kengrexal	Chiesi Farmaceutici S.p.A.	EU/1/15/994/001	Powder for concentrate for solution for injection/infusion	-Cangrelor tetrasodium
Kentera	Teva B.V.	EU/1/03/270/004-005	Gel in sachet	-Oxybutynin hydrochloride
Kentera	Teva B.V.	EU/1/03/270/1-2	Transdermal patch	-Oxybutynin
Keppra	UCB Pharma SA	EU/1/00/146/030	Concentrate for solution for infusion	-Levetiracetam
KEPPRA	UCB Pharma S.A.	EU/1/00/146/006-013	Film Coated Tablet	-LEVETIRACETAM
KEPPRA	UCB Pharma S.A.	EU/1/00/146/014-019	Film Coated Tablet	-LEVETIRACETAM
KEPPRA	UCB Pharma S.A.	EU/1/00/146/020-026	Film Coated Tablet	-LEVETIRACETAM
Keppra 100 mg/ml oral solution	UCB Pharma S.A.	EU/1/00/146/027	Oral solution	-Levetiracetam
Keral 25 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/002/002	Film-coated tablet	-Dexketoprofen
Keral 25 mg granules in sachet	Menarini International Operations Luxembourg S.A.	PA0865/002/007	Granules in sachet	-Dexketoprofen
Keral 25 mg oral solution in sachet	Menarini International Operations Luxembourg S.A.	PA0865/002/006	Oral solution in sachet	-Dexketoprofen
Keral 25mg granules for oral solution	Menarini International Operations Luxembourg S.A.	PA0865/002/005	Granules for oral solution	-Dexketoprofen
Keral 50 mg/2ml solution for injection/infusion	Menarini International Operations Luxembourg S.A.	PA0865/002/003	Solution for injection/infusion	-Dexketoprofen trometamol
Kerendia	Bayer AG	EU/1/21/1616/001-005	Film-coated tablet	-Finerenone
Kerendia	Bayer AG	EU/1/21/1616/006-010	Film-coated tablet	-Finerenone
Kesimpta	Novartis Europharm Limited	EU/1/21/1532/001-002	Solution for injection in pre-filled syringe	-Ofatumumab
Ketalar 10mg/ml Solution for Injection/Infusion	Pfizer Healthcare Ireland	PA0822/013/001	Solution for injection/infusion	-Ketamine hydrochloride
Ketalar 50 mg/ml Solution for Injection/Infusion	Pfizer Healthcare Ireland	PA0822/013/002	Solution for injection/infusion	-Ketamine hydrochloride
Ketoconazole HRA	HRA Pharma Rare Diseases	EU/1/14/965/001	Tablet	-Ketoconazole
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	-Ketotifen hydrogen fumarate
Ketopine 20mg/g Shampoo	Pinewood Laboratories Ltd	PA0281/125/001	Shampoo	-Ketoconazole

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Ketovite Liquid	Taw Pharma (Ireland) Ltd	PA23081/012/001	Oral solution	-Vitamin a palmitate -Ergocalciferol -Choline chloride -Cyanocobalamin
Kevzara	Sanofi Winthrop Industrie	EU/1/17/1196/001-002	Solution for injection	-Sarilumab
Kevzara	Sanofi Winthrop Industrie	EU/1/17/1196/003-008	Solution for injection	-Sarilumab
Keytruda	Merck Sharp & Dohme BV,	EU/1/15/1024/002	Concentrate for solution for infusion	-Pembrolizumab
Kigabeq	Orphelia Pharma SA	EU/1/18/1302/001	Soluble tablet	-Vigabatrin
Kigabeq	Orphelia Pharma SA	EU/1/18/1302/002	Soluble tablet	-Vigabatrin
KIMMTRAK	Immunocore Ireland Limited	EU/1/22/1630/001	Concentrate for solution for infusion	-Tebentafusp
Kineret	Swedish Orphan Biovitrum AB	EU/1/02/203/005-007	Solution for injection in pre-filled syringe	-Anakinra
Kinpeygo	Stada Arzneimittel AG	EU/1/22/1657/001	Modified-release capsule, hard	-Budesonide micronised
Kinzalkomb 40 mg/12.5 mg tablets	Bayer AG	EU/1/02/214/1-5	Tablet	-Telmisartan -Hydrochlorothiazide
Kinzalkomb 80 mg/25 mg tablets	Bayer AG	EU/1/02/214/11-15	Tablet	-Hydrochlorothiazide -Telmisartan
Kinzalmono 40 mg tablets	Bayer AG	EU/1/98/091/001-004	Tablet	-Telmisartan
Kiovig	Baxter AG	EU/1/05/329/001-006	Solution for infusion	-Human normal immunoglobulin
Kirsty	Biosimilar Collaborations Ireland Limited	EU/1/20/1506/001-007	Solution for injection	-Insulin aspart (iasp)
Kisplyx	Eisai GmbH	EU/1/16/1128/001	Capsule, hard	-Lenvatinib mesilate
Kisplyx	Eisai GmbH	EU/1/16/1128/002	Capsule, hard	-Lenvatinib mesilate
Kisqali	Novartis Europharm Limited	EU/1/17/1221/001-012	Film-coated tablet	-Ribociclib
KIVEXA	ViiV Healthcare BV	EU/1/04/298/1-2	Film-coated tablet	-Abacavir sulfate -Lamivudine
Klacid 250 mg film-coated tablets	Viartis Healthcare Limited	PA23355/013/001	Film-coated tablet	-Clarithromycin
Klacid 250mg/5ml Granules for Oral Suspension	Viartis Healthcare Limited	PA23355/013/006	Granules for oral suspension	-Clarithromycin
Klacid Forte 500 mg film-coated tablets	Viartis Healthcare Limited	PA23355/013/002	Film-coated tablet	-Clarithromycin
Klacid IV 500mg Powder for Concentrate for Solution for Infusion	Viartis Healthcare Limited	PA23355/013/003	Powder for concentrate for solution for infusion	-Clarithromycin
Klacid LA 500mg Modified release tablets	Viartis Healthcare Limited	PA23355/013/004	Modified-release tablet	-Clarithromycin
Klacid Paediatric Suspension 125mg/5ml, Granules for Oral Suspension	Viartis Healthcare Limited	PA23355/013/005	Granules for oral suspension	-Clarithromycin
Klaram LA 500 mg prolonged-release tablets	Accord Healthcare Ireland Ltd.	PA2315/133/001	Prolonged-release tablet	-Clarithromycin citrate
Klariger 500 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/093/002	Film-coated tablet	-Clarithromycin
Klean-Prep Powder for oral Solution	Helsinn Birex Pharmaceuticals Limited	PA0294/017/001	Powder for oral solution	-Sodium chloride -Potassium chloride -Macrogol 3350 -Sodium bicarbonate -Sodium sulfate anhydrous

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Kliogest 2 mg/1 mg film-coated tablets	Novo Nordisk A/S	PA0218/022/001	Film-coated tablet	-Estradiol -Norethisterone acetate
Klisyri	Almirall, S.A.	EU/1/21/1558/001	Ointment	-Tirbanibulin
KOGENATE Bayer	Bayer AG	EU/1/00/143/001	Powder and solvent for solution for injection	-Octocog alfa -R-dna (baby hamster kidney expression system)
Kogenate Bayer	Bayer Schering Pharma AG	EU/1/00/143/002	Powder and solvent for solution for injection	-Octocog alfa
Kogenate Bayer	Bayer Schering Pharma AG	EU/1/00/143/003	Powder and solvent for solution for injection	-Octocog alfa
KOGENATE BAYER	Bayer Schering Pharma AG	EU/1/00/143/004	Powder and solvent for solution for injection	-Octocog alfa
Kogenate Bayer	Bayer Schering Pharma AG	EU/1/00/143/005	Powder and solvent for solution for injection	-Octocog alfa
Kogenate Bayer	Bayer Schering Pharma AG	EU/1/00/143/006	Powder and solvent for solution for injection	-Octocog alfa
Kogenate Bayer	Bayer Schering Pharma AG	EU/1/00/143/012-013	Powder and solvent for solution for injection	-Octocog alfa
Kogenate Bayer	Bayer Schering Pharma AG	EU/1/00/143/10-11	Powder and solvent for solution for injection	-Octocog alfa
Komboglyze	AstraZeneca AB	EU/1/11/731/001-006	Film-coated tablet	-Saxagliptin -METFORMIN HYDROCHLORIDE
Komboglyze	AstraZeneca AB	EU/1/11/731/007-012	Film-coated tablet	-METFORMIN HYDROCHLORIDE -Saxagliptin
Konaktion MM Ampoules 10 mg/ml Solution for Injection and Oral Solution	CHEPLAPHARM Arzneimittel GmbH	PA2239/002/001	Solution for injection	-Phytomenadione
Konaktion MM Paediatric Ampoules 2 mg/ 0.2 ml oral solution or solution for injection	CHEPLAPHARM Arzneimittel GmbH	PA2239/002/002	Solution for injection	-Phytomenadione
Konverge 20 mg/5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/017/001	Film-coated tablet	-Olmesartan medoxomil -Amlodipine
Konverge 40 mg/10 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/017/003	Film-coated tablet	-Olmesartan medoxomil -Amlodipine
Konverge 40 mg/5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/017/002	Film-coated tablet	-Olmesartan medoxomil -Amlodipine
Konverge Plus 20 mg/5 mg/12.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/019/001	Film-coated tablet	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
Konverge Plus 40mg/10mg/12.5mg film coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/019/003	Film-coated tablet	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
Konverge Plus 40mg/10mg/25mg film coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/019/005	Film-coated tablet	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Konverge Plus 40mg/5mg/12.5mg film coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/019/002	Film-coated tablet	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
Konverge Plus 40mg/5mg/25mg film coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/019/004	Film-coated tablet	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
Kopen 250mg Tablets	Athlone Pharmaceuticals Limited	PA1418/014/003	Tablet	- Phenoxymethylpenicillin potassium
Kopen Sugar Free 125mg/5ml Powder for Oral Solution	Athlone Pharmaceuticals Limited	PA1418/014/001	Powder for oral solution	- Phenoxymethylpenicillin potassium
Kopen Sugar Free 250mg/5ml Powder for Oral Solution	Athlone Pharmaceuticals Limited	PA1418/014/002	Powder for oral solution	- Phenoxymethylpenicillin potassium
Koselugo	AstraZeneca AB	EU/1/21/1552/001	Capsule, hard	-Selumetinib Sulfate
Koselugo	AstraZeneca AB	EU/1/21/1552/002	Capsule, hard	-Selumetinib Sulfate
Kovaltry	Bayer AG	EU/1/15/1076/001-002	Powder and solvent for solution for injection	-Octocog alfa
Kovaltry	Bayer Pharma AG	EU/1/15/1076/003-004	Powder and solvent for solution for injection	-Octocog alfa
Kovaltry	Bayer Pharma AG	EU/1/15/1076/005-006	Powder and solvent for solution for injection	-Octocog alfa
Kovaltry	Bayer Pharma AG	EU/1/15/1076/007-008	Powder and solvent for solution for injection	-Octocog alfa
Kovaltry	Bayer Pharma AG	EU/1/15/1076/009-010	Powder and solvent for solution for injection	-Octocog alfa
KryptoScan, [81m Kr] Radionuclide generator	Curium Netherlands B.V.	PA0690/007/001	Radionuclide generator	-Krypton (81m kr)
Kuvan	BioMarin International Limited	EU/1/08/481/004	Powder for oral solution	-Sapropterin hydrochloride
Kuvan	BioMarin International Limited	EU/1/08/481/005	Powder for oral solution	-Sapropterin hydrochloride
Kuvan	BioMarin International Limited	EU/1/08/481/1-3	Soluble tablet	-Sapropterin dihydrochloride
Kwells 300 microgram Tablets	Dexcel Pharma GmbH	PA2261/006/001	Tablet	-Hyoscine hydrobromide
Kyleena 19.5 mg intrauterine delivery system	PCO Manufacturing Ltd.	PPA0465/476/001	Intrauterine delivery system	-Levonorgestrel
Kyleena 19.5 mg intrauterine delivery system	IMED Healthcare Ltd.	PPA1463/186/001	Intrauterine delivery system	-Levonorgestrel
Kyleena 19.5 mg intrauterine delivery system	Bayer Limited	PA1410/081/001	Intrauterine delivery system	-Levonorgestrel, micronized
Kymriah	Novartis Europharm Limited	EU/1/18/1297/001	Dispersion for infusion	-AUTOGLAS T CELLS TRANSDUCED WITH LENTIVIRAL VECTOR CONTAINING A CHIMERIC ANTIGEN RECEPTOR DIRECTED AGAINST CD1
Kyntheum (previously known Brodalumab)	LEO Pharma A/S	EU/1/16/1155/001	Solution for injection in pre-filled syringe	-Brodalumab
Kyprolis	Amgen Europe B.V.	EU/1/15/1060/001	Powder for solution for injection	-Carfilzomib

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Kytril 1 mg/1 ml solution for injection	Atnahs Pharma Netherlands B.V.	PA22657/003/001	Solution for injection	-Granisetron hydrochloride
Kytril 1mg film-coated tablets	Atnahs Pharma Netherlands B.V.	PA22657/003/003	Film-coated tablet	-Granisetron hydrochloride
Kytril 2mg film-coated tablets	Atnahs Pharma Netherlands B.V.	PA22657/003/004	Film-coated tablet	-Granisetron hydrochloride
Kytril 3 mg/3 ml solution for injection	Atnahs Pharma Netherlands B.V.	PA22657/003/002	Solution for injection	-Granisetron hydrochloride
Labetalol 5 mg/ml solution for injection/ infusion	S.A.L.F. S.p.A. Laboratorio Farmacologico	PA22760/001/001	Solution for injection/infusion	-Labetalol hydrochloride
Lacosamide Accord	Accord Healthcare S.L.U.	EU/1/17/1230/001-004	Film-coated tablet	-Lacosamide
Lacosamide Accord	Accord Healthcare S.L.U.	EU/1/17/1230/005-008	Film-coated tablet	-Lacosamide
Lacosamide Accord	Accord Healthcare S.L.U.	EU/1/17/1230/009-012	Film-coated tablet	-Lacosamide
Lacosamide Accord	Accord Healthcare S.L.U.	EU/1/17/1230/013-016	Film-coated tablet	-Lacosamide
Lacosamide Accord	Accord Healthcare S.L.U.	EU/1/17/1230/026-027	Solution for infusion	-Lacosamide
Lacosamide Adroiq	Extrovis EU Kft.	EU/1/23/1732/001	Solution for infusion	-Lacosamide
Lacosamide Ascend 10 mg/ml syrup	Ascend GmbH	PA23429/001/001	Syrup	-Lacosamide
Lacosamide Fresenius Kabi 10 mg/ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/078/001	Solution for infusion	-Lacosamide
Lacosamide Krka 100 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/099/002	Film-coated tablet	-Lacosamide
Lacosamide Krka 150 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/099/003	Film-coated tablet	-Lacosamide
Lacosamide Krka 200 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/099/004	Film-coated tablet	-Lacosamide
Lacosamide Krka 50 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/099/001	Film-coated tablet	-Lacosamide
Lacosamide UCB	UCB Pharma S.A.	EU/1/19/1383/001-002	Solution for infusion	-Lacosamide
Lacosamide UCB	UCB Pharma S.A.	EU/1/19/1383/003	Syrup	-Lacosamide
Lacosamide UCB	UCB Pharma S.A.	EU/1/19/1383/004-009	Film-coated tablet	-Lacosamide
Lacosamide UCB	UCB Pharma S.A.	EU/1/19/1383/010-015	Film-coated tablet	-Lacosamide
Lacosamide UCB	UCB Pharma S.A.	EU/1/19/1383/016-021	Film-coated tablet	-Lacosamide
Lacosamide UCB	UCB Pharma S.A.	EU/1/19/1383/022-027	Film-coated tablet	-Lacosamide
Lactecon 3.335g/5ml oral solution	Mylan IRE Healthcare Limited	PA2010/014/001	Oral solution	-Lactulose
Lactulose 10 g/15 ml Oral Solution Sachets	Fresenius Kabi Austria GmbH	PA0773/004/001	Oral solution	-Lactulose
Lactulose Fresenius 670mg/ml oral solution	Fresenius Kabi Austria GmbH	PA0773/003/001	Oral solution	-Lactulose
Laevolac Plum 10 g/15 ml oral solution	Fresenius Kabi Austria GmbH	PA0773/005/001	Oral solution	-Lactulose
Lamictal 100 mg chewable/dispersible tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/009	Chewable/dispersible tablet	-Lamotrigine
Lamictal 100 mg chewable/dispersible tablets	PCO Manufacturing Ltd.	PPA0465/443/003	Chewable/dispersible tablet	-Lamotrigine
Lamictal 100 mg chewable/dispersible tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/003/005	Chewable/dispersible tablet	-Lamotrigine
Lamictal 100 mg chewable/dispersible tablets.	IMED Healthcare Ltd.	PPA1463/066/002	Chewable/dispersible tablet	-Lamotrigine
Lamictal 100 mg tablets	IMED Healthcare Ltd.	PPA1463/066/005	Tablet	-Lamotrigine
Lamictal 100 mg tablets	Originalis B.V.	PPA2306/024/001	Tablet	-Lamotrigine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Lamictal 100 mg tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/003/003	Tablet	-Lamotrigine
Lamictal 100 mg Tablets	Merit Pharmaceuticals Limited	PPA23080/014/002	Tablet	-Lamotrigine
Lamictal 100 mg Tablets	PCO Manufacturing Ltd.	PPA0465/092/010	Tablet	-Lamotrigine
Lamictal 100 mg tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/003	Tablet	-Lamotrigine
Lamictal 2 mg chewable/dispersible tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/005	Chewable/dispersible tablet	-Lamotrigine
Lamictal 200 mg chewable/dispersible tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/010	Chewable/dispersible tablet	-Lamotrigine
Lamictal 200 mg chewable/dispersible tablets	PCO Manufacturing Ltd.	PPA0465/092/009	Chewable/dispersible tablet	-Lamotrigine
Lamictal 200 mg chewable/dispersible tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/003/006	Chewable/dispersible tablet	-Lamotrigine
Lamictal 200 mg chewable/dispersible tablets.	IMED Healthcare Ltd.	PPA1463/066/003	Chewable/dispersible tablet	-Lamotrigine
Lamictal 200 mg tablets	IMED Healthcare Ltd.	PPA1463/066/009	Tablet	-Lamotrigine
Lamictal 200 mg Tablets	PCO Manufacturing Ltd.	PPA0465/092/013	Tablet	-Lamotrigine
Lamictal 200 mg tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/004	Tablet	-Lamotrigine
Lamictal 25 mg chewable/dispersible tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/007	Chewable/dispersible tablet	-Lamotrigine
Lamictal 25 mg chewable/dispersible tablets	PCO Manufacturing Ltd.	PPA0465/443/001	Chewable/dispersible tablet	-Lamotrigine
Lamictal 25 mg chewable/dispersible tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/003/001	Chewable/dispersible tablet	-Lamotrigine
Lamictal 25 mg chewable/dispersible tablets.	IMED Healthcare Ltd.	PPA1463/066/006	Chewable/dispersible tablet	-Lamotrigine
Lamictal 25 mg tablets	IMED Healthcare Ltd.	PPA1463/066/004	Tablet	-Lamotrigine
Lamictal 25 mg tablets	Merit Pharmaceuticals Limited	PPA23080/014/001	Tablet	-Lamotrigine
Lamictal 25 mg tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/003/007	Tablet	-Lamotrigine
Lamictal 25 mg Tablets	PCO Manufacturing Ltd.	PPA0465/092/011	Tablet	-Lamotrigine
Lamictal 25 mg tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/001	Tablet	-Lamotrigine
Lamictal 5 mg chewable/dispersible tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/006	Chewable/dispersible tablet	-Lamotrigine
Lamictal 5 mg chewable/dispersible tablets	PCO Manufacturing Ltd.	PPA0465/092/005	Chewable/dispersible tablet	-Lamotrigine
Lamictal 50 mg chewable/dispersible tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/003/004	Chewable/dispersible tablet	-Lamotrigine
Lamictal 50 mg chewable/dispersible tablets	PCO Manufacturing Ltd.	PPA0465/443/002	Chewable/dispersible tablet	-Lamotrigine
Lamictal 50 mg chewable/dispersible tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/008	Chewable/dispersible tablet	-Lamotrigine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Lamictal 50 mg chewable/dispersible tablets.	IMED Healthcare Ltd.	PPA1463/066/001	Chewable/dispersible tablet	-Lamotrigine
Lamictal 50 mg tablets	IMED Healthcare Ltd.	PPA1463/066/008	Tablet	-Lamotrigine
Lamictal 50 mg tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/003/002	Tablet	-Lamotrigine
Lamictal 50 mg Tablets	PCO Manufacturing Ltd.	PPA0465/092/012	Tablet	-Lamotrigine
Lamictal 50 mg tablets	GlaxoSmithKline (Ireland) Limited	PA1077/061/002	Tablet	-Lamotrigine
Lamisil 1% w/w Cream	PCO Manufacturing Ltd.	PPA0465/151/001	Cream	-Terbinafine hydrochloride
Lamisil 1% w/w Cream	IMED Healthcare Ltd.	PPA1463/192/001	Cream	-Terbinafine hydrochloride
Lamisil 1% w/w Cream	Karo Pharma AB	PA22650/009/001	Cream	-Terbinafine hydrochloride
Lamisil 250 mg Tablets	IMED Healthcare Ltd.	PPA1463/157/001	Tablet	-Terbinafine
Lamisil 250 mg Tablets	PCO Manufacturing Ltd.	PPA0465/096/001	Tablet	-Terbinafine
Lamisil 250 mg Tablets	Novartis Ireland Limited	PA0896/015/001	Tablet	-Terbinafine
Lamisil AT Cream	Karo Pharma AB	PA22650/009/002	Cream	-Terbinafine hydrochloride
Lamisil Once 1% cutaneous solution	Karo Pharma AB	PA22650/009/003	Cutaneous solution	-Terbinafine
LAMIVUDINE TEVA	Teva B.V.	EU/1/09/566/1-5	Film-coated tablet	-LAMIVUDINE
LAMIVUDINE TEVA PHARMA B.V.	Teva B.V.	EU/1/09/596/1-7	Film-coated tablet	-LAMIVUDINE
LAMIVUDINE TEVA PHARMA B.V.	Teva B.V.	EU/1/09/596/8-14	Film-coated tablet	-LAMIVUDINE
Lamotrigine SyriMed 5mg/ml Oral Suspension	Syri Pharma Limited t/a Thame Laboratories	PA22697/018/001	Oral suspension	-Lamotrigine
LAMZEDE	Chiesi Farmaceutici S.p.A.	EU/1/17/1258/001-003	Powder for solution for infusion	-Velmanase alfa
Lanoxin 250 microgram Tablets	Aspen Pharma Trading Limited	PA1691/001/004	Tablet	-Digoxin
Lanoxin 500 micrograms/2ml Solution for Injection	Aspen Pharma Trading Limited	PA1691/001/001	Solution for injection	-Digoxin
Lanoxin PG 50 micrograms/ml Elixir	Aspen Pharma Trading Limited	PA1691/001/002	Oral solution	-Digoxin
Lanoxin PG 62.5 microgram Tablets	Aspen Pharma Trading Limited	PA1691/001/003	Tablet	-Digoxin
Lansoprazole 15 mg gastro-resistant capsules, hard	Accord Healthcare Ireland Ltd.	PA2315/128/001	Gastro-resistant capsule, hard	-Lansoprazole
Lansoprazole 30 mg gastro-resistant capsules, hard	Accord Healthcare Ireland Ltd.	PA2315/128/002	Gastro-resistant capsule, hard	-Lansoprazole
Lansoprazole Krka 15 mg Gastro-resistant Capsules, hard	KRKA, d.d., Novo mesto	PA1347/062/001	Gastro-resistant capsule, hard	-Lansoprazole
Lansoprazole Krka 30 mg Gastro-resistant Capsules, hard	KRKA, d.d., Novo mesto	PA1347/062/002	Gastro-resistant capsule, hard	-Lansoprazole
Lansoprazole Pinewood 15mg Gastro-resistant Capsules, Hard	Pinewood Laboratories Ltd	PA0281/151/001	Gastro-resistant capsule, hard	-Lansoprazole
Lansoprazole Pinewood 30mg Gastro-resistant Capsules, Hard	Pinewood Laboratories Ltd	PA0281/151/002	Gastro-resistant capsule, hard	-Lansoprazole

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Lansoprazole Teva Pharma 15 mg gastro-resistant capsules, hard	Teva B.V.	PA1986/008/001	Gastro-resistant capsule, hard	-Lansoprazole
Lansoprazole Teva Pharma 30 mg gastro-resistant capsules, hard	Teva B.V.	PA1986/008/002	Gastro-resistant capsule, hard	-Lansoprazole
LANTUS	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/001	Solution for injection	-Insulin glargine
Lantus	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/002	Solution for injection	-Insulin glargine
Lantus	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/003	Solution for injection	-Insulin glargine
Lantus	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/004	Solution for injection	-Insulin glargine
Lantus	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/005	Solution for injection in cartridge	-Insulin glargine
Lantus	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/006	Solution for injection in cartridge	-Insulin glargine
Lantus	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/007	Solution for injection in cartridge	-Insulin glargine
Lantus	Sanofi-Aventis Deutschland GmbH	EU/1/00/134/8-37	Solution for injection	-Insulin glargine
Lanvis 40mg Tablets	Aspen Pharma Trading Limited	PA1691/006/001	Tablet	-Tioguanine
Lanzol 15 mg hard gastro-resistant capsules	Rowex Ltd	PA0711/067/001	Gastro-resistant capsule, hard	-Lansoprazole
Lanzol 30 mg hard gastro-resistant capsules	Rowex Ltd	PA0711/067/002	Gastro-resistant capsule, hard	-Lansoprazole
Larig 100 mg Dispersible Tablets	Rowex Ltd	PA0711/085/004	Dispersible tablet	-Lamotrigine
Larig 200 mg Dispersible Tablets	Rowex Ltd	PA0711/085/005	Dispersible tablet	-Lamotrigine
Larig 25 mg Dispersible Tablets	Rowex Ltd	PA0711/085/002	Dispersible tablet	-Lamotrigine
Larig 50 mg Dispersible Tablets	Rowex Ltd	PA0711/085/003	Dispersible tablet	-Lamotrigine
Lartruvo	Eli Lilly Nederland B.V.	EU/1/16/1143/001	Concentrate for solution for infusion	-Olaratumab
Lasix 20mg/2ml Solution for Injection or Infusion	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/052/002	Solution for injection/infusion	-Frusemide
Lassar's Cream.Zinc Oxide 23% w/w & Salicylic Acid 2% w/w	Ovelle Limited	PA0206/014/002	Cream	-Zinc oxide -Salicylic acid
Lassar's PasteZinc Oxide 24% w/w & Salicylic Acid 2% w/w	Ovelle Limited	PA0206/014/001	Cutaneous paste	-Zinc oxide -Salicylic acid
Lataneau Plus 50 microgram/ml + 5 mg/ml Eye Drops, Solution	Alapis S.A.	PA1608/001/001	Eye drops, solution	-Timolol -Latanoprost
Latanoprost/Timolol Zentiva 50 microgram/ml + 5 mg/ml eye drops solution	Zentiva k.s.	PA1701/002/001	Eye drops, solution	-Latanoprost -Timolol
Latuda	Aziende Chimiche Riunite Angelini Francesco	EU/1/14/913/001-007	Film-coated tablet	-Lurasidone hydrochloride
Latuda	Aziende Chimiche Riunite Angelini Francesco	EU/1/14/913/008-014	Film-coated tablet	-Lurasidone hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Latuda	Aziende Chimiche Riunite Angelini Francesco	EU/1/14/913/015-021	Film-coated tablet	-Lurasidone hydrochloride
Laventair Ellipta	GlaxoSmithKline (Ireland) Limited	EU/1/14/899/001-003	Inhalation powder, pre-dispensed	-Umeclidinium bromide -Vilanterol trifenate
Laxido Orange, powder for oral solution	Galen Pharma Ireland Limited	PA22680/001/001	Powder for oral solution	-Macrogol 3350 -Sodium chloride -Sodium hydrogen carbonate -Potassium chloride
Laxido Paediatric Plain, 6.9 g sachet, powder for oral solution	Galen Pharma Ireland Limited	PA22680/001/003	Powder for oral solution in sachet	-Macrogol 3350 -Sodium chloride -Sodium hydrogen carbonate -Potassium chloride
Laxido, powder for oral solution	Galen Pharma Ireland Limited	PA22680/001/002	Powder for oral solution	-Macrogol 3350 -Sodium chloride -Sodium hydrogen carbonate -Potassium chloride
Laxose (Lactulose Solution BP) 3.35g/5ml Oral Solution	Pinewood Laboratories Ltd	PA0281/079/001	Oral solution	-Lactulose
Lecalpin 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/186/001	Film-coated tablet	-Lercanidipine hydrochloride
Lecalpin 20 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/186/002	Film-coated tablet	-Lercanidipine hydrochloride
Lecigon 20 mg/ml + 5 mg/ml + 20 mg/ml intestinal gel	Lobsor Pharmaceuticals AB	PA23144/001/001	Intestinal gel	-Levodopa -Carbidopa monohydrate -Entacapone
Ledaga	Helsinn Birex Pharmaceuticals Limited	EU/1/16/1171/001	Gel	-CHLORMETHINE HYDROCHLORIDE
Leflunomide 10 mg film-coated tablets	Morningside Healthcare (Malta) Limited	PA23142/009/001	Film-coated tablet	-Leflunomide
Leflunomide 20mg film-coated tablets	Morningside Healthcare (Malta) Limited	PA23142/009/002	Film-coated tablet	-Leflunomide
Leflunomide medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/10/637/001-004	Film-coated tablet	-Leflunomide
Leflunomide medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/10/637/005-009	Film-coated tablet	-Leflunomide
Leflunomide medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/10/637/010-012	Film-coated tablet	-Leflunomide
LEFLUNOMIDE RATIOPHARM	Ratiopharm GmbH	EU/1/10/654/003-004	Film-coated tablet	
Leflunomide Winthrop	Zentiva k.s.	EU/1/09/604/10	Film-coated tablet	-Leflunomide
Leflunomide Winthrop	Zentiva k.s.	EU/1/09/604/1-4	Film-coated tablet	-Leflunomide
Leflunomide Winthrop	Zentiva k.s.	EU/1/09/604/5-9	Film-coated tablet	-Leflunomide
Lemsip Decongestant & Flu Capsules with CaffeineParacetamol 500mgPhenylephrine Hydrochloride 6.1mgCaffeine 25mg	Reckitt Benckiser Ireland Ltd	PA0979/027/001	Capsule, hard	-Paracetamol -Phenylephrine hydrochloride -Caffeine anhydrous
Lemsip Max Sinus & Flu Hot Lemon Powder for Oral Solution	Reckitt Benckiser Ireland Ltd	PA0979/020/001	Powder for oral solution	-Paracetamol -PSEUDOEPHEDRINE HYDROCHLORIDE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Lemsip Multirelief capsules Paracetamol 500mg Phenylephrine hydrochloride 6.1mg Guaifenesin 100mg	Reckitt Benckiser Ireland Ltd	PA0979/053/001	Capsule, hard	-Paracetamol -Phenylephrine hydrochloride -Guaifenesin
Lemtrada	Sanofi Belgium	EU/1/13/869/001	Concentrate for solution for infusion	-Alemtuzumab
Lenalidomide Accord 10 mg hard capsules	Accord Healthcare S.L.U.	EU/1/18/1316/006-007	Capsule, hard	-Lenalidomide
Lenalidomide Accord 15 mg hard capsules	Accord Healthcare S.L.U.	EU/1/18/1316/008-009	Capsule, hard	-Lenalidomide
Lenalidomide Accord 2.5 mg hard capsules	Accord Healthcare S.L.U.	EU/1/18/1316/001-002	Capsule, hard	-Lenalidomide
Lenalidomide Accord 20 mg hard capsules	Accord Healthcare S.L.U.	EU/1/18/1316/010	Capsule, hard	-Lenalidomide
Lenalidomide Accord 25 mg hard capsules	Accord Healthcare S.L.U.	EU/1/18/1316/011	Capsule, hard	-Lenalidomide
Lenalidomide Accord 5 mg hard capsules	Accord Healthcare S.L.U.	EU/1/18/1316/003-004	Capsule, hard	-Lenalidomide
Lenalidomide Accord 7.5 mg hard capsules	Accord Healthcare S.L.U.	EU/1/18/1316/005	Capsule, hard	-Lenalidomide
Lenalidomide Clonmel 10 mg hard capsules	Clonmel Healthcare Ltd	PA0126/320/004	Capsule, hard	-Lenalidomide
Lenalidomide Clonmel 15 mg hard capsules	Clonmel Healthcare Ltd	PA0126/320/005	Capsule, hard	-Lenalidomide
Lenalidomide Clonmel 2.5 mg hard capsules	Clonmel Healthcare Ltd	PA0126/320/001	Capsule, hard	-Lenalidomide
Lenalidomide Clonmel 20 mg hard capsules	Clonmel Healthcare Ltd	PA0126/320/006	Capsule, hard	-Lenalidomide
Lenalidomide Clonmel 25 mg hard capsules	Clonmel Healthcare Ltd	PA0126/320/007	Capsule, hard	-Lenalidomide
Lenalidomide Clonmel 5 mg hard capsules	Clonmel Healthcare Ltd	PA0126/320/002	Capsule, hard	-Lenalidomide
Lenalidomide Clonmel 7.5 mg hard capsules	Clonmel Healthcare Ltd	PA0126/320/003	Capsule, hard	-Lenalidomide
Lenalidomide Grindeks 10 mg hard capsules	AS Grindeks	PA22992/004/004	Capsule, hard	-Lenalidomide
Lenalidomide Grindeks 15 mg hard capsules	AS Grindeks	PA22992/004/005	Capsule, hard	-Lenalidomide
Lenalidomide Grindeks 2.5 mg hard capsules	AS Grindeks	PA22992/004/001	Capsule, hard	-Lenalidomide
Lenalidomide Grindeks 20 mg hard capsules	AS Grindeks	PA22992/004/006	Capsule, hard	-Lenalidomide
Lenalidomide Grindeks 25 mg hard capsules	AS Grindeks	PA22992/004/007	Capsule, hard	-Lenalidomide
Lenalidomide Grindeks 5 mg hard capsules	AS Grindeks	PA22992/004/002	Capsule, hard	-Lenalidomide
Lenalidomide Grindeks 7.5 mg hard capsules	AS Grindeks	PA22992/004/003	Capsule, hard	-Lenalidomide
Lenalidomide Krka 10 mg hard capsules	KRKA, d.d., Novo mesto	EU/1/20/1519/007-008	Capsule, hard	-Lenalidomide hydrochloride hydrate -Lenalidomide
Lenalidomide Krka 15 mg hard capsules	KRKA, d.d., Novo mesto	EU/1/20/1519/009-010	Capsule, hard	-Lenalidomide hydrochloride hydrate -Lenalidomide
Lenalidomide Krka 2.5 mg hard capsules	KRKA, d.d., Novo mesto	EU/1/20/1519/001-002	Capsule, hard	-Lenalidomide hydrochloride hydrate -Lenalidomide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Lenalidomide Krka 20 mg hard capsules	KRKA, d.d., Novo mesto	EU/1/20/1519/011-012	Capsule, hard	-Lenalidomide hydrochloride hydrate -Lenalidomide
Lenalidomide Krka 25 mg hard capsules	KRKA, d.d., Novo mesto	EU/1/20/1519/013-014	Capsule, hard	-Lenalidomide hydrochloride hydrate -Lenalidomide
Lenalidomide Krka 5 mg hard capsules	KRKA, d.d., Novo mesto	EU/1/20/1519/003-004	Capsule, hard	-Lenalidomide hydrochloride hydrate -Lenalidomide
Lenalidomide Krka 7.5 mg hard capsules	KRKA, d.d., Novo mesto	EU/1/20/1519/005-006	Capsule, hard	-Lenalidomide hydrochloride hydrate -Lenalidomide
Lenalidomide Mylan 10 mg hard capsules	Mylan IRE Healthcare Limited	EU/1/20/1490/009-010	Capsule, hard	-Lenalidomide
Lenalidomide Mylan 15 mg hard capsules	Mylan IRE Healthcare Limited	EU/1/20/1490/011-012	Capsule, hard	-Lenalidomide
Lenalidomide Mylan 2.5 mg hard capsules	Mylan IRE Healthcare Limited	EU/1/20/1490/001-003	Capsule, hard	-Lenalidomide
Lenalidomide Mylan 20 mg hard capsules	Mylan IRE Healthcare Limited	EU/120/1490/013-015	Capsule, hard	-Lenalidomide
Lenalidomide Mylan 25 mg hard capsules	Mylan IRE Healthcare Limited	EU/1/20/1490/016-018	Capsule, hard	-Lenalidomide
Lenalidomide Mylan 5 mg hard capsules	Mylan IRE Healthcare Limited	EU/1/20/1490/004-005	Capsule, hard	-Lenalidomide
Lenalidomide Mylan 7.5 mg hard capsules	Mylan IRE Healthcare Limited	EU/1/20/1490/006-008	Capsule, hard	-Lenalidomide
Lenalidomide Rowex 10 mg hard capsules	Rowex Ltd	PA0711/302/004	Capsule, hard	-Lenalidomide
Lenalidomide Rowex 15 mg hard capsules	Rowex Ltd	PA0711/302/005	Capsule, hard	-Lenalidomide
Lenalidomide Rowex 2.5 mg hard capsules	Rowex Ltd	PA0711/302/001	Capsule, hard	-Lenalidomide
Lenalidomide Rowex 20 mg hard capsules	Rowex Ltd	PA0711/302/006	Capsule, hard	-Lenalidomide
Lenalidomide Rowex 25 mg hard capsules	Rowex Ltd	PA0711/302/007	Capsule, hard	-Lenalidomide
Lenalidomide Rowex 5 mg hard capsules	Rowex Ltd	PA0711/302/002	Capsule, hard	-Lenalidomide
Lenalidomide Rowex 7.5 mg hard capsules	Rowex Ltd	PA0711/302/003	Capsule, hard	-Lenalidomide
Lenalidomide Teva 10 mg hard capsules	Teva B.V.	PA1986/051/004	Capsule, hard	-Lenalidomide
Lenalidomide Teva 15 mg hard capsules	Teva B.V.	PA1986/051/005	Capsule, hard	-Lenalidomide
Lenalidomide Teva 2.5 mg hard capsules	Teva B.V.	PA1986/051/001	Capsule, hard	-Lenalidomide hydrochloride hydrate -Lenalidomide
Lenalidomide Teva 20 mg hard capsules	Teva B.V.	PA1986/051/006	Capsule, hard	-Lenalidomide
Lenalidomide Teva 25 mg hard capsules	Teva B.V.	PA1986/051/007	Capsule, hard	-Lenalidomide
Lenalidomide Teva 5 mg hard capsules	Teva B.V.	PA1986/051/002	Capsule, hard	-Lenalidomide
Lenalidomide Teva 7.5 mg hard capsules	Teva B.V.	PA1986/051/003	Capsule, hard	-Lenalidomide
Lenvima	Eisai GmbH	EU/1/15/1002/001	Capsule, hard	-Lenvatinib mesylate
Lenvima	Eisai GmbH	EU/1/15/1002/002	Capsule, hard	-Lenvatinib mesylate
Lenzetto 1.53 mg/spray, Transdermal Spray, Solution	Gedeon Richter Plc	PA1330/017/001	Transdermal spray, solution	-Estradiol
Leonore 100 micrograms/20 micrograms coated tablets	Rowex Ltd	PA0711/127/001	Coated tablet	-Levonorgestrel -Ethinylestradiol
Leqvio	Novartis Europharm Limited	EU/1/20/1494/001	Solution for injection in pre-filled syringe	-Inclisiran

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Lercanidipine Clonmel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/187/001	Film-coated tablet	-Lercanidipine hydrochloride
Lercanidipine Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/187/002	Film-coated tablet	-Lercanidipine hydrochloride
Lercanidipine Mylan 10 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/155/001	Film-coated tablet	-Lercanidipine hydrochloride
Lercanidipine Mylan 20mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/155/002	Film-coated tablet	-Lercanidipine hydrochloride
Lercaril 10 mg/10 mg film-coated tablets	Recordati Ireland Limited	PA1404/002/001	Film-coated tablet	-Lercanidipine hydrochloride -Enalapril maleate
Lercaril 10 mg/10 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/198/001	Film-coated tablet	-Lercanidipine hydrochloride -Enalapril maleate
Lercaril 10 mg/10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/472/001	Film-coated tablet	-Enalapril maleate -Lercanidipine hydrochloride
Lercaril 20 mg/10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/472/002	Film-coated tablet	-Enalapril maleate -Lercanidipine hydrochloride
Lercaril 20 mg/10 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/198/002	Film-coated tablet	-Lercanidipine hydrochloride -Enalapril maleate
Lercaril 20 mg/10 mg film-coated tablets	Recordati Ireland Limited	PA1404/002/002	Film-coated tablet	-Enalapril maleate -Lercanidipine hydrochloride
Lercaril 20 mg/20 mg Film-coated Tablets	Recordati Ireland Limited	PA1404/002/003	Film-coated tablet	-Enalapril maleate -Lercanidipine hydrochloride
Lercaril 20 mg/20 mg Film-coated Tablets	PCO Manufacturing Ltd.	PPA0465/472/003	Film-coated tablet	-Enalapril maleate -Lercanidipine hydrochloride
Lescol XL 80 mg Prolonged-release tablets	IMED Healthcare Ltd.	PPA1463/101/001	Prolonged-release tablet	-Fluvastatin
Lescol XL 80 mg Prolonged-release tablets	Ethyx Pharmaceuticals	PA23517/001/001	Prolonged-release tablet	-Fluvastatin
Lescol XL 80 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/404/001	Prolonged-release tablet	-Fluvastatin
Lestace 10 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/008/003	Tablet	-Lisinopril Dihydrate
Lestace 20 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/008/004	Tablet	-Lisinopril Dihydrate
Lestace 5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/008/002	Tablet	-Lisinopril Dihydrate
Letrozole 2.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/109/001	Film-coated tablet	-Letrozole
Letrozole 2.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/198/001	Film-coated tablet	-Letrozole
Letrozole Bluefish 2.5 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/013/001	Film-coated tablet	-Letrozole
Letrozole Mylan 2.5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/116/001	Film-coated tablet	-Letrozole
Letrozole Synthon 2.5 mg film-coated tablets	Synthon BV	PA0840/009/001	Film-coated tablet	-Letrozole
Letrozole Teva 2.5 mg film-coated tablets	Teva Pharma B.V.	PA0749/085/001	Film-coated tablet	-Letrozole
Letybo	Croma-Pharma GmbH	PA0846/001/001	Powder for solution for injection	-Clostridium Botulinum Neurotoxin Type A (900 KD)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Letzo 2.5 mg film-coated tablets	Rowex Ltd	PA0711/190/001	Film-coated tablet	-Letrozole
Leucovorin-Teva 10mg/ml Concentrate for Solution for Infusion	Teva Pharma B.V.	PA0749/001/001	Concentrate for solution for infusion	-Folinic acid
Leukeran 2 mg film-coated tablets	Aspen Pharma Trading Limited	PA1691/007/001	Film-coated tablet	-Chlorambucil
Leuprex 3, 5mg Implant	Rowex Ltd	PA0711/188/001	Implant	-Leuprorelin acetate
Levemir	Novo Nordisk A/S	EU/1/04/278/010-011	Solution for injection in pre-filled pen	-Insulin detemir
LEVEMIR (INSULIN DETEMIR)	Novo Nordisk A/S	EU/1/04/278/1-9	Solution for injection	-Insulin detemir
Levetiracetam 100 mg / mL Concentrate for solution for infusion	Noridem Enterprises Limited	PA1122/026/001	Concentrate for solution for infusion	-Levetiracetam
Levetiracetam 100 mg/ml concentrate for solution for infusion	Esteve Pharmaceuticals GmbH	PA22709/002/001	Concentrate for solution for infusion	-Levetiracetam
Levetiracetam Accord	Accord Healthcare S.L.U.	EU/1/11/712/001-007	Film-coated tablet	-Levetiracetam
Levetiracetam Accord	Accord Healthcare S.L.U.	EU/1/11/712/008-013	Film-coated tablet	-Levetiracetam
Levetiracetam Accord	Accord Healthcare S.L.U.	EU/1/11/712/015-021	Film-coated tablet	-Levetiracetam
Levetiracetam Accord	Accord Healthcare S.L.U.	EU/1/11/712/022-028	Film-coated tablet	-Levetiracetam
LEVETIRACETAM ACTAVIS	Actavis Group PTC ehf	EU/1/11/713/001-010	Film-coated tablet	-LEVETIRACETAM
LEVETIRACETAM ACTAVIS	Actavis Group PTC ehf	EU/1/11/713/011-020	Film-coated tablet	-LEVETIRACETAM
LEVETIRACETAM ACTAVIS	Actavis Group PTC ehf	EU/1/11/713/021-030	Film-coated tablet	-LEVETIRACETAM
LEVETIRACETAM ACTAVIS	Actavis Group PTC ehf	EU/1/11/713/031-040	Film-coated tablet	-LEVETIRACETAM
Levetiracetam Actavis Group 100 mg/ml oral solution	Actavis Group hf	EU/1/11/738/001-003	Oral solution	-Levetiracetam
Levetiracetam Bluefish 1000 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/020/003	Film-coated tablet	-Levetiracetam
Levetiracetam Bluefish 250 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/020/001	Film-coated tablet	-Levetiracetam
Levetiracetam Bluefish 500 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/020/002	Film-coated tablet	-Levetiracetam
Levetiracetam Brillpharma 100 mg/ml oral solution	Brillpharma (Ireland) Limited	PA22749/019/001	Oral solution	-Levetiracetam
Levetiracetam Clonmel 100 mg/ml oral solution	Clonmel Healthcare Ltd	PA0126/368/001	Oral solution	-Levetiracetam
Levetiracetam Clonmel 1000 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/326/003	Film-coated tablet	-Levetiracetam
Levetiracetam Clonmel 250 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/326/001	Film-coated tablet	-Levetiracetam
Levetiracetam Clonmel 500 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/326/002	Film-coated tablet	-Levetiracetam
Levetiracetam Hospira	Pfizer Europe MA EEIG	EU/1/13/889/001-002	Concentrate for solution for infusion	-Levetiracetam
LEVETIRACETAM RATIOPHARM	Ratiopharm GmbH	EU/1/11/702/004-009	Film-coated tablet	-LEVETIRACETAM

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
LEVETIRACETAM RATIOPHARM	Ratiopharm GmbH	EU/1/11/702/010-017	Film-coated tablet	-LEVETIRACETAM
LEVETIRACETAM RATIOPHARM	Ratiopharm GmbH	EU/1/11/702/018-024	Film-coated tablet	-LEVETIRACETAM
LEVETIRACETAM RATIOPHARM	Ratiopharm GmbH	EU/1/11/702/025-031	Film-coated tablet	-LEVETIRACETAM
Levetiracetam ratiopharm 100 mg/ml oral solution	Ratiopharm GmbH	EU/1/11/702/001-003	Oral solution	-Levetiracetam
LEVETIRACETAM SUN	Sun Pharmaceutical Industries Europe B.V.	EU/1/11/741/001	Concentrate for solution for infusion	-LEVETIRACETAM
LEVETIRACETAM TEVA	Teva B.V.	EU/1/11/701/001-004	Film-coated tablet	-LEVETIRACETAM
LEVETIRACETAM TEVA	Teva B.V.	EU/1/11/701/008-014	Film-coated tablet	-LEVETIRACETAM
LEVETIRACETAM TEVA	Teva Pharma B.V.	EU/1/11/701/015-021	Film-coated tablet	-LEVETIRACETAM
LEVETIRACETAM TEVA	Teva B.V.	EU/1/11/701/022-028	Film-coated tablet	-LEVETIRACETAM
Levetiracetam Thame 100 mg/ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/012/001	Oral solution	-Levetiracetam
Levitra	Bayer Schering Pharma AG	EU/1/03/248/013-15	Orodispersible tablet	-Vardenafil hydrochloride trihydrate
LEVITRA	Bayer AG	EU/1/03/248/1-12	Film-coated tablet	-Vardenafil (as hydrochloride trihydrate)
Levobupivacaine 0.625 mg/ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/009/001	Solution for infusion	-Levobupivacaine
Levobupivacaine 1.25 mg/mL solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/009/002	Solution for infusion	-Levobupivacaine
Levobupivacaine 2.5 mg/mL solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/009/003	Solution for injection/infusion	-Levobupivacaine
Levobupivacaine 5.0 mg/mL solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/009/004	Solution for injection/infusion	-Levobupivacaine
Levobupivacaine 7.5 mg/mL solution for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/009/005	Solution for injection/infusion	-Levobupivacaine
Levocetirizine dihydrochloride 5 mg Film-Coated Tablets	Brillpharma (Ireland) Limited	PA22749/003/001	Film-coated tablet	-Levocetirizine dihydrochloride
Levocetirizine Glenmark 5 mg Film- coated Tablets	Glenmark Arzneimittel GmbH	PA22645/003/001	Film-coated tablet	-Levocetirizine dihydrochloride
Levocetirizine Krka 5mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/043/001	Film-coated tablet	-Levocetirizine dihydrochloride
Levodopa/carbidopa/E ntacapone Orion	Orion Corporation	EU/1/11/706/007-011	Film-coated tablet	-Levodopa -Carbidopa monohydrate -Entacapone
Levodopa/carbidopa/E ntacapone Orion	Orion Corporation	EU/1/11/706/012-017	Film-coated tablet	-Levodopa -Entacapone -Carbidopa monohydrate
Levodopa/carbidopa/E ntacapone Orion	Orion Corporation	EU/1/11/706/018-022	Film-coated tablet	-Levodopa -Entacapone -Carbidopa monohydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Levodopa/carbidopa/Entacapone Orion	Orion Corporation	EU/1/11/706/023-028	Film-coated tablet	-Levodopa -Carbidopa monohydrate -Entacapone
Levodopa/carbidopa/Entacapone Orion	Orion Corporation	EU/1/11/706/029-033	Film-coated tablet	-Entacapone -Levodopa -Carbidopa monohydrate
Levodopa/Carbidopa/Entacapone Orion	Orion Corporation	EU/1/11/706/034-38	Film-coated tablet	-Entacapone -Carbidopa monohydrate -Levodopa
Levodopa/Carbidopa/Entacapone Sandoz	Orion Corporation	EU/1/13/859/001-006	Film-coated tablet	-Carbidopa monohydrate -Entacapone -Levodopa
Levodopa/Carbidopa/Entacapone Sandoz	Orion Corporation	EU/1/13/859/007-011	Film-coated tablet	-Entacapone -Carbidopa monohydrate -Levodopa
Levodopa/Carbidopa/Entacapone Sandoz	Orion Corporation	EU/1/13/859/012-017	Film-coated tablet	-Carbidopa monohydrate -Entacapone -Levodopa
Levodopa/Carbidopa/Entacapone Sandoz	Orion Corporation	EU/1/13/859/018-022	Film-coated tablet	-Entacapone -Carbidopa monohydrate -Levodopa
Levodopa/Carbidopa/Entacapone Sandoz	Orion Corporation	EU/1/13/859/023-028	Film-coated tablet	-Levodopa -Carbidopa monohydrate -Entacapone
Levodopa/Carbidopa/Entacapone Sandoz	Orion Corporation	EU/1/13/859/029-033	Film-coated tablet	-Entacapone -Carbidopa monohydrate -Levodopa
Levodopa/Carbidopa/Entacapone Sandoz	Orion Corporation	EU/1/13/859/034-038	Film-coated tablet	-Entacapone -Carbidopa monohydrate -Levodopa
Levofloxacin 5mg/ml solution for infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/008/001	Solution for infusion	-Levofloxacin
Levofloxacin 5mg/ml solution for infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/008/002	Solution for infusion	-Levofloxacin
Levofloxacin 5mg/ml solution for infusion	Noridem Enterprises Limited	PA1122/013/001	Solution for infusion	-Levofloxacin
Levofloxacin 5mg/ml solution for infusion, freeflex bags	Fresenius Kabi Deutschland GmbH	PA2059/010/002	Solution for infusion	-Levofloxacin
Levofloxacin 5mg/ml solution for infusion, LDPE bottles	Fresenius Kabi Deutschland GmbH	PA2059/010/001	Solution for infusion	-Levofloxacin
Levofloxacin Bluefish 250 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/019/001	Film-coated tablet	-Levofloxacin
Levofloxacin Bluefish 500 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/019/002	Film-coated tablet	-Levofloxacin
Levofloxacin Krka 250 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/048/001	Film-coated tablet	-Levofloxacin hemihydrate
Levofloxacin Krka 500 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/048/002	Film-coated tablet	-Levofloxacin hemihydrate
Levonorgestrel Rowex 1.5mg Tablet	Rowex Ltd	PA0711/267/001	Tablet	-Levonorgestrel
Levosert 52 mg intrauterine delivery system	Gedeon Richter Plc	PA1330/022/001	Intrauterine delivery system	-Levonorgestrel

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Levosert SHI 52mg Intrauterine Delivery System	Gedeon Richter Plc	PA1330/022/002	Intrauterine delivery system	-Levonorgestrel
Levosimendan 2.5 mg/ml concentrate for solution for infusion	AS Kalceks	PA2165/015/001	Concentrate for solution for infusion	-Levosimendan
Levothyroxine 100 micrograms per 5 ml oral solution	Amdipharm Limited	PA1142/029/004	Oral solution	-Levothyroxine sodium
Levothyroxine 25 micrograms per 5 ml oral solution	Amdipharm Limited	PA1142/029/002	Oral solution	-Levothyroxine sodium
Levothyroxine 50 micrograms per 5 ml oral solution	Amdipharm Limited	PA1142/029/003	Oral solution	-Levothyroxine sodium
Levothyroxine sodium Aristo 100 micrograms tablets	Aristo Pharma GmbH	PA1983/004/003	Tablet	-Levothyroxine sodium
Levothyroxine sodium Aristo 112 microgram tablets	Aristo Pharma GmbH	PA1983/004/009	Tablet	-Levothyroxine Sodium Anhydrous EP
Levothyroxine sodium Aristo 125 micrograms tablets	Aristo Pharma GmbH	PA1983/004/006	Tablet	-Levothyroxine Sodium Anhydrous EP
Levothyroxine sodium Aristo 137 microgram tablets	Aristo Pharma GmbH	PA1983/004/010	Tablet	-Levothyroxine Sodium Anhydrous EP
Levothyroxine sodium Aristo 150 micrograms tablets	Aristo Pharma GmbH	PA1983/004/007	Tablet	-Levothyroxine Sodium Anhydrous EP
Levothyroxine sodium Aristo 175 microgram tablets	Aristo Pharma GmbH	PA1983/004/011	Tablet	-Levothyroxine Sodium Anhydrous EP
Levothyroxine sodium Aristo 200 micrograms tablets	Aristo Pharma GmbH	PA1983/004/004	Tablet	-Levothyroxine sodium
Levothyroxine sodium Aristo 25 micrograms tablets	Aristo Pharma GmbH	PA1983/004/001	Tablet	-Levothyroxine sodium
Levothyroxine sodium Aristo 50 micrograms tablets	Aristo Pharma GmbH	PA1983/004/002	Tablet	-Levothyroxine sodium
Levothyroxine sodium Aristo 75 micrograms tablets	Aristo Pharma GmbH	PA1983/004/005	Tablet	-Levothyroxine Sodium Anhydrous EP
Levothyroxine sodium Aristo 88 microgram tablets	Aristo Pharma GmbH	PA1983/004/008	Tablet	-Levothyroxine Sodium Anhydrous EP
Levothyroxine Teva 100 micrograms Tablets	Teva Pharma B.V.	PA0749/143/003	Tablet	-Levothyroxine sodium
Levothyroxine Teva 25 micrograms Tablets	Teva Pharma B.V.	PA0749/143/001	Tablet	-Levothyroxine sodium
Levothyroxine Teva 50 micrograms Tablets	Teva Pharma B.V.	PA0749/143/002	Tablet	-Levothyroxine sodium
Lexapro 10 mg film-coated tablets	H. Lundbeck A/S	PA0805/002/002	Film-coated tablet	-Escitalopram
Lexapro 10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/129/001	Film-coated tablet	-Escitalopram
Lexapro 15 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/129/004	Film-coated tablet	-Escitalopram
Lexapro 15 mg film-coated tablets	H. Lundbeck A/S	PA0805/002/003	Film-coated tablet	-Escitalopram
Lexapro 20 mg film-coated tablets	H. Lundbeck A/S	PA0805/002/004	Film-coated tablet	-Escitalopram
Lexapro 20 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/129/002	Film-coated tablet	-Escitalopram

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Lexapro 5 mg film-coated tablets	H. Lundbeck A/S	PA0805/002/001	Film-coated tablet	-Escitalopram
Lexotan 1.5mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/008/001	Tablet	-Bromazepam
Lexotan 3mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/008/002	Tablet	-Bromazepam
Leydex 100 mg Orodispersible Tablets	Leyden Delta BV	PA2241/001/004	Orodispersible tablet	-Clozapine
Leydex 12.5 mg Orodispersible Tablets	Leyden Delta BV	PA2241/001/001	Orodispersible tablet	-Clozapine
Leydex 200 mg Orodispersible Tablets	Leyden Delta BV	PA2241/001/005	Orodispersible tablet	-Clozapine
Leydex 25 mg Orodispersible tablets	Leyden Delta BV	PA2241/001/002	Orodispersible tablet	-Clozapine
Leydex 50 mg Orodispersible Tablets	Leyden Delta BV	PA2241/001/003	Orodispersible tablet	-Clozapine
LG-octaplas, Powder and solvent for solution for infusion	Octapharma (IP) SPRL	PA2219/002/002	Powder and solvent for solution for infusion	-Human plasma protein
LG-octaplas, solution for infusion	Octapharma (IP) SPRL	PA2219/002/001	Solution for infusion	-Human plasma protein
Libmeldy	Orchard Therapeutics (Netherlands) B.V.	EU/1/20/1493/001	Dispersion for infusion	-Autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex
Libmyris	Stada Arzneimittel AG	EU/1/21/1590/001-006	Solution for injection in pre-filled syringe	-Adalimumab
Librium 10mg Hard Capsule	Mylan IRE Healthcare Limited	PA2010/041/002	Capsule, hard	-CHLORDIAZEPOXIDE HYDROCHLORIDE
Librium 5mg Hard Capsules	Mylan IRE Healthcare Limited	PA2010/041/001	Capsule, hard	-CHLORDIAZEPOXIDE HYDROCHLORIDE
Libtayo	Regeneron Ireland U.C.	EU/1/19/1376/001	Concentrate for solution for infusion	-CEMPIIMAB
Licomep 10 mg hard gastro-resistant capsules	Laboratorios LICONSA, S.A.	PA1239/026/001	Gastro-resistant capsule, hard	-Omeprazole
Licomep 20 mg hard gastro-resistant capsules	Laboratorios LICONSA, S.A.	PA1239/026/002	Gastro-resistant capsule, hard	-Omeprazole
Licomep 40 mg hard gastro-resistant capsules	Laboratorios LICONSA, S.A.	PA1239/026/003	Gastro-resistant capsule, hard	-Omeprazole
Lidbree 42 mg/mL intrauterine gel	Gedeon Richter Plc	PA1330/025/001	Intrauterine gel	-Lidocaine
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	-Lidocaine hydrochloride
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	-Lidocaine hydrochloride
Lidocaine Hydrochloride 1% w/v Solution for Injection	Fresenius Kabi Deutschland GmbH	PA2059/003/001	Solution for injection	-Lidocaine Hydrochloride Monohydrate
Lidocaine Hydrochloride 2% w/v Solution for Injection	Fresenius Kabi Deutschland GmbH	PA2059/003/002	Solution for injection	-Lidocaine Hydrochloride Monohydrate
Lidocaine hydrochloride 20 mg/ml, solution for injection/infusion	Laboratoire AGUETTANT	PA1968/012/001	Solution for injection/infusion	-Lidocaine Hydrochloride Monohydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v) solution for injection	Noridem Enterprises Limited	PA1122/027/001	Solution for injection	-Lidocaine Hydrochloride Monohydrate
Lidocaine hydrochloride Noridem 20 mg / mL (2 % w/v) solution for injection	Noridem Enterprises Limited	PA1122/027/002	Solution for injection	-Lidocaine Hydrochloride Monohydrate
Lifmior	Pfizer Europe MA EEIG	EU/1/16/1165/001	Powder and solvent for solution for injection	-Etanercept
Lifmior	Pfizer Europe MA EEIG	EU/1/16/1165/002-004	Powder and solvent for solution for injection	-Etanercept
Lifmior	Pfizer Europe MA EEIG	EU/1/16/1165/005-007	Solution for injection in pre-filled syringe	-Etanercept
Lifmior	Pfizer Europe MA EEIG	EU/1/16/1165/008-010	Solution for injection in pre-filled syringe	-Etanercept
Lifmior	Pfizer Europe MA EEIG	EU/1/16/1165/011-013	Solution for injection in pre-filled pen	-Etanercept
Lignospan Special (20 mg/12.5 microgram per ml) Solution for Injection 1.8 ml	Septodont	PA0196/013/001	Solution for injection	-Adrenaline (epinephrine) -Lidocaine Hydrochloride, anhydrous
Lignospan Special (20 mg/12.5 microgram per ml) Solution for Injection 2.2 ml	Septodont	PA0196/013/002	Solution for injection	-Lidocaine Hydrochloride, anhydrous -Adrenaline (epinephrine)
Linagliptin Clonmel 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/334/001	Film-coated tablet	-Linagliptin
Linagliptin Viatrix	Viatrix Limited	PA23266/013/001	Film-coated tablet	-Linagliptin
Linezolid 2 mg/ ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/011/001	Solution for infusion	-Linezolid
Linezolid 2 mg/ml solution for infusion	KRKA, d.d., Novo mesto	PA1347/057/002	Solution for infusion	-Linezolid
Linezolid 2 mg/ml solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/104/003	Solution for infusion	-Linezolid
Linezolid 600 mg Film-Coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/104/001	Film-coated tablet	-Linezolid (form iii)
Linezolid 600 mg Film-Coated Tablets	Rowex Ltd	PA0711/230/001	Film-coated tablet	-Linezolid
Linezolid Clonmel 600 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/238/001	Film-coated tablet	-Linezolid
Linezolid Krka 600 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/057/001	Film-coated tablet	-Linezolid
Linezolid Teva 600 mg film-coated tablets	Teva Pharma B.V.	PA0749/204/001	Film-coated tablet	-Linezolid
Lioresal 10 mg Tablets	Novartis Ireland Limited	PA0896/017/001	Tablet	-Baclofen
Lioresal 5mg/5ml Oral solution	Novartis Ireland Limited	PA0896/017/002	Oral solution	-Baclofen
Lipantil Micro 200 mg hard capsules	Mylan IRE Healthcare Limited	PA2010/015/002	Capsule, hard	-Fenofibrate
Lipantil Micro 200 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/471/001	Capsule, hard	-Fenofibrate
Lipantil Micro 67 mg hard capsules.	Mylan IRE Healthcare Limited	PA2010/015/001	Capsule, hard	-Fenofibrate
Lipantil Supra 145 mg film-coated tablet	PCO Manufacturing Ltd.	PPA0465/409/001	Film-coated tablet	-Fenofibrate
Lipantil Supra 145mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/015/003	Film-coated tablet	-Fenofibrate
Lipantil Supra 215 mg, film-coated tablet	Mylan IRE Healthcare Limited	PA2010/015/004	Film-coated tablet	-Fenofibrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Lipertance 10mg/5mg/5mg film-coated tablets	Les Laboratoires Servier	PA0568/028/001	Film-coated tablet	-Atorvastatin -Perindopril arginine -Amlodipine
Lipertance 20mg/10mg/10mg film-coated tablets	Les Laboratoires Servier	PA0568/028/004	Film-coated tablet	-Atorvastatin -Perindopril arginine -Amlodipine
Lipertance 20mg/10mg/5mg film-coated tablets	Les Laboratoires Servier	PA0568/028/003	Film-coated tablet	-Atorvastatin -Perindopril arginine -Amlodipine
Lipertance 20mg/5mg/5mg film-coated tablets	Les Laboratoires Servier	PA0568/028/002	Film-coated tablet	-Atorvastatin -Perindopril arginine -Amlodipine
Lipertance 40mg/10mg/10mg film-coated tablets	Les Laboratoires Servier	PA0568/028/005	Film-coated tablet	-Atorvastatin -Perindopril arginine -Amlodipine
Lipiodol Ultra Fluid 38% w/w Solution for injection	Guerbet	PA0686/004/001	Solution for injection	-organically combined iodine.
Lipitor 10 mg chewable tablets	Upjohn EESV	PA23055/017/006	Chewable tablet	-Atorvastatin
Lipitor 10 mg film-coated tablets	Upjohn EESV	PA23055/017/001	Film-coated tablet	-Atorvastatin
Lipitor 10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/075/001	Film-coated tablet	-Atorvastatin
Lipitor 20 mg chewable tablets	Upjohn EESV	PA23055/017/007	Chewable tablet	-Atorvastatin
Lipitor 20 mg film-coated tablets	Upjohn EESV	PA23055/017/002	Film-coated tablet	-Atorvastatin
Lipitor 20 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/075/002	Film-coated tablet	-Atorvastatin
Lipitor 40 mg chewable tablets	Upjohn EESV	PA23055/017/008	Chewable tablet	-Atorvastatin
Lipitor 40 mg film-coated tablets	Upjohn EESV	PA23055/017/003	Film-coated tablet	-Atorvastatin
Lipitor 40 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/075/003	Film-coated tablet	-Atorvastatin
Lipitor 5 mg chewable tablets	Upjohn EESV	PA23055/017/005	Chewable tablet	-Atorvastatin
Lipitor 80 mg film-coated tablets	Upjohn EESV	PA23055/017/004	Film-coated tablet	-Atorvastatin
Lipitor 80 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/075/004	Film-coated tablet	-Atorvastatin
Lipocomb 10 mg/10 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/460/001	Capsule, hard	-Ezetimibe -Rosuvastatin
Lipocomb 10 mg/10 mg hard capsules	EGIS Pharmaceuticals PLC	PA1470/004/001	Capsule, hard	-Rosuvastatin zinc -Ezetimibe
Lipocomb 20 mg/10 mg hard capsules	EGIS Pharmaceuticals PLC	PA1470/004/002	Capsule, hard	-Rosuvastatin zinc -Ezetimibe
Lipocomb 20 mg/10 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/460/002	Capsule, hard	-Rosuvastatin -Ezetimibe
Lipocomb 40 mg/10 mg hard capsules	EGIS Pharmaceuticals PLC	PA1470/004/003	Capsule, hard	-Rosuvastatin zinc -Ezetimibe
Liposic 2 mg/g eye gel	Bausch + Lomb Ireland Limited	PA23259/009/001	Eye gel	-Carbomer
Liprolog	Eli Lilly and Company Limited	EU/1/01/195/028-029	Not assigned	
Liprolog	Eli Lilly Nederland B.V.	EU/1/01/195/22-27	Suspension for injectio	-Insulin lispro
Liprolog	Eli Lilly Nederland B.V.	EU/1/01/195/001	Solution for injection	-Insulin lispro
Liprolog	Eli Lilly Nederland B.V.	EU/1/01/195/002	Solution for injection	-Insulin lispro
Liprolog Mix25	Eli Lilly Nederland B.V.	EU/1/01/195/003	Suspension for injectio	-Insulin lispro
Liprolog Mix25 Pen	Eli Lilly Nederland B.V.	EU/1/01/195/006	Suspension for injectio	-Insulin lispro

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Liprolog Mix50	Eli Lilly Nederland B.V.	EU/1/01/195/004	Suspension for injectio	-Insulin lispro
Liprolog Mix50 Pen	Eli Lilly Nederland B.V.	EU/1/01/195/007	Suspension for injectio	-Insulin lispro
Liprolog-Pen	Eli Lilly Nederland B.V.	EU/1/01/195/005	Solution for injection	-Insulin lispro
Liquid Medical Oxygen 100 % Medicinal gas, cryogenic	SOL S.p.A.	PA1848/005/002	Not assigned	-Oxygen
Liquid Medical Oxygen 100% Medicinal gas, cryogenic	SOL S.p.A.	PA1848/005/001	Not assigned	-Oxygen
LIQUIVISC 2.5 mg/g eye gel	Laboratoires Thea	PA1107/002/001	Eye gel	-Carbomer
Lisinopril 1mg/ml Oral Solution	Taw Pharma (Ireland) Ltd	PA23081/013/001	Oral solution	-Lisinopril Dihydrate
Lisinopril Grindeks 10 mg tablets	AS Grindeks	PA22992/018/002	Tablet	-Lisinopril Dihydrate
Lisinopril Grindeks 20 mg tablets	AS Grindeks	PA22992/018/003	Tablet	-Lisinopril Dihydrate
Lisinopril Grindeks 5 mg tablets	AS Grindeks	PA22992/018/001	Tablet	-Lisinopril Dihydrate
Lisopress 10 mg tablets	Gedeon Richter Plc	PA1330/013/003	Tablet	-Lisinopril
Lisopress 2.5 mg tablets	Gedeon Richter Plc	PA1330/013/001	Tablet	-Lisinopril
Lisopress 20 mg tablets	Gedeon Richter Plc	PA1330/013/004	Tablet	-Lisinopril
Lisopress 5 mg tablets	Gedeon Richter Plc	PA1330/013/002	Tablet	-Lisinopril
Lispril 10 mg Tablets	Rowex Ltd	PA0711/047/003	Tablet	-Lisinopril (as dihydrate)
Lispril 20 mg Tablets	Rowex Ltd	PA0711/047/004	Tablet	-Lisinopril (as dihydrate)
Lispril 5 mg Tablets	Rowex Ltd	PA0711/047/002	Tablet	-Lisinopril Dihydrate
Lispril-Hydrochlorothiazide 10 mg/12.5 mg tablets	Rowex Ltd	PA0711/051/001	Tablet	-Lisinopril Dihydrate -Hydrochlorothiazide
Lispril-Hydrochlorothiazide 20 mg/12.5 mg tablets	Rowex Ltd	PA0711/051/002	Tablet	-Lisinopril Dihydrate -Hydrochlorothiazide
LITAK	Lipomed GmbH	EU/1/04/275/001-002	Solution for injection	-Cladribine
Litfulo	Pfizer Europe MA EEIG	EU/1/23/1755/001-003	Capsule, hard	-Ritlectinib
Lithium Chloride 0.15 mmol/ml. Solution for Injection	LiDCO Netherlands B.V.	PA23039/001/001	Solution for injection	-Lithium chloride
Livazo 1mg film-coated tablets	Kowa Pharmaceutical Europe GmbH	PA2324/001/001	Film-coated tablet	-Pitavastatin calcium
Livazo 2mg film-coated tablets	Kowa Pharmaceutical Europe GmbH	PA2324/001/002	Film-coated tablet	-Pitavastatin calcium
Livazo 4mg film-coated tablets	Kowa Pharmaceutical Europe GmbH	PA2324/001/003	Film-coated tablet	-Pitavastatin calcium
Livial 2.5 mg tablets	Organon Pharma (Ireland) Limited	PA23198/021/001	Tablet	-Tibolone
LIVMARLI	Mirum Pharmaceuticals International B.V.	EU/1/22/1704/001	Oral solution	-Maralixibat Chloride
LIVOGIVA	Theramex Ireland Limited	EU/1/20/1462/001-002	Solution for injection in pre-filled pen	-Teriparatide
Livtency	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/22/1672/001-002	Film-coated tablet	-Maribavir
Lixiana	Daiichi Sankyo Europe GmbH	EU/1/15/993/001	Film-coated tablet	-Edoxaban tosilate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Lixiana	Daiichi Sankyo Europe GmbH	EU/1/15/993/002	Film-coated tablet	-Edoxaban tosilate
Lixiana	Daiichi Sankyo Europe GmbH	EU/1/15/993/003	Film-coated tablet	-Edoxaban tosilate
Locametz	Advanced Accelerator Applications	EU/1/22/1692/001	Kit for radiopharmaceutical preparation	-Gozetotide
Loceryl 5% w/v Medicated Nail Lacquer	PCO Manufacturing Ltd.	PPA0465/234/001	Medicated nail lacquer	-Amorolfine
Loceryl 5% w/v Medicated Nail Lacquer	IMED Healthcare Ltd.	PPA1463/081/001	Medicated nail lacquer	-Amorolfine
Loceryl 5% w/v Medicated Nail Lacquer	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/036/001	Medicated nail lacquer	-Amorolfine
Loceryl 5% w/v Medicated Nail Lacquer	Galderma International	PA22743/009/001	Medicated nail lacquer	-Amorolfine
Locoid Cream 0.1 % w/w	CHEPLAPHARM Arzneimittel GmbH	PA2239/019/001	Cream	-Hydrocortisone butyrate
Locoid Lipocream 0.1% w/w Cream	CHEPLAPHARM Arzneimittel GmbH	PA2239/019/002	Cream	-Hydrocortisone butyrate
Logynon Tablets	Bayer Limited	PA1410/005/001	Coated tablet	-Levonorgestrel micronized -Levonorgestrel micronized -Levonorgestrel micronized -Ethinylestradiol micronized -Ethinylestradiol micronized
Lojuxta	Amryt Pharmaceuticals DAC	EU/1/13/851/001	Capsule, hard	-Lomitapide mesylate
Lojuxta	Amryt Pharmaceuticals DAC	EU/1/13/851/002	Capsule, hard	-Lomitapide mesylate
Lojuxta	Amryt Pharmaceuticals DAC	EU/1/13/851/003	Capsule, hard	-Lomitapide mesylate
Lojuxta	Amryt Pharmaceuticals DAC	EU/1/13/851/004	Capsule, hard	-Lomitapide mesylate
Lojuxta	Amryt Pharmaceuticals DAC	EU/1/13/851/005	Capsule, hard	-Lomitapide mesylate
Lojuxta	Amryt Pharmaceuticals DAC	EU/1/13/851/006	Capsule, hard	-Lomitapide mesylate
Lokelma	AstraZeneca AB	EU/1/17/1173/001-002	Powder for oral suspension	-Sodium zirconium cyclosilicate
Lokelma	AstraZeneca AB	EU/1/17/1173/003-004	Powder for oral suspension	-Sodium zirconium cyclosilicate
Lomexin 2% w/v Cutaneous Spray, Solution	Recordati Industria Chimica e Farmaceutica SpA	PA0812/002/005	Cutaneous spray, solution	-Fenticonazole nitrate
Lomexin 2% w/w Cream	Recordati Industria Chimica e Farmaceutica SpA	PA0812/002/001	Cream	-Fenticonazole nitrate
Loniten 5 mg tablets	Pfizer Healthcare Ireland	PA0822/130/001	Tablet	-Minoxidil
Lonquex	Teva B.V.	EU/1/13/856/001-002	Solution for injection in pre-filled syringe	-Xm22 drug substance lipegfilgrastim
Lonsurf	Les Laboratoires Servier	EU/1/16/1096/001-003	Film-coated tablet	-Trifluridine
Lonsurf	Les Laboratoires Servier	EU/1/16/1096/004-006	Film-coated tablet	-Trifluridine
Lopid 300 mg capsules, hard	Pfizer Healthcare Ireland	PA0822/014/001	Capsule, hard	-Gemfibrozil
Lopid 600 mg film-coated tablet	PCO Manufacturing Ltd.	PPA0465/320/001	Film-coated tablet	-Gemfibrozil

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Lopid 600 mg film-coated tablets	Pfizer Healthcare Ireland	PA0822/014/002	Film-coated tablet	-Gemfibrozil
Lopinavir/Ritonavir Mylan	Mylan Pharmaceuticals Limited	EU/1/15/1067/001-003	Film-coated tablet	-Lopinavir -Ritonavir
Lopinavir/Ritonavir Mylan	Mylan Pharmaceuticals Limited	EU/1/15/1067/004-008	Film-coated tablet	-Lopinavir -Ritonavir
Lorat 10mg Tablets	Rowex Ltd	PA0711/088/001	Tablet	-Loratadine
Loratadine 10 mg Tablets	Azure Pharmaceuticals Ltd	PA22871/008/001	Tablet	-Loratadine
Loratadine Accord 10 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/246/001	Tablet	-Loratadine
Loravis 50 microgram/ml eye drops, solution	Farmaprojects S.A.	PA1391/007/001	Eye drops, solution	-Latanoprost
Lorazepam 1mg tablets	Morningside Healthcare (Malta) Limited	PA23142/007/001	Tablet	-Lorazepam
Lorazepam 2.5 mg tablets	Morningside Healthcare (Malta) Limited	PA23142/007/002	Tablet	-Lorazepam
Lorazepam Macure 4 mg/ml solution for injection	Macure Pharma ApS	PA23199/002/001	Solution for injection	-Lorazepam
Lorviqua	Pfizer Europe MA EEIG	EU/1/19/1355/001	Film-coated tablet	-LORLATINIB
Lorviqua	Pfizer Europe MA EEIG	EU/1/19/1355/002	Film-coated tablet	-LORLATINIB
Losamel 20 mg gastro-resistant tablets	Clonmel Healthcare Ltd	PA0126/115/001	Gastro-resistant tablet	-Omeprazole
Losartan Clonmel 100 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/355/002	Film-coated tablet	-Losartan potassium
Losartan Clonmel 50 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/355/001	Film-coated tablet	-Losartan potassium
Losartan Krka 100 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/020/003	Film-coated tablet	-Losartan potassium
Losartan Krka 25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/020/001	Film-coated tablet	-Losartan potassium
Losartan Krka 50 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/020/002	Film-coated tablet	-Losartan potassium
Losartan Potassium 100 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/059/003	Film-coated tablet	-Losartan potassium
Losartan Potassium 25 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/059/001	Film-coated tablet	-Losartan potassium
Losartan Potassium 50 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/059/002	Film-coated tablet	-Losartan potassium
Losartan Potassium Pinewood 100 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/154/003	Film-coated tablet	-Losartan potassium
Losartan Potassium Pinewood 50 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/154/002	Film-coated tablet	-Losartan potassium
Losartan Rowa 100mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/082/003	Film-coated tablet	-Losartan potassium
Losartan Rowa 50mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/082/002	Film-coated tablet	-Losartan potassium
Losartan Teva 100 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/090/004	Film-coated tablet	-Losartan potassium
Losartan Teva 50 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/090/003	Film-coated tablet	-Losartan potassium

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Losartan/Hydrochlorothiazide Clonmel 100 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/354/002	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Losartan/Hydrochlorothiazide Clonmel 50 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/354/001	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Losartan/Hydrochlorothiazide Krka 100 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/040/002	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Losartan/Hydrochlorothiazide Krka 100 mg/25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/040/003	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Losartan/Hydrochlorothiazide Krka 50 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/040/001	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Losartan/Hydrochlorothiazide Teva 100mg/25mg Film-Coated Tablets	Teva Pharma B.V.	PA0749/026/002	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Losartan/Hydrochlorothiazide Teva 50mg/12.5mg Film-Coated Tablets	Teva Pharma B.V.	PA0749/026/001	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Losec Control 20 mg gastro-resistant tablets	Bayer Limited	PA1410/066/001	Gastro-resistant tablet	-Omeprazole
Losec MUPS 10 mg gastro-resistant tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/009/001	Gastro-resistant tablet	-Omeprazole magnesium
Losec MUPS 10 mg gastro-resistant tablets	PCO Manufacturing Ltd.	PPA0465/423/003	Gastro-resistant tablet	-Omeprazole
Losec MUPS 20 mg gastro-resistant tablets	PCO Manufacturing Ltd.	PPA0465/423/001	Gastro-resistant tablet	-Omeprazole
Losec MUPS 20 mg gastro-resistant tablets	IMED Healthcare Ltd.	PPA1463/141/001	Gastro-resistant tablet	-Omeprazole
Losec MUPS 20 mg gastro-resistant tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/009/002	Gastro-resistant tablet	-Omeprazole
Losec MUPS 40 mg gastro-resistant tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/009/003	Gastro-resistant tablet	-Omeprazole
Lotanos Comp 100 mg/25 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/072/002	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Lotanos Comp 50 mg/12.5 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/072/001	Film-coated tablet	-Losartan potassium -Hydrochlorothiazide
Lotemax 0.5% w/v eye drops, suspension	Dr. Gerhard Mann, chem.-pharm. Fabrik GmbH	PA1245/001/001	Eye drops, suspension	-Loteprednol etabonate
Lovtelar 800 mg film-coated tablets	Pharmathen S.A.	PA1368/022/001	Film-coated tablet	-Sevelamer carbonate
Low Centyl K 1.25 mg/573 mg modified-release tablets	KARO PHARMA AB	PA22650/002/001	Modified-release tablet	-Bendroflumethiazide -Potassium chloride
Loxentia 20mg hard gastro-resistant capsul	KRKA, d.d., Novo mesto	PA1347/051/001	Gastro-resistant capsule, hard	-Duloxetine
Loxentia 40mg hard gastro-resistant capsul	KRKA, d.d., Novo mesto	PA1347/051/003	Gastro-resistant capsule, hard	-Duloxetine
Lucentis	Novartis Europharm Limited	EU/1/06/374/002-004	Solution for injection	-Ranibizumab
LuMark	IDB Holland B.V.,	EU/1/15/1013/001	Radiopharmaceutical precursor, solution	-Lutetium, isotope of mass 177

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Lumebblue	Alfasigma S.p.A	EU/1/20/1470/001	Prolonged-release tablet	-Methylthionium chloride
Lumigan	AbbVie Deutschland GmbH & Co. KG	EU/1/02/205/001-2	Eye drops, solution	-Bimatoprost
Lumigan	AbbVie Deutschland GmbH & Co. KG	EU/1/02/205/3-4	Eye drops, solution	-Bimatoprost
Luminity	Lantheus EU Limited	EU/1/06/361/01-2	Gas and solvent for dispersion for injection/infusion	-Perflutren
Lumykras	Amgen Europe B.V.	EU/1/21/1603/001-003	Film-coated tablet	-Sotorasib
Lunsumio	Roche Registration GmbH	EU/1/22/1649/001	Concentrate for solution for infusion	-Mosunetuzumab
Lunsumio	Roche Registration GmbH	EU/1/22/1649/002	Concentrate for solution for infusion	-Mosunetuzumab
Lupkynis	Otsuka Pharmaceutical Netherlands B.V.	EU/1/22/1678/001	Capsule, soft	-Voclosporin
Lustral 100 mg film-coated tablets	Upjohn EESV	PA23055/001/002	Film-coated tablet	-Sertraline
Lustral 100 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/202/001	Film-coated tablet	-Sertraline
Lustral 100 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/062/002	Film-coated tablet	-Sertraline hydrochloride
Lustral 50 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/062/001	Film-coated tablet	-Sertraline hydrochloride
Lustral 50 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/202/002	Film-coated tablet	-Sertraline
Lustral 50 mg film-coated tablets	Upjohn EESV	PA23055/001/001	Film-coated tablet	-Sertraline
Lutathera	Advanced Accelerator Applications	EU/1/17/1226/001	Solution for infusion	-177lu-dotao-tyr3-octeoate
Lutinus 100 mg vaginal tablets	Ferring Ireland Ltd	PA1009/022/001	Vaginal tablet	-Progesterone
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	-Leuprorelin acetate
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	-Leuprorelin acetate
Luveris	Merck Europe B.V.	EU/1/00/155/001	Powder and solvent for solution for infusion	-Lutropin alfa
Luveris	Merck Europe B.V.	EU/1/00/155/002	Powder and solvent for solution for injection	-Lutropin alfa
Luveris	Merck Europe B.V.	EU/1/00/155/003	Powder and solvent for solution for injection	-Lutropin alfa
Luveris	Merck Europe B.V.	EU/1/00/155/004	Powder and solvent for solution for injection	-Lutropin alfa
Luveris	Merck Europe B.V.	EU/1/00/155/005	Powder and solvent for solution for injection	-Lutropin alfa
Luveris	Merck Europe B.V.	EU/1/00/155/006	Powder and solvent for solution for injection	-Lutropin alfa
Luveris	Merck Europe B.V.	EU/1/00/155/007	Solution for injection	-Lutropin alfa
Luxturna	Novartis Ireland Limited	EU/1/18/1331/001	Concentrate and solvent for solution for injection	-VORETIGENE NEPARVOVEC
Lycimor 300 mg Capsules, Hard	Teva B.V.	PA1986/118/001	Capsule, hard	-Lymecycline

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Lyclear 5% w/w Dermal Cream	GlaxoSmithKline (Ireland) Limited	PA1077/066/001	Cream	-Permethrin
Lyclear Creme Rinse 1% w/w Cutaneous solution	Chefaro Ireland DAC	PA1186/003/001	Cutaneous solution	-Permethrin
Lydisilka	Estetra SPRL	EU/1/21/1548/001-004	Film-coated tablet	-Estetrol monohydrate -Estetrol -Drospirenone
LYFNUA	Merck Sharp & Dohme BV,	EU/1/21/1613/001-004	Film-coated tablet	-Gefapixant
Lymphoseek	Norgine B.V.	EU/1/14/955/001	Kit for radiopharmaceutical preparation	-Tilmanocept
Lymphoseek	Navidea Biopharmaceuticals Europe Ltd	EU/1/14/955/001-002	Kit for radiopharmaceutical preparation	-Tilmanocept
Lynparza	AstraZeneca AB	EU/1/14/959/002-003	Film-coated tablet	-Olaparib
Lynparza	AstraZeneca AB	EU/1/14/959/004-005	Film-coated tablet	-Olaparib
Lyrica 100 mg hard capsules	Upjohn EESV	EU/1/04/279/014-016	Capsule, hard	-Pregabalin
Lyrica 150 mg hard capsules	Upjohn EESV	EU/1/04/279/017-019	Capsule, hard	-Pregabalin
Lyrica 20 mg/ml oral solution	Upjohn EESV	EU/1/04/279/044	Oral solution	-Pregabalin
Lyrica 200 mg hard capsules	Upjohn EESV	EU/1/04/279/020-022	Capsule, hard	-Pregabalin
Lyrica 225 mg hard capsules	Upjohn EESV	EU/1/04/279/033-035	Capsule, hard	-Pregabalin
Lyrica 25 mg hard capsules	Upjohn EESV	EU/1/04/279/001-005	Capsule, hard	-Pregabalin
Lyrica 300 mg hard capsules	Upjohn EESV	EU/1/04/279/023-025	Capsule, hard	-Pregabalin
Lyrica 50 mg hard capsules	Upjohn EESV	EU/1/04/279/006-010	Capsule, hard	-Pregabalin
Lyrica 75 mg hard capsules	Upjohn EESV	EU/1/04/279/011-013	Capsule, hard	-Pregabalin
LysaKare	Advanced Accelerator Applications	EU/1/19/1381/001	Solution for infusion	-L-lysine hydrochloride -L-arginine hydrochloride
LYSODREN	HRA Pharma Rare Diseases	EU/1/04/273/001	Tablet	-Mitotane
Lytgobi	Taiho Pharma Netherlands B.V.	EU/1/23/1741/001-003	Film-coated tablet	-Futibatnib
Lyumjev	Eli Lilly Nederland B.V.	EU/1/20/1422/001-012	Solution for injection	-Insulin lispro
Lyumjev	Eli Lilly Nederland B.V.	EU/1/20/1422/013-015	Solution for injection in pre-filled pen	-Insulin lispro
Lyumjev	Eli Lilly Nederland B.V.	EU/1/20/1422/016-017	Solution for injection	-Insulin lispro
Lyxumia	Sanofi-Aventis Groupe	EU/1/12/811/001	Solution for injection in pre-filled pen	-Lixisenatide
Lyxumia	Sanofi-Aventis Groupe	EU/1/12/811/002-005	Solution for injection in pre-filled pen	-Lixisenatide
Maalox 200mg/175mg per 5ml Oral Suspension	Opella Healthcare France SAS T/A Sanofi	PA23180/009/001	Oral suspension	-Magnesium hydroxide -Aluminium hydroxide
Maalox 400mg/400mg Chewable Tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/009/002	Chewable tablet	-Magnesium hydroxide -Aluminium oxide, hydrated
Maalox Plus 200 mg/175 mg/25 mg Oral Suspension	Opella Healthcare France SAS T/A Sanofi	PA23180/008/001	Oral suspension	-Aluminium hydroxide -Magnesium hydroxide -Simeticone

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Maalox Plus Chewable Tablets 200mg/200mg/25mg	Opella Healthcare France SAS T/A Sanofi	PA23180/008/002	Chewable tablet	-ALUMINIUM OXIDE, HYDRATED PH. EUR -MAGNESIUM HYDROXIDE PH. EUR. -Dimeticone ph. eur. (as simeticone ph. eur.)
MABTHERA	Roche Registration GmbH	EU/1/98/067/001	Concentrate for solution for infusion	-Rituximab
Mabthera	Roche Registration GmbH	EU/1/98/067/002	Concentrate for solution for infusion	-Rituximab
MabThera	Roche Registration GmbH	EU/1/98/067/003	Solution for injection	-Rituximab
MabThera	Roche Registration GmbH	EU/1/98/067/004	Solution for injection	-Rituximab
MACI	Genzyme Europe B.V.	EU/1/13/847/001	Implant	-AUTOLOGOUS CHONDROCYTES
MacroBID 100mg Prolonged-Release Capsules	Amdipharm Limited	PA1142/033/001	Prolonged-release capsule, hard	-Nitrofurantoin
Macrochantin 100mg Capsules, hard	Amdipharm Limited	PA1142/031/002	Capsule, hard	-Nitrofurantoin
Macrochantin 50mg, Capsules, hard	Amdipharm Limited	PA1142/031/001	Capsule, hard	-Nitrofurantoin
Macrolief 13.8g sachet, powder for oral solution	Rowex Ltd	PA0711/224/001	Powder for oral solution	-Macrogol 3350 -Sodium chloride -Sodium hydrogen carbonate -Potassium chloride
Madopar 100 mg/25 mg dispersible tablets	Roche Products (Ireland) Ltd	PA2307/004/003	Dispersible tablet	-Levodopa -Benserazide
Madopar 200 mg/50 mg hard capsules	Roche Products (Ireland) Ltd	PA2307/004/001	Capsule, hard	-Levodopa -Benserazide
Madopar 50 mg/12.5 mg dispersible tablets	Roche Products (Ireland) Ltd	PA2307/004/002	Dispersible tablet	-Levodopa -Benserazide
Magmedi 97 mg tablets	Kora Corporation Limited trading as Kora Healthcare	PA1748/004/001	Tablet	-Magnesium
Magnaspartate 243 mg powder for oral solution	Kora Corporation Limited trading as Kora Healthcare	PA1748/002/001	Powder for oral solution	-Magnesium aspartate dihydrate
Magnesium Sulfate 38.5% w/w Cutaneous Paste	Foran Healthcare Limited,	PA0484/021/001	Cutaneous paste	-Magnesium sulfate dried
Magnesium Sulfate 50 % w/v Solution for Injection/Concentrate for solution for infusion	Ethypharm	PA0549/020/001	Solution for injection/infusion	-Magnesium sulphate heptahydrate
Magnesium Verla 5 mmol granules for oral solution	Rowa Pharmaceuticals Limited	PA0074/062/001	Granules for oral solution	-Magnesium
Maintelyte solution for infusion	Baxter Holding B.V.	PA2299/045/001	Solution for infusion	-Sodium chloride -GLUCOSE MONOHYDRATE PH. EUR. -Sodium acetate, trihydrate -POTASSIUM CHLORIDE PH. EUR. -MAGNESIUM CHLORIDE HEXAHYDRATE PH. EUR.
Majoven XL 150mg Prolonged Release Capsules, Hard	Brillpharma (Ireland) Limited	PA22749/014/003	Prolonged-release capsule, hard	-Venlafaxine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Majoven XL 37.5mg Prolonged Release Capsules, Hard	Brillpharma (Ireland) Limited	PA22749/014/001	Prolonged-release capsule, hard	-Venlafaxine
Majoven XL 75 mg prolonged-release capsules, hard	Brillpharma (Ireland) Limited	PA22749/014/002	Prolonged-release capsule, hard	-Venlafaxine
Malarone 250mg/100mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/111/001	Film-coated tablet	-Atovaquone -PROGUANIL HYDROCHLORIDE
Manerix 150 mg Film-coated Tablets	Mylan IRE Healthcare Limited	PA2010/023/001	Film-coated tablet	-Moclobemide
Mannitol 10% Solution for Infusion BP	Baxter Holding B.V.	PA2299/006/001	Solution for infusion	-Mannitol
Mannitol 15% w/v solution for infusion	Baxter Holding B.V.	PA2299/006/002	Solution for infusion	-Mannitol
Marcaïn 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	-Bupivacaine hydrochloride -Adrenaline tartrate
Marcaïn 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	-Adrenaline tartrate -Bupivacaine hydrochloride
Marcaïn Heavy Steripack 0.5% w/v Solution for Injection	Aspen Pharma Trading Limited	PA1691/024/003	Solution for injection	-Bupivacaine hydrochloride
Marcaïn Polyamp Steripack 0.25% w/v Solution for Injection	Aspen Pharma Trading Limited	PA1691/024/001	Solution for injection	-Bupivacaine hydrochloride
Marcaïn Polyamp Steripack 0.5% w/v Solution for Injection	Aspen Pharma Trading Limited	PA1691/024/002	Solution for injection	-Bupivacaine hydrochloride
Marixino	KRKA, d.d., Novo mesto	EU/1/13/820/001-013	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
Marixino	Krka d.d., Novo mesto	EU/1/13/820/014-026	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
Marviol 150/30 microgram Tablets	Organon Pharma (Ireland) Limited	PA23198/018/001	Tablet	-Desogestrel -Ethinylestradiol
MATEVER	Pharmathen S.A.	EU/1/11/711/001-006	Film-coated tablet	-LEVETIRACETAM
MATEVER	Pharmathen S.A.	EU/1/11/711/007-014	Film-coated tablet	-LEVETIRACETAM
MATEVER	Pharmathen S.A.	EU/1/11/711/015-022	Film-coated tablet	-LEVETIRACETAM
MATEVER	Pharmathen S.A.	EU/1/11/711/023-029	Film-coated tablet	-LEVETIRACETAM
MATEVER	Pharmathen S.A.	EU/1/11/711/030	Concentrate for solution for infusion	-LEVETIRACETAM
Matrifen, 100 micrograms/hour Transdermal patch	Takeda Products Ireland Ltd	PA2229/007/005	Transdermal patch	-Fentanyl
Matrifen, 12 micrograms/hour Transdermal patch	Takeda Products Ireland Ltd	PA2229/007/001	Transdermal patch	-Fentanyl
Matrifen, 25 micrograms/hour Transdermal patch	Takeda Products Ireland Ltd	PA2229/007/002	Transdermal patch	-Fentanyl
Matrifen, 50 micrograms/hour Transdermal patch	Takeda Products Ireland Ltd	PA2229/007/003	Transdermal patch	-Fentanyl
Matrifen, 75 micrograms/hour Transdermal patch	Takeda Products Ireland Ltd	PA2229/007/004	Transdermal patch	-Fentanyl
Mavenclad	Merck Europe B.V.	EU/1/17/1212/001-006	Tablet	-Cladribine
Maviret	AbbVie Deutschland GmbH & Co. KG	EU/1/17/1213/001	Film-coated tablet	-Pibrentasvir -Glecaprevir

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Maviret	AbbVie Deutschland GmbH & Co. KG	EU/1/17/1213/003	Coated granules in sachet	-Glecaprevir -Pibrentasvir
Maxibar 98.45% w/w powder for oral suspension	Bracco Imaging spa	PA1826/002/001	Powder for oral suspension	-Barium sulfate
Maxidex 0.1% w/v Eye Drops, Suspension	Novartis Ireland Limited	PA0896/018/001	Eye drops, suspension	-Dexamethasone
Maxilief Effervescent Tablets Paracetamol 500mg Codeine Phosphate Hemihydrate 8mg Caffeine 30mg	Clonmel Healthcare Ltd	PA0126/113/001	Effervescent tablet	-Paracetamol -Codeine phosphate hemihydrate -Caffeine
Maxitrol 0.1% w/v, 6000 IU/ml, 3500 IU/ml eye drops, suspension	Novartis Ireland Limited	PA0896/019/001	Eye drops, suspension	-Dexamethasone -Polymyxin b sulfate -Neomycin sulfate
Maxolon 10 mg Tablets	Amdipharm Limited	PA1142/011/003	Tablet	-Metoclopramide hydrochloride
Maxolon 5 mg/ml Solution for Injection	Amdipharm Limited	PA1142/011/001	Solution for injection	-Metoclopramide hydrochloride
Mayzent	Novartis Europharm Limited	EU/1/19/1414/001-002	Film-coated tablet	-Siponimid -SIPONIMOD FUMARIC ACID
Mayzent	Novartis Europharm Limited	EU/1/19/1414/007-008	Film-coated tablet	-SIPONIMOD FUMARIC ACID
Mebeverine hydrochloride 135 mg Film-coated Tablets	Azure Pharmaceuticals Ltd	PA22871/006/001	Film-coated tablet	-Mebeverine hydrochloride
Medical Air	BOC Gases Ireland Ltd	PA0208/009/001	Medicinal gas, compressed	-Oxygen
Medical Carbon Dioxide	BOC Gases Ireland Ltd	PA0208/006/001	Medicinal gas, liquefied	-Carbon dioxide
Medical Helium	BOC Gases Ireland Ltd	PA0208/008/001	Medicinal gas, compressed	-Helium
Medical Liquid Oxygen	BOC Gases Ireland Ltd	PA0208/002/001	Medicinal gas, cryogenic	-Oxygen
Medical Nitrous Oxide	BOC Gases Ireland Ltd	PA0208/001/001	Medicinal gas, liquefied	-Nitrous oxide
Medical Oxygen	BOC Gases Ireland Ltd	PA0208/003/001	Medicinal gas, compressed	-Oxygen
Medical Oxygen	Air Liquide Healthcare Ireland Limited	PA22852/001/001	Medicinal gas, compressed	-Oxygen
Medical Oxygen 100% Medicinal gas, compressed	SOL S.p.A.	PA1848/005/003	Medicinal gas, compressed	-Oxygen
Medical Oxygen/Carbon Dioxide mixtures	BOC Gases Ireland Ltd	PA0208/004/001	Medicinal gas, compressed	-Oxygen -Carbon dioxide
Medicinal air synthetic SOL 21.75% v/v medicinal gas, compressed	SOL S.p.A.	PA1848/002/001	Medicinal gas, compressed	-Oxygen
Medijel oromucosal gel Lidocaine hydrochloride 0.66% w/w Aminoacridine hydrochloride 0.05% w/w	Phoenix Labs	PA1113/022/001	Oromucosal gel	-Aminacrine hydrochloride -Lignocaine hydrochloride
Medikinet 10 mg tablets	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/007	Tablet	-Methylphenidate hydrochloride
Medikinet 20 mg tablets	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/008	Tablet	-Methylphenidate hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Medikinet 5 mg tablets	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/006	Tablet	-Methylphenidate hydrochloride
Medikinet MR 10mg modified – release capsules, hard	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/002	Modified-release capsule, hard	-Methylphenidate hydrochloride -Methylphenidate hydrochloride
Medikinet MR 20mg modified – release capsules, hard	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/003	Modified-release capsule, hard	-Methylphenidate hydrochloride -Methylphenidate hydrochloride
Medikinet MR 30mg modified – release capsules, hard	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/004	Modified-release capsule, hard	-Methylphenidate hydrochloride
Medikinet MR 40mg modified – release capsules, hard	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/005	Modified-release capsule, hard	-Methylphenidate hydrochloride -Methylphenidate hydrochloride
Medikinet MR 5mg modified – release capsules, hard	Medice Arzneimittel Putter GmbH & Co. K.G	PA1555/001/001	Modified-release capsule, hard	-Methylphenidate hydrochloride -Methylphenidate hydrochloride
Medirax 2.5 mg nasal spray, solution in single-dose container	Medir B.V.	PA22954/001/001	Nasal spray, solution in single-dose container	-Midazolam hydrochloride
Medirax 3.75 mg nasal spray, solution in single-dose container	Medir B.V.	PA22954/001/002	Nasal spray, solution in single-dose container	-Midazolam hydrochloride
Medirax 5 mg nasal spray, solution in single-dose container	Medir B.V.	PA22954/001/003	Nasal spray, solution in single-dose container	-Midazolam hydrochloride
Medispray oromucosal spray, solution Chlorhexidine digluconate 2 mg/ml Lidocaine hydrochloride 0.5 mg/ml	Clonmel Healthcare Ltd	PA0126/300/001	Oromucosal spray, solution	-Lidocaine hydrochloride -Chlorhexidine digluconate solution
MEFAC 250 mg Hard Capsules	Rowa Pharmaceuticals Limited	PA0074/015/001	Capsule, hard	-Mefenamic acid
MEFAC 500 mg Film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/015/002	Film-coated tablet	-Mefenamic acid
Megace 160 mg tablets	PCO Manufacturing Ltd.	PPA0465/323/002	Tablet	-Megestrol acetate
Megace 160 mg Tablets	IMED Healthcare Ltd.	PPA1463/191/001	Tablet	-Megestrol acetate
Megace 160 mg tablets	PharmaSwiss Ceska republika s.r.o.	PA1696/002/001	Tablet	-Megestrol acetate
Megace 40 mg/ml oral suspension	Originalis B.V.	PPA2306/016/001	Oral suspension	-Megestrol acetate
Megace 40 mg/ml Oral Suspension	IMED Healthcare Ltd.	PPA1463/161/001	Oral suspension	-Megestrol acetate
Megace 40 mg/ml Oral Suspension	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/027/001	Oral suspension	-Megestrol acetate
Megace 40 mg/ml oral suspension	PCO Manufacturing Ltd.	PPA0465/323/001	Oral suspension	-Megestrol acetate
Megace 40 mg/ml Oral Suspension	Bausch Health Ireland Limited	PA22698/024/001	Oral suspension	-Megestrol acetate
Megalotect 100 U/mL solution for infusion	Biotest Pharma GmbH	PA0592/008/001	Solution for infusion	-Human Cytomegalovirus Immunoglobulin
Mekinist 0.5 mg film-coated tablets	Novartis Europharm Limited	EU/1/14/931/01-02	Film-coated tablet	-Trametinib

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Mekinist 1 mg film-coated tablets	Novartis Europharm Limited	EU/1/14/931/03-04	Film-coated tablet	-Trametinib
Mekinist 2 mg film-coated tablets	Novartis Europharm Limited	EU/1/14/931/05-06	Film-coated tablet	-Trametinib
Mektovi	Pierre Fabre Medicament	EU/1/18/1315/001	Film-coated tablet	-BINMETINIB
Meladura 2 mg prolonged-release tablets	Bluefish Pharmaceuticals AB	PA1436/047/001	Prolonged-release tablet	-Melatonin
Melatonin Neurim	RAD Neurim Pharmaceuticals EEC SARL	EU/1/22/1694/001-004	Prolonged-release tablet	-Melatonin
Melatonin Pharma Nord 3 mg film-coated tablet	Pharma Nord ApS	PA1242/002/001	Film-coated tablet	-Melatonin
Meldonium 500 mg hard capsules	AS Grindeks	PA22992/025/001	Capsule, hard	-Meldonium dihydrate
Melfen 200mg Film-coated tablets	Clonmel Healthcare Ltd	PA0126/012/001	Film-coated tablet	-Ibuprofen ph. eur.
Melfen 400mg Film-coated tablets	Clonmel Healthcare Ltd	PA0126/012/002	Film-coated tablet	-Ibuprofen ph. eur.
Meloxicam Chanelle Medical 15 mg Tablets	Chanelle Medical Unlimited Company	PA0688/005/002	Tablet	-Meloxicam
Meloxicam Chanelle Medical 7.5 mg Tablets	Chanelle Medical Unlimited Company	PA0688/005/001	Tablet	-Meloxicam
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	-Melphalan Hydrochloride
Memantine Accord	Accord Healthcare S.L.U.	EU/1/13/880/001-008	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
Memantine Accord	Accord Healthcare S.L.U.	EU/1/13/880/013	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
Memantine Accord	Accord Healthcare S.L.U.	EU/1/13/880/09-12	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
Memantine Clonmel 10mg Film-coated Tablet	Clonmel Healthcare Ltd	PA0126/255/002	Film-coated tablet	-Memantine hydrochloride
Memantine Clonmel 10mg/ml Oral Solution	Clonmel Healthcare Ltd	PA0126/255/001	Oral solution	-Memantine hydrochloride
Memantine Grindeks 10 mg film-coated tablets	AS Grindeks	PA22992/003/001	Film-coated tablet	-Memantine Hydrochloride
Memantine hydrochloride Pinewood 10 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/166/001	Film-coated tablet	-Memantine hydrochloride
Memantine hydrochloride Pinewood 20 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/166/002	Film-coated tablet	-Memantine hydrochloride
Memantine LEK	Pharmathen S.A.	EU/1/13/826/001-006	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
Memantine LEK	Pharmathen S.A.	EU/1/13/826/007-011	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
Memantine Merz	Merz Pharmaceuticals GmbH	EU/1/12/799/001-012	Film-coated tablet	-Memantine (free base) -MEMANTINE HYDROCHLORIDE
Memantine Merz	Merz Pharmaceuticals GmbH	EU/1/12/799/013-024	Film-coated tablet	-Memantine (free base) -MEMANTINE HYDROCHLORIDE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Memantine Merz	Merz Pharmaceuticals GmbH	EU/1/12/799/025-026	Film-coated tablet	-MEMANTINE HYDROCHLORIDE -Memantine (free base)
Memantine Merz	Merz Pharmaceuticals GmbH	EU/1/12/799/027-029	Oral solution	-MEMANTINE HYDROCHLORIDE -Memantine (free base)
Memantine Mylan	Mylan Pharmaceuticals Limited	EU/1/13/827/001-018	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
Memantine Mylan	Mylan Pharmaceuticals Limited	EU/1/13/827/019-036	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
Memantine Ratiopharm	Ratiopharm GmbH	EU/1/13/836/001-12	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
MEMANTINE RATIOPHARM	Ratiopharm GmbH	EU/1/13/836/013-22	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
MEMANTINE RATIOPHARM	Ratiopharm GmbH	EU/1/13/836/023	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
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	-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)
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	-Meningococcal group c oligosaccharide -Corynebacterium diphtheriae crm197 protein
Menjugate 10 micrograms suspension for injection Meningococcal group C conjugate vaccine	GSK Vaccines S.r.l.	PA0919/004/004	Suspension for injectio	-Meningococcal group c oligosaccharide -Corynebacterium diphtheriae crm197 protein
MENOPUR 1200 IU Powder and Solvent for Solution for Injection	Ferring Ireland Ltd	PA1009/015/003	Powder and solvent for solution for injection	-Menotrophin
MENOPUR 1200 IU Powder and Solvent for Solution for Injection	PCO Manufacturing Ltd.	PPA0465/453/002	Powder and solvent for solution for injection	-Menotrophin
MENOPUR 600 IU Powder and Solvent for Solution for Injection	PCO Manufacturing Ltd.	PPA0465/453/001	Powder and solvent for solution for injection	-Menotrophin
MENOPUR 600 IU Powder and Solvent for Solution for Injection	Ferring Ireland Ltd	PA1009/015/002	Powder and solvent for solution for injection	-Menotrophin
MENOPUR® 75 IU Powder and Solvent for Solution for Injection	Ferring Ireland Ltd	PA1009/015/001	Powder and solvent for solution for injection	-Menotrophin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Menotrophin
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	-Menotrophin
Menotrophin Ferring 75 IU powder and solvent for solution for injection.	Ferring Ireland Ltd	PA1009/030/001	Powder and solvent for solution for injection	-Menotrophin
Menquadfi	Sanofi Pasteur	EU/1/20/1483/001-002	Solution for injection	-Neisseria Meningitidis Group A Polysaccharide -Neisseria Meningitidis Group W135 Polysaccharide -N. Meningitidis Group Y Polysaccharide -Tetanus toxoid -N. Meningitidis Group C Polysaccharide
Menthol & Wintergreen Cream	Ovelle Limited	PA0206/022/001	Cream	-Turpentine oil -Oleoresin capsicum -Methyl salicylate -Levomenthol
Menveo	GSK Vaccines S.r.l.	EU/1/10/614/002-003	Powder and solution for solution for injection	-Meningococcal group y oligosaccharide -Meningococcal group a oligosaccharide -Meningococcal group c oligosaccharide -Meningococcal group w-135 oligosaccharide
MEPACT	Takeda France SAS	EU/1/08/502/001	Powder for concentrate for dispersion for infusion	-Mifamurtide
Mepsevii	Ultragenyx Germany GmbH	EU/1/18/1301/001	Concentrate for solution for infusion	-RECOMBINANT HUMAN BETA GLUCURONIDASE; RHGUS
Meptid 100 mg/ml Solution for Injection	Almirall, S.A.	PA0968/005/001	Solution for injection	-Meptazinol
Meptid 200 mg film-coated Tablets	Almirall, S.A.	PA0968/005/002	Film-coated tablet	-Meptazinol
Mercaptopurine Silver Pharma 50 mg tablets	Silver Pharma S.L.	PA23137/001/001	Tablet	-Mercaptopurine
Mercilon 150/20 microgram Tablets	Organon Pharma (Ireland) Limited	PA23198/019/001	Tablet	-Desogestrel -Ethinylestradiol
Meropenem I.V. 1g Powder for solution for injection or infusion	Pfizer Healthcare Ireland	PA0822/190/002	Powder for solution for injection/infusion	-Meropenem
Meropenem 1 g powder for solution for injection or infusion	Venus Pharma GmbH	PA1610/001/002	Powder for solution for injection/infusion	-Meropenem Trihydrate
Meropenem 1 g powder for solution for injection or infusion	Fresenius Kabi Deutschland GmbH	PA2059/012/002	Powder for solution for injection/infusion	-Meropenem Trihydrate
Meropenem 1 g powder for solution for injection or infusion	Acino AG	PA2168/002/002	Powder for solution for injection/infusion	-Meropenem Trihydrate
Meropenem 1 g powder for solution for injection or infusion	Rowex Ltd	PA0711/314/002	Powder for solution for injection/infusion	-Meropenem Trihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Meropenem 1 g powder for solution for injection/infusion	AS Kalceks	PA2165/016/002	Powder for solution for injection/infusion	-Meropenem Trihydrate
Meropenem 1 g powder for solution for injection/infusion	Steriscience B.V.	PA23431/001/002	Powder for solution for injection/infusion	-Meropenem Trihydrate
Meropenem 1g Powder for Solution for Injection or Infusion	Noridem Enterprises Limited	PA1122/015/002	Powder for solution for injection/infusion	-Meropenem
Meropenem 1g powder for solution for injection/infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/006/002	Powder for solution for injection/infusion	-Meropenem
Meropenem 2 g powder for solution for injection/infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/006/003	Powder for solution for injection/infusion	-Meropenem Trihydrate
Meropenem 500 mg powder for solution for injection or infusion	Fresenius Kabi Deutschland GmbH	PA2059/012/001	Powder for solution for injection/infusion	-Meropenem Trihydrate
Meropenem 500 mg powder for solution for injection or infusion	Venus Pharma GmbH	PA1610/001/001	Powder for solution for injection/infusion	-Meropenem
Meropenem 500 mg powder for solution for injection or infusion	Acino AG	PA2168/002/001	Powder for solution for injection/infusion	-Meropenem Trihydrate
Meropenem 500 mg powder for solution for injection or infusion	Rowex Ltd	PA0711/314/001	Powder for solution for injection/infusion	-Meropenem Trihydrate
Meropenem 500 mg powder for solution for injection/infusion	AS Kalceks	PA2165/016/001	Powder for solution for injection/infusion	-Meropenem Trihydrate
Meropenem 500 mg powder for solution for injection/infusion	Steriscience B.V.	PA23431/001/001	Powder for solution for injection/infusion	-Meropenem Trihydrate
Meropenem 500mg Powder for Solution for Injection or Infusion	Noridem Enterprises Limited	PA1122/015/001	Powder for solution for injection/infusion	-Meropenem
Meropenem 500mg powder for solution for injection/infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/006/001	Powder for solution for injection/infusion	-Meropenem
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	-Meropenem
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	-Meropenem
Meropenem Aurobindo 1g Powder for solution for injection or infusion	Eugia Pharma (Malta) Limited	PA23467/002/002	Powder for solution for injection/infusion	-Meropenem
Meropenem Aurobindo 500mg Powder for solution for injection or infusion	Eugia Pharma (Malta) Limited	PA23467/002/001	Powder for solution for injection/infusion	-Meropenem
Meropenem Star Pharmasin 1 g Powder for solution for injection/infusion	Star Pharmasin Ltd	PA22689/001/002	Powder for solution for injection/infusion	-Meropenem Trihydrate
Meropenem Star Pharmasin 500 mg Powder for solution for injection/infusion	Star Pharmasin Ltd	PA22689/001/001	Powder for solution for injection/infusion	-Meropenem Trihydrate
Meroponia 1,000 mg Powder for Solution for Injection or Infusion	Clonmel Healthcare Ltd	PA0126/225/002	Powder for solution for injection/infusion	-Meropenem

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Mestinon 60 mg tablets	PCO Manufacturing Ltd.	PPA0465/492/001	Tablet	-Pyridostigmine bromide
Mestinon 60 mg Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/028/001	Tablet	-Pyridostigmine bromide
Mestinon 60mg Tablets	Mylan IRE Healthcare Limited	PA2010/052/001	Tablet	-Pyridostigmine bromide
Metalyse	Boehringer Ingelheim International GmbH	EU/1/00/169/004	Powder and solvent for solution for injection	-Tenecteplase
Metalyse	Boehringer Ingelheim International GmbH	EU/1/00/169/005	Powder and solvent for solution for injection	-Tenecteplase
Metalyse	Boehringer Ingelheim International GmbH	EU/1/00/169/006	Powder and solvent for solution for injection	-Tenecteplase
Metaperex 400 IU soft capsules	Kora Corporation Limited trading as Kora Healthcare	PA1748/005/001	Capsule, soft	-Rrr alpha-tocoferol
Metaraminol 10 mg/ml Solution for Injection or Infusion	Global Harvest Pharmaceuticals (Ireland) Limited	PA22893/001/001	Solution for injection/infusion	-METARAMINOL TARTRATE
Metformin Accord 1000 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/245/003	Film-coated tablet	-Metformin Hydrochloride
Metformin Accord 500 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/245/001	Film-coated tablet	-Metformin Hydrochloride
Metformin Accord 850 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/245/002	Film-coated tablet	-Metformin Hydrochloride
Metformin Aurobindo 1000 mg film-coated tablets	Aurobindo Pharma (Malta) Limited	PA1445/021/003	Film-coated tablet	-Metformin Hydrochloride
Metformin Aurobindo 500 mg film-coated tablets	Aurobindo Pharma (Malta) Limited	PA1445/021/001	Film-coated tablet	-Metformin Hydrochloride
Metformin Aurobindo 850 mg film-coated tablets	Aurobindo Pharma (Malta) Limited	PA1445/021/002	Film-coated tablet	-Metformin Hydrochloride
Metformin Bluefish 1000 mg, film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/009/003	Film-coated tablet	-Metformin Hydrochloride
Metformin Bluefish 500 mg, Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/009/001	Film-coated tablet	-Metformin Hydrochloride
Metformin Bluefish 850 mg, film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/009/002	Film-coated tablet	-Metformin Hydrochloride
Metformin Hydrochloride 500mg/5ml Oral Solution	Taw Pharma (Ireland) Limited	PA23081/008/001	Oral solution	-Metformin Hydrochloride
Metformin Pinewood 1000 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/213/003	Film-coated tablet	-Metformin Hydrochloride
Metformin Pinewood 500 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/213/001	Film-coated tablet	-Metformin Hydrochloride
Metformin Pinewood 850 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/213/002	Film-coated tablet	-Metformin Hydrochloride
Metformin Teva 1000 mg Film-coated tablets	Teva Pharma B.V.	PA0749/185/003	Film-coated tablet	-Metformin Hydrochloride
Metformin Teva 500 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/185/001	Film-coated tablet	-Metformin Hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Metformin Teva 850 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/185/002	Film-coated tablet	-Metformin Hydrochloride
Methacholine chloride 100 mg Powder for nebuliser solution	Acic Europe Limited	PA2326/001/001	Powder for nebuliser solution	-Methacholine Chloride
Methadone hydrochloride 1 mg/ml oral solution	Alkaloid - INT d.o.o	PA2128/002/001	Oral solution	-Methadone hydrochloride
Methadone Hydrochloride 5 mg tablets	Ascot Laboratories (Ireland) Limited	PA23163/002/001	Tablet	-Methadone hydrochloride
Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution	Taw Pharma (Ireland) Limited	PA23081/011/001	Oral solution	-Methadone hydrochloride
Methadone Mixture DTF (Sugar Free) 1 mg in 1 ml Oral Solution	Ethypharm	PA0549/032/001	Oral solution	-Methadone hydrochloride
Methocarbamol 750 mg film-coated tablets	HBS Healthcare	PA2238/001/001	Film-coated tablet	-Methocarbamol
Methofill 10 mg solution for injection in pre-filled injector	Accord Healthcare Ireland Ltd.	PA2315/060/003	Solution for injection in pre-filled injector	-Methotrexate
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	-Methotrexate
Methofill 15 mg solution for injection in pre-filled injector	Accord Healthcare Ireland Ltd.	PA2315/060/005	Solution for injection in pre-filled injector	-Methotrexate
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	-Methotrexate
Methofill 20 mg solution for injection in pre-filled injector	Accord Healthcare Ireland Ltd.	PA2315/060/007	Solution for injection in pre-filled injector	-Methotrexate
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	-Methotrexate
Methofill 25 mg solution for injection in pre-filled injector	Accord Healthcare Ireland Ltd.	PA2315/060/009	Solution for injection in pre-filled injector	-Methotrexate
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	-Methotrexate
Methofill 30 mg solution for injection in pre-filled injector	Accord Healthcare Ireland Ltd.	PA2315/060/011	Solution for injection in pre-filled injector	-Methotrexate
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	-Methotrexate
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	-Methotrexate
Methotrexate 1 g/10 ml Injection	Pfizer Healthcare Ireland	PA0822/206/006	Solution for injection	-Methotrexate
Methotrexate 10 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/062/002	Tablet	-Methotrexate
Methotrexate 10 mg tablets	Morningside Healthcare (Malta) Limited	PA23142/005/001	Tablet	-Methotrexate
Methotrexate 100 mg/ml concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/061/002	Concentrate for solution for infusion	-Methotrexate
Methotrexate 2.5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/062/001	Tablet	-Methotrexate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Methotrexate 2.5 mg Tablets	Amdipharm Limited	PA1142/030/001	Tablet	-Methotrexate
Methotrexate 2.5mg tablets	Morningside Healthcare (Malta) Limited	PA23142/005/002	Tablet	-Methotrexate
Methotrexate 25mg/ml Solution for Injection	Accord Healthcare Ireland Ltd.	PA2315/061/001	Solution for injection	-Methotrexate
Methotrexate 5 g/50 ml Injection	Pfizer Healthcare Ireland	PA0822/206/007	Solution for injection	-Methotrexate
Methotrexate 5 mg/2 ml Injection	Pfizer Healthcare Ireland	PA0822/206/001	Solution for injection	-Methotrexate
Methotrexate 500 mg/20 ml Injection	Pfizer Healthcare Ireland	PA0822/206/003	Solution for injection	-Methotrexate
Methotrexate 50mg/2ml Injection	Pfizer Healthcare Ireland	PA0822/206/002	Solution for injection	-Methotrexate
Methotrexate Orion 10 mg tablets	Orion Corporation	PA1327/019/002	Tablet	-Methotrexate
Methotrexate Orion 2.5 mg tablets	Orion Corporation	PA1327/019/001	Tablet	-Methotrexate
Methoxyflurane 99.9%, 3 ml inhalation vapour, liquid	Medical Developments MD&P Limited	PA22745/003/001	Inhalation vapour, liquid	-Methoxyflurane
Methoxyflurane Medical Developments MD&P 99.9%, 3 ml inhalation vapour, liquid	Medical Developments MD&P Limited	PA22745/002/001	Inhalation vapour, liquid	-Methoxyflurane
Methylthionium Chloride Proveblue	Provepharm SAS	EU/1/11/682/001	Solution for injection	-Methylthionium chloride
Metoclopramide 5mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/084/001	Solution for injection	-Metoclopramide hydrochloride
Metoclopramide hydrochloride 10 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/204/001	Tablet	-Metoclopramide hydrochloride
Metocor 100 mg Tablets	Rowex Ltd	PA0711/008/002	Tablet	-METOPROLOL TARTRATE
Metocor 50 mg Tablets	Rowex Ltd	PA0711/008/001	Tablet	-METOPROLOL TARTRATE
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	-Methotrexate
Metoject 10 mg solution for injection in pre-filled pen	PCO Manufacturing Ltd.	PPA0465/436/002	Solution for injection in pre-filled pen	-Methotrexate
Metoject 10 mg solution for injection in pre-filled pen	IMED Healthcare Ltd.	PPA1463/172/002	Solution for injection in pre-filled pen	-Methotrexate
Metoject 15 mg solution for injection in pre-filled pen	IMED Healthcare Ltd.	PPA1463/172/003	Solution for injection in pre-filled pen	-Methotrexate
Metoject 15 mg solution for injection in pre-filled pen	PCO Manufacturing Ltd.	PPA0465/436/003	Solution for injection in pre-filled pen	-Methotrexate
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	-Methotrexate
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	-Methotrexate
Metoject 20 mg solution for injection in pre-filled pen	PCO Manufacturing Ltd.	PPA0465/436/004	Solution for injection in pre-filled pen	-Methotrexate
Metoject 20 mg solution for injection in pre-filled pen	IMED Healthcare Ltd.	PPA1463/172/004	Solution for injection in pre-filled pen	-Methotrexate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Metoject 25 mg solution for injection in pre-filled pen	IMED Healthcare Ltd.	PPA1463/172/005	Solution for injection in pre-filled pen	-Methotrexate
Metoject 25 mg solution for injection in pre-filled pen	PCO Manufacturing Ltd.	PPA0465/436/005	Solution for injection in pre-filled pen	-Methotrexate
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	-Methotrexate
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	-Methotrexate
Metoject 50 mg/ml Solution for Injection, pre-filled syringe	PCO Manufacturing Ltd.	PPA0465/436/001	Solution for injection in pre-filled syringe	-Methotrexate
Metoject 7.5 mg solution for injection in pre-filled pen	IMED Healthcare Ltd.	PPA1463/172/001	Solution for injection in pre-filled pen	-Methotrexate
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	-Methotrexate
Metopirone 250mg Soft capsules	HRA Pharma Rare Diseases	PA22888/001/001	Capsule, soft	-Metyrapone
Metronidazole 5 mg/ml solution for infusion	B. Braun Melsungen AG	PA0736/002/001	Solution for infusion	-Metronidazole
Metvix 160 mg/g cream	Galderma International	PA22743/010/001	Cream	-METHYL AMINOLEVULINATE HYDROCHLORIDE
Mevlyq	Yes Pharmaceutical Development Services GmbH	EU/1/23/1789/001	Solution for injection	-Eribulin mesylate
Mezavant XL 1200 mg gastro-resistant, prolonged release tablets	Originalis B.V.	PPA2306/023/001	Prolonged-release tablet	-Mesalazine
Mezavant XL 1200 mg gastro-resistant, prolonged release tablets	IMED Healthcare Ltd.	PPA1463/093/001	Prolonged-release tablet	-Mesalazine
Mezavant XL 1200 mg gastro-resistant, prolonged release tablets	PCO Manufacturing Ltd.	PPA0465/289/001	Prolonged-release tablet	-Mesalazine
Mezavant XL 1200 mg gastro-resistant, prolonged release tablets	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/004/001	Prolonged-release tablet	-Mesalazine
Miacalcic 100 IU/ml solution for injection and infusion	Essential Pharma (M) Limited	PA22644/004/001	Solution for injection/infusion	-Calcitonin
Miacalcic 50 IU/ml solution for injection and infusion	Essential Pharma (M) Limited	PA22644/004/002	Solution for injection/infusion	-Calcitonin
MIBG (123I) 74 MBq/mL solution for injection	Curium Netherlands B.V.	PA0690/005/001	Solution for injection	-Iobenguane
Micardis 20 mg tablets	Boehringer Ingelheim International GmbH	EU/1/98/090/009-012	Tablet	-Telmisartan
Micardis 40 mg tablets	Boehringer Ingelheim International GmbH	EU/1/98/090/001-004	Tablet	-Telmisartan
Micardis 80 mg tablets	Boehringer Ingelheim International GmbH	EU/1/98/090/005-008	Tablet	-Telmisartan
MicardisPlus 40 mg/12.5 mg tablets	Boehringer Ingelheim International GmbH	EU/1/02/213/001-005	Tablet	-Telmisartan -Hydrochlorothiazide
MicardisPlus 80 mg/12.5 mg tablets	Boehringer Ingelheim International GmbH	EU/1/02/213/006-010	Tablet	-Telmisartan -Hydrochlorothiazide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
MicardisPlus 80 mg/25 mg tablets	Boehringer Ingelheim International GmbH	EU/1/02/213/17-23	Tablet	-Telmisartan -Hydrochlorothiazide
Micolette Micro-Enema Rectal Solution	Pinewood Laboratories Ltd	PA0281/115/001	Rectal solution	-Sodium citrate -Sodium lauryl sulphoacetate -Glycerol
Microlax Rectal Solution Sodium Citrate 450mg/5ml Sodium Lauryl Sulphoacetate 45mg/5ml	JNTL Consumer Health I (Ireland) Limited	PA23490/017/001	Rectal solution	-Sodium citrate -Sodium lauryl sulfoacetate
Microlite 100/20 microgram Tablets	Bayer Limited	PA1410/007/001	Tablet	-Ethinylestradiol -Levonorgestrel
Midazolam 1 mg/ml Solution for Injection or Infusion	Accord Healthcare Ireland Ltd.	PA2315/063/001	Solution for injection/infusion	-Midazolam
Midazolam 1 mg/ml solution for injection/infusion	AS Kalceks	PA2165/012/002	Solution for injection/infusion	-Midazolam
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	-Midazolam
Midazolam 2 mg/ml Solution for injection or infusion	Accord Healthcare Ireland Ltd.	PA2315/063/005	Solution for injection/infusion	-Midazolam
Midazolam 5 mg/ml Solution for injection or infusion	Accord Healthcare Ireland Ltd.	PA2315/063/006	Solution for injection/infusion	-Midazolam
Midazolam 5 mg/ml Solution for Injection or Infusion	Accord Healthcare Ireland Ltd.	PA2315/063/002	Solution for injection/infusion	-Midazolam
Midazolam 5 mg/ml solution for injection/infusion	AS Kalceks	PA2165/012/001	Solution for injection/infusion	-Midazolam
Midazolam Rowa 10 mg oromucosal solution	Rowa Pharmaceuticals Limited	PA0074/099/004	Oromucosal solution	-Midazolam
Midazolam Rowa 2.5 mg oromucosal solution	Rowa Pharmaceuticals Limited	PA0074/099/001	Oromucosal solution	-Midazolam
Midazolam Rowa 5 mg oromucosal solution	Rowa Pharmaceuticals Limited	PA0074/099/002	Oromucosal solution	-Midazolam
Midazolam Rowa 7.5 mg oromucosal solution	Rowa Pharmaceuticals Limited	PA0074/099/003	Oromucosal solution	-Midazolam
Midodrine Hydrochloride 2.5 mg tablets	Milstein C.V.	PA23215/001/001	Tablet	-Midodrine hydrochloride
Midodrine Hydrochloride 5 mg tablets	Milstein C.V.	PA23215/001/002	Tablet	-Midodrine hydrochloride
Midodrine Hydrochloride Morningside 2.5 mg tablets	Morningside Healthcare (Malta) Limited	PA23142/008/001	Tablet	-Midodrine hydrochloride
Midodrine Hydrochloride Morningside 5 mg tablets	Morningside Healthcare (Malta) Limited	PA23142/008/002	Tablet	-Midodrine hydrochloride
Midodrine Tillomed 2.5 mg tablets	Tillomed Pharma GmbH	PA23169/002/001	Tablet	-Midodrine hydrochloride
Midodrine Tillomed 5 mg tablets	Tillomed Pharma GmbH	PA23169/002/002	Tablet	-Midodrine hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Midon 2.5 mg tablets	PCO Manufacturing Ltd.	PPA0465/276/001	Tablet	-Midodrine hydrochloride
Midon 2.5 mg tablets	IMED Healthcare Ltd.	PPA1463/160/001	Tablet	-Midodrine hydrochloride
Midon 2.5 mg tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/013/002	Tablet	-Midodrine hydrochloride
Midon 2.5 mg tablets	Merit Pharmaceuticals Limited	PPA23080/024/001	Tablet	-Midodrine hydrochloride
Midon 2.5 mg Tablets	Originalis B.V.	PPA2306/032/001	Tablet	-Midodrine hydrochloride
Midon 2.5 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/016/001	Tablet	-Midodrine hydrochloride
Midon 5 mg tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/016/002	Tablet	-Midodrine hydrochloride
Midon 5 mg tablets	Originalis B.V.	PPA2306/029/001	Tablet	-Midodrine hydrochloride
Midon 5 mg tablets	Merit Pharmaceuticals Limited	PPA23080/024/002	Tablet	-Midodrine hydrochloride
Midon 5 mg tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/013/001	Tablet	-Midodrine hydrochloride
Midon 5 mg tablets	IMED Healthcare Ltd.	PPA1463/160/002	Tablet	-Midodrine hydrochloride
Midon 5 mg Tablets	PCO Manufacturing Ltd.	PPA0465/276/002	Tablet	-Midodrine hydrochloride
Mifegyne 200 mg tablets	EXELGYN	PA22946/001/001	Tablet	-Mifepristone
Mifegyne 600 mg tablets	EXELGYN	PA22946/001/002	Tablet	-Mifepristone
Miglustat Dipharma	Dipharma B.V.	EU/1/18/1346/001	Capsule, hard	-Miglustat
Miglustat GenOrph	Gen.Orph	EU/1/17/1232/001	Capsule, hard	-Miglustat
Migravele Film-coated Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/014/003	Film-coated tablet	-BUCLIZINE HYDROCHLORIDE -Paracetamol -Codeine phosphate hemihydrate
Migravele 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	-Paracetamol -Codeine phosphate hemihydrate -BUCLIZINE HYDROCHLORIDE
Migravele Yellow Film-coated Tablets Paracetamol 500mg Codeine phosphate 8mg	JNTL Consumer Health I (Ireland) Limited	PA23490/014/002	Film-coated tablet	-Paracetamol -Codeine phosphate hemihydrate
Migsun 85 mg/500 mg film-coated tablets	Orion Corporation	PA1327/022/001	Film-coated tablet	-Sumatriptan succinate -Naproxen sodium
Milrinone 1 mg/ml Solution for Injection/Infusion	Pinewood Laboratories Ltd	PA0281/244/001	Solution for injection/infusion	-Milrinone
Mimpara	Amgen Europe B.V.	EU/1/04/292/013	Granules	-Cinacalcet hydrochloride
Mimpara	Amgen Europe B.V.	EU/1/04/292/014	Granules	-Cinacalcet hydrochloride
Mimpara	Amgen Europe B.V.	EU/1/04/292/015	Granules	-Cinacalcet hydrochloride
Mimpara 30 mg film-coated tablets	Amgen Europe B.V.	EU/1/04/292/001-004	Film-coated tablet	-Cinacalcet hydrochloride
Mimpara 60 mg film-coated tablets	Amgen Europe B.V.	EU/1/04/292/005-008	Film-coated tablet	-Cinacalcet hydrochloride
Mimpara 90 mg film-coated tablets	Amgen Europe B.V.	EU/1/04/292/009-012	Film-coated tablet	-Cinacalcet hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
MINESE 60 micrograms/15 micrograms film-coated tablet	Pfizer Healthcare Ireland	PA0822/144/001	Film-coated tablet	-Gestodene -Ethinylestradiol
Minims Artificial Tears 0.35% w/w + 0.44% w/w Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/013/001	Eye drops, solution	-Sodium chloride -Hydroxyethylcellulose
Minims Atropine Sulphate 1% Eye Drops, solution	Bausch + Lomb Ireland Limited	PA23259/007/001	Eye drops, solution	-Atropine sulfate
Minims Chloramphenicol 0.5% Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/010/001	Eye drops, solution	-Chloramphenicol
Minims Cyclopentolate Hydrochloride 1% w/v Eye Drops, solution	Bausch + Lomb Ireland Limited	PA23259/011/001	Eye drops, solution	-Cyclopentolate hydrochloride
Minims Fluorescein Sodium 1%, w/v Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/012/001	Eye drops, solution	-Fluorescein sodium
Minims Fluorescein Sodium 2%, w/v Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/012/002	Eye drops, solution	-Fluorescein sodium
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	-Fluorescein sodium -Lidocaine hydrochloride
Minims Oxybuprocaine Hydrochloride 0.4% w/v Eye Drops Solution	Bausch + Lomb Ireland Limited	PA23259/015/001	Eye drops, solution	-Oxybuprocaine hydrochloride
Minims Phenylephrine Hydrochloride 2.5% w/v eye drops, solution	Bausch + Lomb Ireland Limited	PA23259/016/001	Eye drops, solution	-Phenylephrine hydrochloride
Minims Pilocarpine Nitrate 2% w/v, Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/017/001	Eye drops, solution	-Pilocarpine nitrate
Minims Povidone Iodine 5% w/v Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/018/001	Eye drops, solution	-Iodinated povidone
Minims Prednisolone Sodium Phosphate 0.5% w/v Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/019/001	Eye drops, solution	-Prednisolone sodium phosphate
Minims Proxymetacaine hydrochloride 0.5% w/v, Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/020/001	Eye drops, solution	-PROXYMETACAINE HYDROCHLORIDE
Minims Saline 0.9% w/v Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/021/001	Eye drops, solution	-Sodium chloride
Minims Tetracaine Hydrochloride 0.5% w/v Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/022/001	Eye drops, solution	-Tetracaine hydrochloride
Minims Tetracaine Hydrochloride 1% w/v Eye Drops, Solution	Bausch + Lomb Ireland Limited	PA23259/022/002	Eye drops, solution	-Tetracaine hydrochloride
Minims Tropicamide 0.5% w/v Eye drops, solution	Bausch + Lomb Ireland Limited	PA23259/023/001	Eye drops, solution	-Tropicamide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Minims Tropicamide 1% w/v Eye drops, solution	Bausch + Lomb Ireland Limited	PA23259/023/002	Eye drops, solution	-Tropicamide
Minjuvi	MorphoSys AG	EU/1/21/1570/001	Powder for concentrate for solution for infusion	-Tafasitamab
Minocin SA 100 mg Modified Release Capsules	Mylan IRE Healthcare Limited	PA2010/060/001	Modified-release capsule, hard	-Minocycline hydrochloride
Minosil 100mg Modified-release Capsules	Pinewood Laboratories Ltd	PA0281/132/001	Modified-release capsule, hard	-Minocycline hydrochloride
Minulet 75 micrograms/30 micrograms coated tablets	Pfizer Healthcare Ireland	PA0822/093/001	Coated tablet	-Ethinylloestradiol -Gestodene
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	-Acetylcholine chloride
Miofen 200mg Film-coated Tablet	Alter Pharma	PA22983/001/001	Film-coated tablet	-Ibuprofen
Miofen 400mg Film-coated Tablet	Alter Pharma	PA22983/001/002	Film-coated tablet	-Ibuprofen
Miofen 600mg Film-coated Tablet	Alter Pharma	PA22983/001/003	Film-coated tablet	-Ibuprofen
Miramel 0.088 mg tablets	Clonmel Healthcare Ltd	PA0126/173/001	Tablet	-Pramipexole
Miramel 0.18 mg tablets	Clonmel Healthcare Ltd	PA0126/173/002	Tablet	-Pramipexole
Miramel 0.7 mg tablets	Clonmel Healthcare Ltd	PA0126/173/003	Tablet	-Pramipexole
Mirap 15 mg Film-Coated Tablets	Rowex Ltd	PA0711/062/001	Film-coated tablet	-Mirtazapine
Mirap 30 mg Film-Coated Tablets	Rowex Ltd	PA0711/062/002	Film-coated tablet	-Mirtazapine
Mirap 45 mg Film-Coated Tablets	Rowex Ltd	PA0711/062/003	Film-coated tablet	-Mirtazapine
Mirap DisTab 15 mg Orodispersible Tablets	Rowex Ltd	PA0711/094/001	Orodispersible tablet	-Mirtazapine
Mirap DisTab 30 mg Orodispersible Tablets	Rowex Ltd	PA0711/094/002	Orodispersible tablet	-Mirtazapine
Mirap DisTab 45 mg Orodispersible Tablets	Rowex Ltd	PA0711/094/003	Orodispersible tablet	-Mirtazapine
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/001	Tablet	-Pramipexole dihydrochloride monohydrate
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/003	Tablet	-Pramipexole dihydrochloride monohydrate
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/005	Tablet	-Pramipexole dihydrochloride monohydrate
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/011	Tablet	-Pramipexole dihydrochloride monohydrate
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/028-30	Prolonged-release tablet	-Pramipexole dihydrochloride monohydrate, milled
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/031-33	Prolonged-release tablet	-Pramipexole dihydrochloride monohydrate, milled
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/13-15	Prolonged-release tablet	-Pramipexole dihydrochloride monohydrate, milled

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/16-18	Prolonged-release tablet	-Pramipexole dihydrochloride monohydrate, milled
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/19-21	Prolonged-release tablet	-Pramipexole dihydrochloride monohydrate, milled
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/22-24	Prolonged-release tablet	-Pramipexole dihydrochloride monohydrate, milled
Mirapexin	Boehringer Ingelheim International GmbH	EU/1/97/051/25-27	Prolonged-release tablet	-Pramipexole dihydrochloride monohydrate, milled
Mircera	Roche Registration GmbH	EU/1/07/400/008	Solution for injection in pre-filled syringe	-Methoxy peg-epoetin beta
Mircera	Roche Registration GmbH	EU/1/07/400/009	Solution for injection in pre-filled syringe	-Methoxy peg-epoetin beta
Mircera	Roche Registration GmbH	EU/1/07/400/10	Solution for injection in pre-filled syringe	-Methoxy peg-epoetin beta
Mircera	Roche Registration GmbH	EU/1/07/400/11	Solution for injection in pre-filled syringe	-Methoxy peg-epoetin beta
Mircera	Roche Registration GmbH	EU/1/07/400/12	Solution for injection in pre-filled syringe	-Methoxy peg-epoetin beta
Mircera	Roche Registration GmbH	EU/1/07/400/13	Solution for injection in pre-filled syringe	-Methoxy peg-epoetin beta
Mircera	Roche Registration GmbH	EU/1/07/400/17	Solution for injection in pre-filled syringe	-Methoxy peg-epoetin beta
Mircera	Roche Registration GmbH	EU/1/07/400/18	Solution for injection in pre-filled syringe	-Methoxy peg-epoetin beta
Mircera	Roche Registration GmbH	EU/1/07/400/19	Solution for injection in pre-filled syringe	-Methoxy peg-epoetin beta
Mircera	Roche Registration GmbH	EU/1/07/400/20	Solution for injection in pre-filled syringe	-Methoxy peg-epoetin beta
Mircera	Roche Registration GmbH	EU/1/07/400/21	Solution for injection in pre-filled syringe	-Methoxy peg-epoetin beta
Mirena 52 mg Intrauterine Delivery System	PCO Manufacturing Ltd.	PPA0465/292/001	Intrauterine delivery system	-Levonorgestrel
Mirena 52 mg Intrauterine Delivery System	IMED Healthcare Ltd.	PPA1463/111/001	Intrauterine delivery system	-Levonorgestrel
Mirena 52 mg intrauterine delivery system	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/049/001	Intrauterine delivery system	-Levonorgestrel
Mirena 52 mg intrauterine delivery system	Bayer Limited	PA1410/008/001	Intrauterine delivery system	-Levonorgestrel
Mirpresoc 20 mg Tablets	Laboratorios LICONSA, S.A.	PA1239/017/001	Tablet	-Telmisartan
Mirpresoc 40 mg Tablets	Laboratorios LICONSA, S.A.	PA1239/017/002	Tablet	-Telmisartan
Mirpresoc 80 mg Tablets	Laboratorios LICONSA, S.A.	PA1239/017/003	Tablet	-Telmisartan
Mirtazapine 15 mg Film-Coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/072/001	Film-coated tablet	-Mirtazapine
Mirtazapine 30 mg Film-Coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/072/002	Film-coated tablet	-Mirtazapine
Mirtazapine 45 mg Film-Coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/072/003	Film-coated tablet	-Mirtazapine
Mirtazapine Bluefish 15 mg orodispersible tablets	Bluefish Pharmaceuticals AB	PA1436/001/001	Orodispersible tablet	-Mirtazapine
Mirtazapine Bluefish 30 mg orodispersible tablets	Bluefish Pharmaceuticals AB	PA1436/001/002	Orodispersible tablet	-Mirtazapine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Mirtazapine Bluefish 45 mg orodispersible tablets	Bluefish Pharmaceuticals AB	PA1436/001/003	Orodispersible tablet	-Mirtazapine
Mirvaso	Galderma International S.A.S.	EU/1/13/904/001-003	Gel	-Brimonidine
MisoOne 400 microgram tablets	EXELGYN	PA22946/002/001	Tablet	-Misoprostol
Mistra 2mg/0.03mg Film-Coated Tablets	Gedeon Richter Plc	PA1330/018/001	Film-coated tablet	-Dienogest -Ethinylestradiol
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	-Mitomycin
Mitoxana 1 g Powder for Sterile Concentrate	Baxter Holding B.V.	PA2299/028/001	Powder for concentrate for solution for infusion	-Ifosfamide
Mitoxana 2 g Powder for Sterile Concentrate	Baxter Holding B.V.	PA2299/028/002	Powder for concentrate for solution for infusion	-Ifosfamide
Mivacron 2mg/ml Solution for Injection	Aspen Pharma Trading Limited	PA1691/031/001	Solution for injection	-Mivacurium chloride
Mixtard	Novo Nordisk A/S	EU/1/02/231/003-35,37	Suspension for injectio	-Insulin human -Insulin human
Mixtard	Novo Nordisk A/S	EU/1/02/231/1-25	Suspension for injectio	-Insulin human
M-M-RVAXPRO	Merck Sharp & Dohme BV,	EU/1/06/337/1-13	Powder and solvent for suspension for injection	-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
Modafinil Bluefish 100 mg tablets	Bluefish Pharmaceuticals AB	PA1436/031/001	Tablet	-Modafinil
Modafinil Bluefish 200 mg tablets	Bluefish Pharmaceuticals AB	PA1436/031/002	Tablet	-Modafinil
Modigraf	Astellas Pharma Europe BV	EU/1/09/523/001	Granules for oral suspension	-Tacrolimus
Modigraf	Astellas Pharma Europe BV	EU/1/09/523/002	Granules for oral suspension	-Tacrolimus
Modrasone Cream 0.05% w/w	Morningside Healthcare (Malta) Limited	PA23142/011/001	Cream	-Alclometasone dipropionate
Modrasone Ointment 0.05% w/w	Morningside Healthcare (Malta) Limited	PA23142/011/002	Ointment	-Alclometasone dipropionate
Mogadon 5 mg Tablets	Mylan IRE Healthcare Limited	PA2010/024/001	Tablet	-Nitrazepam
Molaxole powder for oral solution	Viartis Healthcare Limited	PA23355/007/001	Powder for oral solution	-Macrogol 3350 -Sodium chloride -Sodium hydrogen carbonate -Potassium chloride
Molipaxin 100mg Capsules	Neuraxpharm Ireland Limited	PA23229/011/002	Capsule, hard	-Trazodone hydrochloride
Molipaxin 150mg Film-coated Tablets	Neuraxpharm Ireland Limited	PA23229/011/003	Film-coated tablet	-Trazodone hydrochloride
Molipaxin 50mg Capsules	Neuraxpharm Ireland Limited	PA23229/011/001	Capsule, hard	-Trazodone hydrochloride
Mometasone 50 microgram/dose, Nasal spray, Suspension	Rowex Ltd	PA0711/196/001	Nasal spray, suspension	-Mometasone furoate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Monadia 50mcg/actuation Nasal spray, suspension	Diapharm GmbH & Co. KG	PA1958/008/001	Nasal spray, suspension	-Mometasone furoate monohydrate
Monopost Unidose 50 micrograms/ml eye drops, solution in single-dose container	Laboratoires Thea	PA1107/007/001	Eye drops, solution in single-dose container	-Latanoprost
Monopost Unidose 50 micrograms/ml eye drops, solution in single-dose container	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/029/001	Eye drops, solution in single-dose container	-Latanoprost
Monopost Unidose 50 micrograms/ml eye drops, solution in single-dose container	PCO Manufacturing Ltd.	PPA0465/449/001	Eye drops, solution in single-dose container	-Latanoprost
Monopost Unidose 50 micrograms/ml eye drops, solution in single-dose container	IMED Healthcare Ltd.	PPA1463/153/001	Eye drops, solution in single-dose container	-Latanoprost
Monotrim 10 mg/ml Oral Suspension	Taw Pharma (Ireland) Ltd	PA23081/014/001	Oral suspension	-Trimethoprim
Monotrim 100 mg Tablets	Chemidex Pharma Limited	PA22643/002/002	Tablet	-Trimethoprim
Monotrim 200 mg Tablets	Chemidex Pharma Limited	PA22643/002/003	Tablet	-Trimethoprim
Monover 100 mg/ml solution for injection/infusion (ampoules)	Pharmacosmos A/S	PA0982/002/001	Solution for injection/infusion	-Iron
Monover 100 mg/ml solution for injection/infusion (vials)	Pharmacosmos A/S	PA0982/002/002	Solution for injection/infusion	-Iron
Monovo 1mg/g Cream	Almirall Hermal GmbH	PA1548/002/001	Cream	-Mometasone furoate
Montelair 10 mg Film- coated Tablets	Clonmel Healthcare Ltd	PA0126/215/003	Film-coated tablet	-Montelukast
Montelair 4 mg Chewable Tablets	Clonmel Healthcare Ltd	PA0126/215/001	Chewable tablet	-Montelukast
Montelair 5 mg Chewable Tablets	Clonmel Healthcare Ltd	PA0126/215/002	Chewable tablet	-Montelukast
MONTELUKAST 10 mg Film-Coated Tablets	Aurobindo Pharma (Malta) Limited	PA1445/015/001	Film-coated tablet	-Montelukast sodium
Montelukast 10 mg film- coated tablets	KRKA, d.d., Novo mesto	PA1347/039/003	Film-coated tablet	-Montelukast
Montelukast 10 mg film- coated tablets	Accord Healthcare Ireland Ltd.	PA2315/110/003	Film-coated tablet	-Montelukast
Montelukast 4 mg chewable tablets	KRKA, d.d., Novo mesto	PA1347/039/001	Chewable tablet	-Montelukast
Montelukast 5 mg chewable tablets	KRKA, d.d., Novo mesto	PA1347/039/002	Chewable tablet	-Montelukast
Montelukast Bluefish 10 mg Film-coated Tablets	Bluefish Pharmaceuticals AB	PA1436/032/001	Film-coated tablet	-Montelukast sodium
Montelukast Bluefish 4 mg chewable tablets	Bluefish Pharmaceuticals AB	PA1436/033/001	Chewable tablet	-Montelukast sodium
Montelukast Bluefish 5 mg chewable tablets	Bluefish Pharmaceuticals AB	PA1436/033/002	Chewable tablet	-Montelukast sodium
Montelukast Mylan 10 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/119/001	Film-coated tablet	-Montelukast
Montelukast Mylan 4 mg Chewable Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/131/001	Chewable tablet	-Montelukast

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Montelukast Mylan 5 mg Chewable Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/131/002	Chewable tablet	-Montelukast
Montelukast Paediatric 4mg Chewable Tablets	Accord Healthcare Ireland Ltd.	PA2315/110/001	Chewable tablet	-Montelukast sodium
MONTELUKAST Paediatric 5 mg Chewable Tablets	Aurobindo Pharma (Malta) Limited	PA1445/015/003	Chewable tablet	-Montelukast
Montelukast Paediatric 5mg Chewable Tablets	Accord Healthcare Ireland Ltd.	PA2315/110/002	Chewable tablet	-Montelukast
Montelukast Teva 10 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/048/003	Film-coated tablet	-Montelukast
Montelukast Teva 4 mg Chewable Tablets	Teva Pharma B.V.	PA0749/048/001	Chewable tablet	-Montelukast
Montelukast Teva 4 mg Granules For children from 6 months to 5 years of age	Teva Pharma B.V.	PA0749/048/004	Granules	-Montelukast sodium
Montelukast Teva 5 mg Chewable Tablets	Teva Pharma B.V.	PA0749/048/002	Chewable tablet	-Montelukast
Monuril 3 g granules for oral solution	Zambon S.p.A.	PA1441/002/002	Granules for oral solution	-Fosfomycin trometamol
Monuril 3 g granules for oral solution	IMED Healthcare Ltd.	PPA1463/213/001	Granules for oral solution	-Fosfomycin
Monuril 3 g granules for oral solution	PCO Manufacturing Ltd.	PPA0465/485/001	Granules for oral solution	-FOSFOMYCIN TROMETAMOL
Monuril 3 g granules for oral solution	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/044/001	Granules for oral solution	-Fosfomycin
Morphine sulfate 10mg/ml Solution for Injection	AS Kalceks	PA2165/003/001	Solution for injection	-Morphine sulfate
Morphine Sulfate 10mg/ml Solution for injection	Ethypharm	PA0549/023/001	Solution for injection	-Morphine sulfate
Morphine sulfate 15mg/ml Solution for Injection	AS Kalceks	PA2165/003/002	Solution for injection	-Morphine sulfate
Morphine sulfate 30mg/ml Solution for Injection	AS Kalceks	PA2165/003/003	Solution for injection	-Morphine sulfate
Morphine Sulfate 30mg/ml, Solution for injection	Ethypharm	PA0549/023/002	Solution for injection	-Morphine sulfate
Morphine Sulphate 10mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/020/001	Solution for injection	-Morphine sulfate
Morphine Sulphate 1mg/5ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/020/003	Solution for injection	-Morphine sulfate
Morphine Sulphate 30 mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/020/004	Solution for injection	-Morphine sulfate
Morphine Sulphate 60 mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/020/008	Solution for injection	-Morphine sulfate
Morsadex 50 mg/2 ml solution for injection/infusion	AS Kalceks	PA2165/002/001	Solution for injection/infusion	-Dexketoprofen trometamol
Motilium 10 mg Film-Coated Tablets	PCO Manufacturing Ltd.	PPA0465/272/002	Film-coated tablet	-Domperidone

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Motilium 10mg Film-Coated Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/022/002	Film-coated tablet	-Domperidone
Motilium 10mg Film-Coated Tablets	IMED Healthcare Ltd.	PPA1463/195/001	Film-coated tablet	-Domperidone
Motilium 1mg/ml Oral Suspension	JNTL Consumer Health I (Ireland) Limited	PA23490/039/001	Oral suspension	-Domperidone
Motilium Fastmelts 10mg Orodispersible Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/022/001	Orodispersible tablet	-Domperidone
Motilium Rx 10 mg Film-coated Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/039/002	Film-coated tablet	-Domperidone
Motusol Max 2 % w/w gel	Teva B.V.	PA1986/093/002	Gel	-Diclofenac sodium
Motusol Rx 1 % w/w gel	Teva B.V.	PA1986/093/001	Gel	-Diclofenac sodium
Mounjaro	Eli Lilly Nederland B.V.	EU/1/22/1685/001-003	Solution for injection in pre-filled pen	-Tirzepatide
Mounjaro	Eli Lilly Nederland B.V.	EU/1/22/1685/004-006	Solution for injection in pre-filled pen	-Tirzepatide
Mounjaro	Eli Lilly Nederland B.V.	EU/1/22/1685/007-009	Solution for injection in pre-filled pen	-Tirzepatide
Mounjaro	Eli Lilly Nederland B.V.	EU/1/22/1685/010-012	Solution for injection in pre-filled pen	-Tirzepatide
Mounjaro	Eli Lilly Nederland B.V.	EU/1/22/1685/013-015	Solution for injection in pre-filled pen	-Tirzepatide
Mounjaro	Eli Lilly Nederland B.V.	EU/1/22/1685/016-018	Solution for injection in pre-filled pen	-Tirzepatide
Moventig	Kyowa Kirin Holdings B.V.	EU/1/14/962/001-003	Film-coated tablet	-Naloxegol oxalate
Moventig	Kyowa Kirin Holdings B.V.	EU/1/14/962/004-007	Film-coated tablet	-Naloxegol oxalate
Movicol Paediatric Chocolate Flavour 6.9 g sachet powder for oral solution	Norgine Healthcare B.V.	PA23265/001/002	Powder for oral solution	-Macrogol 3350 -Sodium bicarbonate -Sodium chloride -Potassium chloride
Movicol 13.8 g sachet powder for oral solution	Norgine Healthcare B.V.	PA23265/001/005	Powder for oral solution	-Macrogol 3350 -Sodium bicarbonate -Sodium chloride -Potassium chloride
Movicol 13.8g sachet, powder for oral solution	Novalus Healthcare Limited	PPA1925/002/001	Powder for oral solution	-Macrogol 3350 -Sodium bicarbonate -Sodium chloride -Potassium chloride
Movicol Chocolate 13.9 g sachet powder for oral solution	Norgine Healthcare B.V.	PA23265/001/001	Powder for oral solution	-Macrogol 3350 -Sodium bicarbonate -Sodium chloride -Potassium chloride
Movicol Liquid Orange Flavour, Concentrate for Oral Solution	Norgine Healthcare B.V.	PA23265/002/001	Concentrate for oral solution	-Macrogol 3350 -Sodium chloride -Sodium hydrogen carbonate -Potassium chloride
Movicol Paediatric Plain 6.9 g sachet powder for oral solution	Norgine Healthcare B.V.	PA23265/001/003	Powder for oral solution	-Macrogol 3350 -Sodium bicarbonate -Sodium chloride -Potassium chloride
Movicol Plain 13.7 g sachet powder for oral solution	Norgine Healthcare B.V.	PA23265/001/004	Powder for oral solution	-Macrogol 3350 -Sodium bicarbonate -Sodium chloride -Potassium chloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Movicol Ready to Take 13.9 g/25 ml oral solution in sachet	Norgine Healthcare B.V.	PA23265/002/002	Oral solution in sachet	-Macrogol 3350 -Sodium chloride -Sodium hydrogen carbonate -Potassium chloride
Moviprep Orange, powder for oral solution	Norgine B.V.	PA1336/001/002	Powder for oral solution	-Macrogol 3350 -Sodium sulfate anhydrous -Sodium chloride -Potassium chloride -Ascorbic acid -Sodium ascorbate
MOVIPREP powder for oral solution	PCO Manufacturing Ltd.	PPA0465/428/001	Powder for oral solution	-Sodium ascorbate -Ascorbic acid -Potassium chloride -Sodium chloride -Sodium sulphate anhydrous -Macrogol 3350
Moviprep, powder for oral solution	Primecrown 2010 Limited	PPA1633/070/001	Powder for oral solution	-Potassium chloride -Ascorbic acid -Sodium sulfate anhydrous -Macrogol 3350 -Sodium chloride -Sodium ascorbate
MOVIPREP, powder for oral solution	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/034/001	Powder for oral solution	-Macrogol 3350 -Sodium sulphate anhydrous -Sodium chloride -Potassium chloride -Ascorbic acid -Sodium ascorbate
Moviprep, powder for oral solution	Norgine B.V.	PA1336/001/001	Powder for oral solution	-Macrogol 3350 -Sodium sulfate anhydrous -Sodium chloride -Potassium chloride -Ascorbic acid -Sodium ascorbate
MOVYMIA	Stada Arzneimittel AG	EU/1/16/1161/001-002	Solution for injection	-Teriparatide
Moxifloxacin 400 mg/250 ml Solution for Infusion, FreeFlex bags	Fresenius Kabi Deutschland GmbH	PA2059/013/002	Solution for infusion	-Moxifloxacin
Moxifloxacin 400 mg/250 ml Solution for Infusion, KabiPac bottles	Fresenius Kabi Deutschland GmbH	PA2059/013/001	Solution for infusion	-Moxifloxacin
Mozobil	Genzyme Europe B.V.	EU/1/09/537/001	Solution for injection	-Plerixafor
MST Continus 10 mg Prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/004/002	Prolonged-release tablet	-Morphine sulfate
MST Continus 100mg Prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/004/006	Prolonged-release tablet	-Morphine sulfate
MST Continus 15 mg Prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/004/003	Prolonged-release tablet	-Morphine sulfate
MST Continus 30 mg Prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/004/004	Prolonged-release tablet	-Morphine sulfate
MST Continus 5 mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/004/001	Prolonged-release tablet	-Morphine sulfate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
MST Continus 60 mg Prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/004/005	Prolonged-release tablet	-Morphine sulfate
Mubucho 111 mg film-coated tablets	Zentiva k.s.	PA1701/003/006	Film-coated tablet	-Dasatinib
Mubucho 16 mg film-coated tablets	Zentiva k.s.	PA1701/003/001	Film-coated tablet	-Dasatinib
Mubucho 40 mg film-coated tablets	Zentiva k.s.	PA1701/003/002	Film-coated tablet	-Dasatinib
Mubucho 55 mg film-coated tablets	Zentiva k.s.	PA1701/003/003	Film-coated tablet	-Dasatinib
Mubucho 63 mg film-coated tablets	Zentiva k.s.	PA1701/003/004	Film-coated tablet	-Dasatinib
Mubucho 79 mg film-coated tablets	Zentiva k.s.	PA1701/003/005	Film-coated tablet	-Dasatinib
Mucotex 250 mg/5 ml syrup	Amdeepcha (Malta) Ltd	PA23153/001/001	Syrup	-Carbocisteine
Mupleo	Shionogi B.V.	EU/1/18/1348/001	Film-coated tablet	-LUSUTROMBOPAG
Multaq	Sanofi Winthrop Industrie	EU/1/09/591/1-4	Film-coated tablet	-Dronedarone hydrochloride
multiBic 2 mmol/l potassium solution for haemodialysis/haemofiltration	Fresenius Medical Care Deutschland GmbH	PA1350/009/002	Solution for haemodialysis/haemofiltration	-Sodium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Glucose monohydrate -Sodium hydrogen carbonate -Potassium chloride
multiBic 4 mmol/l potassium solution for haemodialysis/haemofiltration	Fresenius Medical Care Deutschland GmbH	PA1350/009/003	Solution for haemodialysis/haemofiltration	-Sodium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Glucose monohydrate -Sodium hydrogen carbonate -Potassium chloride
multiBic potassium-free solution for haemodialysis/haemofiltration	Fresenius Medical Care Deutschland GmbH	PA1350/009/001	Solution for haemodialysis/haemofiltration	-Sodium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Glucose monohydrate -Sodium hydrogen carbonate
MultiHance 529 mg/ml solution for injection in pre-filled syringe	Bracco Imaging spa	PA1826/001/002	Solution for injection in pre-filled syringe	-Gadobenate dimeglumine
MultiHance, 0.5M solution for injection	Bracco Imaging spa	PA1826/001/001	Solution for injection	-Gadobenate dimeglumine
Murexal 10 mg/mL solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/010/001	Solution for injection in pre-filled syringe	-Suxamethonium chloride
Murine irritation & redness relief, 0.012% w/v, eye drops solution	Elara Pharmservices Europe Limited	PA22637/008/001	Eye drops, solution	-Naphazoline hydrochloride
MVABEA	Janssen-Cilag International NV	EU/1/20/1445/001	Suspension for injectio	-MVA-BN-FILO
MVASI	Amgen Technology (Ireland) UC	EU/1/17/1246/001-002	Concentrate for solution for infusion	-Bevacizumab
Myalepta	Amryt Pharmaceuticals DAC	EU/1/18/1276/001-002	Powder for solution for injection	-Metreleptin
Mybufen 200 mg Film-coated Tablets	Bluefish Pharmaceuticals AB	PA1436/039/001	Film-coated tablet	-Ibuprofen

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Mybufen Max 400 mg Film-coated Tablets	Bluefish Pharmaceuticals AB	PA1436/039/002	Film-coated tablet	-Ibuprofen
Mycamine	Astellas Pharma GmbH	EU/1/08/448/001	Powder for solution for infusion	-Micafungin sodium
Mycamine 100 mg powder for solution for infusion	Astellas Pharma GmbH	EU/1/08/448/002	Powder for solution for infusion	-Micafungin sodium
Mycapssa	FGK Representative Service GmbH	EU/1/22/1690/001	Gastro-resistant capsule, hard	-OCTREOTIDE ACETATE
Myclausen	Herbert J. Passauer GmbH & Co. KG	EU/1/10/647/001-002	Film-coated tablet	-Mycophenolate mofetil
Myclausen	Herbert J. Passauer GmbH & Co. KG	EU/1/10/647/003-004	Capsule, hard	-Mycophenolate mofetil
Mycobutin 150mg Hard Capsules	Pfizer Healthcare Ireland	PA0822/109/001	Capsule, hard	-Rifabutin
Mycolat 250 mg hard capsules	Rowex Ltd	PA0711/129/001	Capsule, hard	-Mycophenolate mofetil
Mycolat 500 mg Film-coated tablets	Rowex Ltd	PA0711/129/002	Film-coated tablet	-Mycophenolate mofetil
Mycophenolate Mofetil 500 mg film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/192/001	Film-coated tablet	-Mycophenolate mofetil
Mycophenolate Mofetil 500 mg Film-coated Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/039/001	Film-coated tablet	-MYCOPHENOLATE MOFETIL
Mycophenolate Mofetil Accord 250 mg capsules	Accord Healthcare Ireland Ltd.	PA2315/064/001	Capsule, hard	-Mycophenolate mofetil
Mycophenolate mofetil Clonmel 250 mg capsules hard	Clonmel Healthcare Ltd	PA0126/195/001	Capsule, hard	-Mycophenolate mofetil
Mycophenolate mofetil Clonmel 500 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/195/002	Film-coated tablet	-Mycophenolate mofetil
Mycophenolate mofetil Teva	Teva B.V.	EU/1/07/439/1-2	Capsule, hard	-Mycophenolate mofetil
Mycophenolate mofetil Teva	Teva Pharma B.V.	EU/1/07/439/3-4	Film-coated tablet	-Mycophenolate mofetil
Mycostatin 100,000 units/ml Oral Suspension (Ready Mixed)	Substipharma	PA1677/007/007	Oral suspension	-Nystatin
Mydrilate 0.5% w/v Eye Drops	Esteve Pharmaceuticals GmbH	PA22709/003/001	Eye drops, solution	-Cyclopentolate hydrochloride
Mydrilate 1.0% w/v Eye Drops	Esteve Pharmaceuticals GmbH	PA22709/003/002	Eye drops, solution	-Cyclopentolate hydrochloride
Myfenax	Teva B.V.	EU/1/07/438/1-2	Capsule, hard	-Mycophenolate mofetil
Myfenax	Teva B.V.	EU/1/07/438/3-4	Film-coated tablet	-Mycophenolate mofetil
Myfortic 180 mg gastro-resistant tablets	Novartis Ireland Limited	PA0896/023/001	Gastro-resistant tablet	-Mycophenolic acid
Myfortic 360 mg gastro-resistant tablets	Novartis Ireland Limited	PA0896/023/002	Gastro-resistant tablet	-Mycophenolic acid
Myfortic 360 mg gastro-resistant tablets	PCO Manufacturing Ltd.	PPA0465/505/001	Gastro-resistant tablet	-Mycophenolate sodium
Mykronor 5 micrograms/ml, solution for injection/infusion	Laboratoire AGUETTANT	PA1968/013/001	Solution for injection/infusion	-Noradrenaline tartrate
Myleran 2 mg film-coated tablets	Aspen Pharma Trading Limited	PA1691/008/001	Film-coated tablet	-Busulfan
Mylotarg	Pfizer Europe MA EEIG	EU/1/18/1277/001	Powder for concentrate for solution for infusion	-Gemtuzumab ozogamicin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Myocet	Teva B.V.	EU/1/00/141/001	Powder, dispersion and solvent for concentrate for dispersion for infusion	-DOXORUBICIN HYDROCHLORIDE
MYOVIEV 230 micrograms kit for radiopharmaceutical preparation	GE Healthcare AS	PA0735/012/001	Kit for radiopharmaceutical preparation	-Tetrofosmin
Myozyme	Genzyme Europe B.V.	EU/1/06/333/1-3	Powder for concentrate for solution for infusion	-Alglucosidase alfa
Myrelez 120 mg solution for injection in pre-filled syringe	Amdipharm Limited	PA1142/039/003	Solution for injection in pre-filled syringe	-Lanreotide
Myrelez 60 mg solution for injection in pre-filled syringe	Amdipharm Limited	PA1142/039/001	Solution for injection in pre-filled syringe	-Lanreotide
Myrelez 90 mg solution for injection in pre-filled syringe	Amdipharm Limited	PA1142/039/002	Solution for injection in pre-filled syringe	-Lanreotide
Mysildecard ((previously known as Sildenafil Mylan Pharma))	Viartis Limited	EU/1/16/1134/001-003	Film-coated tablet	-Sildenafil citrate
Mysimba	Orexigen Therapeutics Ireland Limited	EU/1/14/988/001	Prolonged-release tablet	-Naltrexone hydrochloride -BUPROPION HYDROCHLORIDE
Mysoline 250 mg Tablets	IMED Healthcare Ltd.	PPA1463/179/001	Tablet	-Primidone
Mysoline 250mg Tablets	Laboratoires SERB	PA1777/001/001	Tablet	-Primidone
Myzaar 100 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/087/003	Film-coated tablet	-Losartan potassium
Myzaar 50 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/087/002	Film-coated tablet	-Losartan potassium
Nabumetone Tillomed 500 mg Film-coated Tablets	Tillomed Pharma GmbH	PA22720/001/001	Film-coated tablet	-Nabumetone
Nacsys 600 mg Effervescent Tablets	Alpex Pharma (Irl) Limited	PA2166/001/001	Effervescent tablet	-Acetylcysteine
Naglazyme	BioMarin International Limited	EU/1/05/324/001	Concentrate for solution for infusion	-Galsulfase
Nalderm 250 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/068/001	Tablet	-Terbinafine hydrochloride
Naloxone Accord	Accord Healthcare Ireland Ltd.	PA2315/254/001	Solution for injection in pre-filled syringe	-Naloxone hydrochloride dihydrate
Naloxone Hydrochloride 400 micrograms/ml Solution for Injection or Infusion	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/111/002	Solution for injection/infusion	-NALOXONE HYDROCHLORIDE
Naltrexone 50 mg film-coated tablets	Aop Orphan Pharmaceuticals GmbH	PA0934/003/001	Film-coated tablet	-Naltrexone hydrochloride
Naltrexone Hydrochloride 50mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/111/001	Film-coated tablet	-Naltrexone hydrochloride
Namuscla	Lupin Europe GmbH	EU/1/18/1325/001-004	Capsule, hard	-Mexiletine hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Nanocis 0.24 mg kit for radiopharmaceutical preparation	CIS bio International	PA0677/006/001	Kit for radiopharmaceutical preparation	-Rhenium sulphide
Naprosyn EC 250mg Gastro-resistant Tablets	Atnahs Pharma Netherlands B.V.	PA22657/002/001	Gastro-resistant tablet	-Naproxen
Naprosyn EC 500mg Gastro-resistant Tablets	Atnahs Pharma Netherlands B.V.	PA22657/002/002	Gastro-resistant tablet	-Naproxen
Naproxen 250 mg Gastro-resistant Tablets	Azure Pharmaceuticals Ltd	PA22871/007/001	Gastro-resistant tablet	-Naproxen
Naratriptan 2.5 mg film-coated tablet	Renata Pharmaceuticals (Ireland) Limited	PA22865/008/001	Film-coated tablet	-Naratriptan hydrochloride
Naraverg 2.5 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/065/001	Film-coated tablet	-Naratriptan
Naropin 10 mg/ml solution for injection	Aspen Pharma Trading Limited	PA1691/026/003	Solution for injection	-Ropivacaine Hydrochloride
Naropin 2 mg/ml solution for injection	Aspen Pharma Trading Limited	PA1691/026/001	Solution for injection	-Ropivacaine Hydrochloride
Naropin 7.5 mg/ml solution for injection	Aspen Pharma Trading Limited	PA1691/026/002	Solution for injection	-Ropivacaine Hydrochloride
NASACORT 55 micrograms/dose nasal spray, suspension	Lexon (UK) Ltd	PPA1097/032/001	Nasal spray, suspension	-Triamcinolone acetonide
NASACORT 55 micrograms/dose, nasal spray, suspension	Opella Healthcare France SAS T/A Sanofi	PA23180/001/001	Nasal spray, suspension	-Triamcinolone acetonide
Nasacort Allergy 55 micrograms/dose nasal spray, suspension	Opella Healthcare France SAS T/A Sanofi	PA23180/001/002	Nasal spray, suspension	-Triamcinolone acetonide
Naseptin 0.1% & 0.5% w/w Nasal Cream	Alliance Pharma (Ireland) Limited	PA2325/009/001	Nasal cream	-Chlorhexidine Dihydrochloride -Neomycin sulfate
Nasobec 50 Micrograms Aqueous Nasal Spray	Teva B.V.	PA1986/055/001	Nasal spray, suspension	-Beclometasone dipropionate
Nasofan Aqueous 50 microgram Nasal Spray Suspension	Teva B.V.	PA1986/084/001	Nasal spray, suspension	-Fluticasone propionate
NASONEX 50 micrograms/actuation Nasal Spray, Suspension	Organon Pharma (Ireland) Limited	PA23198/011/001	Nasal spray, suspension	-Mometasone furoate
NASONEX 50 micrograms/actuation Nasal Spray, Suspension	PCO Manufacturing Ltd.	PPA0465/146/001	Nasal spray, suspension	-Mometasone furoate
NASONEX 50 micrograms/actuation Nasal Spray, Suspension	IMED Healthcare Ltd.	PPA1463/102/001	Nasal spray, suspension	-Mometasone furoate
Nasonex 50 micrograms/actuation Nasal Spray, Suspension	Merit Pharmaceuticals Limited	PPA23080/001/001	Nasal spray, suspension	-Mometasone furoate
Nasorinit 137 micrograms/50 micrograms per actuation nasal spray, suspension	Clonmel Healthcare Ltd	PA0126/358/001	Nasal spray, suspension	-Azelastine hydrochloride -Fluticasone propionate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Nasusaf 137 micrograms/50 micrograms per actuation nasal spray, suspension	Teva B.V.	PA1986/109/001	Nasal spray, suspension	-Azelastine hydrochloride -Fluticasone propionate
Natpar	Shire Pharmaceuticals Ireland Limited	EU/1/15/1078/001	Powder and solvent for solution for injection	-Parathyroid hormone (rdna)
Natpar	Shire Pharmaceuticals Ireland Limited	EU/1/15/1078/002	Powder and solvent for solution for injection	-Parathyroid hormone (rdna)
Natpar	Shire Pharmaceuticals Ireland Limited	EU/1/15/1078/003	Powder and solvent for solution for injection	-Parathyroid hormone (rdna)
Natpar	Shire Pharmaceuticals Ireland Limited	EU/1/15/1078/004	Powder and solvent for solution for injection	-Parathyroid hormone (rdna)
Natrilix SR 1.5 mg, prolonged-release film-coated tablets	Les Laboratoires Servier	PA0568/005/001	Prolonged-release tablet	-Indapamide
Nature's Bounty Hypericum Hard Capsules	Holland & Barrett Limited	TR23157/004/001	Capsule, hard	
NAVELBINE 10 mg/ml concentrate for solution for infusion	Pierre Fabre Medicament	PA0329/011/003	Concentrate for solution for infusion	-Vinorelbine
NAVELBINE 20 mg soft capsule	Pierre Fabre Medicament	PA0329/011/001	Capsule, soft	-Vinorelbine tartrate
NAVELBINE 30 mg soft capsule	Pierre Fabre Medicament	PA0329/011/002	Capsule, soft	-Vinorelbine
NAVELBINE 80 mg soft capsule	Pierre Fabre Medicament	PA0329/011/004	Capsule, soft	-Vinorelbine tartrate
Nebido 1000 mg/4 ml, solution for injection	Grunenthal Pharma Ltd	PA2242/015/001	Solution for injection	-Testosterone Undecanoate
Nebilet 5 mg tablets	Menarini International Operations Luxembourg S.A.	PA0865/005/001	Tablet	-Nebivolol
Nebilet Plus 5 mg/12.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/015/001	Film-coated tablet	-Nebivolol -Hydrochlorothiazide
Nebilet Plus 5 mg/25 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/015/002	Film-coated tablet	-Nebivolol -Hydrochlorothiazide
Nebimel 5 mg tablets	Clonmel Healthcare Ltd	PA0126/165/001	Tablet	-Nebivolol hydrochloride
Nebivolol 10mg tablets	Glenmark Arzneimittel GmbH	PA22645/002/001	Tablet	-Nebivolol
Nebivolol Accord 5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/247/001	Tablet	-Nebivolol hydrochloride
Nebivolol Teva 5 mg Tablets	Teva Pharma B.V.	PA0749/078/001	Tablet	-Nebivolol
Nebol 5 mg Tablets	Rowex Ltd	PA0711/120/001	Tablet	-Nebivolol hydrochloride
Nefopam Hydrochloride 30 mg Film-coated Tablets	Brown & Burk IR Limited	PA23148/007/001	Film-coated tablet	-Nefopam hydrochloride
Nefrosol solution for haemofiltration	B. Braun Avitum AG	PA2146/001/001	Solution for haemofiltration	-Sodium chloride ph.eur. -Sodium hydrogen carbonate -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Glucose monohydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Nefrosol with 2 mmol/l Potassium solution for haemofiltration	B. Braun Avitum AG	PA2146/001/002	Solution for haemofiltration	-Sodium chloride ph.eur. -Sodium hydrogen carbonate -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Glucose monohydrate -Potassium chloride
Nefrosol with 4 mmol/l Potassium solution for haemofiltration	B. Braun Avitum AG	PA2146/001/003	Solution for haemofiltration	-Sodium chloride ph.eur. -Sodium hydrogen carbonate -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Glucose monohydrate -Potassium chloride
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	-Neisseria meningitidis c -Tetanus toxoid
NEMDATINE	Actavis Group PTC ehf	EU/1/13/824/001-002	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
Nemdatine	Actavis Group hf	EU/1/13/824/003-010	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
NEMDATINE	Actavis Group PTC ehf	EU/1/13/824/011-013	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
Nemdatine	Actavis Group PTC ehf	EU/1/13/824/014-017	Film-coated tablet	-MEMANTINE HYDROCHLORIDE
NEMDATINE	Actavis Group PTC ehf	EU/1/13/824/018	Film-coated tablet	-MEMANTINE HYDROCHLORIDE -MEMANTINE HYDROCHLORIDE -MEMANTINE HYDROCHLORIDE -MEMANTINE HYDROCHLORIDE
Neoclarityn	N.V. Organon	EU/1/00/161/001	Film-coated tablet	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/002	Film-coated tablet	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/003	Film-coated tablet	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/004	Film-coated tablet	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/005	Film-coated tablet	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/006	Film-coated tablet	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/007	Film-coated tablet	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/008	Film-coated tablet	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/009	Film-coated tablet	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/010	Film-coated tablet	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/011	Film-coated tablet	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/012	Film-coated tablet	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/013	Film-coated tablet	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/014	Oral solution	-Desloratidine
NEOCLARITYN	N.V. Organon	EU/1/00/161/015	Oral solution	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/016	Oral solution	-Desloratidine
Neoclarityn	Merck Sharp & Dohme Ltd	EU/1/00/161/017	Oral solution	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/018	Oral solution	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/019	Oral solution	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/020	Oral solution	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/021	Oral solution	-Desloratidine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Neoclarityn	N.V. Organon	EU/1/00/161/022	Oral lyophilisate	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/023	Oral lyophilisate	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/024	Oral lyophilisate	-Desloratidine
Neoclarityn	Schering Plough Europe	EU/1/00/161/025	Oral lyophilisate	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/026	Oral lyophilisate	-Desloratidine
Neoclarityn	Schering Plough Europe	EU/1/00/161/027	Oral lyophilisate	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/028	Oral lyophilisate	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/029	Oral lyophilisate	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/030	Oral lyophilisate	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/031	Oral lyophilisate	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/032	Oral lyophilisate	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/033	Oral lyophilisate	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/034	Oral lyophilisate	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/35-46	Orodispersible tablet	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/47-58	Orodispersible tablet	-Desloratidine
Neoclarityn	N.V. Organon	EU/1/00/161/59-67	Oral solution	-Desloratidine, micronized
Neo-Cytamen 1000 micrograms/ml Solution for Injection	RPH Pharmaceuticals AB	PA1638/004/001	Solution for injection	-Hydroxocobalamin
Neofordex	Laboratoires CTRS	EU/1/15/1053/001	Tablet	-Dexamethasone acetate
NeoMercazole 20 mg Tablets	Amdipharm Limited	PA1142/002/002	Tablet	-Carbimazole
NeoMercazole 5 mg Tablets	Amdipharm Limited	PA1142/002/001	Tablet	-Carbimazole
Neophyr 1000 ppm mol/mol, medicinal gas, compressed	SOL S.p.A.	PA1848/001/001	Medicinal gas, compressed	-Nitric oxide
Neophyr 225 ppm mol/mol, medicinal gas, compressed	SOL S.p.A.	PA1848/001/003	Medicinal gas, compressed	-Nitric oxide
Neophyr 450 ppm mol/mol, medicinal gas, compressed	SOL S.p.A.	PA1848/001/002	Medicinal gas, compressed	-Nitric oxide
Neoral 100 mg/ml concentrate for oral solution	Novartis Ireland Limited	PA0896/024/004	Concentrate for oral solution	-Ciclosporin
Neoral 100mg Soft Capsules	Novartis Ireland Limited	PA0896/024/003	Capsule, soft	-Ciclosporin
Neoral 25 mg Soft Capsules	Novartis Ireland Limited	PA0896/024/001	Capsule, soft	-Ciclosporin
Neoral 50mg Soft Capsules	Novartis Ireland Limited	PA0896/024/002	Capsule, soft	-Ciclosporin
NEORECORMON	Roche Registration Limited	EU/1/97/31/45-46	Solution for injection	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/019	Powder and solvent for concentrate for solution for infusion	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/025	Solution for injection in pre-filled syringe	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/026	Solution for injection in pre-filled syringe	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/029	Solution for injection in pre-filled syringe	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/030	Solution for injection in pre-filled syringe	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/031	Solution for injection in pre-filled syringe	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/032	Solution for injection in pre-filled syringe	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/033	Solution for injection in pre-filled syringe	-Epoetin beta

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
NeoRecormon	Roche Registration GmbH	EU/1/97/031/034	Solution for injection in pre-filled syringe	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/035	Solution for injection in pre-filled syringe	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/036	Solution for injection in pre-filled syringe	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/037	Solution for injection in pre-filled syringe	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/038	Solution for injection in pre-filled syringe	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/041	Solution for injection in pre-filled syringe	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/042	Solution for injection in pre-filled syringe	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/043	Solution for injection in pre-filled syringe	-Epoetin beta
NeoRecormon	Roche Registration GmbH	EU/1/97/031/044	Solution for injection in pre-filled syringe	-Epoetin beta
Neotigason 10 mg capsules	Teva B.V.	PA1986/113/001	Capsule, hard	-Acitretin
Neotigason 25 mg capsules	Teva B.V.	PA1986/113/002	Capsule, hard	-Acitretin
Neotigason 25 mg capsules	Originalis B.V.	PPA2306/020/001	Capsule, hard	-Acitretin
Neparvis	Novartis Europharm Limited	EU/1/16/1103/001	Film-coated tablet	-Sacubitril valsartan
Neparvis	Novartis Europharm Limited	EU/1/16/1103/002-004	Film-coated tablet	-Sacubitril valsartan
Neparvis	Novartis Europharm Limited	EU/1/16/1103/005-007	Film-coated tablet	-Sacubitril valsartan
Neparvis	Novartis Europharm Limited	EU/1/16/1103/018	Granules	-Sacubitril -Valsartan
Neparvis	Novartis Europharm Limited	EU/1/16/1103/019	Granules	-Sacubitril -Valsartan
Nepexto	Biosimilar Collaborations Ireland Limited	EU/1/120/1436/001-00	Solution for injection in pre-filled syringe	-Etanercept
Nepexto	Biosimilar Collaborations Ireland Limited	EU/1/120/1436/003-00	Solution for injection in pre-filled syringe	-Etanercept
Nepexto	Biosimilar Collaborations Ireland Limited	EU/1/20/1436/005-006	Solution for injection in pre-filled pen	-Etanercept
Nerlynx	Pierre Fabre Medicament	EU/1/18/1311/001	Film-coated tablet	-Neratinib
Neulasta	Amgen Europe B.V.	EU/1/02/227/001-002	Solution for injection	-Pegfilgrastim
Neupogen 30 MU (0.3 mg/ml) Solution for injection filgrastim	Amgen Europe B.V.	PA1026/001/001	Solution for injection	-Filgrastim
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	-Filgrastim
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	-Filgrastim
Neupro	Schwarz Pharma Limited	EU/1/05/331/10-12,32-37	Transdermal patch	-Rotigotine
Neupro	UCB Pharma SA	EU/1/05/331/1-3,14-20	Transdermal patch	-Rotigotine
Neupro	UCB Pharma SA	EU/1/05/331/38-46	Transdermal patch	-Rotigotine
Neupro	Schwarz Pharma Limited	EU/1/05/331/4-6,21-25	Transdermal patch	-Rotigotine
Neupro	UCB Pharma SA	EU/1/05/331/47-55	Transdermal patch	-Rotigotine
Neupro	Schwarz Pharma Limited	EU/1/05/331/7-9,26-31	Transdermal patch	-Rotigotine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Neuraceq	Life Molecular Imaging GmbH	EU/1/13/906/001	Solution for injection	-Florbetaben
Neurontin 100 mg hard capsules	Upjohn EESV	PA23055/004/001	Capsule, hard	-Gabapentin
Neurontin 300 mg hard capsules	Upjohn EESV	PA23055/004/002	Capsule, hard	-Gabapentin
Neurontin 300 mg Hard Capsules	PCO Manufacturing Ltd.	PPA0465/097/001	Capsule, hard	-Gabapentin
Neurontin 400 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/097/002	Capsule, hard	-Gabapentin
Neurontin 400 mg hard capsules	Upjohn EESV	PA23055/004/003	Capsule, hard	-Gabapentin
Neurontin 600 mg film-coated tablets	Upjohn EESV	PA23055/004/004	Film-coated tablet	-Gabapentin
Neurontin 800 mg film-coated tablets	Upjohn EESV	PA23055/004/005	Film-coated tablet	-Gabapentin
Neurostil 100 mg capsules, hard	Teva Pharma B.V.	PA0749/164/001	Capsule, hard	-Gabapentin
Neurostil 300 mg capsules, hard	Teva Pharma B.V.	PA0749/164/002	Capsule, hard	-Gabapentin
Neurostil 400 mg capsules, hard	Teva Pharma B.V.	PA0749/164/003	Capsule, hard	-Gabapentin
Neutrogena T/Gel Shampoo 5 mg/ml	Johnson & Johnson (Ireland) Limited	PA0330/014/001	Shampoo	-Coal tar
Nevanac	Novartis Europharm Limited	EU/1/07/433/001	Eye drops, suspension	-Nepafenac
Nevanac	Novartis Europharm Limited	EU/1/07/433/002	Eye drops, suspension	-Nepafenac
Nexavar	Bayer AG	EU/1/06/342/01	Film-coated tablet	-Sorafenib (as tosylate)
Nexazole 20 mg hard gastro-resistant capsules	Pinewood Laboratories Ltd	PA0281/146/001	Gastro-resistant capsule, hard	-Esomeprazole
Nexazole 40 mg hard gastro-resistant capsules	Pinewood Laboratories Ltd	PA0281/146/002	Gastro-resistant capsule, hard	-Esomeprazole
Nexium 10 mg gastro-resistant granules for oral suspension, sachet	Grunenthal Pharma Ltd	PA2242/013/001	Gastro-resistant granules for oral suspension in sachet	-Esomeprazole
Nexium 20 mg gastro-resistant tablets	Grunenthal Pharma Ltd	PA2242/013/002	Gastro-resistant tablet	-Esomeprazole
Nexium 20 mg gastro-resistant tablets	PCO Manufacturing Ltd.	PPA0465/083/001	Gastro-resistant tablet	-Esomeprazole
Nexium 20 mg gastro-resistant tablets	Originalis B.V.	PPA2306/025/001	Gastro-resistant tablet	-Esomeprazole
Nexium 20 mg gastro-resistant tablets	IMED Healthcare Ltd.	PPA1463/002/001	Gastro-resistant tablet	-Esomeprazole
Nexium 20 mg gastro-resistant tablets	Merit Pharmaceuticals Limited	PPA23080/003/001	Gastro-resistant tablet	-Esomeprazole
Nexium 20 mg gastro-resistant tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/015/001	Gastro-resistant tablet	-Esomeprazole
Nexium 40 mg gastro-resistant tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/015/002	Gastro-resistant tablet	-Esomeprazole
Nexium 40 mg gastro-resistant tablets	Merit Pharmaceuticals Limited	PPA23080/003/002	Gastro-resistant tablet	-Esomeprazole
Nexium 40 mg gastro-resistant tablets	IMED Healthcare Ltd.	PPA1463/002/002	Gastro-resistant tablet	-Esomeprazole
Nexium 40 mg gastro-resistant tablets	Originalis B.V.	PPA2306/025/002	Gastro-resistant tablet	-Esomeprazole
Nexium 40 mg gastro-resistant tablets	PCO Manufacturing Ltd.	PPA0465/083/002	Gastro-resistant tablet	-Esomeprazole
Nexium 40 mg gastro-resistant tablets	Grunenthal Pharma Ltd	PA2242/013/003	Gastro-resistant tablet	-Esomeprazole

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Nexium Control	GlaxoSmithKline Dungarvan Limited	EU/1/13/860/001-002	Gastro-resistant tablet	-Esomeprazole magnesium trihydrate
Nexium I.V. 40 mg Powder for solution for injection/infusion	Grunenthal Pharma Ltd	PA2242/013/004	Powder for solution for injection/infusion	-Esomeprazole
NexoBrid	MediWound Germany GmbH	EU/1/12/803/001	Powder and gel for gel	-Partially purified bromelain
NexoBrid	MediWound Germany GmbH	EU/1/12/803/002	Powder and gel for gel	-Partially purified bromelain
Nexpovio	Karyopharm Europe GmbH	EU/1/21/1537/001-004	Film-coated tablet	-Selinexor
Nexviadyne	Genzyme Europe B.V.	EU/1/21/1579/001-004	Powder for concentrate for solution for infusion	-Avalglucosidase Alfa
NGENLA	Pfizer Europe MA EEIG	EU/1/21/1617/001	Solution for injection	-Somatrogon
NGENLA	Pfizer Europe MA EEIG	EU/1/21/1617/002	Solution for injection	-Somatrogon
Nicam 4% w/w Gel	Dermal Laboratories (Ireland) Limited	PA23128/012/001	Gel	-Nicotinamide
Nicorandil 10mg Tablets	Dexcel Pharma GmbH	PA2261/003/001	Tablet	-Nicorandil
Nicorandil 20mg Tablets	Dexcel Pharma GmbH	PA2261/003/002	Tablet	-Nicorandil
Nicorette Invisi Extra Strength 25 mg/16 hours transdermal patch	PCO Manufacturing Ltd.	PPA0465/187/009	Transdermal patch	-Nicotine
Nicorette Invisi Extra Strength 25 mg/16 hours Transdermal Patch	IMED Healthcare Ltd.	PPA1463/210/003	Transdermal patch	-Nicotine
Nicorette Invisi Extra Strength 25mg/16 hours Transdermal Patch	JNTL Consumer Health I (Ireland) Limited	PA23490/019/007	Transdermal patch	-Nicotine
Nicospray 1 mg/spray oromucosal spray, solution	Clonmel Healthcare Ltd	PA0126/309/001	Oromucosal spray, solution	-Nicotine
Nicotinell Spearmint 2 mg medicated chewing- gum	Haleon Ireland Limited	PA0678/134/001	Medicated chewing- gum	-Nicotine
Nicotinell Spearmint 4 mg medicated chewing- gum	Haleon Ireland Limited	PA0678/134/002	Medicated chewing- gum	-Nicotine
Nicotinell Tropical Fruit 2 mg medicated chewing-gum	Haleon Ireland Limited	PA0678/135/001	Medicated chewing- gum	-Nicotine
Nicotinell Tropical Fruit 4 mg medicated chewing-gum	Haleon Ireland Limited	PA0678/135/002	Medicated chewing- gum	-Nicotine
Night Nurse Capsules Paracetamol 500 mg Promethazine Hydrochloride 10 mg Dextromethorphan Hydrobromide 7.5 mg	Haleon Ireland Limited	PA0678/021/001	Capsule, hard	-Paracetamol -Promethazine hydrochloride -Dextromethorphan hydrobromide
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	-Paracetamol -Promethazine hydrochloride -Dextromethorphan hydrobromide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Nilemdo	Daiichi Sankyo Europe GmbH	EU/1/20/1425/001-006	Film-coated tablet	-Bempedoic Acid
Nimbex 2mg/ml solution for injection/infusion	Aspen Pharma Trading Limited	PA1691/030/001	Solution for injection/infusion	-Cisatracurium Besilate
Nimenrix	Pfizer Europe MA EEIG	EU/1/12/767/001-007	Powder and solvent for solution for injection	-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
Nimotop 0.02% w/v Concentrate for Solution for Infusion	Bayer Limited	PA1410/030/002	Concentrate for solution for infusion	-Nimodipine
Nimotop 30 mg film-coated tablets	Bayer Limited	PA1410/030/001	Film-coated tablet	-Nimodipine
Nimvastid	KRKA, d.d., Novo mesto	EU/1/09/525/14-19	Capsule, hard	-Rivastigmine hydrogen tartrate
Nimvastid	KRKA, d.d., Novo mesto	EU/1/09/525/1-7	Capsule, hard	-Rivastigmine hydrogen tartrate
Nimvastid	KRKA, d.d., Novo mesto	EU/1/09/525/20-25	Capsule, hard	-Rivastigmine hydrogen tartrate
NIMVASTID	Krka d.d., Novo mesto	EU/1/09/525/26-31	Orodispersible Tablet	-RIVASTIGMINE HYDROGEN TARTRATE
NIMVASTID	Krka d.d., Novo mesto	EU/1/09/525/32-36	Orodispersible Tablet	-RIVASTIGMINE HYDROGEN TARTRATE
NIMVASTID	Krka d.d., Novo mesto	EU/1/09/525/37-41	Orodispersible Tablet	-RIVASTIGMINE HYDROGEN TARTRATE
NIMVASTID	Krka d.d., Novo mesto	EU/1/09/525/42-46	Orodispersible Tablet	-RIVASTIGMINE HYDROGEN TARTRATE
Nimvastid	KRKA, d.d., Novo mesto	EU/1/09/525/8-13	Capsule, hard	-Rivastigmine hydrogen tartrate
NINLARO	Takeda Pharma A/S	EU/1/16/1094/001	Capsule, hard	-Ixazomib citrate
NINLARO	Takeda Pharma A/S	EU/1/16/1094/002	Capsule, hard	-Ixazomib citrate
NINLARO	Takeda Pharma A/S	EU/1/16/1094/003	Capsule, hard	-Ixazomib citrate
Nintedanib Clonmel 100 mg soft capsules	Clonmel Healthcare Ltd	PA0126/383/001	Capsule, soft	-Nintedanib esylate
Nintedanib Clonmel 150 mg soft capsules	Clonmel Healthcare Ltd	PA0126/383/002	Capsule, soft	-Nintedanib esylate
Niopam 300, Solution for injection, glass bottles	Bracco Imaging spa	PA1826/004/003	Solution for injection	-Iopamidol
Niopam 340, Solution for Injection, glass bottles	Bracco Imaging spa	PA1826/004/004	Solution for injection	-Iopamidol
Niopam 370, Solution for Injection, glass bottles	Bracco Imaging spa	PA1826/004/005	Solution for injection	-Iopamidol

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Pentostatin
NiQuitin 2mg Lozenge	Chefaro Ireland DAC	PA1186/018/007	Compressed lozenge	-Nicotine
NiQuitin 4 mg Lozenge	Chefaro Ireland DAC	PA1186/018/008	Compressed lozenge	-Nicotine
Nithiodote Solution for Injection	Hope Pharmaceuticals Ltd	PA22874/003/001	Solution for injection	-SODIUM NITRITE -Sodium thiosulfate
Nitisinone Dipharma 10 mg hard capsules	Dipharma Arzneimittel GmbH	PA23449/001/002	Capsule, hard	-Nitisinone
Nitisinone Dipharma 2 mg hard capsules	Dipharma Arzneimittel GmbH	PA23449/001/003	Capsule, hard	-Nitisinone
Nitisinone Dipharma 20 mg hard capsules	Dipharma Arzneimittel GmbH	PA23449/001/004	Capsule, hard	-Nitisinone
Nitisinone Dipharma 5 mg hard capsules	Dipharma Arzneimittel GmbH	PA23449/001/001	Capsule, hard	-Nitisinone
Nitoman 25 mg Tablets	Bausch Health Ireland Limited	PA22698/022/001	Tablet	-Tetrabenazine
Nitrofurantoin 100 mg Capsules, hard	Azure Pharmaceuticals Ltd	PA22871/024/002	Capsule, hard	-Nitrofurantoin
Nitrofurantoin 50 mg Capsules, hard.	Azure Pharmaceuticals Ltd	PA22871/024/001	Capsule, hard	-Nitrofurantoin
Nitrolingual Pumpspray 400 micrograms per metered dose, sublingual spray	G Pohl-Boskamp GmbH & Co. KG	PA2243/001/001	Sublingual spray, solution	-Glyceryl trinitrate
Nitrous oxide Medicinal SOL, 100 % v/v, medicinal gas, liquefied	SOL S.p.A.	PA1848/004/001	Medicinal gas, liquefied	-Nitrous oxide
Nityr	Cycle Pharmaceuticals (Europe) Ltd	EU/1/18/1290/001	Tablet	-Nitisinone
Nivestim	Pfizer Europe MA EEIG	EU/1/10/631/001-3	Solution for injection/infusion	-Filgrastim
Nivestim	Pfizer Europe MA EEIG	EU/1/10/631/004-6	Solution for injection/infusion	-Filgrastim
Nivestim	Pfizer Europe MA EEIG	EU/1/10/631/007-9	Solution for injection/infusion	-Filgrastim
Nizoral 20 mg/g Cream	Clonmel Healthcare Ltd	PA0126/315/003	Cream	-Ketoconazole
Nizoral 20 mg/g Cream	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/008/001	Cream	-Ketoconazole
Nizoral 20mg/g shampoo	Clonmel Healthcare Ltd	PA0126/315/002	Shampoo	-Ketoconazole
Nizoral Dandruff 20mg/g Shampoo	Clonmel Healthcare Ltd	PA0126/315/001	Shampoo	-Ketoconazole
Nolpacid 20 mg gastro-resistant tablets	KRKA, d.d., Novo mesto	PA1347/032/001	Gastro-resistant tablet	-Pantoprazole
Nolpaza 20 mg gastro-resistant tablets	KRKA, d.d., Novo mesto	PA1347/006/001	Gastro-resistant tablet	-Pantoprazole
Nolpaza 40 mg gastro-resistant tablets	KRKA, d.d., Novo mesto	PA1347/006/002	Gastro-resistant tablet	-Pantoprazole
Nolxado 10 mg/5 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/085/001	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE -Naloxone hydrochloride dihydrate
Nolxado 20 mg/10 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/085/002	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE -Naloxone hydrochloride dihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Nolxado 40 mg/20 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/085/003	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE -Naloxone hydrochloride dihydrate
Non-drowsy Sinutab Tablets Paracetamol 500mg Pseudoephedrine hydrochloride 30mg	JNTL Consumer Health I (Ireland) Limited	PA23490/020/001	Tablet	-PSEUDOEPHEDRINE HYDROCHLORIDE -Paracetamol
Non-Drowsy Sudafed Decongestant 30mg/5ml Syrup	Johnson & Johnson (Ireland) Limited	PA0330/057/001	Syrup	-PSEUDOEPHEDRINE HYDROCHLORIDE
Non-Drowsy Sudafed Decongestant 60 mg Film-Coated Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/034/002	Film-coated tablet	-PSEUDOEPHEDRINE HYDROCHLORIDE
Non-Drowsy Sudaplus Tablets Paracetamol 500mg Pseudoephedrine hydrochloride 30mg	JNTL Consumer Health I (Ireland) Limited	PA23490/021/001	Tablet	-Paracetamol -PSEUDOEPHEDRINE HYDROCHLORIDE
Non-Drowsy Sudapro Head Cold 200mg / 30mg Film-coated Tablets	Johnson & Johnson (Ireland) Limited	PA0330/056/001	Film-coated tablet	-Ibuprofen -PSEUDOEPHEDRINE HYDROCHLORIDE
Noqturina 25 microgram oral lyophilisate	Ferring Ireland Ltd	PA1009/027/001	Oral lyophilisate	-DESMOPRESSIN ACETATE
Noqturina 50 microgram oral lyophilisate	Ferring Ireland Ltd	PA1009/027/002	Oral lyophilisate	-DESMOPRESSIN ACETATE
Noradrenaline (Norepinephrine) 0.08 mg/mL solution for infusion	Laboratoire AGUETTANT	PA1968/001/001	Solution for infusion	-Noradrenaline
Noradrenaline (Norepinephrine) 1 mg/ml concentrate for solution for infusion	AS Kalceks	PA2165/009/001	Concentrate for solution for infusion	-Noradrenaline
Noradrenaline (Norepinephrine) 1:1000 Concentrate For Solution For Infusion	Pfizer Healthcare Ireland	PA0822/219/001	Concentrate for solution for infusion	-Noradrenaline acid tartrate
Noradrenaline (Norepinephrine) Kabi 1 mg/ml concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/073/001	Concentrate for solution for infusion	-Sodium chloride -Noradrenaline tartrate
Nordimet	Nordic Group B.V.	EU/1/16/1124/001	Solution for injection in pre-filled pen	-Methotrexate
Nordimet	Nordic Group B.V.	EU/1/16/1124/002	Solution for injection in pre-filled pen	-Methotrexate
Nordimet	Nordic Group B.V.	EU/1/16/1124/003	Solution for injection in pre-filled pen	-Methotrexate
Nordimet	Nordic Group B.V.	EU/1/16/1124/004	Solution for injection in pre-filled pen	-Methotrexate
Nordimet	Nordic Group B.V.	EU/1/16/1124/005	Solution for injection in pre-filled pen	-Methotrexate
Nordimet	Nordic Group B.V.	EU/1/16/1124/006	Solution for injection in pre-filled pen	-Methotrexate
Nordimet	Nordic Group B.V.	EU/1/16/1124/007	Solution for injection in pre-filled pen	-Methotrexate
Nordimet	Nordic Group B.V.	EU/1/16/1124/008	Solution for injection in pre-filled pen	-Methotrexate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Somatropin
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	-Somatropin
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	-Somatropin
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	-Somatropin
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	-Somatropin
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	-Somatropin
Nordurine 0.1 mg Tablets	Ferring Ireland Ltd	PA1009/017/001	Tablet	-DESMOPRESSIN ACETATE
Nordurine 0.2 mg Tablets	Ferring Ireland Ltd	PA1009/017/002	Tablet	-DESMOPRESSIN ACETATE
Noriday 350 micrograms Tablets	Pfizer Healthcare Ireland	PA0822/131/001	Tablet	-Norethisterone
Noriday 350 micrograms tablets	PCO Manufacturing Ltd.	PPA0465/310/001	Tablet	-Norethisterone
NORLEVO 1.5 mg tablet	PCO Manufacturing Ltd.	PPA0465/288/001	Tablet	-Levonorgestrel
NORLEVO® 1.5 mg tablet	Laboratoire HRA Pharma	PA1166/002/001	Tablet	-Levonorgestrel
Normacol 62% w/w Granules	Norgine B.V.	PA1336/007/001	Granules	-Sterculia
Normosang 25 mg/ml, concentrate for solution for infusion	Recordati Rare Diseases	PA0928/001/001	Concentrate for solution for infusion	-Human hemin
Nortem 10mg Tablets	Teva B.V.	PA1986/085/001	Tablet	-Temazepam
Nortem 20mg Tablets	Teva B.V.	PA1986/085/002	Tablet	-Temazepam
Nortriptyline 10 mg Film-coated Tablets	Pharmafile Limited	PA0599/005/001	Film-coated tablet	-Nortriptyline
Nortriptyline 25 mg Film-coated Tablets	Pharmafile Limited	PA0599/005/002	Film-coated tablet	-Nortriptyline
Norvir	AbbVie Deutschland GmbH & Co. KG	EU/1/96/016/005-006	Film-coated tablet	-Ritonavir
Norvir	AbbVie Deutschland GmbH & Co. KG	EU/1/96/016/009	Powder for oral suspension	-Ritonavir
Notiabolfen XL 150 Prolonged-release Tablet	Accord Healthcare Ireland Ltd.	PA2315/066/005	Prolonged-release tablet	-Quetiapine fumarate
Notiabolfen XL 200 mg prolonged-release Tablet	Accord Healthcare Ireland Ltd.	PA2315/066/001	Prolonged-release tablet	-Quetiapine fumarate
Notiabolfen XL 300 mg prolonged-release Tablet	Accord Healthcare Ireland Ltd.	PA2315/066/002	Prolonged-release tablet	-Quetiapine fumarate
Notiabolfen XL 400 mg prolonged-release Tablet	Accord Healthcare Ireland Ltd.	PA2315/066/003	Prolonged-release tablet	-Quetiapine fumarate
Notiabolfen XL 50 mg prolonged-release tablets	Accord Healthcare Ireland Ltd.	PA2315/066/004	Prolonged-release tablet	-Quetiapine fumarate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
NovaThirteen	Novo Nordisk A/S	EU/1/12/775/001	Powder and solvent for solution for injection	-Rfxiii drug substance
Novistig 0.5 mg/ml + 2.5 mg/ml solution for injection	Sintetica GmbH	PA22835/003/001	Solution for injection	-Glycopyrronium bromide -Neostigmine Metilsulfate
NovoEight	Novo Nordisk A/S	EU/1/13/888/001	Powder and solvent for solution for injection	-Turoctocog alfa
NovoEight	Novo Nordisk A/S	EU/1/13/888/002	Powder and solvent for solution for injection	-Turoctocog alfa
NovoEight	Novo Nordisk A/S	EU/1/13/888/003	Powder and solvent for solution for injection	-Turoctocog alfa
NovoEight	Novo Nordisk A/S	EU/1/13/888/004	Powder and solvent for solution for injection	-Turoctocog alfa
NovoEight	Novo Nordisk A/S	EU/1/13/888/005	Powder and solvent for solution for injection	-Turoctocog alfa
NovoEight	Novo Nordisk A/S	EU/1/13/888/006	Powder and solvent for solution for injection	-Turoctocog alfa
Novofem film-coated tablets	Novo Nordisk A/S	PA0218/053/001	Film-coated tablet	-Estradiol -Norethisterone acetate -Estradiol
NovoMix 30 FlexPen	Novo Nordisk A/S	EU/1/00/142/09-010	Suspension for injectio	-Insulin aspart
NovoMix 30 Penfill	Novo Nordisk A/S	EU/1/00/142/004-05	Suspension for injectio	-Insulin aspart
NovoMix 50 FlexPen	Novo Nordisk A/S	EU/1/00/142/14-16	Suspension for injectio	-Insulin aspart
NovoMix 50 PenFill	Novo Nordisk A/S	EU/1/00/142/11-13	Suspension for injectio	-Insulin aspart
NovoMix 70 FlexPen	Novo Nordisk A/S	EU/1/00/142/020-022	Suspension for injectio	-Insulin aspart
NovoMix 70 Penfill	Novo Nordisk A/S	EU/1/00/142/017-19	Suspension for injectio	-Insulin aspart
NOVONORM	Novo Nordisk A/S	EU/1/98/076/001	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/002	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/003	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/004	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/005	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/006	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/007	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/008	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/009	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/010	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/011	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/012	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/013	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/014	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/015	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/016	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/017	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/018	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/019	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/020	Tablet	-Repaglinide
NovoNorm	Novo Nordisk A/S	EU/1/98/076/021	Tablet	-Repaglinide
NovoRapid	Novo Nordisk A/S	EU/1/99/119/012	Solution for injection	-Insulin aspart
NovoRapid	Novo Nordisk A/S	EU/1/99/119/001	Solution for injection	-Insulin aspart
NovoRapid FlexPen	Novo Nordisk A/S	EU/1/99/119/009-011	Solution for injection in pre-filled pen	-Insulin aspart

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
NovoRapid FlexTouch	Novo Nordisk A/S	EU/1/99/119/019	Solution for injection in pre-filled pen	-Insulin aspart
NovoRapid InnoLet	Novo Nordisk A/S	EU/1/99/119/012-014	Solution for injection in pre-filled pen	-Insulin aspart
NOVORAPID INNOLET	Novo Nordisk A/S	EU/1/99/119/013	Solution for injection/infusion	-Insulin aspart
NOVORAPID NOVOLET	Novo Nordisk A/S	EU/1/99/119/005	Solution for injection	-Insulin aspart
NovoRapid Penfill	Novo Nordisk A/S	EU/1/99/119/003	Solution for injection in pre-filled pen	-Insulin aspart
NovoRapid PumpCart	Novo Nordisk A/S	EU/1/99/119/024-025	Solution for injection in cartridge	-Insulin aspart
NovoSeven	Novo Nordisk A/S	EU/1/96/006/003	Powder and solvent for solution for injection	-Factor viia human, recombinant
NovoSeven (400 KIU)	Novo Nordisk A/S	EU/1/96/006/007	Powder and solvent for solution for injection	-Eptacog alfa (activated)
NovoSeven (100 KIU)	Novo Nordisk A/S	EU/1/96/006/005	Powder and solvent for solution for injection	-Eptacog alfa (activated)
NovoSeven (250 KIU)	Novo Nordisk A/S	EU/1/96/006/006	Powder and solvent for solution for injection	-Eptacog alfa (activated)
NovoSeven (50 KIU)	Novo Nordisk A/S	EU/1/96/006/004	Powder and solvent for solution for injection	-Eptacog alfa (activated)
Noxafil	Merck Sharp & Dohme BV,	EU/1/05/320/004	Concentrate for solution for infusion	-Posaconazole
Noxafil	Merck Sharp & Dohme BV,	EU/1/05/320/005	Gastro-resistant powder for oral suspension	-Posaconazole
Noxafil 100 mg gastro-resistant tablets	Merck Sharp & Dohme BV,	EU/1/05/320/002-003	Gastro-resistant tablet	-Posaconazole
Noxafil 40 mg/ml oral suspension	Merck Sharp & Dohme BV,	EU/1/05/320/001	Oral suspension	-Posaconazole
Nozinan 25 mg/ml solution for injection/infusion	Neuraxpharm Ireland Limited	PA23229/008/001	Solution for injection/infusion	-LEVOMEPRMAZINE HYDROCHLORIDE
Nplate 250 micrograms	Amgen Europe B.V.	EU/1/08/497/1,3	Powder for solution for injection	-Romiplostim
Nplate 250 micrograms /500 micrograms	Amgen Europe B.V.	EU/1/08/497/5-8	Powder and solvent for solution for injection	-Romiplostim
Nplate 500 micrograms	Amgen Europe B.V.	EU/1/08/497/2,4	Powder for solution for injection	-Romiplostim
Nubega	Bayer AG	EU/1/20/1432/001	Film-coated tablet	-Darolutamide
Nucala	GlaxoSmithKline Trading Services Limited	EU/1/15/1043/001-002	Powder for solution for injection	-Mepolizumab
Nucala	GlaxoSmithKline Trading Services Limited	EU/1/15/1043/003-004	Solution for injection in pre-filled pen	-Mepolizumab
Nucala	GlaxoSmithKline Trading Services Limited	EU/1/15/1043/005-006	Solution for injection in pre-filled syringe	-Mepolizumab
Nucala	GlaxoSmithKline Trading Services Limited	EU/1/15/1043/009-010	Solution for injection in pre-filled syringe	-Mepolizumab
Nuceiva	Evolus Pharma Ltd.	EU/1/19/1364/001	Powder for solution for injection	-Botulinum Toxin Type A
Nuceiva	Evolus Pharma Ltd.	EU/1/19/1364/002	Powder for solution for injection	-Botulinum Toxin Type A
Nulibry	TMC Pharma (EU) Limited	EU/1/22/1684/001	Powder for solution for injection	-Fosdenopterin hydrobromide dihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Nulojix	Bristol-Myers Squibb Pharma EEIG	EU/1/11/694/001-002	Powder for concentrate for solution for infusion	-Belatacept
Numeta G13%E Preterm emulsion for infusion	Baxter Holding B.V.	PA2299/030/003	Emulsion for infusion	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Numeta G16%E emulsion for infusion	Baxter Holding B.V.	PA2299/030/001	Emulsion for infusion	-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
Numeta G19%E emulsion for infusion	Baxter Holding B.V.	PA2299/030/002	Emulsion for infusion	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Nuprin 75mg gastro-resistant tablets	Accord Healthcare Ireland Ltd.	PA2315/189/001	Gastro-resistant tablet	-Acetylsalicylic acid
Nurofen 200 mg coated tablets	PCO Manufacturing Ltd.	PPA0465/430/002	Coated tablet	-Ibuprofen
Nurofen 200 mg Coated Tablets	Reckitt Benckiser Ireland Ltd	PA0979/032/006	Coated tablet	-Ibuprofen
Nurofen 5% w/w Gel	Reckitt Benckiser Ireland Ltd	PA0979/032/003	Gel	-Ibuprofen
Nurofen Advance 200mg Tablets	Reckitt Benckiser Ireland Ltd	PA0979/075/001	Film-coated tablet	-Ibuprofen lysinate
Nurofen Cold & Flu film-coated tablets Ibuprofen 200mg Pseudoephedrine hydrochloride 30mg	PCO Manufacturing Ltd.	PPA0465/337/002	Film-coated tablet	-Ibuprofen -PSEUDOEPHEDRINE HYDROCHLORIDE
Nurofen Cold & Flu Film-coated Tablets Ibuprofen 200mg Pseudophedrine hydrochloride 30mg	Reckitt Benckiser Ireland Ltd	PA0979/033/001	Film-coated tablet	-Ibuprofen -PSEUDOEPHEDRINE HYDROCHLORIDE
Nurofen Durance 200 mg medicated plaster	Reckitt Benckiser Ireland Ltd	PA0979/032/018	Medicated plaster	-Ibuprofen
Nurofen Express 200 mg Tablets	Reckitt Benckiser Ireland Ltd	PA0979/032/010	Coated tablet	-Ibuprofen
Nurofen Express Maximum Strength 400 mg Tablets	Reckitt Benckiser Ireland Ltd	PA0979/032/011	Coated tablet	-Ibuprofen
Nurofen Express Maximum Strength 400 mg tablets	PCO Manufacturing Ltd.	PPA0465/430/001	Coated tablet	-Ibuprofen
Nurofen Express Maximum Strength 400 mg Tablets	IMED Healthcare Ltd.	PPA1463/217/001	Coated tablet	-Ibuprofen
Nurofen for children 100 mg chewable capsules, Soft	Reckitt Benckiser Ireland Ltd	PA0979/069/001	Capsule, soft	-Ibuprofen -Ibuprofen
Nurofen for Children 60 mg Suppositories Age 3 months to 2 years	Reckitt Benckiser Ireland Ltd	PA0979/032/007	Suppository	-Ibuprofen
Nurofen for Children Cold & Flu & Pain Orange 100mg/5ml Oral Suspension	Reckitt Benckiser Ireland Ltd	PA0979/066/001	Oral suspension	-Ibuprofen
Nurofen for Children Cold & Flu & Pain Strawberry 100mg/5ml Oral Suspension	Reckitt Benckiser Ireland Ltd	PA0979/067/001	Oral suspension	-Ibuprofen
Nurofen for Children Meltlets 100mg Orodispersible Tablets	Reckitt Benckiser Ireland Ltd	PA0979/032/005	Orodispersible tablet	-Ibuprofen
Nurofen for Children Orange 100 mg/5 ml oral suspension	Reckitt Benckiser Ireland Ltd	PA0979/032/001	Oral suspension	-Ibuprofen
Nurofen for Children Orange 100 mg/5 ml oral suspension	PCO Manufacturing Ltd.	PPA0465/337/001	Oral suspension	-Ibuprofen
Nurofen for Children Sachets 100 mg/5 ml Oral Suspension	Reckitt Benckiser Ireland Ltd	PA0979/032/008	Oral suspension	-Ibuprofen
Nurofen for Children Six Plus Orange 200 mg/5 ml oral suspension	Reckitt Benckiser Ireland Ltd	PA0979/056/001	Oral suspension	-Ibuprofen

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Nurofen for Children Six Plus Strawberry 200 mg/5 ml oral suspension	Reckitt Benckiser Ireland Ltd	PA0979/056/002	Oral suspension	-Ibuprofen
Nurofen for Children Strawberry 100 mg/5 ml oral suspension	Reckitt Benckiser Ireland Ltd	PA0979/032/009	Oral suspension	-Ibuprofen
Nurofen Long Lasting 300 mg Prolonged Release Hard Capsules	Reckitt Benckiser Ireland Ltd	PA0979/032/015	Prolonged-release capsule, hard	-Ibuprofen
Nurofen Long Lasting 300 mg prolonged-release tablets	Reckitt Benckiser Ireland Ltd	PA0979/081/001	Prolonged-release tablet	-Ibuprofen
Nurofen Plus Tablets Ibuprofen 200 mg Codeine Phosphate Hemihydrate 12.8 mg	PCO Manufacturing Ltd.	PPA0465/410/001	Film-coated tablet	-Ibuprofen -Codeine phosphate hemihydrate
Nurofen Plus Tablets Ibuprofen 200mg Codeine Phosphate Hemihydrate 12.8mg	Reckitt Benckiser Ireland Ltd	PA0979/034/001	Film-coated tablet	-Ibuprofen -Codeine phosphate hemihydrate
Nurofen Rapid Relief 200mg Liquid Capsules	Reckitt Benckiser Ireland Ltd	PA0979/032/012	Capsule, soft	-Ibuprofen
Nurofen Rapid Relief Max 400 mg soft capsules	Reckitt Benckiser Ireland Ltd	PA0979/085/001	Capsule, soft	-Ibuprofen
Nurofen Rapid Relief Maximum Strength 400 mg Liquid Capsules	IMED Healthcare Ltd.	PPA1463/220/001	Capsule, soft	-Ibuprofen
Nurofen Rapid Relief Maximum Strength 400 mg liquid capsules	PCO Manufacturing Ltd.	PPA0465/446/001	Capsule, soft	-Ibuprofen
Nurofen Rapid Relief Maximum Strength 400mg Liquid Capsules	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/050/001	Capsule, soft	-Ibuprofen
Nurofen Rapid Relief Maximum Strength 400mg Liquid Capsules	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/057/001	Capsule, soft	-Ibuprofen
Nurofen Rapid Relief Maximum Strength 400mg Liquid Capsules	Reckitt Benckiser Ireland Ltd	PA0979/032/013	Capsule, soft	-Ibuprofen
Nurofen Sinus and Pain Film-Coated Tablets Ibuprofen 200mg Pseudoephedrine Hydrochloride 30mg	Reckitt Benckiser Ireland Ltd	PA0979/065/001	Film-coated tablet	-Ibuprofen -PSEUDOEPHEDRINE HYDROCHLORIDE
Nu-Seals 300 mg Gastro-resistant Tablets	Alliance Pharma (Ireland) Limited	PA2325/010/002	Gastro-resistant tablet	-Acetylsalicylic acid
Nu-seals 75 mg gastro-resistant tablets	Alliance Pharma (Ireland) Limited	PA2325/010/001	Gastro-resistant tablet	-Acetylsalicylic acid
Nustendi	Daiichi Sankyo Europe GmbH	EU/1/20/1424/001-006	Film-coated tablet	-Bempeidoic Acid

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Nutriflex basal Solution for Infusion	B. Braun Melsungen AG	PA0736/005/001	Solution for infusion	-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
Nutriflex peri Solution for Infusion	B. Braun Melsungen AG	PA0736/006/001	Solution for infusion	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Nutriflex plus Solution for Infusion	B. Braun Melsungen AG	PA0736/007/001	Solution for infusion	-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
Nutriflex special Solution for infusion	B. Braun Melsungen AG	PA0736/008/001	Solution for infusion	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Nutrineal Solution for Peritoneal Dialysis 4 with 1.1% Amino Acids	Baxter Holding B.V.	PA2299/016/001	Solution for peritoneal dialysis	-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
NutropinAq	Ipsen Pharma	EU/1/00/164/003-004	Solution for injection	-Somatropin
NutropinAq	Ipsen Pharma	EU/1/00/164/005	Solution for injection	-Somatropin
NuvaRing 0.120 mg/0.015 mg per 24 hours, vaginal delivery system	Organon Pharma (Ireland) Limited	PA23198/020/001	Vaginal delivery system	-Etonogestrel -Ethinylestradiol
Nuvaxovid	Novavax CZ	EU/1/21/1618/001	Dispersion for injection	-SARS-CoV-2 spike protein recombinant
Nuwiq	Octapharma AB	EU/1/14/936/001	Powder and solvent for solution for injection	-Simoctocog alfa
Nuwiq	Octapharma AB	EU/1/14/936/002	Powder and solvent for solution for injection	-Simoctocog alfa
Nuwiq	Octapharma AB	EU/1/14/936/003	Powder and solvent for solution for injection	-Simoctocog alfa
Nuwiq	Octapharma AB	EU/1/14/936/004	Powder and solvent for solution for injection	-Simoctocog alfa
Nuwiq	Octapharma AB	EU/1/14/936/005	Powder and solvent for solution for injection	-Simoctocog alfa
Nuwiq	Octapharma AB	EU/1/14/936/006	Powder and solvent for solution for injection	-Simoctocog alfa
Nuwiq	Octapharma AB	EU/1/14/936/007	Powder and solvent for solution for injection	-Simoctocog alfa
Nuwiq	Octapharma AB	EU/1/14/936/008	Powder and solvent for solution for injection	-Simoctocog alfa
Nytamel 10 mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/117/002	Film-coated tablet	-Zolpidem tartrate
Nytamel 5 mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/117/001	Film-coated tablet	-Zolpidem tartrate
Nytol One-A-Night 50 mg Tablets	Chefaro Ireland DAC	PA1186/016/001	Tablet	-Diphenhydramine hydrochloride
Nyvepria	Pfizer Europe MA EEIG	EU/1/20/1486/001	Solution for injection	-Pegfilgrastim
Nyxoid	Mundipharma Corporation (Ireland) Limited	EU/1/17/1238/001	Nasal spray, solution in single-dose container	-Naloxone hydrochloride dihydrate
Obiltoxaximab SFL	SFL Regulatory Services GmbH	EU/1/20/1485/001	Concentrate for solution for infusion	-Obiltoxaximab
Obizur	Baxter Innovations GmbH	EU/1/15/1035/001-003	Powder and solvent for solution for injection	-Susoctocog alfa

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Ocaliva	Advanz Pharma Limite	EU/1/16/1139/001	Film-coated tablet	-Obeticholic acid
Ocaliva	Advanz Pharma Limite	EU/1/16/1139/002	Film-coated tablet	-Obeticholic acid
Occlusal 26% w/w Cutaneous Solution	Alliance Pharma (Ireland) Limited	PA2325/011/001	Cutaneous solution	-Salicylic acid
Ocrevus	Roche Registration GmbH	EU/1/17/1231/001-002	Concentrate for solution for infusion	-Ocrelizumab
Octanate 1000 IU powder and solvent for solution for injection	Octapharma (IP) SPRL	PA2219/004/003	Powder and solvent for solution for injection	-Human coagulation factor viii
Octanate 250 IU.Powder and solvent for solution for injection	Octapharma (IP) SPRL	PA2219/004/001	Powder and solvent for solution for injection	-Human plasmafraction (factor viii)
Octanate 500 IU powder and solvent for solution for injection	Octapharma (IP) SPRL	PA2219/004/002	Powder and solvent for solution for injection	-Human coagulation factor viii
Octaplex 1000 IU coagulation factor IX per vial, powder and solvent for solution for infusionHuman Prothrombin Complex	Octapharma (IP) SPRL	PA2219/005/002	Powder and solvent for solution for infusion	-Human coagulation factor ii -Human coagulation factor vii -Human coagulation factor ix -Human coagulation factor x -Protein c -Protein s
Octaplex 500 IU coagulation factor IX per vial, powder and solvent for solution for infusionHuman Prothrombin Complex	Octapharma (IP) SPRL	PA2219/005/001	Powder and solvent for solution for infusion	-Human plasma coagulation factor ii -Human plasma coagulation factor vii -Human plasma coagulation factor ix -Human plasma coagulation factor x -Protein c -Protein s
Octreoscan 111 MBq/mL, kit for radiopharmaceutical preparation	Curium Netherlands B.V.	PA0690/001/001	Kit for radiopharmaceutical preparation	-Indium (111 in) chloride solution -Pentetreotide
Octreotide 100 micrograms/1 ml solution for injection	Pfizer Healthcare Ireland	PA0822/218/002	Solution for injection	-OCTREOTIDE ACETATE
Octreotide 50 micrograms/1 ml solution for injection	Pfizer Healthcare Ireland	PA0822/218/001	Solution for injection	-OCTREOTIDE ACETATE
Octreotide 500 micrograms/1 ml solution for injection	Pfizer Healthcare Ireland	PA0822/218/004	Solution for injection	-OCTREOTIDE ACETATE
Odefsey	Gilead Sciences Ireland UC	EU/1/16/1112/001-002	Film-coated tablet	-Emtricitabine -Rilpivirine -Tenofovir alafenamide
Odomzo	Sun Pharmaceutical Industries Europe B.V.	EU/1/15/1030/001-002	Capsule, hard	-Sonidegib
Odrik 1mg Hard Capsules	Mylan IRE Healthcare Limited	PA2010/005/002	Capsule, hard	-Trandolapril
Odrik 2mg Hard Capsules	Mylan IRE Healthcare Limited	PA2010/005/003	Capsule, hard	-Trandolapril
Oestrogel Pump-Pack 750 micrograms/actuation Gel	Laboratoires Besins International	PA1054/004/001	Gel	-Estradiol hemihydrate
Ofev	Boehringer Ingelheim International GmbH	EU/1/14/979/001-002	Capsule, soft	-Nintedanib

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Ofev	Boehringer Ingelheim International GmbH	EU/1/14/979/003-004	Capsule, soft	-Nintedanib
Ofost 10 IU/ml concentrate for solution for infusion or solution for intramuscular injection	AS Grindeks	PA22992/001/002	Solution for injection/infusion	-Oxytocin
Ofost 5 IU/ml concentrate for solution for infusion or solution for intramuscular injection	AS Grindeks	PA22992/001/001	Solution for injection/infusion	-Oxytocin
Ogivri	Biosimilar Collaborations Ireland Limited	EU/1/18/1341/001	Powder for concentrate for solution for infusion	-Trastuzumab
Ogivri	Biosimilar Collaborations Ireland Limited	EU/1/18/1341/002	Powder for concentrate for solution for infusion	-Trastuzumab
Ogluo	Tetris Pharma B.V.	EU/1/20/1523/001-002	Solution for injection in pre-filled pen	-GLUCAGON
Ogluo	Tetris Pharma B.V.	EU/1/20/1523/003-004	Solution for injection in pre-filled syringe	-GLUCAGON
Ogluo	Tetris Pharma B.V.	EU/1/20/1523/005-006	Solution for injection in pre-filled pen	-GLUCAGON
Ogluo	Tetris Pharma B.V.	EU/1/20/1523/007-008	Solution for injection in pre-filled syringe	-GLUCAGON
Oilatum Emollient 63.4% w/w Bath Additive	Clonmel Healthcare Ltd	PA0126/322/001	Bath additive	-Liquid paraffin light
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	-Light liquid paraffin -Benzalkonium chloride -Triclosan
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	-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	-Risperidone
Okedi	Laboratorios Farmacéuticos ROVI, S.A.	EU/1/21/1621/002	Powder and solvent for prolonged-release suspension for injection	-Risperidone
Olanzapine 10mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/210/004	Film-coated tablet	-Olanzapine
Olanzapine 10mg Orodispersible Tablets	Accord Healthcare Ireland Ltd.	PA2315/229/002	Orodispersible tablet	-Olanzapine
Olanzapine 15mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/210/005	Film-coated tablet	-Olanzapine
Olanzapine 15mg Orodispersible Tablets	Accord Healthcare Ireland Ltd.	PA2315/229/003	Orodispersible tablet	-Olanzapine
Olanzapine 2.5mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/210/001	Film-coated tablet	-Olanzapine
Olanzapine 20mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/210/006	Film-coated tablet	-Olanzapine
Olanzapine 20mg Orodispersible Tablets	Accord Healthcare Ireland Ltd.	PA2315/229/004	Orodispersible tablet	-Olanzapine
Olanzapine 5 mg Orodispersible Tablets	Accord Healthcare Ireland Ltd.	PA2315/229/001	Orodispersible tablet	-Olanzapine
Olanzapine 5mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/210/002	Film-coated tablet	-Olanzapine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Olanzapine 7.5mg Film-coated Tablets	Clonmel Healthcare Ltd	PA0126/210/003	Film-coated tablet	-Olanzapine
Olanzapine Accord 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/112/004	Film-coated tablet	-Olanzapine
Olanzapine Accord 15 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/112/005	Film-coated tablet	-Olanzapine
Olanzapine Accord 2.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/112/001	Film-coated tablet	-Olanzapine
Olanzapine Accord 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/112/002	Film-coated tablet	-Olanzapine
Olanzapine Accord 7.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/112/003	Film-coated tablet	-Olanzapine form 1
Olanzapine Apotex	Apotex Europe B.V.	EU/1/10/635/001	Film-coated tablet	-Olanzapine
OLANZAPINE APOTEX	Apotex Europe B.V.	EU/1/10/635/002-3	Film-coated tablet	-OLANZAPINE
OLANZAPINE APOTEX	Apotex Europe B.V.	EU/1/10/635/004-5	Film-coated tablet	-OLANZAPINE
OLANZAPINE APOTEX	Apotex Europe B.V.	EU/1/10/635/006-7	Film-coated tablet	-OLANZAPINE
Olanzapine Apotex	Apotex Europe B.V.	EU/1/10/635/008-9	Orodispersible tablet	-Olanzapine
Olanzapine Apotex	Apotex Europe B.V.	EU/1/10/635/010-11	Orodispersible tablet	-Olanzapine
OLANZAPINE APOTEX	Apotex Europe B.V.	EU/1/10/635/012	Orodispersible Tablet	-OLANZAPINE
OLANZAPINE APOTEX	Apotex Europe B.V.	EU/1/10/635/013-14	Orodispersible Tablet	-OLANZAPINE
Olanzapine Glenmark	Glenmark Arzneimittel GmbH	EU/1/09/587/10-12	Tablet	-Olanzapine
Olanzapine Glenmark	Glenmark Arzneimittel GmbH	EU/1/09/587/1-3	Tablet	-Olanzapine
Olanzapine Glenmark	Glenmark Arzneimittel GmbH	EU/1/09/587/13-15	Tablet	-Olanzapine
Olanzapine Glenmark	Glenmark Arzneimittel GmbH	EU/1/09/587/16-17	Tablet	-Olanzapine
Olanzapine Glenmark	Glenmark Arzneimittel GmbH	EU/1/09/587/4-6	Tablet	-Olanzapine
Olanzapine Glenmark	Glenmark Arzneimittel GmbH	EU/1/09/587/7-9	Tablet	-Olanzapine
Olanzapine Glenmark Europe	Glenmark Arzneimittel GmbH	EU/1/09/588/10-12	Orodispersible tablet	-Olanzapine
Olanzapine Glenmark Europe	Glenmark Arzneimittel GmbH	EU/1/09/588/1-3	Orodispersible tablet	-Olanzapine
Olanzapine Glenmark Europe	Glenmark Arzneimittel GmbH	EU/1/09/588/4-6	Orodispersible tablet	-Olanzapine
Olanzapine Glenmark Europe	Glenmark Arzneimittel GmbH	EU/1/09/588/7-9	Orodispersible tablet	-Olanzapine
Olanzapine Mylan	Mylan Pharmaceuticals Limited	EU/1/08/475/13-17	Film-coated tablet	-Olanzapine
Olanzapine Mylan	Mylan Pharmaceuticals Limited	EU/1/08/475/1-6	Film-coated tablet	-Olanzapine
Olanzapine Mylan	Mylan Pharmaceuticals Limited	EU/1/08/475/18-24	Film-coated tablet	-Olanzapine
Olanzapine Mylan	Mylan Pharmaceuticals Limited	EU/1/08/475/25-29	Film-coated tablet	-Olanzapine
Olanzapine Mylan	Mylan Pharmaceuticals Limited	EU/1/08/475/30-34	Film-coated tablet	-Olanzapine
Olanzapine Mylan	Mylan Pharmaceuticals Limited	EU/1/08/475/7-12	Film-coated tablet	-Olanzapine
Olanzapine Teva	Teva Pharma B.V.	EU/1/07/427/004-007	Film-coated tablet	-Olanzapine
Olanzapine Teva	Teva Pharma B.V.	EU/1/07/427/008-010	Film-coated tablet	-Olanzapine
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/11-14	Film-coated tablet	-OLANZAPINE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/1-3	Film-coated tablet	-OLANZAPINE
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/16-19	Film-coated tablet	-OLANZAPINE
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/20-22	Film-coated tablet	-OLANZAPINE
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/23-26	Orodispersible Tablet	-OLANZAPINE
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/27-30	Orodispersible Tablet	-OLANZAPINE
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/31-34	Orodispersible Tablet	-OLANZAPINE
OLANZAPINE TEVA	Teva B.V.	EU/1/07/427/35-37	Orodispersible Tablet	-OLANZAPINE
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	-Octreotide
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	-Octreotide
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	-Octreotide
OLAZAX	Glenmark Pharmaceuticals s.r.o.	EU/1/09/597/001	Tablet	-OLANZAPINE I
OLAZAX	Glenmark Pharmaceuticals s.r.o.	EU/1/09/597/002	Tablet	-OLANZAPINE I
OLAZAX	Glenmark Pharmaceuticals s.r.o.	EU/1/09/597/003	Tablet	-OLANZAPINE I
OLAZAX	Glenmark Pharmaceuticals s.r.o.	EU/1/09/597/004	Tablet	-OLANZAPINE I
OLAZAX	Glenmark Pharmaceuticals s.r.o.	EU/1/09/597/005	Tablet	-OLANZAPINE I
Olazax Disperzi	Glenmark Pharmaceuticals s.r.o.	EU/1/09/592/001	Orodispersible tablet	-Olanzapine
Olazax Disperzi	Glenmark Pharmaceuticals s.r.o.	EU/1/09/592/002	Orodispersible tablet	-Olanzapine
Olazax Disperzi	Glenmark Pharmaceuticals s.r.o.	EU/1/09/592/003	Orodispersible tablet	-Olanzapine
Olazax Disperzi	Glenmark Pharmaceuticals s.r.o.	EU/1/09/592/004	Orodispersible tablet	-Olanzapine
Olazax Disperzi	Glenmark Pharmaceuticals s.r.o.	EU/1/09/592/005	Orodispersible tablet	-Olanzapine
Olmesartan /Amlodipine Mylan 20 mg/ 5 mg film coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/185/001	Film-coated tablet	-Olmesartan medoxomil -Amlodipine besilate
Olmesartan /Amlodipine Mylan 40 mg/ 10 mg film coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/185/003	Film-coated tablet	-Olmesartan medoxomil -Amlodipine besilate
Olmesartan /Amlodipine Mylan 40 mg/ 5 mg film coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/185/002	Film-coated tablet	-Olmesartan medoxomil -Amlodipine besilate
Olmesartan Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/060/001	Film-coated tablet	-Olmesartan medoxomil
Olmesartan Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/060/002	Film-coated tablet	-Olmesartan medoxomil
Olmesartan Krka 40 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/060/003	Film-coated tablet	-Olmesartan medoxomil
Olmesartan Medoxomil 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/113/001	Film-coated tablet	-Olmesartan medoxomil
Olmesartan medoxomil 10 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/214/001	Film-coated tablet	-Olmesartan medoxomil

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Olmesartan medoxomil 20 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/214/002	Film-coated tablet	-Olmesartan medoxomil
Olmesartan Medoxomil 20 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/113/002	Film-coated tablet	-Olmesartan medoxomil
Olmesartan Medoxomil 40 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/113/003	Film-coated tablet	-Olmesartan medoxomil
Olmesartan medoxomil 40 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/214/003	Film-coated tablet	-Olmesartan medoxomil
Olmesartan Medoxomil Clonmel 10 mg film- coated tablets	Clonmel Healthcare Ltd	PA0126/273/001	Film-coated tablet	-Olmesartan medoxomil
Olmesartan Medoxomil Clonmel 20 mg film- coated tablets	Clonmel Healthcare Ltd	PA0126/273/002	Film-coated tablet	-Olmesartan medoxomil
Olmesartan Medoxomil Clonmel 40 mg film- coated tablet	Clonmel Healthcare Ltd	PA0126/273/003	Film-coated tablet	-Olmesartan medoxomil
Olmesartan medoxomil/Amlodipine 20 mg/5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/074/001	Film-coated tablet	-Olmesartan medoxomil -Amlodipine
Olmesartan medoxomil/Amlodipine 40 mg/10 mg film- coated tablets	Accord Healthcare Ireland Ltd.	PA2315/074/003	Film-coated tablet	-Olmesartan medoxomil -Amlodipine
Olmesartan medoxomil/Amlodipine 40 mg/5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/074/002	Film-coated tablet	-Olmesartan medoxomil -Amlodipine
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	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
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	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
Olmesartan medoxomil/Amlodipine /Hydrochlorothiazide Accord 40 mg/10 mg/25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/158/005	Film-coated tablet	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
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	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
Olmesartan medoxomil/Amlodipine /Hydrochlorothiazide Accord 40 mg/5 mg/25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/158/004	Film-coated tablet	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Olmesartan medoxomil/Amlodipine /Hydrochlorothiazide Clonmel 20 mg/5 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/312/001	Film-coated tablet	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
Olmesartan medoxomil/Amlodipine /Hydrochlorothiazide Clonmel 40 mg/10 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/312/003	Film-coated tablet	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
Olmesartan medoxomil/Amlodipine /Hydrochlorothiazide Clonmel 40 mg/10 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/312/005	Film-coated tablet	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
Olmesartan medoxomil/Amlodipine /Hydrochlorothiazide Clonmel 40 mg/5 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/312/002	Film-coated tablet	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
Olmesartan medoxomil/Amlodipine /Hydrochlorothiazide Clonmel 40 mg/5 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/312/004	Film-coated tablet	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
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	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
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	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
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	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
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	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
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	-Olmesartan medoxomil -Amlodipine -Hydrochlorothiazide
Olmesartan Medoxomil/Hydrochlorothiazide 20 mg/12.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/106/001	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide
Olmesartan Medoxomil/Hydrochlorothiazide 20 mg/25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/106/002	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Olmesartan Medoxomil/Hydrochlorothiazide 40 mg/12.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/106/003	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide
Olmesartan Medoxomil/Hydrochlorothiazide 40 mg/25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/106/004	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide
Olmesartan Rowex 10 mg film-coated tablets	Rowex Ltd	PA0711/255/001	Film-coated tablet	-Olmesartan medoxomil
Olmesartan Rowex 20 mg film-coated tablets	Rowex Ltd	PA0711/255/002	Film-coated tablet	-Olmesartan medoxomil
Olmesartan Rowex 40 mg film-coated tablets	Rowex Ltd	PA0711/255/003	Film-coated tablet	-Olmesartan medoxomil
Olmesartan/Amlodipine Clonmel 20 mg/5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/293/001	Film-coated tablet	-Olmesartan medoxomil -Amlodipine besilate
Olmesartan/Amlodipine Clonmel 40 mg/10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/293/003	Film-coated tablet	-Olmesartan medoxomil -Amlodipine besilate
Olmesartan/Amlodipine Clonmel 40 mg/5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/293/002	Film-coated tablet	-Olmesartan medoxomil -Amlodipine besilate
Olmesartan/Amlodipine Krka 20 mg/5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/075/001	Film-coated tablet	-Olmesartan medoxomil -Amlodipine besilate
Olmesartan/Amlodipine Krka 40 mg/10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/075/003	Film-coated tablet	-Olmesartan medoxomil -Amlodipine besilate
Olmesartan/Amlodipine Krka 40 mg/5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/075/002	Film-coated tablet	-Olmesartan medoxomil -Amlodipine besilate
Olmesartan/Hydrochlorothiazide Clonmel 20 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/260/001	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide
Olmesartan/Hydrochlorothiazide Clonmel 20 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/260/002	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide
Olmesartan/Hydrochlorothiazide Clonmel 40 mg/12.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/260/003	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide
Olmesartan/Hydrochlorothiazide Clonmel 40 mg/25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/260/004	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide
Olmesartan/Hydrochlorothiazide Krka 20 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/061/001	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide
Olmesartan/Hydrochlorothiazide Krka 20 mg/25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/061/002	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide
Olmesartan/Hydrochlorothiazide Krka 40 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/061/003	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide
Olmesartan/Hydrochlorothiazide Krka 40 mg/25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/061/004	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide
Olumiant	Eli Lilly Nederland B.V.	EU/1/16/1170/001-008	Film-coated tablet	-Baricitinib

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Olumiant	Eli Lilly Nederland B.V.	EU/1/16/1170/009-016	Film-coated tablet	-Baricitinib
Olumiant	Eli Lilly Nederland B.V.	EU/1/16/1170/017-019	Film-coated tablet	-Baricitinib
Omacor 1000 mg Soft Capsules	BASF AS	PA1099/001/001	Capsule, soft	-Omega-3-acid ethyl esters
Omacor 1000 mg Soft Capsules	PCO Manufacturing Ltd.	PPA0465/335/001	Capsule, soft	-Omega-3-acid ethyl esters 90
Omacor 1000 mg Soft Capsules	IMED Healthcare Ltd.	PPA1463/042/001	Capsule, soft	-Omega-3-acid ethyl esters
Omeflex peri emulsion for infusion	B. Braun Melsungen AG	PA0736/033/002	Emulsion for infusion	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Omeflex plus emulsion for infusion	B. Braun Melsungen AG	PA0736/039/001	Emulsion for infusion	<ul style="list-style-type: none"> -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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Omeflex special emulsion for infusion	B. Braun Melsungen AG	PA0736/040/001	Emulsion for infusion	-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
Omeflex special without electrolytes emulsion for infusion	B. Braun Melsungen AG	PA0736/038/001	Emulsion for infusion	-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
Omeprazole 10 mg Gastro-resistant Capsules, hard	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/203/001	Gastro-resistant capsule, hard	-Omeprazole
Omeprazole 10 mg gastro-resistant capsules, hard	Accord Healthcare Ireland Ltd.	PA2315/129/001	Gastro-resistant capsule, hard	-Omeprazole

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Omeprazole 20 mg gastro-resistant capsules, hard	Accord Healthcare Ireland Ltd.	PA2315/129/002	Gastro-resistant capsule, hard	-Omeprazole
Omeprazole 20 mg Gastro-resistant Capsules, hard	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/203/002	Gastro-resistant capsule, hard	-Omeprazole
Omeprazole 40 mg Gastro-resistant Capsules, hard	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/203/003	Gastro-resistant capsule, hard	-Omeprazole
Omeprazole 40 mg gastro-resistant capsules, hard	Accord Healthcare Ireland Ltd.	PA2315/129/003	Gastro-resistant capsule, hard	-Omeprazole
Omeprazole Bluefish 10 mg gastro-resistant capsules	Bluefish Pharmaceuticals AB	PA1436/007/001	Gastro-resistant capsule, hard	-Omeprazole
Omeprazole Bluefish 20 mg gastro-resistant capsules	Bluefish Pharmaceuticals AB	PA1436/007/002	Gastro-resistant capsule, hard	-Omeprazole
Omeprazole Bluefish 40 mg gastro-resistant capsules	Bluefish Pharmaceuticals AB	PA1436/007/003	Gastro-resistant capsule, hard	-Omeprazole
Omeprazole Pinewood 20 mg gastro-resistant capsules, hard	Pinewood Laboratories Ltd	PA0281/152/001	Gastro-resistant capsule, hard	-Omeprazole
Omeprazole Rowa 20 mg Gastro-resistant Capsules, hard	Rowa Pharmaceuticals Limited	PA0074/075/002	Gastro-resistant capsule, hard	-Omeprazole
Omeprazole Rowa 40 mg Gastro-Resistant Capsules, hard	Rowa Pharmaceuticals Limited	PA0074/075/003	Gastro-resistant capsule, hard	-Omeprazole
Omeprazole Teva 10 mg gastro-resistant capsules, hard	Teva Pharma B.V.	PA0749/160/001	Gastro-resistant capsule, hard	-Omeprazole
Omeprazole Teva 20 mg gastro-resistant capsules, hard	Teva Pharma B.V.	PA0749/160/002	Gastro-resistant capsule, hard	-Omeprazole
Omeprazole Teva 40 mg Gastro-resistant Capsules, hard	Teva Pharma B.V.	PA0749/160/003	Gastro-resistant capsule, hard	-Omeprazole
Omesar 10 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/011/001	Film-coated tablet	-Olmesartan medoxomil
Omesar 20 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/011/002	Film-coated tablet	-Olmesartan medoxomil
Omesar 40 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/011/003	Film-coated tablet	-Olmesartan medoxomil
Omesar Plus 20 mg/12.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/014/001	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide
Omesar Plus 20 mg/25 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/014/002	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide
Omesar Plus 40 mg/12.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/014/003	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide
Omesar Plus 40 mg/25 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/014/004	Film-coated tablet	-Olmesartan medoxomil -Hydrochlorothiazide
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	-Phenylephrine hydrochloride -Ketorolac trometamol
Omjjara	GlaxoSmithKline Trading Services Limited	EU/1/23/1782/001	Film-coated tablet	-Momelotinib Dihydrochloride Monohydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Omjjara	GlaxoSmithKline Trading Services Limited	EU/1/23/1782/002	Film-coated tablet	-Momelotinib Dihydrochloride Monohydrate
Omjjara	GlaxoSmithKline Trading Services Limited	EU/1/23/1782/003	Film-coated tablet	-Momelotinib Dihydrochloride Monohydrate
Omnixel, 400 micrograms prolonged release tablets, film-coated	PCO Manufacturing Ltd.	PPA0465/171/001	Prolonged-release tablet	-Tamsulosin hydrochloride
Omnixel®, 400 micrograms prolonged release tablets, film-coated	IMED Healthcare Ltd.	PPA1463/025/001	Prolonged-release tablet	-Tamsulosin hydrochloride
Omnixel®, 400 micrograms prolonged release tablets, film-coated	Astellas Pharma Co. Limited	PA1241/006/001	Prolonged-release tablet	-Tamsulosin hydrochloride
Omnipaque 140 mg l/ml Solution for Injection (Glass)	GE Healthcare AS	PA0735/006/001	Solution for injection	-Iohexol
Omnipaque 180 mg l/ml Solution for Injection (Glass)	GE Healthcare AS	PA0735/006/002	Solution for injection	-Iohexol
Omnipaque 240 mg l/ml Solution for Injection (Glass)	GE Healthcare AS	PA0735/006/004	Solution for injection	-Iohexol
Omnipaque 240 mg l/ml Solution for Injection (Polypropylene)	GE Healthcare AS	PA0735/006/023	Solution for injection	-Iohexol
Omnipaque 300 mg l/ml Solution for Injection (Glass)	GE Healthcare AS	PA0735/006/008	Solution for injection	-Iohexol
Omnipaque 300 mg l/ml Solution for Injection (Polypropylene)	GE Healthcare AS	PA0735/006/018	Solution for injection	-Iohexol
Omnipaque 350 mg l/ml Solution for Injection (Glass)	GE Healthcare AS	PA0735/006/013	Solution for injection	-Iohexol
Omnipaque 350 mg l/ml Solution for Injection (Polypropylene)	GE Healthcare AS	PA0735/006/020	Solution for injection	-Iohexol
Omnitrope	Sandoz GmbH	EU/1/06/332/001	Powder and solvent for solution for injection	-Somatropin
Omnitrope	Sandoz GmbH	EU/1/06/332/002-003	Powder and solvent for solution for injection	-Somatropin
Omnitrope	Sandoz GmbH	EU/1/06/332/004-006	Solution for injection in cartridge	-Somatropin
Omnitrope	Sandoz GmbH	EU/1/06/332/007-009	Solution for injection in cartridge	-Somatropin
Omnitrope	Sandoz GmbH	EU/1/06/332/010-012	Solution for injection in cartridge	-Somatropin
OmvoH	Eli Lilly Nederland B.V.	EU/1/23/1736/001	Concentrate for solution for infusion	-MIRIKIZUMAB
Onbevzi	Samsung Bioepis NL B.V.	EU/1/20/1499/001-002	Concentrate for solution for infusion	-Bevacizumab
Onbrez Breezhaler	Novartis Europharm Limited	EU/1/09/593/1-5	Inhalation powder, hard capsule	-Indacaterol maleate
Onbrez Breezhaler	Novartis Europharm Limited	EU/1/09/593/6-10	Inhalation powder, hard capsule	-Indacaterol maleate
Oncaspar	Les Laboratoires Servier	EU/1/15/1070/001	Solution for injection/infusion	-Pegaspargase

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Oncaspar	Les Laboratoires Servier	EU/1/15/1070/002	Powder for solution for injection/infusion	-Pegaspargase
Ondansetron 2 mg/ml Solution for Injection or Infusion	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/083/001	Solution for injection/infusion	-Ondansetron
Ondansetron 2 mg/ml Solution for Injection or Infusion	Accord Healthcare Ireland Ltd.	PA2315/168/001	Solution for injection/infusion	-Ondansetron
Ondansetron 2 mg/ml solution for injection/infusion	AS Kalceks	PA2165/013/001	Solution for injection/infusion	-Ondansetron
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	-Ondansetron hydrochloride dihydrate
Ondansetron 2mg/ml Solution for Injection	Baxter Holding B.V.	PA2299/037/001	Solution for injection	-Ondansetron
Ondansetron 2mg/ml Solution for Injection	Noridem Enterprises Limited	PA1122/004/001	Solution for injection	-Ondansetron
Ondansetron 4 mg film-coated tablets	Teva Pharma B.V.	PA0749/009/001	Film-coated tablet	-Ondansetron
Ondansetron 4 mg/5 ml syrup	Syri Pharma Limited t/a Thame Laboratories	PA22697/013/001	Syrup	-Ondansetron
Ondansetron 8 mg film-coated tablets	Teva Pharma B.V.	PA0749/009/002	Film-coated tablet	-Ondansetron
Ondansetron Kabi 0.08 mg/ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/080/001	Solution for infusion	-Ondansetron hydrochloride dihydrate
Ondansetron Kabi 0.16 mg/ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/080/002	Solution for infusion	-Ondansetron hydrochloride dihydrate
Ondansetron Kabi 2 mg/ml solution for injection	Fresenius Kabi Deutschland GmbH	PA2059/048/001	Solution for injection	-Ondansetron
Ondexxya Powder for solution for infusion	AstraZeneca AB	EU/1/18/1345/001	Powder for solution for infusion	-Andexant alfa
Ondran 4 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/127/001	Film-coated tablet	-Ondansetron
Ondran 8 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/127/002	Film-coated tablet	-Ondansetron
One-Alpha 0.25 micrograms soft capsules	CHEPLAPHARM Arzneimittel GmbH	PA2239/017/002	Capsule, soft	-Alfacalcidol
One-Alpha 1 microgram soft capsules	CHEPLAPHARM Arzneimittel GmbH	PA2239/017/001	Capsule, soft	-Alfacalcidol
One-Alpha 1 microgram soft capsules	IMED Healthcare Ltd.	PPA1463/167/001	Capsule, soft	-Alfacalcidol
One-Alpha 1 microgram soft capsules	PCO Manufacturing Ltd.	PPA0465/134/002	Capsule, soft	-Alfacalcidol
One-Alpha 2 micrograms/ml oral drops	CHEPLAPHARM Arzneimittel GmbH	PA2239/017/003	Oral drops, solution	-Alfacalcidol
Ongentys	BIAL-Portela & Ca, S.A	EU/1/15/1066/001	Capsule, hard	-Opicapone
Ongentys	BIAL-Portela & Ca, S.A	EU/1/15/1066/002-007	Capsule, hard	-Opicapone
Onglyza	AstraZeneca AB	EU/1/09/545/011-015	Film-coated tablet	-Saxagliptin
Onglyza	AstraZeneca AB	EU/1/09/545/1-10	Film-coated tablet	-Saxagliptin
Onivyde pegylated liposomal	Les Laboratoires Servier	EU/1/16/1130/001	Concentrate for solution for infusion	-Irinotecan hydrochloride trihydrate
Onpattro	Alnylam Netherlands B.V.	EU/1/18/1320/001	Concentrate for solution for infusion	-PATISIRAN SODIUM

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Ontilyv	BIAL-Portela & Ca, S.A	EU/1/21/1578/001-004	Capsule, hard	-Opicapone
Ontozry	Angelini Pharma Italia S.P.A.	EU/1/21/1530/001	Film-coated tablet	-Cenobamate
Ontozry	Angelini Pharma Italia S.P.A.	EU/1/21/1530/002-004	Film-coated tablet	-Cenobamate
Ontozry	Angelini Pharma Italia S.P.A.	EU/1/21/1530/005-007	Film-coated tablet	-Cenobamate
Ontozry	Angelini Pharma Italia S.P.A.	EU/1/21/1530/008-010	Film-coated tablet	-Cenobamate
Ontozry	Angelini Pharma Italia S.P.A.	EU/1/21/1530/011-013	Film-coated tablet	-Cenobamate
Ontruzant	Samsung Bioepis NL B.V.	EU/1/17/1241/001	Powder for concentrate for solution for infusion	-Trastuzumab
Onureg	Celgene Europe B.V.	EU/1/21/1556/001-002	Film-coated tablet	-Azacitidine
Onureg	Celgene Europe B.V.	EU/1/21/1556/003-004	Film-coated tablet	-Azacitidine
Onytec 80mg/g medicated nail lacquer	Polichem S.A.	PA1005/002/001	Medicated nail lacquer	-Ciclopirox
Opatanol	Novartis Europharm Limited	EU/1/02/217/001	Eye drops, solution	-Olopatadine hydrochloride
Opatanol	Novartis Europharm Limited	EU/1/02/217/002	Eye drops, solution	-Olopatadine hydrochloride
Opdivo	Bristol-Myers Squibb Pharma EEIG	EU/1/15/1014/001-002	Concentrate for solution for infusion	-Nivolumab -Nivolumab
Opdualag	Bristol-Myers Squibb Pharma EEIG	EU/1/22/1679/001	Concentrate for solution for infusion	-RELATLIMAB -Nivolumab
Opfolda	Amicus Therapeutics Europe Limited	EU/1/23/1737/001-002	Capsule, hard	-Miglustat
Oprymeia	KRKA, d.d., Novo mesto	EU/1/08/469/026-029	Prolonged-release tablet	-Pramipexole
Oprymeia	KRKA, d.d., Novo mesto	EU/1/08/469/030-033	Prolonged-release tablet	-Pramipexole
Oprymeia	KRKA, d.d., Novo mesto	EU/1/08/469/034-037	Prolonged-release tablet	-Pramipexole
OPRYMEA	Krka d.d., Novo mesto	EU/1/08/469/038-041	Prolonged-release tablet	-PRAMIPEXOLE
Oprymeia	KRKA, d.d., Novo mesto	EU/1/08/469/042-045	Prolonged-release tablet	-Pramipexole
OPRYMEA	Krka d.d., Novo mesto	EU/1/08/469/046-049	Prolonged-release tablet	-PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE
Oprymeia	KRKA, d.d., Novo mesto	EU/1/08/469/050-053	Prolonged-release tablet	-Pramipexole dihydrochloride monohydrate
Oprymeia 0.088 mg tablets	KRKA, d.d., Novo mesto	EU/1/08/469/1-5	Tablet	-Pramipexole
Oprymeia 0.18 mg tablets	KRKA, d.d., Novo mesto	EU/1/08/469/6-10	Tablet	-Pramipexole
OPRYMEA 0.35 MG TABLETS	Krka d.d., Novo mesto	EU/1/08/469/11-15	Tablet	-PRAMIPEXOLE
Oprymeia 0.7 mg tablets	KRKA, d.d., Novo mesto	EU/1/08/469/16-20	Tablet	-Pramipexole
OPRYMEA 1.1 MG TABLETS	Krka d.d., Novo mesto	EU/1/08/469/21-25	Tablet	-PRAMIPEXOLE
Opsumit	Janssen Pharmaceutica NV	EU/1/13/893/001-003	Film-coated tablet	-Macitentan
Opticrom 2 % w/v Eye Drops, solution	Clonmel Healthcare Ltd	PA0126/381/001	Eye drops, solution	-Sodium cromoglicate
Opticrom allergy 2% w/v eye drops, solution	Clonmel Healthcare Ltd	PA0126/381/002	Eye drops, solution	-Sodium cromoglicate
Opticrom Allergy Single Dose 2% w/v eye drops, solution	Clonmel Healthcare Ltd	PA0126/381/003	Eye drops, solution	-Sodium cromoglicate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Optilast, 0.5 mg/ml Eye Drops, solution	Mylan IRE Healthcare Limited	PA2010/047/001	Eye drops, solution	-Azelastine hydrochloride
Optiray 240 mg l/ml PFS solution for injection	Guerbet	PA0686/007/002	Solution for injection	-loversol
Optiray 240 mg l/ml solution for injection or infusion	Guerbet	PA0686/007/001	Solution for injection/infusion	-loversol
Optiray 300 mg l/ml PFS solution for injection	Guerbet	PA0686/007/004	Solution for injection	-loversol
Optiray 300 mg l/ml solution for injection or infusion	Guerbet	PA0686/007/003	Solution for injection/infusion	-loversol
Optiray 320 mg l/ml solution for injection or infusion	Guerbet	PA0686/007/005	Solution for injection/infusion	-loversol
Optiray 350 mg l/ml PFS solution for injection	Guerbet	PA0686/007/007	Solution for injection	-loversol
Optiray 350 mg l/ml solution for injection or infusion	Guerbet	PA0686/007/006	Solution for injection/infusion	-loversol
Optison	GE Healthcare AS	EU/1/98/065/001	Dispersion for injection	-Perflutren -Human albumin microspheres
Optison	GE Healthcare AS	EU/1/98/065/002	Dispersion for injection	-Perflutren -Human albumin microspheres
OPTISULIN	Aventis Pharma Deutschland GmbH	EU/1/00/133/001	Solution for injection	-Insulin glargine
Optisulin	Aventis Pharma Deutschland GmbH	EU/1/00/133/002	Solution for injection	-Insulin glargine
Optisulin	Aventis Pharma Deutschland GmbH	EU/1/00/133/003	Solution for injection	-Insulin glargine
Optisulin	Aventis Pharma Deutschland GmbH	EU/1/00/133/004	Solution for injection	-Insulin glargine
Optisulin	Aventis Pharma Deutschland GmbH	EU/1/00/133/005	Solution for injection in cartridge	-Insulin glargine
Optisulin	Aventis Pharma Deutschland GmbH	EU/1/00/133/006	Solution for injection in cartridge	-Insulin glargine
Optisulin	Aventis Pharma Deutschland GmbH	EU/1/00/133/007	Solution for injection in cartridge	-Insulin glargine
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	-Hamamelis water -Naphazoline hydrochloride
Optruma	Eli Lilly Nederland B.V.	EU/1/98/074/001	Film-coated tablet	-Raloxifene
Optruma	Eli Lilly Nederland B.V.	EU/1/98/074/002	Film-coated tablet	-Raloxifene
Optruma	Eli Lilly Nederland B.V.	EU/1/98/074/003	Film-coated tablet	-Raloxifene
Optruma	Eli Lilly Nederland B.V.	EU/1/98/074/004	Film-coated tablet	-Raloxifene
Opzelura	Incyte Biosciences Distribution B.V.	EU/1/23/1726/001	Cream	-Ruxolitinib
Oralair 100IR & 300IR sublingual tablets	STALLERGENES	PA2113/001/001	Sublingual tablet	-Grass pollen allergen extract
Oralair 300 IR sublingual tablets	STALLERGENES	PA2113/001/002	Sublingual tablet	-Grass pollen allergen extract
Oramorph Concentrated oral solution 20 mg/ml	Glenwood GmbH	PA2256/004/002	Oral solution	-Morphine sulfate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Oramorph Oral Solution 10 mg/5 ml	Glenwood GmbH	PA2256/004/001	Oral solution	-Morphine sulfate
Oramox 125 mg/5 ml Powder for Oral Suspension	Athlone Pharmaceuticals Limited	PA1418/013/001	Powder for oral suspension	-Amoxicillin trihydrate
Oramox 250 mg/5 ml Powder for Oral Suspension	Athlone Pharmaceuticals Limited	PA1418/013/002	Powder for oral suspension	-Amoxicillin
Oramox 250mg Hard Capsules	Athlone Pharmaceuticals Limited	PA1418/013/003	Capsule, hard	-Amoxicillin
Oramox 500mg Hard Capsules	Athlone Pharmaceuticals Limited	PA1418/013/004	Capsule, hard	-Amoxicillin trihydrate
Oraqix 25/25 mg per g Periodontal gel	DENTSPLY DeTrey GmbH	PA1045/004/001	Periodontal gel	-Lidocaine -Prilocaine
Orencia	Bristol-Myers Squibb Pharma EEIG	EU/1/07/389/004-009	Solution for injection in pre-filled syringe	-Abatacept
Orencia	Bristol-Myers Squibb Pharma EEIG	EU/1/07/389/013	Solution for injection in pre-filled syringe	-Abatacept
Orencia	Bristol-Myers Squibb Pharma EEIG	EU/1/07/389/014	Solution for injection in pre-filled syringe	-Abatacept
Orencia	Bristol-Myers Squibb Pharma EEIG	EU/1/07/389/1-3	Powder for concentrate for solution for infusion	-Abatacept
Orfadin	Swedish Orphan Biovitrum AB	EU/1/04/303/004	Capsule, hard	-Nitisinone
Orfadin	Swedish Orphan Biovitrum AB	EU/1/04/303/005	Oral suspension	-Nitisinone
ORFADIN	Swedish Orphan International AB	EU/1/04/303/1-3	Capsule, hard	-Nitisinone
Orgalutran	N.V. Organon	EU/1/00/130/001	Solution for injection	-Ganirelix
Orgalutran	N.V. Organon	EU/1/00/130/002	Solution for injection	-Ganirelix
Orgaran 750 anti-Xa units/0.6ml Solution for injection	Mylan IRE Healthcare Limited	PA2010/068/001	Solution for injection	-Danaparoid sodium
Orgovyx	Accord Healthcare S.L.U.	EU/1/22/1642/001	Film-coated tablet	-Relugolix
Orkambi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/15/1059/001	Film-coated tablet	-Lumacaftor -Ivacaftor
Orkambi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/15/1059/005	Film-coated tablet	-Lumacaftor -Ivacaftor
Orkambi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/15/1059/005-006	Granules in sachet	-Ivacaftor -Lumacaftor
Orkambi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/15/1059/006	Granules in sachet	-Lumacaftor -Ivacaftor
Orkambi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/15/1059/007	Granules in sachet	-Ivacaftor -Lumacaftor
Orkambi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/15/1059/008	Granules	-Lumacaftor -Ivacaftor
Orladeyo	BioCryst Ireland Ltd	EU/1/21/1544/001	Capsule, hard	-Berotralstat hydrochloride -Berotralstat
Orlistat Accord 120 mg hard capsules	Accord Healthcare Ireland Ltd.	PA2315/263/001	Capsule, hard	-Orlistat
Orosoothe 0.15% w/v Oromucosal Spray	Phoenix Labs	PA1113/016/001	Oromucosal spray	-BENZYDAMINE HYDROCHLORIDE
Oroxine 100 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/004	Tablet	-Levothyroxine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Oroxine 125 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/005	Tablet	-Levothyroxine
Oroxine 150 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/006	Tablet	-Levothyroxine
Oroxine 175 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/007	Tablet	-Levothyroxine
Oroxine 200 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/008	Tablet	-Levothyroxine
Oroxine 25 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/001	Tablet	-Levothyroxine sodium
Oroxine 50 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/002	Tablet	-Levothyroxine
Oroxine 75 microgram tablets	Aspen Pharma Trading Limited	PA1691/013/003	Tablet	-Levothyroxine
Orphacol	Laboratoires CTRS	EU/1/13/870/001-003	Capsule, hard	-Cholic acid
Orphacol	Laboratoires CTRS	EU/1/13/870/004-006	Capsule, hard	-Cholic acid
Orserdu	Stemline Therapeutics B.V.	EU/1/23/1757/001	Film-coated tablet	-Elacestrant Dihydrochloride
Orserdu	Stemline Therapeutics B.V.	EU/1/23/1757/002	Film-coated tablet	-Elacestrant Dihydrochloride
Oslif Breezhaler	Novartis Europharm Limited	EU/1/09/586/1-5	Inhalation powder, hard capsule	-Indacaterol maleate
Oslif Breezhaler	Novartis Europharm Limited	EU/1/09/586/6-10	Inhalation powder, hard capsule	-Indacaterol maleate
Osmohale, inhalation powder, hard capsule	Pharmaxis Europe Limited	PA22655/001/001	Inhalation powder, hard capsule	-Mannitol
OSTEOCIS 3mg kit for radiopharmaceutical preparation	CIS bio International	PA0677/007/001	Kit for radiopharmaceutical preparation	-Sodium oxidronate
Osteomel Once Weekly 70 mg tablets	Clonmel Healthcare Ltd	PA0126/148/002	Tablet	-Alendronic acid
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	-Apremilast -Apremilast -Apremilast
Otezla 30 mg film-coated tablets	Amgen Europe B.V.	EU/1/14/981/002-003	Film-coated tablet	-Apremilast
Otrivine Adult 0.1% w/v Nasal Drops, Solution	Haleon Ireland Limited	PA0678/120/001	Nasal drops, solution	-Xylometazoline hydrochloride
Otrivine Adult Menthol 0.1% w/v Nasal Spray, Solution	Haleon Ireland Limited	PA0678/120/004	Nasal spray, solution	-Xylometazoline hydrochloride
Otrivine Congestion Relief 0.1% w/v Nasal Spray, Solution	Haleon Ireland Limited	PA0678/120/002	Nasal spray, solution	-Xylometazoline hydrochloride
Otrivine Congestion Relief Menthol 0.1% w/v Nasal Spray	Haleon Ireland Limited	PA0678/120/005	Nasal spray, solution	-Xylometazoline hydrochloride
Otrivine Extra Dual Relief 0.5mg/ml + 0.6mg/ml nasal spray, solution	Haleon Ireland Limited	PA0678/131/001	Nasal spray, solution	-Xylometazoline hydrochloride -Ipratropium bromide
Otrivine Sinusitis Relief 0.1% w/v Nasal Spray, Solution	Haleon Ireland Limited	PA0678/120/003	Nasal spray, solution	-Xylometazoline hydrochloride
Otrivine-Antistin Eye Drops	Laboratoires Thea	PA1107/008/001	Eye drops, solution	-Xylometazoline hydrochloride -ANTAZOLINE SULFATE
Ovaleap	Theramex Ireland Limited	EU/1/13/871/001-003	Solution for injection	-Follitropin alfa
OVALEAP	Teva B.V.	EU/1/13/871/002	Solution for Injection	-FOLLITROPIN ALFA
OVALEAP	Teva B.V.	EU/1/13/871/003	Solution for Injection	-FOLLITROPIN ALFA

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Ovestin 1mg per gram Vaginal Cream	Aspen Pharma Trading Limited	PA1691/017/001	Vaginal cream	-Estriol
Ovitrelle	Merck Europe B.V.	EU/1/00/165/001	Powder and solvent for solution for injection	-Choriogonadotropin alfa
Ovitrelle	Merck Europe B.V.	EU/1/00/165/002	Powder and solvent for solution for infusion	-Choriogonadotropin alfa
Ovitrelle	Merck Europe B.V.	EU/1/00/165/003	Powder and solvent for solution for infusion	-Choriogonadotropin alfa
Ovitrelle	Merck Europe B.V.	EU/1/00/165/004	Powder and solvent for solution for injection	-Choriogonadotropin alfa
Ovitrelle	Merck Europe B.V.	EU/1/00/165/005	Powder and solvent for solution for injection	-Choriogonadotropin alfa
Ovitrelle	Merck Europe B.V.	EU/1/00/165/006	Powder and solvent for solution for injection	-Choriogonadotropin alfa
Ovitrelle	Ares-Serono (Europe) Limited	EU/1/00/165/007	Solution for injection in pre-filled syringe	-Choriogonadotropin alfa
Ovitrelle	Merck Europe B.V.	EU/1/00/165/008	Solution for injection in pre-filled syringe	-Choriogonadotropin alfa
Ovranette 150 micrograms/30 micrograms coated tablets	Pfizer Healthcare Ireland	PA0822/094/001	Coated tablet	-Ethinylestradiol -Levonorgestrel
Ovreea 30 micrograms/150 micrograms coated tablets	Gedeon Richter Plc	PA1330/015/001	Coated tablet	-Ethinylestradiol -Levonorgestrel
Oxaliplatin 5 mg/ml concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/049/001	Concentrate for solution for infusion	-Oxaliplatin
Oxaliplatin 5mg/ml Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/114/001	Concentrate for solution for infusion	-Oxaliplatin
Oxaliplatin medac 5 mg/ml powder for solution for infusion	medac Gesellschaft für klinische Spezialpräparate mbH	PA0623/008/001	Powder for solution for infusion	-Oxaliplatin
Oxbryta	Pfizer Europe MA EEIG	EU/1/21/1622/001	Film-coated tablet	-Voxelotor
Oxervate	Dompe farmaceutici SpA	EU/1/17/1197/01	Eye drops, solution	-Recombinant human nerve growth factor (rhngf)
Oxis Turbohaler 12, inhalation powder	AstraZeneca AB	PA1019/015/002	Inhalation powder	-Formoterol fumarate dihydrate
Oxis Turbohaler 6, inhalation powder	AstraZeneca AB	PA1019/015/001	Inhalation powder	-Formoterol fumarate dihydrate
Oxlumo	Alnylam Netherlands B.V.	EU/1/20/1496/001	Solution for injection	-Lumasiran sodium
Oxybuprocaine Agepha 4 mg/ml eye drops, solution	AGEPHA Pharma s.r.o.	PA22584/002/001	Eye drops, solution	-Oxybuprocaine hydrochloride
Oxybutynin hydrochloride 2.5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/038/001	Tablet	-Oxybutynin hydrochloride
Oxybutynin hydrochloride 2.5 mg/5 ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/014/001	Oral solution	-Oxybutynin hydrochloride
Oxybutynin hydrochloride 5 mg/5 ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/014/002	Oral solution	-Oxybutynin hydrochloride
Oxybutynin Hydrochloride 5mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/038/002	Tablet	-Oxybutynin hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Oxycodone Hydrochloride 10 mg/ml Solution for Injection or Infusion	Pinewood Laboratories Ltd	PA0281/235/001	Solution for injection/infusion	-OXYCODONE HYDROCHLORIDE
Oxycodone hydrochloride 10 mg/ml solution for injection/infusion	AS Kalceks	PA2165/005/001	Solution for injection/infusion	-OXYCODONE HYDROCHLORIDE
Oxycodone hydrochloride 10mg/ml solution for injection or infusion	hameln pharma gmbh	PA2237/001/001	Solution for injection/infusion	-OXYCODONE HYDROCHLORIDE
Oxycodone hydrochloride 50 mg/ml solution for injection/infusion	AS Kalceks	PA2165/005/002	Solution for injection/infusion	-OXYCODONE HYDROCHLORIDE
Oxycodone hydrochloride 50mg/ml solution for injection or infusion	Pinewood Laboratories Ltd	PA0281/235/002	Solution for injection/infusion	-OXYCODONE HYDROCHLORIDE
Oxycodone hydrochloride Rowex 10 mg Hard capsules	Rowex Ltd	PA0711/286/002	Capsule, hard	-OXYCODONE HYDROCHLORIDE
Oxycodone hydrochloride Rowex 20 mg Hard capsules	Rowex Ltd	PA0711/286/003	Capsule, hard	-OXYCODONE HYDROCHLORIDE
Oxycodone hydrochloride Rowex 5 mg Hard capsules	Rowex Ltd	PA0711/286/001	Capsule, hard	-OXYCODONE HYDROCHLORIDE
Oxycodone Lannacher SR 10 mg prolonged release tablet	Lannacher Heilmittel Ges.m.b.H	PA0947/003/002	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE
Oxycodone Lannacher SR 20 mg prolonged release tablets	Lannacher Heilmittel Ges.m.b.H	PA0947/003/003	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE
Oxycodone Lannacher SR 40 mg prolonged release tablets	Lannacher Heilmittel Ges.m.b.H	PA0947/003/004	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE
Oxycodone Lannacher SR 5 mg prolonged release tablet	Lannacher Heilmittel Ges.m.b.H	PA0947/003/001	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE
Oxycodone Lannacher SR 80 mg prolonged release tablets	Lannacher Heilmittel Ges.m.b.H	PA0947/003/005	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE
OxyContin 10 mg prolonged release tablets	Mundipharma Pharmaceuticals Limited	PA1688/005/002	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE
OxyContin 20 mg prolonged release tablets	Mundipharma Pharmaceuticals Limited	PA1688/005/003	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE
OxyContin 40 mg prolonged release tablets	Mundipharma Pharmaceuticals Limited	PA1688/005/004	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE
OxyContin 5 mg prolonged release tablets	Mundipharma Pharmaceuticals Limited	PA1688/005/001	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE
OxyContin 80 mg prolonged release tablets	Mundipharma Pharmaceuticals Limited	PA1688/005/005	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE
OxyNorm 10 mg hard capsules	Mundipharma Pharmaceuticals Limited	PA1688/006/005	Capsule, hard	-OXYCODONE HYDROCHLORIDE
OxyNorm 10 mg/ml, solution for injection or infusion	Mundipharma Pharmaceuticals Limited	PA1688/006/001	Solution for injection/infusion	-OXYCODONE HYDROCHLORIDE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
OxyNorm 20 mg hard capsules	Mundipharma Pharmaceuticals Limited	PA1688/006/006	Capsule, hard	-OXYCODONE HYDROCHLORIDE
OxyNorm 5 mg hard capsules	Mundipharma Pharmaceuticals Limited	PA1688/006/004	Capsule, hard	-OXYCODONE HYDROCHLORIDE
OxyNorm 50 mg/ml, solution for injection or infusion	Mundipharma Pharmaceuticals Limited	PA1688/006/010	Solution for injection/infusion	-OXYCODONE HYDROCHLORIDE
OxyNorm concentrate 10mg/ml oral solution	Mundipharma Pharmaceuticals Limited	PA1688/006/003	Oral solution	-OXYCODONE HYDROCHLORIDE
OxyNorm Dispersa 10 mg Orodispersible Tablets	Mundipharma Pharmaceuticals Limited	PA1688/006/008	Orodispersible tablet	-OXYCODONE HYDROCHLORIDE
OxyNorm Dispersa 20 mg orodispersible tablets	Mundipharma Pharmaceuticals Limited	PA1688/006/009	Orodispersible tablet	-OXYCODONE HYDROCHLORIDE
OxyNorm Dispersa 5 mg Orodispersible Tablets	Mundipharma Pharmaceuticals Limited	PA1688/006/007	Orodispersible tablet	-OXYCODONE HYDROCHLORIDE
OxyNorm liquid 1mg/ml oral solution	Mundipharma Pharmaceuticals Limited	PA1688/006/002	Oral solution	-OXYCODONE HYDROCHLORIDE
Oxytocin 10 IU/ml Concentrate for Solution for Infusion	Pinewood Laboratories Ltd	PA0281/239/001	Concentrate for solution for infusion	-Oxytocin
Oyavas	Stada Arzneimittel AG	EU/1/20/1510/001-002	Concentrate for solution for infusion	-Bevacizumab
Ozalin 2 mg/ml oral solution in single-dose container	Primex Pharmaceuticals Oy	PA1719/002/001	Oral solution in single-dose container	-Midazolam
Ozawade	Bioprojet Pharma	EU/1/21/1546/001	Film-coated tablet	-Pitolisant hydrochloride
Ozawade	Bioprojet Pharma	EU/1/21/1546/002-003	Film-coated tablet	-Pitolisant hydrochloride
Ozempic	Novo Nordisk A/S	EU/1/17/1251/002	Solution for injection in pre-filled pen	-Semaglutide
Ozempic	Novo Nordisk A/S	EU/1/17/1251/002-006	Solution for infusion in pre-filled syringe	-semaglutide
Ozempic	Novo Nordisk A/S	EU/1/17/1251/003-004	Solution for injection in pre-filled pen	-Semaglutide
Ozempic	Novo Nordisk A/S	EU/1/17/1251/005-006	Solution for injection in pre-filled pen	-Semaglutide
Ozempic®	Novo Nordisk A/S	EU/1/17/1251/010-011	Solution for injection in pre-filled pen	-Semaglutide
Ozurdex	AbbVie Deutschland GmbH & Co. KG	EU/1/10/638/001	Intravitreal implant in applicator	-Dexamethasone
Pabal 100 micrograms/ml, solution for injection	Ferring Ireland Ltd	PA1009/021/001	Solution for injection	-Carbetocin
Pabrinex Intravenous High Potency Concentrate for Solution for Infusion	Kyowa Kirin Holdings B.V.	PA2288/001/001	Concentrate for solution for infusion	-Ascorbic acid -Riboflavin -Pyridoxine hydrochloride -Nicotinamide -Thiamine hydrochloride -Glucose (as monohydrate)
Paclitaxel 6 mg/ml concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/180/001	Concentrate for solution for infusion	-Paclitaxel
Paclitaxel 6 mg/ml concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/050/001	Concentrate for solution for infusion	-Paclitaxel

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Paclitaxel 6 mg/ml, Concentrate for Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/115/001	Concentrate for solution for infusion	-Paclitaxel
Padcev	Astellas Pharma Europe B.V.	EU/1/21/1615/001	Powder for concentrate for solution for infusion	-Enfortumab Vedotin
Padcev	Astellas Pharma Europe B.V.	EU/1/21/1615/002	Powder for concentrate for solution for infusion	-Enfortumab Vedotin
Paedisol Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/029/001	Solution for infusion	-Sodium chloride -Potassium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Sodium acetate trihydrate -Glucose monohydrate
PAGLITAZ	Krka d.d., Novo mesto	EU/1/11/721/001-007	Tablet	-PIOGLITAZONE HYDROCHLORIDE
PAGLITAZ	Krka d.d., Novo mesto	EU/1/11/721/008-014	Tablet	-PIOGLITAZONE HYDROCHLORIDE
PAGLITAZ	Krka d.d., Novo mesto	EU/1/11/721/015-021	Tablet	-PIOGLITAZONE HYDROCHLORIDE
Palexia 100 mg film-coated tablets	Grunenthal Pharma Ltd	PA2242/012/003	Film-coated tablet	-Tapentadol
PALEXIA 20 mg/ml oral solution	Grunenthal Pharma Ltd	PA2242/012/011	Oral solution	-Tapentadol hydrochloride
PALEXIA 4 mg/ml oral solution	Grunenthal Pharma Ltd	PA2242/012/010	Oral solution	-Tapentadol hydrochloride
Palexia 50 mg film-coated tablets	Grunenthal Pharma Ltd	PA2242/012/001	Film-coated tablet	-Tapentadol
Palexia 75 mg film-coated tablets	Grunenthal Pharma Ltd	PA2242/012/002	Film-coated tablet	-Tapentadol
Palexia SR 100 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/012/005	Prolonged-release tablet	-Tapentadol
Palexia SR 150 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/012/006	Prolonged-release tablet	-Tapentadol
Palexia SR 200 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/012/007	Prolonged-release tablet	-Tapentadol
PALEXIA SR 25 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/012/009	Prolonged-release tablet	-Tapentadol hydrochloride
Palexia SR 250 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/012/008	Prolonged-release tablet	-Tapentadol
Palexia SR 50 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/012/004	Prolonged-release tablet	-Tapentadol
Palforzia	Aimmune Therapeutics Netherlands B.V.	EU/1/20/1495/001	Oral powder in capsules for opening	-Arachis Hypogaea Allergens
Palforzia	Aimmune Therapeutics Netherlands B.V.	EU/1/20/1495/002-003	Oral powder in capsules for opening	-Arachis Hypogaea Allergens
Palforzia	Aimmune Therapeutics Netherlands B.V.	EU/1/20/1495/004	Oral powder in capsules for opening	-Arachis Hypogaea Allergens
Palforzia	Aimmune Therapeutics Netherlands B.V.	EU/1/20/1495/005-010	Oral powder in capsules for opening	-Arachis Hypogaea Allergens
Palforzia	Aimmune Therapeutics Netherlands B.V.	EU/1/20/1495/011	Oral powder in capsules for opening	-Arachis Hypogaea Allergens

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Palforzia	Aimmune Therapeutics Netherlands B.V.	EU/1/20/1495/012-013	Oral powder in sachet	-Arachis Hypogaea Allergens
Paliperidone Janssen 100 mg prolonged-release suspension for injection.	Janssen-Cilag International NV	EU/1/14/971/004	Prolonged-release suspension for injection	-Paliperidone palmitate (r092670)
Paliperidone Janssen 150 mg and Paliperidone Janssen 100 mg prolonged-release suspension for injection.	Janssen-Cilag International NV	EU/1/14/971/006	Prolonged-release suspension for injection	-Paliperidone palmitate (r092670) -Paliperidone palmitate (r092670)
Paliperidone Janssen 150 mg prolonged-release suspension for injection.	Janssen-Cilag International NV	EU/1/14/971/005	Prolonged-release suspension for injection	-Paliperidone palmitate (r092670)
Paliperidone Janssen 25 mg prolonged-release suspension for injection.	Janssen-Cilag International NV	EU/1/14/971/001	Prolonged-release suspension for injection	-Paliperidone palmitate (r092670)
Paliperidone Janssen 50 mg prolonged-release suspension for injection.	Janssen-Cilag International NV	EU/1/14/971/002	Prolonged-release suspension for injection	-Paliperidone palmitate (r092670)
Paliperidone Janssen 75 mg prolonged-release suspension for injection.	Janssen-Cilag International NV	EU/1/14/971/003	Prolonged-release suspension for injection	-Paliperidone palmitate (r092670)
Paliperidone Janssen-Cilag International 100 mg prolonged-release suspension for injection	Janssen Pharmaceutica NV	EU/1/20/1453/004	Prolonged-release suspension for injection	-Paliperidone palmitate
Paliperidone Janssen-Cilag International 150 mg and Paliperidone Janssen-Cilag International 100 mg prolonged-release suspension for injection	Janssen Pharmaceutica NV	EU/1/20/1453/006	Prolonged-release suspension for injection	-Paliperidone palmitate
Paliperidone Janssen-Cilag International 150 mg prolonged-release suspension for injection	Janssen Pharmaceutica NV	EU/1/20/1453/005	Prolonged-release suspension for injection	-Paliperidone palmitate
Paliperidone Janssen-Cilag International 25 mg prolonged-release suspension for injection	Janssen Pharmaceutica NV	EU/1/20/1453/001	Prolonged-release suspension for injection	-Paliperidone palmitate
Paliperidone Janssen-Cilag International 50 mg prolonged-release suspension for injection	Janssen Pharmaceutica NV	EU/1/20/1453/002	Prolonged-release suspension for injection	-Paliperidone palmitate
Paliperidone Janssen-Cilag International 75 mg prolonged-release suspension for injection	Janssen Pharmaceutica NV	EU/1/20/1453/003	Prolonged-release suspension for injection	-Paliperidone palmitate
Paliperidone Krka 3 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/092/001	Prolonged-release tablet	-Paliperidone

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Paliperidone Krka 6 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/092/002	Prolonged-release tablet	-Paliperidone
Paliperidone Krka 9 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/092/003	Prolonged-release tablet	-Paliperidone
Paliperidone Teva 100 mg prolonged-release suspension for injection	Norton Waterford	PA0436/050/004	Prolonged-release suspension for injection	-Paliperidone
Paliperidone Teva 150 mg and Paliperidone Teva 100 mg prolonged-release suspension for injection	Norton Waterford	PA0436/050/006	Prolonged-release suspension for injection	-Paliperidone -Paliperidone
Paliperidone Teva 150 mg prolonged-release suspension for injection	Norton Waterford	PA0436/050/005	Prolonged-release suspension for injection	-Paliperidone
Paliperidone Teva 25 mg prolonged-release suspension for injection	Norton Waterford	PA0436/050/001	Prolonged-release suspension for injection	-Paliperidone
Paliperidone Teva 50 mg prolonged-release suspension for injection	Norton Waterford	PA0436/050/002	Prolonged-release suspension for injection	-Paliperidone
Paliperidone Teva 75 mg prolonged-release suspension for injection	Norton Waterford	PA0436/050/003	Prolonged-release suspension for injection	-Paliperidone
Palladone 1.3 mg capsules	Mundipharma Pharmaceuticals Limited	PA1688/007/001	Capsule, hard	-Hydromorphone hydrochloride
Palladone 2.6 mg capsules	Mundipharma Pharmaceuticals Limited	PA1688/007/002	Capsule, hard	-Hydromorphone hydrochloride
Palladone SR 16 mg Prolonged-release Capsules	Mundipharma Pharmaceuticals Limited	PA1688/007/010	Prolonged-release capsule, hard	-Hydromorphone hydrochloride
Palladone SR 2 mg prolonged release capsules, hard	Mundipharma Pharmaceuticals Limited	PA1688/007/007	Prolonged-release capsule, hard	-Hydromorphone hydrochloride
Palladone SR 4 mg Prolonged-release Capsules	Mundipharma Pharmaceuticals Limited	PA1688/007/008	Prolonged-release capsule, hard	-Hydromorphone hydrochloride
Palladone SR 8 mg Prolonged-release Capsules	Mundipharma Pharmaceuticals Limited	PA1688/007/009	Prolonged-release capsule, hard	-Hydromorphone hydrochloride
Palmeux 100 mg prolonged-release suspension for injection in pre-filled syringe	Amdipharm Limited	PA1142/040/004	Prolonged-release suspension for injection in pre-filled syringe	-Paliperidone palmitate
Palmeux 150 mg prolonged-release suspension for injection in pre-filled syringe	Amdipharm Limited	PA1142/040/005	Prolonged-release suspension for injection in pre-filled syringe	-Paliperidone palmitate
Palmeux 25 mg prolonged-release suspension for injection in pre-filled syringe	Amdipharm Limited	PA1142/040/001	Prolonged-release suspension for injection in pre-filled syringe	-Paliperidone palmitate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Palmeux 50 mg prolonged-release suspension for injection in pre-filled syringe	Amdipharm Limited	PA1142/040/002	Prolonged-release suspension for injection in pre-filled syringe	-Paliperidone palmitate
Palmeux 75 mg prolonged-release suspension for injection in pre-filled syringe	Amdipharm Limited	PA1142/040/003	Prolonged-release suspension for injection in pre-filled syringe	-Paliperidone palmitate
Palonosetron 250 micrograms Solution for injection	Fresenius Kabi Deutschland GmbH	PA2059/014/001	Solution for injection	-Palonosetron hydrochloride
Palonosetron 250 micrograms solution for injection in pre-filled syringe	Fresenius Kabi Deutschland GmbH	PA2059/014/002	Solution for injection in pre-filled syringe	-Palonosetron hydrochloride
Palonosetron Accord	Accord Healthcare S.L.U.	EU/1/16/1104/001	Solution for injection	-Palonosetron hydrochloride
Palynziq	BioMarin International Limited	EU/1/19/1362/001	Solution for injection in pre-filled syringe	-PEGVALIASE
Palynziq	BioMarin International Limited	EU/1/19/1362/002	Solution for injection in pre-filled syringe	-PEGVALIASE
Palynziq	BioMarin International Limited	EU/1/19/1362/003-004	Solution for injection in pre-filled syringe	-PEGVALIASE
Panadeine Extra Strength Tablets Paracetamol 500 mg Codeine Phosphate hemihydrate 12.8 mg	Haleon Ireland Limited	PA0678/026/003	Film-coated tablet	-Paracetamol -Codeine phosphate hemihydrate
Panadol Cold and Flu Relief Orange Effervescent Tablets Paracetamol 500 mg Caffeine 65 mg	Haleon Ireland Limited	PA0678/105/002	Effervescent tablet	-Paracetamol -Caffeine
Panadol Extra 500mg/65mg Soluble Effervescent Tablets	Haleon Ireland Limited	PA0678/039/010	Effervescent tablet	-Paracetamol -Caffeine
Panadol Fever and Congestion Film-coated Tablets Paracetamol 500mg Pseudoephedrine Hydrochloride 30mg	Haleon Ireland Limited	PA0678/094/001	Film-coated tablet	-Paracetamol -PSEUDOEPHEDRINE HYDROCHLORIDE
Panadol Max Strength Fever and Congestion Hot Lemon Powder for Oral Solution Paracetamol 1000mg Phenylephrine hydrochloride 10mg Ascorbic Acid 40mg	Haleon Ireland Limited	PA0678/035/001	Powder for oral solution	-Paracetamol -Phenylephrine hydrochloride -Ascorbic acid
Panadol Night	Haleon Ireland Limited	PA0678/039/008	Film-coated tablet	-Paracetamol -Diphenhydramine hydrochloride
Panadol Sinus Relief Film Coated Tablets Paracetamol 500mg Caffeine 25mg Phenylephrine Hydrochloride 5mg	Haleon Ireland Limited	PA0678/044/001	Film-coated tablet	-Paracetamol -Caffeine -Phenylephrine hydrochloride
Panagram Max 1g Film coated tablets	Haleon Ireland Limited	PA0678/039/009	Film-coated tablet	-Paracetamol

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Pandemic influenza vaccine (H5N1) MedImmune - pandemic influenza vaccine h5n1 (live attenuated, nasal)	AstraZeneca AB	EU/1/16/1089/001	Nasal spray, suspension	-Strain. a/vietnam/1203/2004 (h5n1) strain (live attenuated)
Pantium 20 mg Gastro-resistant tablets	Clonmel Healthcare Ltd	PA0126/175/001	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate
Pantium 40mg Gastro-Resistant Tablets	Clonmel Healthcare Ltd	PA0126/175/002	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate
Pantoprazole 40 mg Powder for Solution for Injection	Laboratorio Reig Jofre, S.A.	PA1618/001/001	Powder for solution for injection	-Pantoprazole
Pantoprazole 40 mg powder for solution for injection	AS Kalceks	PA2165/020/001	Powder for solution for injection	-Pantoprazole sodium sesquihydrate
Pantoprazole Azevedos 40 mg powder for solution for injection/infusion	Laboratórios Azevedos - Indústria Farmacéutica S.A	PA1852/001/001	Powder for solution for injection/infusion	-Pantoprazole sodium sesquihydrate
Pantoprazole Bluefish 20 mg gastro-resistant tablets	Bluefish Pharmaceuticals AB	PA1436/008/001	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate
Pantoprazole Bluefish 40 mg gastro-resistant tablets	Bluefish Pharmaceuticals AB	PA1436/008/002	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate
Pantoprazole Mylan 20 mg Gastro-resistant Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/146/001	Gastro-resistant tablet	-Pantoprazole
Pantoprazole Mylan 40 mg Gastro-resistant Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/146/002	Gastro-resistant tablet	-Pantoprazole
Pantoprazole Noridem 40 mg Powder for Solution for Injection	Noridem Enterprises Limited	PA1122/011/001	Powder for solution for injection	-Pantoprazole
Pantoprazole Teva Pharma 20 mg gastro-resistant tablets	Teva Pharma B.V.	PA0749/144/001	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate
Pantoprazole Teva Pharma 40 mg gastro-resistant tablets	Teva Pharma B.V.	PA0749/144/002	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate
PANTOZOL Control	Takeda GmbH	EU/1/09/517/001	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate
PANTOZOL Control	Takeda GmbH	EU/1/09/517/001-004	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate
Pantup 20 mg gastro-resistant tablets	Rowa Pharmaceuticals Limited	PA0074/069/001	Gastro-resistant tablet	-Pantoprazole
Pantup 40 mg gastro-resistant tablets	Rowa Pharmaceuticals Limited	PA0074/069/002	Gastro-resistant tablet	-Pantoprazole
Pantup Relief 20 mg Gastro-resistant tablets	Rowex Ltd	PA0711/142/003	Gastro-resistant tablet	-Pantoprazole
Panzyga, 100 mg/ml solution for infusion	Octapharma (IP) SPRL	PA2219/010/001	Solution for infusion	-Human normal immunoglobulin
Paracetamol 10 mg/ml Solution for Infusion	Accord Healthcare Ireland Ltd.	PA2315/170/001	Solution for infusion	-Paracetamol
Paracetamol 10 mg/ml solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/218/001	Solution for infusion	-Paracetamol
Paracetamol 10 mg/ml solution for infusion	Baxter Holding B.V.	PA2299/049/001	Solution for infusion	-Paracetamol
Paracetamol 10 mg/ml solution for infusion	Baxter Holding B.V.	PA2299/056/001	Solution for infusion	-Paracetamol
Paracetamol 10 mg/ml Solution for Infusion	Laboratoire AGUETTANT	PA1968/021/001	Solution for infusion	-Paracetamol

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Paracetamol 10 mg/ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/015/001	Solution for infusion	-Paracetamol
Paracetamol 10 mg/ml solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/015/002	Solution for infusion	-Paracetamol
Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour Paracetamol 1000mg, Phenylephrine HCl 12.2mg Powder for oral solution	WICK Pharma - Zweigniederlassung der Procter & Gamble GmbH	PA2294/001/001	Powder for oral solution	-Phenylephrine hydrochloride -Paracetamol
Paracetamol 10mg/ml solution for infusion	B. Braun Melsungen AG	PA0736/035/001	Solution for infusion	-Paracetamol
Paracetamol 125 mg suppositories	Phoenix Labs	PA1113/004/004	Suppository	-Paracetamol
Paracetamol 250mg Suppositories	Phoenix Labs	PA1113/004/001	Suppository	-Paracetamol
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	-Paracetamol -Guaifenesin -Phenylephrine hydrochloride
Paracetamol 500mg Suppositories	Phoenix Labs	PA1113/004/002	Suppository	-Paracetamol
Paracetamol 500mg/5ml Oral Solution	Pinewood Laboratories Ltd	PA0281/243/001	Oral solution	-Paracetamol
Paracetamol 500mg/Guaifenesin 100mg/Phenylephrine hydrochloride 6.1mg capsules, hard	Chefaro Ireland DAC	PA1186/025/001	Capsule, hard	-Paracetamol -Guaifenesin -Phenylephrine hydrochloride
Paracetamol 80 mg suppositories	Phoenix Labs	PA1113/004/003	Suppository	-Paracetamol
Paracetamol Genmed 500 mg tablets	Genmed B.V.	PA1519/001/001	Tablet	-Paracetamol
Paracetamol Krka 500 mg tablets	KRKA, d.d., Novo mesto	PA1347/095/001	Tablet	-Paracetamol
Paracetamol Teva 500 mg film-coated tablets	Teva B.V.	PA1986/101/001	Film-coated tablet	-Paracetamol
Paracetamol/Codeine 500 mg/30 mg, effervescent tablets	Brillpharma (Ireland) Limited	PA22749/009/001	Effervescent tablet	-Paracetamol -Codeine phosphate hemihydrate
Paracetamol/Codeine phosphate hemihydrate Accord 500 mg/30 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/255/001	Tablet	-Paracetamol -Codeine phosphate hemihydrate
Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord 500 mg/8 mg/30 mg effervescent tablets	Accord Healthcare Ireland Ltd.	PA2315/267/001	Effervescent tablet	-Paracetamol -Codeine phosphate hemihydrate -Caffeine
Paracodin 0.20% w/w Syrup	Teofarma S.R.L.	PA1235/004/002	Syrup	-Dihydrocodeine tartrate
Paracodin 10 mg Tablets	Teofarma S.R.L.	PA1235/004/003	Tablet	-Dihydrocodeine Hydrogen Tartrate
Paracodin 10 mg/g Oral Drops, Solution	Teofarma S.R.L.	PA1235/004/001	Oral drops, solution	-Dihydrocodeine hydrorhodanide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Paralief Cold & Flu hard capsules Paracetamol 300 mg Caffeine 25 mg Phenylephrine hydrochloride 5 mg	Clonmel Healthcare Ltd	PA0126/272/001	Capsule, hard	-Paracetamol -Caffeine -Phenylephrine hydrochloride
Paralief Hot Lemon Drink 600 mg powder for oral solution in sachet	Clonmel Healthcare Ltd	PA0126/020/006	Powder for oral solution in sachet	-Paracetamol
Paralief Night Film-coated Tablets Paracetamol 500 mg Diphenhydramine hydrochloride 25 mg	Clonmel Healthcare Ltd	PA0126/338/001	Film-coated tablet	-Paracetamol -Diphenhydramine hydrochloride
Paralief Sinus Tablets Paracetamol 500 mg Pseudoephedrine hydrochloride 30 mg	Clonmel Healthcare Ltd	PA0126/339/001	Tablet	-Paracetamol -PSEUDOEPHEDRINE HYDROCHLORIDE
Paralink 180 mg suppositories	Phoenix Healthcare Ltd	PA1721/006/002	Suppository	-Paracetamol
Paralink 500 mg suppositories	Phoenix Healthcare Ltd	PA1721/006/003	Suppository	-Paracetamol
Parecoxib 40 mg powder and solvent for solution for injection	Noridem Enterprises Limited	PA1122/028/001	Powder and solvent for solution for injection	-Parecoxib
Parecoxib 40 mg powder for solution for injection	Noridem Enterprises Limited	PA1122/028/002	Powder for solution for injection	-Parecoxib
Paricalcitol 5 micrograms/ml solution for injection	Pinewood Laboratories Ltd	PA0281/163/001	Solution for injection	-Paricalcitol
PARIET 10 mg gastro-resistant tablet	Janssen Sciences Ireland UC	PA22612/009/001	Gastro-resistant tablet	-Rabeprazole sodium
PARIET 20 mg gastro-resistant tablet	Janssen Sciences Ireland UC	PA22612/009/002	Gastro-resistant tablet	-Rabeprazole sodium
Parlodol 2.5 mg Tablets	Mylan IRE Healthcare Limited	PA2010/042/001	Tablet	-BROMOCRIPTINE MESILATE
Parnate 10 mg coated tablets	Amdipharm Limited	PA1142/035/001	Coated tablet	-Tranlycypromine
Parox 10mg Film-Coated Tablets	Rowex Ltd	PA0711/052/003	Film-coated tablet	-Paroxetine
Parox 20mg Film-Coated Tablets	Rowex Ltd	PA0711/052/001	Film-coated tablet	-Paroxetine hydrochloride
Parox 30 mg Film-Coated Tablets	Rowex Ltd	PA0711/052/004	Film-coated tablet	-Paroxetine
Parsabiv	Amgen Europe B.V.	EU/1/16/1142/001-004	Solution for injection	-Etelcalcetide hydrochloride
Parsabiv	Amgen Europe B.V.	EU/1/16/1142/005-008	Solution for injection	-Etelcalcetide hydrochloride
Parsabiv	Amgen Europe B.V.	EU/1/16/1142/009-012	Solution for injection	-Etelcalcetide hydrochloride
Parvolex 200mg/ml concentrate for Solution for Infusion	Phoenix Labs	PA1113/008/001	Concentrate for solution for infusion	-Acetylcysteine
Paxlovid	Pfizer Europe MA EEIG	EU/1/22/1625/001	Film-coated tablet	-PF-07321332
Pazenir	Ratiopharm GmbH	EU/1/18/1317/001	Powder for dispersion for infusion	-Paclitaxel
Pazopanib Accord 200 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/265/001	Film-coated tablet	-Pazopanib hydrochloride
Pazopanib Accord 400 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/265/002	Film-coated tablet	-Pazopanib hydrochloride
PecFent	Kyowa Kirin Holdings B.V.	EU/1/10/644/001-002	Nasal spray, solution	-Fentanyl, as citrate salt
PecFent	Kyowa Kirin Holdings B.V.	EU/1/10/644/003-004	Nasal spray, solution	-Fentanyl, as citrate salt

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
PEDEA	Recordati Rare Diseases	EU/1/04/284/001	Solution for injection	-Ibuprofen
Pedippi 2 mg/ml powder for oral suspension	Xeolas Pharmaceuticals Limited	PA1572/002/001	Powder for oral suspension	-Omeprazole
Pedippi 4 mg/ml powder for oral suspension	Xeolas Pharmaceuticals Limited	PA1572/002/002	Powder for oral suspension	-Omeprazole
Peditrace concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/051/001	Concentrate for solution for infusion	-Zinc chloride -Copper chloride 2H ₂ O -Manganese chloride 4H ₂ O -Sodium selenite anhydrous -Sodium fluoride -Potassium iodide
Pedmarqsi	Fennec Pharmaceuticals (EU) Limited	EU/1/23/1734/001	Solution for infusion	-Sodium thiosulfate
Pegasys	Pharmaand GmbH	EU/1/02/221/003-004	Solution for injection	-Peginterferon-alfa-2a
Pegasys	Pharmaand GmbH	EU/1/02/221/005-006	Solution for injection in pre-filled syringe	-Peginterferon-alfa-2a
Pegfilgrastim Mundipharma	Mundipharma Corporation (Ireland) Limited	EU/1/19/1409/001	Solution for injection in pre-filled syringe	-Pegfilgrastim
Peglax 10 g powder for oral solution in sachet	Casen-Recordati S.L.	PA2028/003/001	Powder for oral solution	-Macrogol 4000
Peiotal 25 microgram/125 microgram/dose pressurised inhalation, suspension	Genetic S.p.A.	PA23010/001/002	Pressurised inhalation, suspension	-Salmeterol -Fluticasone propionate
Peiotal 25 microgram/250 microgram/dose pressurised inhalation, suspension	Genetic S.p.A.	PA23010/001/003	Pressurised inhalation, suspension	-Salmeterol -Fluticasone propionate
Peiotal 25 microgram/50 microgram/dose pressurised inhalation, suspension	Genetic S.p.A.	PA23010/001/001	Pressurised inhalation, suspension	-Salmeterol -Fluticasone propionate
Pelgraz	Accord Healthcare S.L.U.	EU/1/18/1313/001	Solution for injection in pre-filled syringe	-Pegfilgrastim
Pelmeg	Mundipharma Corporation (Ireland) Limited	EU/1/18/1328/001	Solution for injection in pre-filled syringe	-Pegfilgrastim
Pemazyre	Incyte Biosciences Distribution B.V.	EU/1/21/1535/001-002	Tablet	-Pemigatinib
Pemazyre	Incyte Biosciences Distribution B.V.	EU/1/21/1535/003-004	Tablet	-Pemigatinib
Pemazyre	Incyte Biosciences Distribution B.V.	EU/1/21/1535/005-006	Tablet	-Pemigatinib
Pemetrexed 25 mg/ml concentrate for solution for infusion	BioOrganics BV	PA1082/004/001	Concentrate for solution for infusion	-Pemetrexed
Pemetrexed Accord	Accord Healthcare S.L.U.	EU/1/15/1071/001	Powder for concentrate for solution for infusion	-Pemetrexed disodium -Pemetrexed
Pemetrexed Accord	Accord Healthcare S.L.U.	EU/1/15/1071/002	Powder for concentrate for solution for infusion	-Pemetrexed disodium -Pemetrexed
Pemetrexed Accord	Accord Healthcare S.L.U.	EU/1/15/1071/003	Powder for concentrate for solution for infusion	-Pemetrexed -Pemetrexed disodium

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Pemetrexed Accord	Accord Healthcare S.L.U.	EU/1/15/1071/004-007	Concentrate for solution for infusion	-Pemetrexed -Pemetrexed Disodium Hemipentahydrate
Pemetrexed Baxter	Baxter Holding B.V.	EU/1/22/1705/001	Powder for concentrate for solution for infusion	-Pemetrexed disodium heptahydrate
Pemetrexed Baxter	Baxter Holding B.V.	EU/1/22/1705/002	Powder for concentrate for solution for infusion	-Pemetrexed disodium heptahydrate
Pemetrexed Clonmel 25 mg/ml concentrate for solution for infusion	Clonmel Healthcare Ltd	PA0126/270/001	Concentrate for solution for infusion	-Pemetrexed
Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion	EVER Valinject GmbH	PA1774/005/001	Concentrate for solution for infusion	-Pemetrexed
Pemetrexed Fresenius Kabi	Fresenius Kabi Deutschland GmbH	EU/1/16/1115/001	Concentrate for solution for infusion	-Pemetrexed
Pemetrexed Fresenius Kabi	Fresenius Kabi Deutschland GmbH	EU/1/16/1115/002	Concentrate for solution for infusion	-Pemetrexed
Pemetrexed Fresenius Kabi	Fresenius Kabi Deutschland GmbH	EU/1/16/1115/003-005	Concentrate for solution for infusion	-Pemetrexed
Pemetrexed Hospira	Pfizer Europe MA EEIG	EU/1/15/1057/001	Powder for concentrate for solution for infusion	-Pemetrexed disodium
Pemetrexed Hospira	Pfizer Europe MA EEIG	EU/1/15/1057/002	Powder for concentrate for solution for infusion	-Pemetrexed disodium
Pemetrexed Hospira	Pfizer Europe MA EEIG	EU/1/15/1057/003	Powder for concentrate for solution for infusion	-Pemetrexed disodium
Pemetrexed Hospira	Pfizer Europe MA EEIG	EU/1/15/1057/004-006	Concentrate for solution for infusion	-Pemetrexed Disodium Hemipentahydrate -Pemetrexed
Pemetrexed Hospira Limited	Pfizer Europe MA EEIG	EU/1/17/1183/001	Powder for concentrate for solution for infusion	-Pemetrexed ditromethamine
Pemetrexed Hospira Limited	Pfizer Europe MA EEIG	EU/1/17/1183/002	Powder for concentrate for solution for infusion	-Pemetrexed ditromethamine
Pemetrexed Hospira Limited	Pfizer Europe MA EEIG	EU/1/17/1183/003	Powder for concentrate for solution for infusion	-Pemetrexed ditromethamine
Pemetrexed Krka	KRKA, d.d., Novo mesto	EU/1/18/1283/001	Powder for concentrate for solution for infusion	-Pemetrexed disodium heptahydrate
Pemetrexed Krka	KRKA, d.d., Novo mesto	EU/1/18/1283/002	Powder for concentrate for solution for infusion	-Pemetrexed disodium heptahydrate
Pemetrexed Lilly	Eli Lilly Nederland B.V.	EU/1/15/1034/001	Powder for concentrate for solution for infusion	-Pemetrexed disodium heptahydrate
PEMETREXED LILLY	Eli Lilly Nederland B.V.	EU/1/15/1034/002	Powder for concentrate for solution for infusion	-PEMETREXED DISODIUM HEPTAHYDRATE
Pemetrexed Medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/15/1038/001	Powder for concentrate for solution for infusion	-Pemetrexed
PEMETREXED MEDAC	Medac Gesellschaft für Klinische Spezialpräparate mbH	EU/1/15/1038/002	Powder for concentrate for solution for infusion	-PEMETREXED
PEMETREXED MEDAC	Medac Gesellschaft für Klinische Spezialpräparate mbH	EU/1/15/1038/003	Powder for concentrate for solution for infusion	-PEMETREXED

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Pemetrexed
Pemetrexed Sandoz	Sandoz GmbH	EU/1/15/1037/001	Powder for concentrate for solution for infusion	-Pemetrexed
POMETREXED SANDOZ	Sandoz GmbH	EU/1/15/1037/002	Powder for concentrate for solution for infusion	-POMETREXED
POMETREXED SANDOZ	Sandoz GmbH	EU/1/15/1037/003	Powder for concentrate for solution for infusion	-POMETREXED
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	-Pemetrexed
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	-Pemetrexed
Pendrex 2mg tablets	Rowex Ltd	PA0711/118/001	Tablet	-Perindopril tert-butylamine
Pendrex 4mg tablets	Rowex Ltd	PA0711/118/002	Tablet	-Perindopril tert-butylamine
Pendrex 8 mg tablets	Rowex Ltd	PA0711/118/004	Tablet	-Perindopril tert-butylamine
Pendrex Plus 4mg/1.25mg tablets	Rowex Ltd	PA0711/171/001	Tablet	-Indapamide -Perindopril tert-butylamine
Pentasa 1 g prolonged-release tablets	IMED Healthcare Ltd.	PPA1463/110/002	Prolonged-release tablet	-Mesalazine
Pentasa 1 g prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/450/003	Prolonged-release tablet	-Mesalazine
Pentasa 1 g prolonged-release tablets	Ferring Ireland Ltd	PA1009/006/007	Prolonged-release tablet	-Mesalazine
Pentasa 1 g suppositories	Originalis B.V.	PPA2306/010/001	Suppository	-Mesalazine
Pentasa 10 mg/ml Rectal Suspension	Ferring Ireland Ltd	PA1009/006/003	Rectal suspension	-Mesalazine
Pentasa 1g Suppositories	Ferring Ireland Ltd	PA1009/006/002	Suppository	-Mesalazine
Pentasa 1g Suppositories	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/048/001	Suppository	-Mesalazine
Pentasa 500 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/450/002	Prolonged-release tablet	-Mesalazine
Pentasa 500 mg prolonged-release tablets	IMED Healthcare Ltd.	PPA1463/110/001	Prolonged-release tablet	-Mesalazine
Pentasa 500 mg prolonged-release tablets	Ferring Ireland Ltd	PA1009/006/005	Prolonged-release tablet	-Mesalazine
Pentasa Sachet 1g prolonged-release granules	Ferring Ireland Ltd	PA1009/006/001	Prolonged-release granules	-Mesalazine
Pentasa Sachet 2 g prolonged-release granules	PCO Manufacturing Ltd.	PPA0465/450/001	Prolonged-release granules	-Mesalazine
Pentasa Sachet 2 g prolonged-release granules	IMED Healthcare Ltd.	PPA1463/190/001	Prolonged-release granules	-Mesalazine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Pentasa Sachet 2g prolonged-release granules	Originalis B.V.	PPA2306/010/002	Prolonged-release granules	-Mesalazine
Pentasa Sachet 2g prolonged-release granules	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/048/002	Prolonged-release granules	-Mesalazine
Pentasa Sachet 2g prolonged-release granules	Ferring Ireland Ltd	PA1009/006/006	Prolonged-release granules	-Mesalazine
Pentasa Sachet 4 g Prolonged-release granules	Ferring Ireland Ltd	PA1009/006/008	Prolonged-release granules	-Mesalazine
Pentasa Sachet 4 g prolonged-release granules	IMED Healthcare Ltd.	PPA1463/190/002	Prolonged-release granules	-Mesalazine
Pentasa Sachet 4 g prolonged-release granules	PCO Manufacturing Ltd.	PPA0465/450/004	Prolonged-release granules	-Mesalazine
Pentrox 99.9%, 3 ml inhalation vapour, liquid	Medical Developments MD&P Limited	PA22745/001/001	Inhalation vapour, liquid	-Methoxyflurane
Pepaxti	Oncopeptides AB	EU/1/22/1669/001	Powder for concentrate for solution for infusion	-Melphalan Flufenamide Hydrochloride
Pepcid AC 10 mg Film-coated Tablets	Johnson & Johnson (Ireland) Limited	PA0330/053/001	Film-coated tablet	-Famotidine
Pepcid Duo Chewable Tablets Famotidine 10mg Magnesium Hydroxide 165mg Calcium Carbonate 800mg	JNTL Consumer Health I (Ireland) Limited	PA23490/027/001	Chewable tablet	-Famotidine -Magnesium hydroxide -Calcium carbonate
Perdamel 0.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/169/002	Film-coated tablet	-Risperidone
Perdamel 1 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/169/003	Film-coated tablet	-Risperidone
Perdamel 2 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/169/004	Film-coated tablet	-Risperidone
Perdamel 3 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/169/005	Film-coated tablet	-Risperidone
Perdamel 4 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/169/006	Film-coated tablet	-Risperidone
Pergoveris	Merck Europe B.V.	EU/1/07/396/004	Solution for injection in pre-filled pen	-Lutropin alfa -Follitropin alfa
Pergoveris	Merck Europe B.V.	EU/1/07/396/005	Solution for injection in pre-filled pen	-Lutropin alfa -Follitropin alfa
Pergoveris	Merck Europe B.V.	EU/1/07/396/006	Solution for injection in pre-filled pen	-Lutropin alfa -Follitropin alfa
Pergoveris	Merck Europe B.V.	EU/1/07/396/1-3	Powder and solvent for solution for injection	-Lutropin alfa -Follitropin alfa
Perindopril Arginine Clonmel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/366/002	Film-coated tablet	-Perindopril arginine
Perindopril Arginine Clonmel 2.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/366/003	Film-coated tablet	-Perindopril arginine
Perindopril Arginine Clonmel 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/366/001	Film-coated tablet	-Perindopril arginine
Perindopril Arginine TAD 10 mg tablets	TAD Pharma GmbH	PA0876/010/002	Tablet	-Perindopril arginine
Perindopril Arginine TAD 5 mg tablets	TAD Pharma GmbH	PA0876/010/001	Tablet	-Perindopril arginine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Perindopril arginine/amlodipine TAD 10 mg/10 mg tablets	TAD Pharma GmbH	PA0876/012/004	Tablet	-Perindopril arginine -Amlodipine
Perindopril arginine/amlodipine TAD 10 mg/5 mg tablets	TAD Pharma GmbH	PA0876/012/003	Tablet	-Perindopril arginine -Amlodipine
Perindopril arginine/amlodipine TAD 5 mg/10 mg tablets	TAD Pharma GmbH	PA0876/012/002	Tablet	-Perindopril arginine -Amlodipine
Perindopril arginine/amlodipine TAD 5 mg/5 mg tablets	TAD Pharma GmbH	PA0876/012/001	Tablet	-Perindopril arginine -Amlodipine
Perindopril arginine/Indapamide TAD 10 mg/2.5 mg tablets	TAD Pharma GmbH	PA0876/011/002	Tablet	-Perindopril arginine -Indapamide
Perindopril arginine/Indapamide TAD 5 mg/1.25 mg tablets	TAD Pharma GmbH	PA0876/011/001	Tablet	-Perindopril arginine -Indapamide
Perindopril arginine/Indapamide/Amlodipine Krka 10 mg/2.5 mg/10 mg tablets	KRKA, d.d., Novo mesto	PA1347/112/003	Tablet	-Perindopril arginine -Indapamide -Amlodipine besilate
Perindopril arginine/Indapamide/Amlodipine Krka 10 mg/2.5 mg/5 mg tablets	KRKA, d.d., Novo mesto	PA1347/112/002	Tablet	-Perindopril arginine -Indapamide -Amlodipine besilate
Perindopril arginine/Indapamide/Amlodipine Krka 5 mg/1.25 mg/5 mg tablets	KRKA, d.d., Novo mesto	PA1347/112/001	Tablet	-Perindopril arginine -Indapamide -Amlodipine besilate
Perindopril Krka 2 mg tablets	KRKA, d.d., Novo mesto	PA1347/041/001	Tablet	-Perindopril tert-butylamine
Perindopril Krka 4 mg tablets	KRKA, d.d., Novo mesto	PA1347/041/002	Tablet	-Perindopril tert-butylamine
Perindopril Krka 8 mg tablets	KRKA, d.d., Novo mesto	PA1347/041/003	Tablet	-Perindopril tert-butylamine
Perindopril Tosilate Teva 10mg Film-coated Tablets	Teva Pharma B.V.	PA0749/168/003	Film-coated tablet	-Perindopril tosilate
Perindopril Tosilate Teva 5mg Film-coated Tablets	Teva Pharma B.V.	PA0749/168/002	Film-coated tablet	-Perindopril tosilate
Perindopril tosilate/Amlodipine Teva 10mg/10mg tablets	Teva Pharma B.V.	PA0749/197/004	Tablet	-Perindopril tosilate -Amlodipine
Perindopril tosilate/Amlodipine Teva 10mg/5mg tablets	Teva Pharma B.V.	PA0749/197/003	Tablet	-Perindopril tosilate -Amlodipine besilate
Perindopril tosilate/Amlodipine Teva 5mg/10mg tablets	Teva Pharma B.V.	PA0749/197/002	Tablet	-Perindopril tosilate -Amlodipine
Perindopril tosilate/Amlodipine Teva 5mg/5mg tablets	Teva Pharma B.V.	PA0749/197/001	Tablet	-Perindopril tosilate -Amlodipine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Perindopril Tosilate/Amlodipine Teva B.V. 10 mg/10 mg Tablets	Teva B.V.	PA1986/098/004	Tablet	-Perindopril tosilate -Amlodipine
Perindopril Tosilate/Amlodipine Teva B.V. 10 mg/5 mg Tablets	Teva B.V.	PA1986/098/003	Tablet	-Perindopril tosilate -Amlodipine
Perindopril Tosilate/Amlodipine Teva B.V. 5 mg/10 mg Tablets	Teva B.V.	PA1986/098/002	Tablet	-Perindopril tosilate -Amlodipine
Perindopril Tosilate/Amlodipine Teva B.V. 5 mg/5 mg Tablets	Teva B.V.	PA1986/098/001	Tablet	-Perindopril tosilate -Amlodipine
Perindopril tosilate/Indapamide 10 mg/2.5 mg film-coated tablets	Teva B.V.	PA1986/025/001	Film-coated tablet	-Perindopril tosilate -Indapamide
Perindopril tosilate/Indapamide Teva 2.5 mg/0.625 mg Film-coated tablets	Teva Pharma B.V.	PA0749/170/001	Film-coated tablet	-Perindopril tosilate -Indapamide
Perindopril tosilate/Indapamide Teva 5 mg/1.25 mg film-coated tablets	Teva Pharma B.V.	PA0749/170/002	Film-coated tablet	-Perindopril tosilate -Indapamide
Perindopril/amlodipine Krka 4 mg/10 mg tablets	KRKA, d.d., Novo mesto	PA1347/084/002	Tablet	-Perindopril tert-butylamine -Amlodipine besilate
Perindopril/amlodipine Krka 4 mg/5 mg tablets	KRKA, d.d., Novo mesto	PA1347/084/001	Tablet	-Perindopril tert-butylamine -Amlodipine besilate
Perindopril/amlodipine Krka 8 mg/10 mg tablets	KRKA, d.d., Novo mesto	PA1347/084/004	Tablet	-Perindopril tert-butylamine -Amlodipine besilate
Perindopril/amlodipine Krka 8 mg/5 mg tablets	KRKA, d.d., Novo mesto	PA1347/084/003	Tablet	-Perindopril tert-butylamine -Amlodipine besilate
Periochip 2.5 mg Dental Insert	Dexcel Pharma GmbH	PA2261/005/001	Periodontal insert	-Chlorhexidine gluconate
Perjeta	Roche Registration GmbH	EU/1/13/813/001	Concentrate for solution for infusion	-Pertuzumab
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	-Paracetamol -Guaifenesin -Phenylephrine hydrochloride
Perrigo Cold & Flu Tablets Paracetamol 250 mg Guaifenesin 100 mg Phenylephrine hydrochloride 5 mg	Chefaro Ireland DAC	PA1186/021/001	Film-coated tablet	-Paracetamol -Guaifenesin -Phenylephrine hydrochloride
Pethidine Hydrochloride 50mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/014/001	Solution for injection	-Pethidine hydrochloride
Peyona	Chiesi Farmaceutici S.p.A.	EU/1/09/528/001	Solution for infusion	-Caffeine citrate
Pheburane	Eurocept International BV	EU/1/13/822/001	Granules	-Sodium 4-phenylbutyrate
Pheburane	Eurocept International BV	EU/1/13/822/006	Oral solution	-Sodium phenylbutyrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
PHELINUN	Adienne S.r.l. S.U.	EU/1/20/1487/001	Powder and solvent for concentrate for solution for infusion	-MELPHALAN HYDROCHLORIDE
PHELINUN	Adienne S.r.l. S.U.	EU/1/20/1487/002	Powder and solvent for concentrate for solution for infusion	-MELPHALAN HYDROCHLORIDE
Phenergan 25 mg film-coated tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/011/002	Film-coated tablet	-Promethazine hydrochloride
Phenergan 5 mg/5 ml oral solution	Opella Healthcare France SAS T/A Sanofi	PA23180/011/001	Oral solution	-Promethazine hydrochloride
Phenobarbital 15 mg Tablets	Clonmel Healthcare Ltd	PA0126/019/001	Tablet	-Phenobarbital
Phenobarbital 30 mg Tablets	Clonmel Healthcare Ltd	PA0126/019/002	Tablet	-Phenobarbital
Phenoxymethylpenicillin Sugar Free 125mg/5ml Powder for Oral solution	Brown & Burk IR Limited	PA23148/002/001	Powder for oral solution	- Phenoxymethylpenicillin
Phenoxymethylpenicillin Sugar Free 250mg/5ml Powder for Oral solution	Brown & Burk IR Limited	PA23148/002/002	Powder for oral solution	- Phenoxymethylpenicillin
Phenylephrine 100 micrograms/ml solution for injection/infusion	Laboratoire AGUETTANT	PA1968/007/002	Solution for injection/infusion	-Phenylephrine hydrochloride
Phenylephrine 50 micrograms/ml, solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/007/001	Solution for injection in pre-filled syringe	-Phenylephrine hydrochloride
Phenylephrine Hydrochloride 10 mg/ml solution for injection/infusion	Athlone Pharmaceuticals Limited	PA1418/011/001	Solution for injection/infusion	-Phenylephrine hydrochloride
Phesgo	Roche Registration GmbH	EU/1/20/1497/001	Solution for injection	-Pertuzumab -Trastuzumab
Phesgo	Roche Registration GmbH	EU/1/20/1497/002	Solution for injection	-Pertuzumab -Trastuzumab
Phizamol 500 mg effervescent tablets	Accord Healthcare Ireland Ltd.	PA2315/065/001	Effervescent tablet	-Paracetamol
Phorpain	Amdipharm Limited	PA1142/026/001	Gel	-Ibuprofen
Phospho-soda 24.4g/10.8g Oral solution	Casen-Recordati S.L.	PA2028/004/001	Oral solution	-Sodium phosphate dibasic dodecahydrate -Sodium phosphate dibasic dihydrate
Phoxilium 1.2 mmol/l phosphate Solution for haemodialysis/haemofiltration	Baxter Holding B.V.	PA2299/053/001	Solution for haemodialysis/haemofiltration	-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	-Aminophylline hydrate
Phymet DTF 1 mg/ml Syrup	GlaxoSmithKline (Ireland) Limited	PA1077/074/001	Syrup	-Methadone hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Glucose monohydrate -Sodium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Sodium (s)-lactate solution -Sodium bicarbonate
Physioneal 35 Glucose 1.36% w/v / 13.6 mg/ml Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/007	Solution for peritoneal dialysis	-Glucose monohydrate -Sodium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Sodium bicarbonate -Sodium (s)-lactate solution
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	-Glucose monohydrate -Sodium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Sodium (s)-lactate solution -Sodium bicarbonate
Physioneal 35 Glucose 2.27% w/v / 22.7 mg/ml Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/008	Solution for peritoneal dialysis	-Glucose monohydrate -Sodium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Sodium bicarbonate -Sodium (s)-lactate solution
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	-Glucose monohydrate -Sodium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Sodium (s)-lactate solution -Sodium bicarbonate
Physioneal 35 Glucose 3.86% w/v / 38.6 mg/ml Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/009	Solution for peritoneal dialysis	-Glucose monohydrate -Sodium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Sodium bicarbonate -Sodium (s)-lactate solution
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	-Glucose monohydrate -Sodium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Sodium (s)-lactate solution -Sodium bicarbonate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Glucose monohydrate -Sodium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Sodium bicarbonate -Sodium (s)-lactate solution
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	-Glucose monohydrate -Sodium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Sodium (s)-lactate solution -Sodium bicarbonate
Physioneal 40 Glucose 2.27% w/v / 22.7 mg/ml Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/005	Solution for peritoneal dialysis	-Glucose monohydrate -Sodium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Sodium bicarbonate -Sodium (s)-lactate solution
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	-Glucose monohydrate -Sodium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Sodium (s)-lactate solution -Sodium bicarbonate
Physioneal 40 Glucose 3.86% w/v / 38.6 mg/ml Solution for peritoneal dialysis	Baxter Holding B.V.	PA2299/022/006	Solution for peritoneal dialysis	-Glucose monohydrate -Sodium chloride -Calcium chloride dihydrate -Magnesium chloride hexahydrate -Sodium bicarbonate -Sodium (s)-lactate solution
Picolax 10mg / 3.5g / 12 g Powder for Oral Solution	Ferring Ireland Ltd	PA1009/003/001	Powder for oral solution	-Sodium picosulfate -Magnesium oxide, light -Citric acid
Pifeltro	Merck Sharp & Dohme BV,	EU/1/18/1332/001-002	Film-coated tablet	-Doravirine
Pinacort 3 mg modified release hard capsules	Pinewood Laboratories Ltd	PA0281/251/001	Modified-release capsule, hard	-Budesonide
Pinadone 1 mg/ml Oral Solution	Pinewood Laboratories Ltd	PA0281/061/001	Oral solution	-Methadone hydrochloride
Pinamox 125 mg/5 ml Powder for Oral Suspension	Athlone Laboratories Ltd	PA0298/010/001	Powder for oral suspension	-Amoxicillin
Pinamox 250 mg/5 ml Powder for Oral Suspension	Athlone Laboratories Ltd	PA0298/010/002	Powder for oral suspension	-Amoxicillin
Pinamox 250mg hard capsules	Athlone Laboratories Ltd	PA0298/010/003	Capsule, hard	-Amoxicillin trihydrate
Pinamox 500mg hard Capsules	Athlone Laboratories Ltd	PA0298/010/004	Capsule, hard	-Amoxicillin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Pioglitazone Accord	Accord Healthcare S.L.U.	EU/1/11/722/001-010	Tablet	-Pioglitazone hydrochloride
Pioglitazone Accord	Accord Healthcare S.L.U.	EU/1/11/722/011-020	Tablet	-Pioglitazone hydrochloride
Pioglitazone Accord	Accord Healthcare S.L.U.	EU/1/11/722/021-030	Tablet	-Pioglitazone hydrochloride
Pioglitazone Actavis	Actavis Group hf	EU/1/12/755/001-009	Tablet	-Pioglitazone hydrochloride
Pioglitazone Actavis	Actavis Group hf	EU/1/12/755/010-018	Tablet	-Pioglitazone hydrochloride
Pioglitazone Actavis	Actavis Group hf	EU/1/12/755/019-027	Tablet	-Pioglitazone hydrochloride
Piperacillin Tazobactam 2 g/0.25 g powder for solution for infusion	Viartis Limited	PA23266/021/001	Powder for solution for infusion	-Piperacillin sodium -Tazobactam (as sodium salt)
Piperacillin Tazobactam 4 g/0.5 g powder for solution for infusion	Viartis Limited	PA23266/021/002	Powder for solution for infusion	-Piperacillin sodium -Tazobactam (as sodium salt)
Piperacillin/Tazobactam 2 g/0.25 g powder for solution for infusion	AS Kalceks	PA2165/018/001	Powder for solution for infusion	-Piperacillin -Tazobactam
Piperacillin/Tazobactam 2 g/0.25g powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/016/001	Powder for solution for infusion	-Piperacillin -Tazobactam
Piperacillin/Tazobactam 2g/0.25g powder for solution for infusion	Noridem Enterprises Limited	PA1122/012/001	Powder for solution for infusion	-Piperacillin -Tazobactam
Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/016/002	Powder for solution for infusion	-Piperacillin -Tazobactam
Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion	AS Kalceks	PA2165/018/002	Powder for solution for infusion	-Piperacillin -Tazobactam
Piperacillin/Tazobactam 4g/0.5g powder for solution for infusion	Stravencon Ltd	PA1947/001/001	Powder for solution for infusion	-Piperacillin sodium -Tazobactam sodium
Piperacillin/Tazobactam 4g/0.5g powder for solution for infusion	Noridem Enterprises Limited	PA1122/012/002	Powder for solution for infusion	-Piperacillin -Tazobactam
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	-Piperacillin -Tazobactam
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	-Piperacillin -Tazobactam
Piperacillin/Tazobactam Clonmel 4 g/0.5 g powder for solution for infusion	Clonmel Healthcare Ltd	PA0126/363/001	Powder for solution for infusion	-Piperacillin -Tazobactam
Piperin 4 g/0.5 g powder for solution for infusion	Clonmel Healthcare Ltd	PA0126/180/002	Powder for solution for infusion	-Piperacillin -Tazobactam
Piperin 4 g/0.5 g Powder for Solution for Infusion	Rowex Ltd	PA0711/113/002	Powder for solution for infusion	-Piperacillin -Tazobactam
Piqray	Novartis Europharm Limited	EU/1/20/1455/001-003	Film-coated tablet	-Alpelisib
Piqray	Novartis Europharm Limited	EU/1/20/1455/004-006	Film-coated tablet	-Alpelisib
Piqray	Novartis Europharm Limited	EU/1/20/1455/007-009	Film-coated tablet	-Alpelisib

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Pirfenidone Accord 267 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/270/001	Film-coated tablet	-Pirfenidone
Pirfenidone Accord 801 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/270/002	Film-coated tablet	-Pirfenidone
Pirfenidone APS 267 mg Film-coated tablets	Axunio Pharma GmbH	PA23438/002/001	Film-coated tablet	-Pirfenidone
Pirfenidone APS 534 mg Film-coated tablets	Axunio Pharma GmbH	PA23438/002/002	Film-coated tablet	-Pirfenidone
Pirfenidone APS 801 mg film-coated tablets	Axunio Pharma GmbH	PA23438/002/003	Film-coated tablet	-Pirfenidone
Pirfenidone axunio 267 mg film-coated tablets	Axunio Pharma GmbH	EU/1/22/1655/001-004	Film-coated tablet	-Pirfenidone
Pirfenidone axunio 534 mg film-coated tablets	Axunio Pharma GmbH	EU/1/22/1655/005-006	Film-coated tablet	-Pirfenidone
Pirfenidone Axunio 801 film-coated tablets	Axunio Pharma GmbH	EU/1/22/1655/007-010	Film-coated tablet	-Pirfenidone
Pirfenidone Cipla 267 mg Film-coated Tablets	Cipla Europe NV	PA1963/016/001	Film-coated tablet	-Pirfenidone
Pirfenidone Cipla 801 mg Film-coated Tablets	Cipla Europe NV	PA1963/016/002	Film-coated tablet	-Pirfenidone
Pirfenidone Clonmel 267 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/350/001	Film-coated tablet	-Pirfenidone
Pirfenidone Clonmel 801 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/350/002	Film-coated tablet	-Pirfenidone
Pirfenidone Teva 267 mg Film-coated Tablets	Norton Waterford	PA0436/048/001	Film-coated tablet	-Pirfenidone
Pirfenidone Teva 801 mg Film-coated Tablets	Norton Waterford	PA0436/048/002	Film-coated tablet	-Pirfenidone
Pirfenidone Viatrix 267 mg film-coated tablets	Viatrix Limited	EU/1/22/1707/001-007	Film-coated tablet	-Pirfenidone
Pirfenidone Viatrix 534 mg film-coated tablets	Viatrix Limited	EU/1/22/1707/008-010	Film-coated tablet	-Pirfenidone
Pirfenidone Viatrix 801 mg film-coated tablets	Viatrix Limited	EU/1/22/1707/011-015	Film-coated tablet	-Pirfenidone
Piriton Allergy 4mg Tablets	Haleon Ireland Limited	PA0678/080/001	Tablet	-Chlorpheniramine maleate
Pivmecillinam hydrochloride Karo Pharma 400 mg film-coated tablets	Karo Pharma AB	PA22650/003/001	Film-coated tablet	-Pivmecillinam hydrochloride
Pixuvri	Les Laboratoires Servier	EU/1/12/764/001	Powder for concentrate for solution for infusion	-Pixantrone
Plaquenil 200mg Film-coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/155/001	Film-coated tablet	-Hydroxychloroquine sulfate
Plasma-Lyte 148 & Glucose 5% w/v solution for infusion	Baxter Holding B.V.	PA2299/007/001	Solution for infusion	-Glucose monohydrate -Sodium chloride -Potassium chloride -Magnesium chloride hexahydrate -Sodium acetate trihydrate -Sodium gluconate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Plasma-Lyte® 148 (pH 7.4) solution for infusio	Baxter Holding B.V.	PA2299/032/001	Solution for infusion	-Sodium chloride -Potassium chloride -Magnesium chloride hexahydrate -Sodium acetate trihydrate -Sodium gluconate
Plavix	Sanofi Winthrop Industrie	EU/1/98/069/001-007	Film-coated tablet	-Clopidogrel hydrogensulfate
Plavix	Sanofi Winthrop Industrie	EU/1/98/069/008-010	Film-coated tablet	-Clopidogrel hydrogensulfate
Plegridy	Biogen Netherlands B.V.	EU/1/14/934/001	Solution for injection in pre-filled syringe	-Peginterferon beta-1a
Plegridy	Biogen Netherlands B.V.	EU/1/14/934/002	Solution for injection in pre-filled pen	-Peginterferon beta-1a
Plegridy	Biogen Netherlands B.V.	EU/1/14/934/003-004	Solution for injection in pre-filled syringe	-Peginterferon beta-1a
Plegridy	Biogen Netherlands B.V.	EU/1/14/934/003-006	Solution for injection	-Peginterferon beta-1a
Plegridy	Biogen Netherlands B.V.	EU/1/14/934/003-008	Solution for injection in pre-filled pen	-Peginterferon beta-1a
Plegridy	Biogen Netherlands B.V.	EU/1/14/934/005-006	Solution for injection in pre-filled pen	-Peginterferon beta-1a
Plenadren	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/11/715/001	Modified-release tablet	-Hydrocortisone
Plenadren, Hydrocortisone	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/11/715/002	Modified-release tablet	-Hydrocortisone
Plendil 10 mg prolonged-release tablets	Glenwood GmbH	PA2256/005/003	Prolonged-release tablet	-Felodipine
Plendil 10 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/405/002	Prolonged-release tablet	-Felodipine
Plendil 2.5 mg prolonged-release tablets	Glenwood GmbH	PA2256/005/001	Prolonged-release tablet	-Felodipine
Plendil 5 mg prolonged-release tablets	Glenwood GmbH	PA2256/005/002	Prolonged-release tablet	-Felodipine
Plendil 5 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/405/001	Prolonged-release tablet	-Felodipine
Plendil 5 mg prolonged-release tablets	IMED Healthcare Ltd.	PPA1463/183/001	Prolonged-release tablet	-Felodipine
Plenvu powder for oral solution	Norgine B.V.	PA1336/005/001	Powder for oral solution	-Macrogol 3350 -Sodium sulfate anhydrous -Sodium chloride -Potassium chloride -Macrogol 3350 -Sodium chloride -Potassium chloride -Sodium ascorbate -Ascorbic acid
Plerixafor 20 mg/ml solution for injection	MSN Labs Europe Limited	PA23250/001/001	Solution for injection	-Plerixafor
Plerixafor Accord	Accord Healthcare S.L.U.	EU/1/22/1701/001	Solution for injection	-Plerixafor
Plerixafor Seacross 20 mg/ml solution for injection	Seacross Pharma (Europe) Limited	PA22766/007/001	Solution for injection	-Plerixafor

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Pliaglis 70mg/g + 70mg/g cream	Croma-Pharma GmbH	PA0846/003/001	Cream	-Lidocaine -Tetracaine
Pluvicto	Advanced Accelerator Applications	EU/1/22/1703/001	Solution for injection/infusion	-Lutetium (177Lu) vipivotide tetraxetan
PNEUMOVAX 23 solution for injection in a vial Pneumococcal Polysaccharide Vaccin	Merck Sharp & Dohme Ireland (Human Health) Limited	PA1286/055/001	Solution for injection	-Pneumococcal vaccine
PNEUMOVAX 23 solution for injection in pre-filled syringe Pneumococcal Polysaccharide Vaccin	Merck Sharp & Dohme Ireland (Human Health) Limited	PA1286/055/002	Solution for injection in pre-filled syringe	-Pneumococcal vaccine
Polivy	Roche Registration GmbH	EU/1/19/1388/001	Powder for concentrate for solution for infusion	-Polatuzumab Vedotin
Pomalidomide Viatrix	Viatrix Limited	EU/1/23/1785/001-004	Capsule, hard	-Pomalidomide
Pomalidomide Viatrix	Viatrix Limited	EU/1/23/1785/005-008	Capsule, hard	-Pomalidomide
Pomalidomide Viatrix	Viatrix Limited	EU/1/23/1785/009-012	Capsule, hard	-Pomalidomide
Pomalidomide Viatrix	Viatrix Limited	EU/1/23/1785/013-016	Capsule, hard	-Pomalidomide
Pombiliti	Amicus Therapeutics Europe Limited	EU/1/22/1714/001-003	Powder for concentrate for solution for injection/infusion	-Cipaglucosidase alfa
Ponstan 250 mg Capsules	Chemidex Pharma Limited	PA22643/001/001	Capsule, hard	-Mefenamic acid
Ponstan Forte 500 mg Film-coated Tablets	Chemidex Pharma Limited	PA22643/001/002	Film-coated tablet	-Mefenamic acid
Ponvory	Janssen-Cilag International NV	EU/1/21/1550/001	Film-coated tablet	-Ponesimod
Ponvory	Janssen-Cilag International NV	EU/1/21/1550/002	Film-coated tablet	-Ponesimod
Posaconazole Accord 100 mg gastro-resistant tablets	Accord Healthcare S.L.U.	EU/1/19/1379/001-004	Gastro-resistant tablet	-Posaconazole
Posaconazole AHCL 40 mg/ml oral suspension	Accord Healthcare S.L.U.	EU/1/19/1380/001	Oral suspension	-Posaconazole
Posaconazole Clonmel 100 mg gastro-resistant tablets	Clonmel Healthcare Ltd	PA0126/307/001	Gastro-resistant tablet	-Posaconazole
Posaconazole Mylan 100 mg gastro-resistant tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/188/001	Gastro-resistant tablet	-Posaconazole
Posaconazole Teva 100 mg gastro-resistant tablets	Teva B.V.	PA1986/091/001	Gastro-resistant tablet	-Posaconazole
POTACTASOL	Actavis Group PTC ehf	EU/1/10/660/001	Powder for concentrate for solution for infusion	-TOPOTECAN HYDROCHLORIDE
POTACTASOL	Actavis Group PTC ehf	EU/1/10/660/002	Powder for concentrate for solution for infusion	-TOPOTECAN HYDROCHLORIDE
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	-Potassium chloride -Glucose
Potassium Chloride 0.15% w/v & Glucose 5% w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/053/001	Solution for infusion	-Potassium chloride -Glucose

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Potassium chloride -Sodium chloride
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	-Potassium chloride -Sodium chloride
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	-Potassium chloride -Sodium chloride -Glucose anhydrous
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	-Potassium chloride -Glucose (as monohydrate)
Potassium Chloride 0.3% w/v & Glucose 5% w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/053/002	Solution for infusion	-Potassium chloride -Glucose
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	-Potassium chloride -Sodium chloride
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	-Potassium chloride -Sodium chloride
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	-Potassium chloride -Sodium chloride -Glucose monohydrate
Potassium Chloride 15% w/v Concentrate for Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/054/001	Concentrate for solution for infusion	-Potassium chloride
Potassium Chloride 15% w/v concentrate for solution for infusion	Noridem Enterprises Limited	PA1122/003/001	Concentrate for solution for infusion	-Potassium chloride
Potassium Chloride 15% w/v Concentrate for Solution for Infusion	B. Braun Medical Limited	PA0179/030/002	Concentrate for solution for infusion	-Potassium chloride
Potassium Chloride 15% w/v Concentrate for Solution for Infusion	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/106/001	Concentrate for solution for infusion	-Potassium chloride
Potassium iodide G.L. Pharma 65 mg tablets	G.L. Pharma GmbH	PA1770/001/001	Tablet	-Potassium iodide
Potassium Phosphate 1mmol/ml + 0.6mmol/ml Concentrate for Solution for Infusion	B. Braun Medical Limited	PA0179/005/001	Concentrate for solution for infusion	-Dipotassium phosphate -Potassium dihydrogen phosphate
POTELIGEO	Kyowa Kirin Holdings B.V.	EU/1/18/1335/001	Concentrate for solution for infusion	-MOGAMULIZUMAB
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/0026	Coated granules	-Dabigatran etexilate mesilate
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/0027	Coated granules	-Dabigatran etexilate mesilate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/0029	Coated granules	-Dabigatran etexilate mesilate
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/009-013	Capsule, hard	-Dabigatran etexilate mesilate
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/025	Coated granules	-Dabigatran etexilate mesilate
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/028	Coated granules	-Dabigatran etexilate mesilate
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/030	Coated granules	-Dabigatran etexilate mesilate
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/1-4	Capsule, hard	-Dabigatran etexilate
Pradaxa	Boehringer Ingelheim International GmbH	EU/1/08/442/5-8	Capsule, hard	-Dabigatran etexilate
Praluent	Sanofi-Aventis Groupe	EU/1/15/1031/001-003	Solution for injection in pre-filled pen	-Alirocumab
Praluent	Sanofi-Aventis Groupe	EU/1/15/1031/004-006	Solution for injection in pre-filled syringe	-Alirocumab
Praluent	Sanofi-Aventis Groupe	EU/1/15/1031/007-009	Solution for injection in pre-filled pen	-Alirocumab
Praluent	Sanofi-Aventis Groupe	EU/1/15/1031/010-012	Solution for injection in pre-filled syringe	-Alirocumab
Praluent	Sanofi-Aventis Groupe	EU/1/15/1031/019-020	Solution for injection	-Alirocumab
Pramipexole Teva	Teva Pharma B.V.	EU/1/08/490/13-16	Tablet	-Pramipexole dihydrochloride monohydrate
Pramipexole Teva	Teva Pharma B.V.	EU/1/08/490/1-4	Tablet	-Pramipexole dihydrochloride monohydrate
PRAMIPEXOLE TEVA	Teva B.V.	EU/1/08/490/5-8	Tablet	-PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE
PRAMIPEXOLE TEVA	Teva B.V.	EU/1/08/490/9-12	Tablet	-PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE
PRANDIN	Novo Nordisk A/S	EU/1/00/162/001	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/002	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/003	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/004	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/005	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/006	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/007	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/008	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/009	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/010	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/011	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/012	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/013	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/014	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/015	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/016	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/017	Tablet	-Repaglinide
Prandin	Novo Nordisk A/S	EU/1/00/162/018	Tablet	-Repaglinide
Prasugrel Accord 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/157/002	Film-coated tablet	-Prasugrel
Prasugrel Accord 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/157/001	Film-coated tablet	-Prasugrel
Prasugrel Krka 10 mg Film-coated tablets	KRKA, d.d., Novo mesto	PA1347/080/002	Film-coated tablet	-Prasugrel
Prasugrel Krka 5 mg Film-coated tablets	KRKA, d.d., Novo mesto	PA1347/080/001	Film-coated tablet	-Prasugrel
Prasugrel Mylan	Mylan Pharmaceuticals Limited	EU/1/18/1273/001	Film-coated tablet	-Prasugrel

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Prasugrel Mylan	Mylan Pharmaceuticals Limited	EU/1/18/1273/002	Film-coated tablet	-Prasugrel
Pravafenix	Laboratoires SMB S.A.	EU/1/11/679/001-006	Capsule, hard	-Fenofibrate -Pravastatin sodium
Pravamel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/140/001	Film-coated tablet	-Pravastatin sodium
Pravamel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/140/002	Film-coated tablet	-Pravastatin sodium
Pravamel 40 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/140/003	Film-coated tablet	-Pravastatin sodium
Pravastatin Mylan 10 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/136/001	Tablet	-Pravastatin sodium
Pravastatin Mylan 20 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/136/002	Tablet	-Pravastatin sodium
Pravastatin Mylan 40 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/136/003	Tablet	-Pravastatin sodium
Pravastatin Sodium 10 mg Tablets	Norton Waterford	PA0436/046/001	Tablet	-Pravastatin sodium
Pravastatin Sodium 20 mg Tablets	Norton Waterford	PA0436/046/002	Tablet	-Pravastatin sodium
Pravastatin Sodium 40 mg Tablets	Norton Waterford	PA0436/046/003	Tablet	-Pravastatin sodium
Pravitin 10 mg Tablets	Rowex Ltd	PA0711/058/001	Tablet	-Pravastatin sodium
Pravitin 20 mg Tablets	Rowex Ltd	PA0711/058/002	Tablet	-Pravastatin sodium
Pravitin 40 mg Tablets	Rowex Ltd	PA0711/058/004	Tablet	-Pravastatin sodium
Praxbind	Boehringer Ingelheim International GmbH	EU/1/15/1056/001	Solution for injection/infusion	-Idarucizumab
Praxilene 100 mg Capsules	Merck Serono (Ireland) Limited	PA2286/003/001	Capsule, hard	-NAFTIDROFURYL OXALATE
Pred Forte 1% w/v, Eye Drops Suspension	AbbVie Limited	PA1824/010/001	Eye drops, suspension	-Prednisolone acetate
Pred Mild Sterile Ophthalmic Suspension, 0.12% w/v, Eye Drops, Suspension	AbbVie Limited	PA1824/009/001	Eye drops, suspension	-Prednisolone acetate
Prednesol 5mg Tablets	Phoenix Labs	PA1113/001/001	Tablet	-Prednisolone
Prednisolone 1 mg Tablets	Clonmel Healthcare Ltd	PA0126/027/002	Tablet	-Prednisolone
Prednisolone 20 mg Rectal Foam	Chemidex Pharma Limited	PA22643/003/001	Rectal foam	-Prednisolone
Prednisolone 5 mg soluble tablets	Amdipharm Limited	PA1142/034/001	Soluble tablet	-Prednisolone
Prednisolone 5 mg Tablets	Clonmel Healthcare Ltd	PA0126/027/001	Tablet	-Prednisolone
Pregabalin 100 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/004	Capsule, hard	-Pregabalin
Pregabalin 150 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/005	Capsule, hard	-Pregabalin
Pregabalin 20 mg/ml oral solution	Chanelle Medical Unlimited Company	PA0688/064/001	Oral solution	-Pregabalin
Pregabalin 200 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/006	Capsule, hard	-Pregabalin
Pregabalin 225 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/007	Capsule, hard	-Pregabalin
Pregabalin 25 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/001	Capsule, hard	-Pregabalin
Pregabalin 300 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/008	Capsule, hard	-Pregabalin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Pregabalin 50 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/002	Capsule, hard	-Pregabalin
Pregabalin 75 mg capsules, hard	Brillpharma (Ireland) Limited	PA22749/015/003	Capsule, hard	-Pregabalin
Pregabalin Accord 100 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/034-044	Capsule, hard	-Pregabalin
Pregabalin Accord 150 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/045-055	Capsule, hard	-Pregabalin
Pregabalin Accord 200 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/056-066	Capsule, hard	-Pregabalin
Pregabalin Accord 225 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/067-077	Capsule, hard	-Pregabalin
Pregabalin Accord 25 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/001-011	Capsule, hard	-Pregabalin
Pregabalin Accord 300 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/078-088	Capsule, hard	-Pregabalin
Pregabalin Accord 50 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/012-022	Capsule, hard	-Pregabalin
Pregabalin Accord 75 mg hard capsules	Accord Healthcare S.L.U.	EU/1/15/1027/023-033	Capsule, hard	-Pregabalin
PREGABALIN BASICS 20 mg/ml oral solution	Basics GmbH	PA23067/001/001	Oral solution	-Pregabalin
Pregabalin Clonmel 100 mg capsules, hard	Clonmel Healthcare Ltd	PA0126/290/004	Capsule, hard	-Pregabalin
Pregabalin Clonmel 150 mg capsules, hard	Clonmel Healthcare Ltd	PA0126/290/005	Capsule, hard	-Pregabalin
Pregabalin Clonmel 200 mg capsules, hard	Clonmel Healthcare Ltd	PA0126/290/006	Capsule, hard	-Pregabalin
Pregabalin Clonmel 25 mg capsules, hard	Clonmel Healthcare Ltd	PA0126/290/001	Capsule, hard	-Pregabalin
Pregabalin Clonmel 300 mg capsules, hard	Clonmel Healthcare Ltd	PA0126/290/008	Capsule, hard	-Pregabalin
Pregabalin Clonmel 50 mg capsules, hard	Clonmel Healthcare Ltd	PA0126/290/002	Capsule, hard	-Pregabalin
Pregabalin Clonmel 75 mg capsules, hard	Clonmel Healthcare Ltd	PA0126/290/003	Capsule, hard	-Pregabalin
Pregabalin Krka 100 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/004	Capsule, hard	-Pregabalin
Pregabalin Krka 150 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/005	Capsule, hard	-Pregabalin
Pregabalin Krka 200 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/006	Capsule, hard	-Pregabalin
Pregabalin Krka 225 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/007	Capsule, hard	-Pregabalin
Pregabalin Krka 25mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/001	Capsule, hard	-Pregabalin
Pregabalin Krka 300 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/008	Capsule, hard	-Pregabalin
Pregabalin Krka 50 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/002	Capsule, hard	-Pregabalin
Pregabalin Krka 75 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/050/003	Capsule, hard	-Pregabalin
Pregabalin Mylan 100 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/023-027	Capsule, hard	-Pregabalin
Pregabalin Mylan 150 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/028-034	Capsule, hard	-Pregabalin
Pregabalin Mylan 200 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/035-039	Capsule, hard	-Pregabalin
Pregabalin Mylan 225 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/040-044	Capsule, hard	-Pregabalin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Pregabalin Mylan 25 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/001-008	Capsule, hard	-Pregabalin
Pregabalin Mylan 300 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/045-050	Capsule, hard	-Pregabalin
Pregabalin Mylan 50 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/009-015	Capsule, hard	-Pregabalin
Pregabalin Mylan 75 mg hard capsules	Mylan Pharmaceuticals Limited	EU/1/15/997/016-022	Capsule, hard	-Pregabalin
Pregabalin Pfizer 100 mg hard capsules	Upjohn EESV	EU/1/14/916/020-023	Capsule, hard	-Pregabalin
Pregabalin Pfizer 150 mg hard capsules	Upjohn EESV	EU/1/14/916/024-029	Capsule, hard	-Pregabalin
Pregabalin Pfizer 200 mg hard capsules	Upjohn EESV	EU/1/14/916/030-033	Capsule, hard	-Pregabalin
Pregabalin Pfizer 225 mg hard capsules	Upjohn EESV	EU/1/14/916/034-037	Capsule, hard	-Pregabalin
Pregabalin Pfizer 25 mg hard capsules	Upjohn EESV	EU/1/14/916/001-007	Capsule, hard	-Pregabalin
Pregabalin Pfizer 300 mg hard capsules	Upjohn EESV	EU/1/14/916/038-043	Capsule, hard	-Pregabalin
Pregabalin Pfizer 50 mg hard capsules	Upjohn EESV	EU/1/14/916/008-013	Capsule, hard	-Pregabalin
Pregabalin Pfizer 75 mg hard capsules	Upjohn EESV	EU/1/14/916/014-019	Capsule, hard	-Pregabalin
Pregabalin Pinewood 100 mg hard capsules	Pinewood Laboratories Ltd	PA0281/217/004	Capsule, hard	-Pregabalin
Pregabalin Pinewood 150 mg hard capsules	Pinewood Laboratories Ltd	PA0281/217/005	Capsule, hard	-Pregabalin
Pregabalin Pinewood 200 mg hard capsules	Pinewood Laboratories Ltd	PA0281/217/006	Capsule, hard	-Pregabalin
Pregabalin Pinewood 25 mg hard capsules	Pinewood Laboratories Ltd	PA0281/217/001	Capsule, hard	-Pregabalin
Pregabalin Pinewood 300 mg hard capsules	Pinewood Laboratories Ltd	PA0281/217/007	Capsule, hard	-Pregabalin
Pregabalin Pinewood 50 mg hard capsules	Pinewood Laboratories Ltd	PA0281/217/002	Capsule, hard	-Pregabalin
Pregabalin Pinewood 75 mg hard capsules	Pinewood Laboratories Ltd	PA0281/217/003	Capsule, hard	-Pregabalin
Pregabalin Sandoz 100 mg hard capsules	Sandoz GmbH	EU/1/15/1011/034-041	Capsule, hard	-Pregabalin
Pregabalin Sandoz 150 mg hard capsules	Sandoz GmbH	EU/1/15/1011/042-056	Capsule, hard	-Pregabalin
Pregabalin Sandoz 200 mg hard capsules	Sandoz GmbH	EU/1/15/1011/057-062	Capsule, hard	-Pregabalin
Pregabalin Sandoz 225 mg hard capsules	Sandoz GmbH	EU/1/15/1011/063-068	Capsule, hard	-Pregabalin
Pregabalin Sandoz 25 mg hard capsules	Sandoz GmbH	EU/1/15/1011/001-010	Capsule, hard	-Pregabalin
Pregabalin Sandoz 300 mg hard capsules	Sandoz GmbH	EU/1/15/1011/069-083	Capsule, hard	-Pregabalin
Pregabalin Sandoz 50 mg hard capsules	Sandoz GmbH	EU/1/15/1011/011-017	Capsule, hard	-Pregabalin
Pregabalin Sandoz 75 mg hard capsules	Sandoz GmbH	EU/1/15/1011/018-033	Capsule, hard	-Pregabalin
Pregabalin Sandoz GmbH 100 mg hard capsules	Sandoz GmbH	EU/1/15/1012/034-041	Capsule, hard	-Pregabalin
Pregabalin Sandoz GmbH 150 mg hard capsules	Sandoz GmbH	EU/1/15/1012/042-056	Capsule, hard	-Pregabalin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Pregabalin Sandoz GmbH 200 mg hard capsules	Sandoz GmbH	EU/1/15/1012/057-062	Capsule, hard	-Pregabalin
Pregabalin Sandoz GmbH 225 mg hard capsules	Sandoz GmbH	EU/1/15/1012/063-068	Capsule, hard	-Pregabalin
Pregabalin Sandoz GmbH 25 mg hard capsules	Sandoz GmbH	EU/1/15/1012/001-010	Capsule, hard	-Pregabalin
Pregabalin Sandoz GmbH 300 mg hard capsules	Sandoz GmbH	EU/1/15/1012/069-083	Capsule, hard	-Pregabalin
Pregabalin Sandoz GmbH 50 mg hard capsules	Sandoz GmbH	EU/1/15/1012/011-017	Capsule, hard	-Pregabalin
Pregabalin Sandoz GmbH 75 mg hard capsules	Sandoz GmbH	EU/1/15/1012/018-033	Capsule, hard	-Pregabalin
Pregabalin Teva 100 mg capsules, hard	Teva B.V.	PA1986/001/004	Capsule, hard	-Pregabalin
Pregabalin Teva 150 mg capsules, hard	Teva B.V.	PA1986/001/005	Capsule, hard	-Pregabalin
Pregabalin Teva 200 mg capsules, hard	Teva B.V.	PA1986/001/006	Capsule, hard	-Pregabalin
Pregabalin Teva 25 mg capsules, hard	Teva B.V.	PA1986/001/001	Capsule, hard	-Pregabalin
Pregabalin Teva 300 mg capsules, hard	Teva B.V.	PA1986/001/008	Capsule, hard	-Pregabalin
Pregabalin Teva 50 mg capsules, hard	Teva B.V.	PA1986/001/002	Capsule, hard	-Pregabalin
Pregabalin Teva 75 mg capsules, hard	Teva B.V.	PA1986/001/003	Capsule, hard	-Pregabalin
Pregabalin Zentiva 100 mg hard capsules	Zentiva k.s.	EU/1/15/1021/014-016	Capsule, hard	-Pregabalin
Pregabalin Zentiva 150 mg hard capsules	Zentiva k.s.	EU/1/15/1021/017-019	Capsule, hard	-Pregabalin
Pregabalin Zentiva 200 mg hard capsules	Zentiva k.s.	EU/1/15/1021/020-022	Capsule, hard	-Pregabalin
Pregabalin Zentiva 225 mg hard capsules	Zentiva k.s.	EU/1/15/1021/023-025	Capsule, hard	-Pregabalin
Pregabalin Zentiva 25 mg hard capsules	Zentiva k.s.	EU/1/15/1021/001-005	Capsule, hard	-Pregabalin
Pregabalin Zentiva 300 mg hard capsules	Zentiva k.s.	EU/1/15/1021/026-028	Capsule, hard	-Pregabalin
Pregabalin Zentiva 50 mg hard capsules	Zentiva k.s.	EU/1/15/1021/006-010	Capsule, hard	-Pregabalin
Pregabalin Zentiva 75 mg hard capsules	Zentiva k.s.	EU/1/15/1021/011-013	Capsule, hard	-Pregabalin
PreHevbri	VBI Vaccines B.V.	EU/1/22/1641	Suspension for injectio	-Hepatitis b surface antigen
Premarin 0.3 mg Prolonged-release tablets	Pfizer Healthcare Ireland	PA0822/095/001	Prolonged-release tablet	-Conjugated estrogens
Premarin 0.625 mg Prolonged-release tablets	Pfizer Healthcare Ireland	PA0822/095/002	Prolonged-release tablet	-Conjugated estrogens
Premarin 1.25 mg Prolonged-release tablets	Pfizer Healthcare Ireland	PA0822/095/003	Prolonged-release tablet	-Conjugated estrogens
Prenoxad 0.91 mg/ml solution for injection in a pre-filled syringe	Ethypharm	PA0549/021/001	Solution for injection in pre-filled syringe	-Naloxone hydrochloride dihydrate
PREPANDEMIC INFLUENZA	GSK Vaccines S.r.l.	EU/1/10/657/001-002	Suspension for Injection	-H5N1 (A/VIETNAM/1194/2004)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Pretomanid FGK	Mylan IRE Healthcare Limited	EU/1/20/1437/001-005	Tablet	-Pretomanid
PREVENAR	Wyeth Lederle Vaccines S.A.	EU/1/00/167/001	Suspension for injectio	-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)
Prevenar	Wyeth Lederle Vaccines S.A.	EU/1/00/167/002	Suspension for injectio	-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)
Prevenar	Wyeth Lederle Vaccines S.A.	EU/1/00/167/003	Suspension for injection in pre-filled syringe	-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)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Prevenar	Wyeth Lederle Vaccines S.A.	EU/1/00/167/008	Suspension for injection in pre-filled syringe	-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
Prevenar	Wyeth Lederle Vaccines S.A.	EU/1/00/167/4-7	Suspension for injectio	-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)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Prevenar 13	Pfizer Europe MA EEIG	EU/1/09/590/1-6	Suspension for injectio	-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
Prevora 100mg/ml Dental Solution	CHX Technologies Europe Limited	PA1205/001/001	Dental solution	-CHLORHEXIDINE DIACETATE
Prevymis	Merck Sharp & Dohme BV,	EU/1/17/1245/001	Film-coated tablet	-LETERMOVIR
Prevymis	Merck Sharp & Dohme BV	EU/1/17/1245/002	Film-coated tablet	-LETERMOVIR
Prevymis	Merck Sharp & Dohme BV	EU/1/17/1245/003	Concentrate for solution for infusion	-LETERMOVIR
Prevymis	Merck Sharp & Dohme BV	EU/1/17/1245/004	Concentrate for solution for infusion	-LETERMOVIR
Prezista	Janssen-Cilag International NV	EU/1/06/380/001	Tablet	-Darunavir
Prezista	Janssen-Cilag International NV	EU/1/06/380/003	Film-coated tablet	-Darunavir
Prezista	Janssen-Cilag International NV	EU/1/06/380/004	Film-coated tablet	-Darunavir (as ethanolate)
Prezista	Janssen-Cilag International NV	EU/1/06/380/005	Film-coated tablet	-Darunavir (as ethanolate)
Prezista	Janssen-Cilag International NV	EU/1/06/380/006	Oral suspension	
Prezista	Janssen-Cilag International NV	EU/1/06/380/007	Film-coated tablet	-Darunavir (as ethanolate)
PREZISTA 600 mg film-coated tablets	Janssen-Cilag International NV	EU/1/06/380/002	Film-coated tablet	-Darunavir (as ethanolate)
Priadel 200mg prolonged-release tablets	Essential Pharma Limited	PA22587/001/001	Prolonged-release tablet	-Lithium carbonate
Priadel 400mg prolonged-release tablets	Essential Pharma Limited	PA22587/001/002	Prolonged-release tablet	-Lithium carbonate
PRIALT	Esteve Pharmaceuticals GmbH	EU/1/04/302/1-3	Solution for infusion	-Ziconotide
Priligy 30 mg film-coated tablets	A. Menarini Pharmaceuticals Ireland Ltd	PA1833/001/001	Film-coated tablet	-Dapoxetine
Priligy 60 mg film-coated tablets	A. Menarini Pharmaceuticals Ireland Ltd	PA1833/001/002	Film-coated tablet	-Dapoxetine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Primacine 125 mg/5 ml Granules for Oral Suspension	Pinewood Laboratories Ltd	PA0281/026/007	Granules for oral suspension	-Erythromycin ethylsuccinate
Primacine 250 mg/5 ml Granules for Oral Suspension	Pinewood Laboratories Ltd	PA0281/026/008	Granules for oral suspension	-Erythromycin ethylsuccinate
Primacine 500 mg/5 ml Granules for Oral Suspension	Pinewood Laboratories Ltd	PA0281/026/009	Granules for oral suspension	-Erythromycin ethylsuccinate
Primene 10% Solution for Infusion	Baxter Holding B.V.	PA2299/018/001	Solution for infusion	-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
Primovist 0.25 mmol/ml, solution for injection	Bayer Limited	PA1410/021/002	Solution for injection	-Gadoxetic acid, disodium
Primovist 0.25 mmol/ml, solution for injection, pre-filled syringe	Bayer Limited	PA1410/021/001	Solution for injection in pre-filled syringe	-Gadoxetic acid, disodium
Priorix - Powder and solvent for solution for injection in a pre-filled syringe Measles, Mumps and Rubella vaccine (live)	GlaxoSmithKline (Ireland) Limited	PA1077/036/001	Powder and solvent for solution for injection in pre-filled syringe	-Measles virus - schwarz strain live attenuated -Mumps vaccine rit 4385 live attenuated -Rubella virus (ra 27/3 strain)
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	-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)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Primasol 2 mmol/l Potassium solution for haemodialysis/haemofiltration	Baxter Holding B.V.	PA2299/052/001	Solution for haemodialysis/haemofiltration	-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
Primasol 2 mmol/l Potassium solution for haemodialysis/haemofiltration	Baxter Holding B.V.	PA2299/052/002	Solution for haemodialysis/haemofiltration	-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
Primasol 4 mmol/l Potassium solution for haemodialysis/haemofiltration	Baxter Holding B.V.	PA2299/052/003	Solution for haemodialysis/haemofiltration	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Primasol 4 mmol/l Potassium solution for haemodialysis/haemofiltration	Baxter Holding B.V.	PA2299/052/004	Solution for haemodialysis/haemofiltration	-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
Pritor 20 mg tablets	Bayer AG	EU/1/98/089/011-014	Tablet	-Telmisartan
Pritor 40 mg tablets	Bayer AG	EU/1/98/089/001-005	Tablet	-Telmisartan
Pritor 80 mg tablets	Bayer AG	EU/1/98/089/006-010	Tablet	-Telmisartan
PritorPlus 40 mg/12.5 mg tablets	Bayer AG	EU/1/02/215/1-5	Tablet	-Telmisartan -Hydrochlorothiazide
PritorPlus 80 mg/25 mg tablets	Bayer AG	EU/1/02/215/15-21	Tablet	-Hydrochlorothiazide -Telmisartan
Privigen (Human normal immunoglobulin)	CSL Behring GmbH	EU/1/08/446/1-3	Solution for infusion	-Human normal immunoglobulin
Procoralan	Les Laboratoires Servier	EU/1/05/316/1-7	Film-coated tablet	-Ivabradine
Procoralan	Les Laboratoires Servier	EU/1/05/316/8-14	Film-coated tablet	-Ivabradine
Proctosedyl Ointment	Phoenix Labs	PA1113/029/001	Ointment	-Hydrocortisone -Cinchocaine Hydrochloride -Aesculin -Framycetin sulphate
Procysbi	Chiesi Farmaceutici S.p.A.	EU/1/13/861/001	Gastro-resistant capsule, hard	-Cysteamine bitartrate
Procysbi	Chiesi Farmaceutici S.p.A.	EU/1/13/861/002	Gastro-resistant capsule, hard	-Cysteamine bitartrate
Procysbi	Chiesi Farmaceutici S.p.A.	EU/1/13/861/003	Gastro-resistant granules	-Mercaptamine bitartrate
Procysbi	Chiesi Farmaceutici S.p.A.	EU/1/13/861/004	Gastro-resistant granules	-Mercaptamine bitartrate
Produodopa 240 mg/ml + 12 mg/ml solution for infusion	AbbVie Limited	PA1824/002/003	Solution for infusion	-Foslevodopa -Foscarbidopa
Pro-Epanutin 75 mg/ml concentrate for solution for infusion/solution for injection	Pfizer Healthcare Ireland	PA0822/019/001	Solution for injection/infusion	-Fosphenytoin sodium
Profloxin 250 mg film-coated Tablets	Clonmel Healthcare Ltd	PA0126/203/001	Film-coated tablet	-Ciprofloxacin
Profloxin 500 mg film-coated Tablets	Clonmel Healthcare Ltd	PA0126/203/002	Film-coated tablet	-Ciprofloxacin
Progesterone 400 mg pessaries	Gedeon Richter Plc	PA1330/027/001	Pessary	-Progesterone
Prograf 0.5 mg hard capsules	Astellas Pharma Co. Limited	PA1241/014/001	Capsule, hard	-Tacrolimus
Prograf 0.5 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/435/001	Capsule, hard	-Tacrolimus
Prograf 0.5 mg hard capsules	IMED Healthcare Ltd.	PPA1463/165/001	Capsule, hard	-Tacrolimus

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Prograf 1 mg hard capsules	Astellas Pharma Co. Limited	PA1241/014/002	Capsule, hard	-Tacrolimus
Prograf 5 mg hard capsules	Astellas Pharma Co. Limited	PA1241/014/003	Capsule, hard	-Tacrolimus
Prograf 5 mg/ml concentrate for solution for infusion	Astellas Pharma Co. Limited	PA1241/014/004	Concentrate for solution for infusion	-Tacrolimus
ProHance, 279.3 mg/ml, Solution for Injection, 10 ml vial	Bracco International B.V.	PA0788/001/002	Solution for injection	-Gadoteridol
ProHance, 279.3 mg/ml, Solution for Injection, 15 ml vial	Bracco International B.V.	PA0788/001/003	Solution for injection	-Gadoteridol
ProHance, 279.3 mg/ml, solution for injection, 20 ml vial	Bracco International B.V.	PA0788/001/004	Solution for injection	-Gadoteridol
Prolastin 4000 mg, powder and solvent for solution for infusion	Grifols Deutschland GmbH	PA1405/002/002	Powder and solvent for solution for infusion	-Human alpha1-proteinase inhibitor
Prolastin 5000 mg, powder and solvent for solution for infusion	Grifols Deutschland GmbH	PA1405/002/003	Powder and solvent for solution for infusion	-Human alpha1-proteinase inhibitor
Prolastin1000mg, powder and solvent for solution for infusion	Grifols Deutschland GmbH	PA1405/002/001	Powder and solvent for solution for infusion	-Alpha-1-proteinase inhibitor
Prolia	Amgen Europe B.V.	EU/1/10/618/1-4	Solution for injection	-Denosumab
PROMETAX	Novartis Europharm Limited	EU/1/98/092/001	Capsule, hard	-Rivastigmine hydrogen tartrate
Prometax	Novartis Europharm Limited	EU/1/98/092/002	Capsule, hard	-Rivastigmine hydrogen tartrate
Prometax	Novartis Europharm Limited	EU/1/98/092/003	Capsule, hard	-Rivastigmine hydrogen tartrate
Prometax	Novartis Europharm Limited	EU/1/98/092/004	Capsule, hard	-Rivastigmine hydrogen tartrate
Prometax	Novartis Europharm Limited	EU/1/98/092/005	Capsule, hard	-Rivastigmine hydrogen tartrate
Prometax	Novartis Europharm Limited	EU/1/98/092/006	Capsule, hard	-Rivastigmine hydrogen tartrate
Prometax	Novartis Europharm Limited	EU/1/98/092/007	Capsule, hard	-Rivastigmine hydrogen tartrate
Prometax	Novartis Europharm Limited	EU/1/98/092/008	Capsule, hard	-Rivastigmine hydrogen tartrate
Prometax	Novartis Europharm Limited	EU/1/98/092/009	Capsule, hard	-Rivastigmine hydrogen tartrate
Prometax	Novartis Europharm Limited	EU/1/98/092/010	Capsule, hard	-Rivastigmine hydrogen tartrate
Prometax	Novartis Europharm Limited	EU/1/98/092/011	Capsule, hard	-Rivastigmine hydrogen tartrate
Prometax	Novartis Europharm Limited	EU/1/98/092/012	Capsule, hard	-Rivastigmine hydrogen tartrate
Prometax	Novartis Europharm Limited	EU/1/98/092/013	Oral solution	-Rivastigmine hydrogen tartrate
Prometax	Novartis Europharm Limited	EU/1/98/092/027-030	Transdermal patch	-Rivastigmine
Prometax	Novartis Europharm Limited	EU/1/98/092/19-22	Transdermal patch	-Rivastigmine base
Prometax	Novartis Europharm Limited	EU/1/98/092/23-26	Transdermal patch	-Rivastigmine base
Propafenone Hydrochloride 150mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/116/001	Film-coated tablet	-Propafenone hydrochloride
Propafenone Hydrochloride 300mg Film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/116/002	Film-coated tablet	-Propafenone hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Propress 10 mg vaginal delivery system	Ferring Ireland Ltd	PA1009/029/001	Vaginal delivery system	-Dinoprostone
Propinorm XL 30 mg Modified-Release Capsules	Apogepha Arzneimittel GmbH	PA0803/005/001	Modified-release capsule, hard	-Propiverine hydrochloride
Propofol 1 % (10 mg/1 ml) Fresenius emulsion for injection or infusion, ampoule	Fresenius Kabi Deutschland GmbH	PA2059/055/001	Emulsion for injection/infusion	-Propofol
Propofol 1 % (10 mg/1 ml) Fresenius emulsion for injection or infusion, vial	Fresenius Kabi Deutschland GmbH	PA2059/055/002	Emulsion for injection/infusion	-Propofol
Propofol 1% (10 mg/ml) emulsion for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/017/001	Emulsion for injection/infusion	-Propofol
Propofol 1% (10 mg/ml) emulsion for injection/infusion	Fresenius Kabi Deutschland GmbH	PA2059/017/002	Emulsion for injection/infusion	-Propofol
Propofol 10 mg/ml Emulsion for injection/infusion	Baxter Holding B.V.	PA2299/038/001	Emulsion for injection/infusion	-Propofol
Propofol 2 % (20 mg/1 ml) Fresenius emulsion for injection or infusion, ampoule	Fresenius Kabi Deutschland GmbH	PA2059/055/003	Emulsion for injection/infusion	-Propofol
Propofol 2 % (20 mg/1 ml) Fresenius emulsion for injection or infusion, vial	Fresenius Kabi Deutschland GmbH	PA2059/055/004	Emulsion for injection/infusion	-Propofol
Propofol 20 mg/ml Emulsion for injection/infusion	Baxter Holding B.V.	PA2299/038/002	Emulsion for injection/infusion	-Propofol
Propofol-Lipuro 1 % (10 mg/ml) emulsion for injection or infusion	B. Braun Melsungen AG	PA0736/018/001	Emulsion for injection/infusion	-Propofol
Propofol-Lipuro 1 % (10 mg/ml) emulsion for injection or infusion	B. Braun Melsungen AG	PA0736/018/002	Emulsion for injection/infusion	-Propofol
Propofol-Lipuro 2 % (20 mg/ml) emulsion for injection or infusion	B. Braun Melsungen AG	PA0736/018/003	Emulsion for injection/infusion	-Propofol
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	-Propofol
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	-Propofol
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	-Propofol
Propranolol Azure 10 mg film-coated tablets	Azure Pharmaceuticals Ltd	PA22871/031/001	Film-coated tablet	-Propranolol hydrochloride
Propranolol Azure 40 mg film-coated tablets	Azure Pharmaceuticals Ltd	PA22871/031/002	Film-coated tablet	-Propranolol hydrochloride
Propylthiouracil 50 mg tablets	Halewood Chemicals (Ireland) Limited	PA22902/001/001	Tablet	-Propylthiouracil

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Proquad	Merck Sharp & Dohme BV,	EU/1/05/323/1-13	Powder and solvent for suspension for injection	-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	IMED Healthcare Ltd.	PPA1463/127/001	Film-coated tablet	-Finasteride
Proscar 5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/098/001	Film-coated tablet	-Finasteride
Proscar 5mg Film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/007/001	Film-coated tablet	-Finasteride
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	-Leuprorelin acetate
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	-Leuprorelin acetate
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	-Leuprorelin acetate
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	-Leuprorelin acetate
Prostasan soft capsule	A.Vogel Ireland Limited	TR2309/002/001	Capsule, soft	-Sabalis serrulatae extractum spissum
Prostin E2 1 mg Vaginal Gel	Pfizer Healthcare Ireland	PA0822/178/001	Vaginal gel	-Dinoprostone
Prostin E2 1mg/ml Concentrate for solution for infusion	Pfizer Healthcare Ireland	PA0822/133/003	Concentrate for solution for infusion	-Dinoprostone
Prostin E2 2 mg Vaginal Gel	Pfizer Healthcare Ireland	PA0822/178/002	Vaginal gel	-Dinoprostone
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	-Protamine sulphate
Protaphane	Novo Nordisk A/S	EU/1/02/234/016-017	Suspension for injectio	-Insulin human
Protaphane	Novo Nordisk A/S	EU/1/02/234/1-15	Suspension for injectio	-Insulin human
Prothiaden 25 mg Hard Capsules	Teofarma S.R.L.	PA1235/005/001	Capsule, hard	-Dothiepine hydrochloride
Prothiaden 75mg Coated Tablets	Teofarma S.R.L.	PA1235/005/002	Coated tablet	-Dosulepin hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Prothromplex TOTAL 500 IU powder and solvent for solution for injection	Baxalta Innovations GmbH	PA2004/005/002	Powder and solvent for solution for injection	-Human coagulation factor ii -Human coagulation factor vii -Human coagulation factor ix -Human coagulation factor x -Human Protein C
Prothromplex TOTAL 600 IU powder and solvent for solution for injection	Baxalta Innovations GmbH	PA2004/005/001	Powder and solvent for solution for injection	-Human coagulation factor ii -Human coagulation factor vii -Human coagulation factor ix -Human coagulation factor x -Protein c
Protium 20 mg gastro-resistant tablets	Takeda Products Ireland Ltd	PA2229/010/001	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate
Protium 40 mg gastro-resistant tablets	Takeda Products Ireland Ltd	PA2229/010/002	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate
Protium i.v. 40 mg Powder for Solution for Injection	Takeda Products Ireland Ltd	PA2229/010/003	Powder for solution for injection	-Pantoprazole sodium sesquihydrate
Protizole 20 mg gastro-resistant tablet	Accord Healthcare Ireland Ltd.	PA2315/260/001	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate
Protizole 40 mg gastro-resistant tablet	Accord Healthcare Ireland Ltd.	PA2315/260/002	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate
PROTOPIC	LEO Pharma A/S	EU/1/02/201/001	Ointment	-Tacrolimus
PROTOPIC	LEO Pharma A/S	EU/1/02/201/002	Ointment	-Tacrolimus
PROTOPIC	LEO Pharma A/S	EU/1/02/201/003	Ointment	-Tacrolimus
PROTOPIC	LEO Pharma A/S	EU/1/02/201/004	Ointment	-Tacrolimus
PROTOPIC	LEO Pharma A/S	EU/1/02/201/005	Ointment	-Tacrolimus
PROTOPIC	LEO Pharma A/S	EU/1/02/201/006	Ointment	-Tacrolimus
Prousan 250mg Capsules, Hard	PRO.MED.CS Praha a.s.	PA2179/002/001	Capsule, hard	-Ursodeoxycholic acid
Prousan 400 mg film-coated tablets	PRO.MED.CS Praha a.s.	PA2179/001/002	Film-coated tablet	-Ursodeoxycholic acid
Prousan 500 mg film-coated tablets	PRO.MED.CS Praha a.s.	PA2179/001/001	Film-coated tablet	-Ursodeoxycholic acid
Provera 10 mg tablets	Pfizer Healthcare Ireland	PA0822/134/003	Tablet	-Medroxyprogesterone acetate
Provera 2.5 mg tablets	Pfizer Healthcare Ireland	PA0822/134/001	Tablet	-Medroxyprogesterone acetate
Provigil 100 mg tablets	Teva Pharma B.V.	PA0749/198/001	Tablet	-Modafinil
Provigil 100 mg tablets	PCO Manufacturing Ltd.	PPA0465/415/001	Tablet	-Modafinil
Provigil 200 mg tablets	Teva Pharma B.V.	PA0749/198/002	Tablet	-Modafinil
PROZAC	Clear Pharmacy	DPR1596/008/001	Capsule, hard	-FLUOXETINE HYDROCHLORIDE
Prozamel 20 mg Capsules, Hard	Clonmel Healthcare Ltd	PA0126/110/001	Capsule, hard	-FLUOXETINE HYDROCHLORIDE
Prucalopride 1 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/260/001	Film-coated tablet	-Prucalopride Succinate
Prucalopride 2 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/260/002	Film-coated tablet	-Prucalopride Succinate
Prucalopride Aristo 1 mg film-coated tablets	Aristo Pharma GmbH	PA1983/010/001	Film-coated tablet	-Prucalopride Succinate
Prucalopride Aristo 2 mg film-coated tablets	Aristo Pharma GmbH	PA1983/010/002	Film-coated tablet	-Prucalopride Succinate
Pulmicort Respules 0.5 mg/2 ml Nebuliser Suspension	AstraZeneca AB	PA1019/017/001	Nebuliser suspension	-Budesonide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Pulmicort Respules 1 mg /2 ml Nebuliser Suspension	AstraZeneca AB	PA1019/017/002	Nebuliser suspension	-Budesonide
Pulmicort Respules 1 mg /2 ml Nebuliser Suspension	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/059/001	Nebuliser suspension	-Budesonide
Pulmicort Turbohaler 100 micrograms Inhalation Powder	AstraZeneca AB	PA1019/017/003	Inhalation powder	-Budesonide
Pulmicort Turbohaler 200 micrograms Inhalation Powder	AstraZeneca AB	PA1019/017/004	Inhalation powder	-Budesonide
Pulmicort Turbohaler 400 micrograms Inhalation Powder	AstraZeneca AB	PA1019/017/005	Inhalation powder	-Budesonide
PULMOCIS 2 mg kit for radiopharmaceutical preparation	CIS bio International	PA0677/003/001	Kit for radiopharmaceutical preparation	-Human albumin macro aggregated
PULMOTEC Graphite crucible for the preparation of Technegas inhalation	Cyclomedica Ireland Ltd	PA1034/001/001	Kit for radiopharmaceutical preparation	-Graphites
Pulmozyme 2500 U/ 2.5ml, nebuliser solution	Roche Products (Ireland) Ltd	PA2307/005/001	Nebuliser solution	-Dornase alfa
Pulmozyme 2500 U/2.5 ml nebuliser solution	PCO Manufacturing Ltd.	PPA0465/433/001	Nebuliser solution	-Dornase alfa
Puregon	N.V. Organon	EU/1/96/008/017	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/018	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/019	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/020	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/021	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/022	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/023	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/024	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/025	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/026	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/027	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/028	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/029	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/030	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/031	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/032	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/033	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/034	Solution for injection	-Follitropin beta
PUREGON	N.V. Organon	EU/1/96/008/038	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/039	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/040	Solution for injection	-Follitropin beta
Puregon	N.V. Organon	EU/1/96/008/041	Solution for injection	-Follitropin beta
Puri-Nethol 50 mg Tablets	PCO Manufacturing Ltd.	PPA0465/455/001	Tablet	-Mercaptopurine monohydrate
Puri-Nethol 50 mg Tablets	IMED Healthcare Ltd.	PPA1463/128/001	Tablet	-Mercaptopurine monohydrate
Puri-Nethol 50 mg Tablets	Aspen Pharma Trading Limited	PA1691/009/001	Tablet	-Mercaptopurine monohydrate
Pyclari	Curium Pet France	EU/1/23/1746/001	Solution for injection	-2-(3-{1-carboxy-5-[(6-[(18)F]fluoro-pyridine-3-carbonyl)-amino]-pentyl}-ureido)-pentanedioic acid
Pylobactell	Torbet Laboratories Ireland Limited	EU/1/98/064/01	Soluble tablet	-13c-urea

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Pyranistole 200 mg prolonged release capsules	Renata Pharmaceuticals (Ireland) Limited	PA22865/001/001	Prolonged-release capsule, hard	-Dipyridamole
Pyrukynd	Agios Netherlands B.V.	EU/1/22/1662/001-003	Film-coated tablet	-Mitapivat Sulfate
Pyrukynd	Agios Netherlands B.V.	EU/1/22/1662/004-005	Film-coated tablet	-Mitapivat Sulfate
Pyrukynd	Agios Netherlands B.V.	EU/1/22/1662/006	Film-coated tablet	-Mitapivat Sulfate
Qaialdo	Nova Laboratories Ireland Limited	EU/1/23/1731/001	Oral suspension	-Spironolactone
Qarziba	EUSA Pharma (Netherlands) B.V.	EU/1/17/1191/001	Concentrate for solution for infusion	-Dinutuximab beta
Qdenga	Takeda GmbH	EU/1/22/1699/001	Powder and solvent for solution for injection	-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
Qdenga	Takeda GmbH	EU/1/22/1699/002	Powder and solvent for solution for injection	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Qdenga	Takeda GmbH	EU/1/22/1699/003	Powder and solvent for solution for injection	-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
Qdenga	Takeda GmbH	EU/1/22/1699/004	Powder and solvent for solution for injection	-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
Qinlock	Deciphera Pharmaceuticals (Netherlands) B.V.	EU/1/21/1569/001-002	Tablet	-Ripretinib
Qlaira film-coated tablets	Bayer Limited	PA1410/058/001	Film-coated tablet	-Estradiol valerate -Estradiol valerate -Dienogest -Dienogest -Estradiol valerate
Qtern	AstraZeneca AB	EU/1/16/1108/001-004	Film-coated tablet	-Dapagliflozin -Saxagliptin
Quadramet	CIS bio International	EU/1/97/057/001	Solution for injection	-SAMARIUM (153SM) EDTMP

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-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)
Quentiax SR 150mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/045/001	Prolonged-release tablet	-Quetiapine hemifumarate
Quentiax SR 200 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/045/002	Prolonged-release tablet	-Quetiapine hemifumarate
Quentiax SR 300 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/045/003	Prolonged-release tablet	-Quetiapine hemifumarate
Quentiax SR 400 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/045/005	Prolonged-release tablet	-Quetiapine hemifumarate
Quentiax SR 50mg Prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/045/004	Prolonged-release tablet	-Quetiapine
Questran 4g/sachet, Powder for oral suspension	CHEPLAPHARM Arzneimittel GmbH	PA2239/005/001	Powder for oral suspension	-Colestyramine resin
Quetex 100 mg film-coated tablets	Rowex Ltd	PA0711/156/003	Film-coated tablet	-Quetiapine
Quetex 200 mg film-coated tablets	Rowex Ltd	PA0711/156/004	Film-coated tablet	-Quetiapine
Quetex 25mg film-Coated tablets	Rowex Ltd	PA0711/156/001	Film-coated tablet	-Quetiapine
Quetex 300 mg film-coated tablets	Rowex Ltd	PA0711/156/005	Film-coated tablet	-Quetiapine
Quetex XR 200 mg prolonged-release tablets	Rowex Ltd	PA0711/258/002	Prolonged-release tablet	-Quetiapine
Quetex XR 300 mg prolonged-release tablets	Rowex Ltd	PA0711/258/003	Prolonged-release tablet	-Quetiapine
Quetex XR 400 mg prolonged-release tablets	Rowex Ltd	PA0711/258/004	Prolonged-release tablet	-Quetiapine
Quetex XR 50 mg prolonged-release tablets	Rowex Ltd	PA0711/258/001	Prolonged-release tablet	-Quetiapine
Quetiapine 100 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/117/002	Film-coated tablet	-Quetiapine
Quetiapine 200 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/117/003	Film-coated tablet	-Quetiapine
Quetiapine 25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/117/001	Film-coated tablet	-Quetiapine
Quetiapine 300 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/117/004	Film-coated tablet	-Quetiapine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Quetiapine Fair-Med 100 mg film-coated tablets	Fairmed Healthcare GmbH	PA1789/002/002	Film-coated tablet	-Quetiapine
Quetiapine Fair-Med 150 mg film-coated tablets	Fairmed Healthcare GmbH	PA1789/002/003	Film-coated tablet	-Quetiapine
Quetiapine Fair-Med 200 mg film-coated tablets	Fairmed Healthcare GmbH	PA1789/002/004	Film-coated tablet	-Quetiapine
Quetiapine Fair-Med 25 mg film-coated tablets	Fairmed Healthcare GmbH	PA1789/002/001	Film-coated tablet	-Quetiapine
Quetiapine Fair-Med 300 mg film-coated tablets	Fairmed Healthcare GmbH	PA1789/002/005	Film-coated tablet	-Quetiapine
Quetiapine Fair-Med Starterpack	Fairmed Healthcare GmbH	PA1789/002/006	Film-coated tablet	-Quetiapine -Quetiapine -Quetiapine
Quetiapine Krka 100mg Film-coated Tablets	KRKA, d.d., Novo mesto	PA1347/027/002	Film-coated tablet	-Quetiapine
Quetiapine Krka 200mg Film-coated Tablets	KRKA, d.d., Novo mesto	PA1347/027/003	Film-coated tablet	-Quetiapine
Quetiapine Krka 25mg Film-coated Tablets	KRKA, d.d., Novo mesto	PA1347/027/001	Film-coated tablet	-Quetiapine
Quetiapine Krka 300mg Film-coated Tablets	KRKA, d.d., Novo mesto	PA1347/027/004	Film-coated tablet	-Quetiapine
Quinine Sulphate 300 mg film coated tablets	Teva B.V.	PA1986/052/001	Film-coated tablet	-Quinine sulfate
Quinoderm 10% w/w + 0.5% w/w Cream	Alliance Pharma (Ireland) Limited	PA2325/012/001	Cream	-Benzoyl peroxide hydrous -Potassium Hydroxyquinoline Sulphate
Quinoderm 5% w/w + 0.5% w/w Cream	Alliance Pharma (Ireland) Limited	PA2325/012/002	Cream	-Benzoyl peroxide hydrous -Potassium Hydroxyquinoline Sulphate
Quinsair	Chiesi Farmaceutici S.p.A.	EU/1/14/973/001	Nebuliser solution	-Levofloxacin
Quofenix	A. Menarini Industrie Farmaceutische Riunite S.r.l.	EU/1/19/1393/001	Powder for concentrate for solution for infusion	-DELAFLORACIN MEGLUMINE
Qutenza	Grünenthal GmbH	EU/1/09/524/001-002	Cutaneous patch	-Capsaicin
Quviviq	Idorsia Pharmaceuticals Deutschland GmbH	EU/1/22/1638/001-002	Film-coated tablet	-Daridorexant hydrochloride
Rabeprazole Krka 10mg Gastro-Resistant Tablets	KRKA, d.d., Novo mesto	PA1347/030/001	Gastro-resistant tablet	-Rabeprazole sodium
Rabeprazole Krka 20mg Gastro-Resistant Tablets	KRKA, d.d., Novo mesto	PA1347/030/002	Gastro-resistant tablet	-Rabeprazole sodium
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	-Inactivated Rabies Virus Strain PM/WI 38 1503 3M
Raener 2 mg/0.03 mg film-coated tablets	Laboratorios Leon Farma, S.A.	PA1474/011/001	Film-coated tablet	-Dienogest micronized -Ethinylestradiol micronized
Raloxifene Teva	Teva B.V.	EU/1/10/627/1-3	Film-coated tablet	-Raloxifene hydrochloride
Ramilo 1.25 mg tablets	Rowex Ltd	PA0711/063/001	Tablet	-Ramipril

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Ramilo 10 mg Tablets	Rowex Ltd	PA0711/063/004	Tablet	-Ramipril
Ramilo 2.5 mg tablets	Rowex Ltd	PA0711/063/002	Tablet	-Ramipril
Ramilo 5 mg tablets	Rowex Ltd	PA0711/063/003	Tablet	-Ramipril
Ramipril Krka 1.25 mg tablets	KRKA, d.d., Novo mesto	PA1347/042/001	Tablet	-Ramipril
Ramipril Krka 10 mg tablets	KRKA, d.d., Novo mesto	PA1347/042/004	Tablet	-Ramipril
Ramipril Krka 2.5 mg tablets	KRKA, d.d., Novo mesto	PA1347/042/002	Tablet	-Ramipril
Ramipril Krka 5 mg tablets	KRKA, d.d., Novo mesto	PA1347/042/003	Tablet	-Ramipril
Ramipril Teva Pharma 1.25mg Tablets	Teva Pharma B.V.	PA0749/177/001	Tablet	-Ramipril
Ramipril Teva Pharma 10mg Tablets	Teva Pharma B.V.	PA0749/177/004	Tablet	-Ramipril
Ramipril Teva Pharma 2.5mg Tablets	Teva Pharma B.V.	PA0749/177/002	Tablet	-Ramipril
Ramipril Teva Pharma 5mg Tablets	Teva Pharma B.V.	PA0749/177/003	Tablet	-Ramipril
Ramitace 10mg Tablets	Clonmel Healthcare Ltd	PA0126/163/003	Tablet	-Ramipril
Ramitace 2.5mg Tablets	Clonmel Healthcare Ltd	PA0126/163/001	Tablet	-Ramipril
Ramitace 5 mg tablets	Clonmel Healthcare Ltd	PA0126/163/002	Tablet	-Ramipril
Ramonna 1500 microgram Tablet	Gedeon Richter Plc	PA1330/021/001	Tablet	-Levonorgestrel
Ranexa	Menarini International Operations Luxembourg S.A.	EU/1/08/462/1,2,7,8	Prolonged-release tablet	-Ranolazine
Ranexa 500 mg prolonged-release tablets	Menarini International Operations Luxembourg S.A.	EU/1/08/462/3,4,9,10	Prolonged-release tablet	-Ranolazine
Ranexa 750 mg prolonged-release tablets	Menarini International Operations Luxembourg S.A.	EU/1/08/462/5,6,11,12	Prolonged-release tablet	-Ranolazine
Raniviso	Midas Pharma GmbH	EU/1/22/1673/001	Solution for injection	-Ranibizumab
Ranolazine Clonmel 375 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/356/001	Prolonged-release tablet	-Ranolazine
Ranolazine Clonmel 500 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/356/002	Prolonged-release tablet	-Ranolazine
Ranolazine Clonmel 750 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/356/003	Prolonged-release tablet	-Ranolazine
Ranolazine Krka 375 mg prolonged release tablets	KRKA, d.d., Novo mesto	PA1347/109/001	Prolonged-release tablet	-Ranolazine
Ranolazine Krka 500 mg prolonged release tablets	KRKA, d.d., Novo mesto	PA1347/109/002	Prolonged-release tablet	-Ranolazine
Ranolazine Krka 750 mg prolonged release tablets	KRKA, d.d., Novo mesto	PA1347/109/003	Prolonged-release tablet	-Ranolazine
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/001	Oral solution	-Sirolimus
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/002	Oral solution	-Sirolimus
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/005	Oral solution	-Sirolimus
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/007	Coated tablet	-Sirolimus
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/008	Coated tablet	-Sirolimus

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/009-010	Coated tablet	-Sirolimus
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/013-014	Coated tablet	-Sirolimus
Rapamune	Pfizer Europe MA EEIG	EU/1/01/171/14	Coated tablet	-Sirolimus
Rapibloc 300 mg powder for solution for infusion	Orpha-Devel Handels und Vertriebs GmbH	PA1353/007/001	Powder for solution for infusion	-Landiolol hydrochloride
Rapifen 500 micrograms/ml solution for injection or infusion	Piramal Critical Care B.V.	PA22583/001/001	Solution for injection/infusion	-ALFENTANIL HYDROCHLORIDE
Rapilysin	Actavis Group hf	EU/1/96/018/001	Powder and solvent for solution for injection	-Retepase
Rapiscan	GE Healthcare AS	EU/1/10/643/001	Solution for injection	-Regadenoson
Raporsin 4 mg prolonged-release tablets	Accord Healthcare Ireland Ltd.	PA2315/005/002	Prolonged-release tablet	-Doxazosin mesilate
Raporsin 8mg prolonged release tablets	Accord Healthcare Ireland Ltd.	PA2315/005/001	Prolonged-release tablet	-Doxazosin
Rapydan 70 mg/70 mg medicated plaster	Eurocept International BV	PA1591/001/001	Medicated plaster	-Lidocaine -Tetracaine
Rasagiline Accord 1 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/174/001	Tablet	-Rasagiline
Rasagiline Bluefish 1 mg tablets	Bluefish Pharmaceuticals AB	PA1436/028/001	Tablet	-Rasagiline
Rasagiline Clonmel 1 mg tablets	Clonmel Healthcare Ltd	PA0126/276/001	Tablet	-Rasagiline
Rasagiline Krka 1 mg tablets	KRKA, d.d., Novo mesto	PA1347/088/001	Tablet	-Rasagiline
Rasagiline Mylan 1 mg tablets	Mylan Pharmaceuticals Limited	EU/1/16/1090/001-012	Tablet	-Rasagiline
Rasagiline Ratiopharm 1 mg tablets	Teva B.V.	EU/1/14/977/001-007	Tablet	-Rasagiline
Rasagiline Rowex 1 mg tablets	Rowex Ltd	PA0711/264/001	Tablet	-Rasagiline
Rasagiline Teva 1 mg tablets	Teva B.V.	PA1986/017/001	Tablet	-Rasagiline
Rasilez	Noden Pharma DAC	EU/1/07/405/11-20,31-40	Film-coated tablet	-Aliskiren hemifumarate
Ratiograstim 30 MIU/0.5 ml solution for injection	Ratiopharm GmbH	EU/1/08/444/1-4	Solution for injection/infusion	-Filgrastim
Ratiograstim 48 MIU/0.8 ml solution for injection	Ratiopharm GmbH	EU/1/08/444/5-8	Solution for injection/infusion	-Filgrastim
Ravicti	Immedica Pharma AB	EU/1/15/1062/001-004	Oral liquid	-Glycerol phenylbutyrate
Raxone	Chiesi Farmaceutici S.p.A.	EU/1/15/1020/001	Film-coated tablet	-Idebenone
Rayvow	Eli Lilly Nederland B.V.	EU/1/21/1587/001-010	Film-coated tablet	-Lasmiditan Succinate
Rayvow	Eli Lilly Nederland B.V.	EU/1/21/1587/011-020	Film-coated tablet	-Lasmiditan Succinate
Rayvow	Eli Lilly Nederland B.V.	EU/1/21/1587/021-030	Film-coated tablet	-Lasmiditan Succinate
Razolager 15 mg hard gastro-resistant capsules	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/065/001	Gastro-resistant capsule, hard	-Lansoprazole
Razolager 30 mg hard gastro-resistant capsules	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/065/002	Gastro-resistant capsule, hard	-Lansoprazole

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Razole 10 mg Gastro-resistant tablets	Rowa Pharmaceuticals Limited	PA0074/073/001	Gastro-resistant tablet	-Rabeprazole sodium
Razole 20 mg Gastro-resistant tablets	Rowa Pharmaceuticals Limited	PA0074/073/002	Gastro-resistant tablet	-Rabeprazole sodium
Reagila	Gedeon Richter Plc	EU/1/17/1209/001-010	Capsule, hard	-Cariprazine hydrochloride
Reagila	Gedeon Richter Plc	EU/1/17/1209/011-020	Capsule, hard	-Cariprazine hydrochloride
Reagila	Gedeon Richter Plc	EU/1/17/1209/021-028	Capsule, hard	-Cariprazine hydrochloride
Reagila	Gedeon Richter Plc	EU/1/17/1209/029-036	Capsule, hard	-Cariprazine hydrochloride
Rebif	Merck Europe B.V.	EU/1/98/063/008,18	Solution for injection in cartridge	-Interferon beta-1-a
Rebif	Merck Europe B.V.	EU/1/98/063/009,019	Solution for injection in cartridge	-Interferon beta-1-a
Rebif	Merck Europe B.V.	EU/1/98/063/010	Solution for injection in cartridge	-Interferon beta-1-a
REBIF	Merck Europe B.V.	EU/1/98/063/017	Solution for injection in pre-filled pen	-Interferon beta - 1a
REBIF	Merck Europe B.V.	EU/1/98/063/001,11-13	Solution for injection in pre-filled pen	-Interferon beta - 1a
Rebif	Merck Europe B.V.	EU/1/98/063/002	Solution for injection in pre-filled syringe	-Interferon beta - 1a
Rebif	Merck Europe B.V.	EU/1/98/063/003	Solution for injection in pre-filled syringe	-Interferon beta - 1a
Rebif	Merck Europe B.V.	EU/1/98/063/004	Solution for injection in pre-filled syringe	-Interferon beta - 1a
Rebif	Merck Europe B.V.	EU/1/98/063/005	Solution for injection in pre-filled syringe	-Interferon beta - 1a
Rebif	Merck Europe B.V.	EU/1/98/063/006	Solution for injection in pre-filled syringe	-Interferon beta - 1a
Rebif Starter Pack	Merck Europe B.V.	EU/1/98/063/007	Solution for injection in pre-filled syringe	-Interferon beta - 1a
Reblozyl	Bristol-Myers Squibb Pharma EEIG	EU/1/20/1452/001	Powder for solution for injection	-Luspatercept
Reblozyl	Bristol-Myers Squibb Pharma EEIG	EU/1/20/1452/002	Powder for solution for injection	-Luspatercept
Recarbrio	Merck Sharp & Dohme BV,	EU/1/19/1420/001	Powder for solution for infusion	-Imipenem -Cilastatin -Relebactam
Rectogesic 4 mg/g Rectal Ointment	Kyowa Kirin Holdings B.V.	PA2288/001/003	Rectal ointment	-Glyceryl trinitrate
Redoxon Double Action 1000 mg/10 mg Effervescent Tablets	Bayer Limited	PA1410/050/001	Effervescent tablet	-Ascorbic acid -Zinc citrate trihydrate
ReFacto	Pfizer Europe MA EEIG	EU/1/99/103/004	Powder and solvent for solution for injection	-Recombinant antihemophilic factor
ReFacto	Pfizer Europe MA EEIG	EU/1/99/103/002	Powder and solvent for solution for injection	-Recombinant antihemophilic factor
REFACTO AF	Pfizer Europe MA EEIG	EU/1/99/103/003	Powder and solvent for solution for injection	-Recombinant antihemophilic factor
ReFacto AF	Pfizer Europe MA EEIG	EU/1/99/103/005	Powder and solvent for solution for injection in pre-filled syringe	-Moroctocog alfa
ReFacto AF	Pfizer Europe MA EEIG	EU/1/99/103/006	Powder and solvent for solution for injection in pre-filled syringe	-Moroctocog alfa

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
ReFacto AF	Pfizer Europe MA EEIG	EU/1/99/103/007	Powder and solvent for solution for injection in pre-filled syringe	-Moroctocog alfa
ReFacto AF	Pfizer Europe MA EEIG	EU/1/99/103/008	Powder and solvent for solution for injection in pre-filled syringe	-Moroctocog alfa
REFACTO AF	Pfizer Europe MA EEIG	EU/1/99/103/001	Powder and solvent for solution for injection	-Recombinant antihemophilic factor
Refixia	Novo Nordisk A/S	EU/1/17/1193/001	Powder and solvent for solution for injection	-Nonacog beta pegol
Refixia	Novo Nordisk A/S	EU/1/17/1193/002	Powder and solvent for solution for injection	-Nonacog beta pegol
Refixia	Novo Nordisk A/S	EU/1/17/1193/003	Powder and solvent for solution for injection	-Nonacog beta pegol
Refixia	Novo Nordisk A/S	EU/1/17/1193/004	Powder and solvent for solution for injection	-Nonacog beta pegol
REFLAD 50 mg film-coated tablets	PRO.MED.CS Praha a.s.	PA2179/003/001	Film-coated tablet	-Itopride hydrochloride
Refresh Ophthalmic 1.4%w/v + 0.6%w/v Eye Drops Solution	AbbVie Limited	PA1824/013/001	Eye drops, solution	-Povidone -Polyvinyl Alcohol
Regaine Extra Strength 5% w/v Cutaneous Solution	JNTL Consumer Health I (Ireland) Limited	PA23490/038/002	Cutaneous solution	-Minoxidil
Regaine for Women Extra Strength Scalp Foam 5% w/w Cutaneous Foam	JNTL Consumer Health I (Ireland) Limited	PA23490/018/002	Cutaneous foam	-Minoxidil
Regaine for Women Regular Strength 2% w/v Cutaneous Solution	JNTL Consumer Health I (Ireland) Limited	PA23490/038/001	Cutaneous solution	-Minoxidil
Regiocit Solution for haemofiltration	Baxter Holding B.V.	PA2299/054/001	Solution for haemofiltration	-Sodium citrate -Sodium chloride
Regkirona	Celltrion Healthcare Hungary Kft.	EU/1/21/1597/001	Concentrate for solution for infusion	-Regdanvimab
Regurin 20 mg coated tablets	PCO Manufacturing Ltd.	PPA0465/281/001	Coated tablet	-Trospium chloride
Regurin 20 mg coated tablets	Viartis Healthcare Limited	PA23355/005/001	Coated tablet	-Trospium chloride
Regurin 20 mg coated tablets	IMED Healthcare Ltd.	PPA1463/143/001	Coated tablet	-Trospium chloride
REKAMBYS	Janssen-Cilag International NV	EU/1/20/1482/001	Prolonged-release suspension for injection	-Rilpivirine
REKAMBYS	Janssen-Cilag International NV	EU/1/20/1482/002	Prolonged-release suspension for injection	-Rilpivirine
Rekovellev	Ferring Pharmaceuticals A/S	EU/1/16/1150/004	Solution for injection	-Follitropin delta
Rekovellev	Ferring Pharmaceuticals A/S	EU/1/16/1150/005	Solution for injection	-Follitropin delta
Rekovellev	Ferring Pharmaceuticals A/S	EU/1/16/1150/006	Solution for injection	-Follitropin delta
Relenza 5mg/dose, inhalation powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/011/001	Inhalation powder, pre-dispensed	-Zanamivir
Relestat, 0.5 mg/ml, eye drops, solution	AbbVie Limited	PA1824/018/001	Eye drops, solution	-Epinastine hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Reletrans 10 micrograms/hour Transdermal Patches	Rowex Ltd	PA0711/236/002	Transdermal patch	-Buprenorphine
Reletrans 15 micrograms/hour Transdermal Patches	Rowex Ltd	PA0711/236/003	Transdermal patch	-Buprenorphine
Reletrans 20 micrograms/hour Transdermal Patches	Rowex Ltd	PA0711/236/004	Transdermal patch	-Buprenorphine
Reletrans 5 micrograms/hour Transdermal Patches	Rowex Ltd	PA0711/236/001	Transdermal patch	-Buprenorphine
Relifex 1g film-coated tablets	Mylan IRE Healthcare Limited	PA2010/036/002	Film-coated tablet	-Nabumetone
Relifex 500 mg film-coated Tablets	Mylan IRE Healthcare Limited	PA2010/036/001	Film-coated tablet	-Nabumetone
Relistor	Bausch Health Ireland Limited	EU/1/08/463/004-008	Solution for injection in pre-filled syringe	-Methylnaltrexone bromide
RELISTOR	Bausch Health Ireland Limited	EU/1/08/463/1-3	Solution for injection	-Methylnaltrexone bromide
Relistor	Bausch Health Ireland Limited	EU/1/08/463/8-11	Solution for injection in pre-filled syringe	-Methylnaltrexone bromide
Relpax 40 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/491/001	Film-coated tablet	-ELETRIPTAN
RELPAx 40 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/009/001	Film-coated tablet	-ELETRIPTAN
RELPAx 40mg film-coated tablets	Upjohn EESV	PA23055/002/002	Film-coated tablet	-ELETRIPTAN
Relvar Ellipta	GlaxoSmithKline (Ireland) Limited	EU/1/13/886/001-003	Inhalation powder, pre-dispensed	-Fluticasone furoate micronised -Vilanterol trifrenatate micronised
Relvar Ellipta	GlaxoSmithKline (Ireland) Limited	EU/1/13/886/004-006	Inhalation powder, pre-dispensed	-Fluticasone furoate micronised -Vilanterol trifrenatate micronised
Remicade	Janssen Biologics B.V.	EU/1/99/116/001-5	Powder for concentrate for solution for infusion	-Infliximab
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	-Remifentanil
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	-Remifentanil
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	-Remifentanil
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	-Remifentanil
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	-Remifentanil

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Remifentanil
REMINYL 4 mg/ml oral solution	Originalis B.V.	PPA2306/012/001	Oral solution	-Galantamine
REMINYL 4 mg/ml oral solution	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/003/001	Oral solution	-Galantamine hydrobromide
REMINYL XL 16 mg prolonged-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/003/003	Prolonged-release capsule, hard	-Galantamine hydrobromide
Reminyl XL 16 mg prolonged-release capsules, hard	PCO Manufacturing Ltd.	PPA0465/166/004	Prolonged-release capsule, hard	-GALANTAMINE HYDROBROMIDE
Reminyl XL 16 mg prolonged-release capsules, hard	Originalis B.V.	PPA2306/008/001	Prolonged-release capsule, hard	-Galantamine
Reminyl XL 24 mg prolonged-release capsules, hard	Originalis B.V.	PPA2306/009/001	Prolonged-release capsule, hard	-Galantamine
Reminyl XL 24 mg prolonged-release capsules, hard	PCO Manufacturing Ltd.	PPA0465/166/003	Prolonged-release capsule, hard	-Galantamine
REMINYL XL 24 mg prolonged-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/003/004	Prolonged-release capsule, hard	-Galantamine
REMINYL XL 8 mg prolonged-release capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/003/002	Prolonged-release capsule, hard	-Galantamine hydrobromide
Reminyl XL 8 mg prolonged-release capsules, hard	PCO Manufacturing Ltd.	PPA0465/166/002	Prolonged-release capsule, hard	-Galantamine
Remsima	Celltrion Healthcare Hungary Kft.	EU/1/13/853/001	Powder for concentrate for solution for infusion	-Infliximab
Remsima	Celltrion Healthcare Hungary Kft.	EU/1/13/853/006-011	Solution for injection in pre-filled syringe	-Infliximab
Remsima	Celltrion Healthcare Hungary Kft.	EU/1/13/853/012-014	Solution for injection in pre-filled pen	-Infliximab
Renagel	Genzyme Europe B.V.	EU/1/99/123/005	Film-coated tablet	-Sevelamer
Renagel	Genzyme Europe B.V.	EU/1/99/123/006	Film-coated tablet	-Sevelamer
Renagel	Genzyme Europe B.V.	EU/1/99/123/007	Film-coated tablet	-Sevelamer
Renagel	Genzyme Europe B.V.	EU/1/99/123/008	Film-coated tablet	-Sevelamer
Renagel	Genzyme Europe B.V.	EU/1/99/123/009	Film-coated tablet	-Sevelamer
Renagel	Genzyme Europe B.V.	EU/1/99/123/010	Film-coated tablet	-Sevelamer
RENAGEL	Genzyme Europe B.V.	EU/1/99/123/011	Tablets	-SEVELAMER
Renagel	Genzyme Europe B.V.	EU/1/99/123/011-013	Film-coated tablet	-Sevelamer
RENOCIS 1 mg kit for radiopharmaceutical preparation	CIS bio International	PA0677/005/001	Kit for radiopharmaceutical preparation	-Dimercaptosuccinic acid
Renvela	Genzyme Europe B.V.	EU/1/09/521/008	Powder for oral suspension	-Sevelamer carbonate
Renvela	Genzyme Europe B.V.	EU/1/09/521/1-3	Film-coated tablet	-Sevelamer carbonate
Renvela	Genzyme Europe B.V.	EU/1/09/521/4-5	Powder for oral suspension	-Sevelamer carbonate
Renvela	Genzyme Europe B.V.	EU/1/09/521/6-7	Powder for oral suspension	-Sevelamer carbonate
Repaglinide Accord	Accord Healthcare S.L.U.	EU/1/11/743/001-005	Tablet	-Repaglinide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Repaglinide Accord	Accord Healthcare S.L.U.	EU/1/11/743/006-010	Tablet	-Repaglinide
Repaglinide Accord	Accord Healthcare S.L.U.	EU/1/11/743/011-015	Tablet	-Repaglinide
REPAGLINIDE KRKA	Krka d.d., Novo mesto	EU/1/09/579/13-18	Tablet	-REPAGLINIDE
REPAGLINIDE KRKA	Krka d.d., Novo mesto	EU/1/09/579/1-6	Tablet	-REPAGLINIDE
REPAGLINIDE KRKA	Krka d.d., Novo mesto	EU/1/09/579/7-12	Tablet	-REPAGLINIDE
REPAGLINIDE TEVA	Teva B.V.	EU/1/09/530/11-15	Tablet	-REPAGLINIDE
REPAGLINIDE TEVA	Teva B.V.	EU/1/09/530/1-5	Tablet	-REPAGLINIDE
REPAGLINIDE TEVA	Teva Pharma B.V.	EU/1/09/530/6-10	Tablet	-REPAGLINIDE
Repatha	Amgen Europe B.V.	EU/1/15/1016/001-005	Solution for injection	-Evolocumab
Repatha	Amgen Europe B.V.	EU/1/15/1016/006-007	Solution for injection	-Evolocumab
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	-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
REPLAGAL 1MG/ML	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/01/189/001	Concentrate for solution for infusion	-Agalsidase alfa
REPSO	Teva B.V.	EU/1/11/674/006-010	Film-coated tablet	-LEFLUNOMIDE
Requip 0.25 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/037/001	Film-coated tablet	-Ropinirole hydrochloride
Requip 1 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/037/003	Film-coated tablet	-Ropinirole hydrochloride
Requip 2 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/037/004	Film-coated tablet	-Ropinirole hydrochloride
Requip 5 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/037/005	Film-coated tablet	-Ropinirole hydrochloride
Requip-Modutab 2 mg Prolonged-Release Tablets	GlaxoSmithKline (Ireland) Limited	PA1077/037/006	Prolonged-release tablet	-Ropinirole hydrochloride
Requip-Modutab 2 mg Prolonged-Release Tablets	PCO Manufacturing Ltd.	PPA0465/279/002	Prolonged-release tablet	-Ropinirole hydrochloride
Requip-Modutab 2 mg Prolonged-Release Tablets	IMED Healthcare Ltd.	PPA1463/163/001	Prolonged-release tablet	-Ropinirole
Requip-Modutab 4 mg Prolonged-Release Tablets	IMED Healthcare Ltd.	PPA1463/163/002	Prolonged-release tablet	-Ropinirole
Requip-Modutab 4 mg prolonged-release tablets	Originalis B.V.	PPA2306/002/002	Prolonged-release tablet	-Ropinirole
Requip-Modutab 4 mg Prolonged-Release Tablets	PCO Manufacturing Ltd.	PPA0465/279/003	Prolonged-release tablet	-Ropinirole hydrochloride
Requip-Modutab 4 mg Prolonged-Release Tablets	GlaxoSmithKline (Ireland) Limited	PA1077/037/008	Prolonged-release tablet	-Ropinirole hydrochloride
Requip-Modutab 8 mg Prolonged-Release Tablets	GlaxoSmithKline (Ireland) Limited	PA1077/037/009	Prolonged-release tablet	-Ropinirole hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Requip-Modutab 8 mg prolonged-release tablets	Originalis B.V.	PPA2306/002/001	Prolonged-release tablet	-Ropinirole
Requip-Modutab 8 mg Prolonged-Release Tablets	IMED Healthcare Ltd.	PPA1463/163/003	Prolonged-release tablet	-Ropinirole
Requip-Modutab 8mg Prolonged-Release Tablets	PCO Manufacturing Ltd.	PPA0465/279/001	Prolonged-release tablet	-Ropinirole hydrochloride
Resolor 1 mg film-coated tablets	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/09/581/001	Film-coated tablet	-Prucalopride Succinate
Resolor 2 mg film-coated tablets	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/09/581/002	Film-coated tablet	-Prucalopride Succinate
Respreeza	CSL Behring GmbH	EU/1/15/1006/001	Powder and solvent for solution for injection	-Human alpha1-proteinase inhibitor
Retacrit	Pfizer Europe MA EEIG	EU/1/07/431/1-6	Solution for injection in pre-filled syringe	-Epoetin zeta
Retacrit	Pfizer Europe MA EEIG	EU/1/07/431/17-19	Solution for injection in pre-filled syringe	-Epoetin zeta
Retacrit	Pfizer Europe MA EEIG	EU/1/07/431/7-16	Solution for injection in pre-filled syringe	-Epoetin zeta
Retrovir 10 mg/ml IV concentrate for solution for infusion	ViiV Healthcare BV	PA22575/001/003	Concentrate for solution for infusion	-Zidovudine
Retrovir 100 mg capsules, hard	ViiV Healthcare BV	PA22575/001/001	Capsule, hard	-Zidovudine
Retrovir 100 mg/10 ml oral solution	ViiV Healthcare BV	PA22575/001/002	Oral solution	-Zidovudine
Retsevmio	Eli Lilly Nederland B.V.	EU/1/20/1527/001	Capsule, hard	-Selpercatinib
Retsevmio	Eli Lilly Nederland B.V.	EU/1/20/1527/002-003	Capsule, hard	-Selpercatinib
Revatio	Upjohn EESV	EU/1/05/318/001	Film-coated tablet	-Sildenafil
Revatio	Upjohn EESV	EU/1/05/318/002	Solution for injection	-Sildenafil citrate for parenteral use
Revatio	Upjohn EESV	EU/1/05/318/003	Powder for oral suspension	-Sildenafil citrate
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	-Diphtheria toxoid -Tetanus toxoid -POLIOVIRUS, TYPE 1 -Poliovirus, type 2 -Poliovirus, type 3
Revestive	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/12/787/001	Powder and solvent for solution for injection	-Teduglutide
Revestive	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/12/787/003	Powder and solvent for solution for injection	-Teduglutide
Revinty Ellipta	GlaxoSmithKline (Ireland) Limited	EU/1/14/929/001-003	Inhalation powder, pre-dispensed	-Fluticasone furoate micronised -Vilanterol
Revinty Ellipta	GlaxoSmithKline (Ireland) Limited	EU/1/14/929/004-006	Inhalation powder, pre-dispensed	-Fluticasone furoate micronised -Vilanterol
Revlimid 10 mg hard capsules	Bristol-Myers Squibb Pharma EEIG	EU/1/07/391/002	Capsule, hard	-Lenalidomide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Revlimid 15 mg hard capsules	Bristol-Myers Squibb Pharma EEIG	EU/1/07/391/003	Capsule, hard	-Lenalidomide
Revlimid 2.5 mg hard capsules	Bristol-Myers Squibb Pharma EEIG	EU/1/07/391/005	Capsule, hard	-Lenalidomide
Revlimid 20 mg hard capsules	Bristol-Myers Squibb Pharma EEIG	EU/1/07/391/009	Capsule, hard	-Lenalidomide
Revlimid 25 mg hard capsules	Bristol-Myers Squibb Pharma EEIG	EU/1/07/391/004	Capsule, hard	-Lenalidomide
Revlimid 5 mg hard capsules	Bristol-Myers Squibb Pharma EEIG	EU/1/07/391/001	Capsule, hard	-Lenalidomide
Revlimid 7.5 mg hard capsules	Bristol-Myers Squibb Pharma EEIG	EU/1/07/391/006	Capsule, hard	-Lenalidomide
Revolade	Novartis Europharm Limited	EU/1/10/612/007-009	Film-coated tablet	-Eltrombopag (sb-497115)
Revolade	Novartis Europharm Limited	EU/1/10/612/013	Powder for oral suspension	-Eltrombopag olamine
Revolade	Novartis Europharm Limited	EU/1/10/612/1-3	Film-coated tablet	-Eltrombopag olamine
Revolade	Novartis Europharm Limited	EU/1/10/612/4-6	Film-coated tablet	-Eltrombopag olamine
Reyataz	Bristol-Myers Squibb Pharma EEIG	EU/1/03/267/012	Oral powder	-Atazanavir sulfate
Reyataz	Bristol-Myers Squibb Pharma EEIG	EU/1/03/267/01-7	Capsule, hard	-Atazanavir
Reyataz	Bristol-Myers Squibb Pharma EEIG	EU/1/03/267/8-9	Capsule, hard	-Atazanavir sulfate
REZOLSTA	Janssen-Cilag International NV	EU/1/14/967/001	Film-coated tablet	-Darunavir -Cobicistat
Rezzayo	Mundipharma GmbH	EU/1/23/1775/001	Powder for concentrate for solution for infusion	-Rezafungin acetate
Rhinaspray 21 micrograms per metered dose, Nasal Spray Solution	Opella Healthcare France SAS T/A Sanofi	PA23180/021/001	Nasal spray, solution	-Ipratropium bromide
Rhinex Relief 50 micrograms/actuation Nasal spray, suspension	Rowex Ltd	PA0711/279/001	Nasal spray, suspension	-Mometasone furoate
Rhinolast 140 micrograms per Spray, Nasal Spray	Mylan IRE Healthcare Limited	PA2010/037/001	Nasal spray, solution	-Azelastine hydrochloride
Rhinolast Hayfever 140 micrograms per spray, nasal spray solution	Mylan IRE Healthcare Limited	PA2010/037/002	Nasal spray, solution	-Azelastine hydrochloride
Rhinolast S nasal spray, solution	Mylan IRE Healthcare Limited	PA2010/037/003	Nasal spray, solution	-Azelastine hydrochloride
Rhokiinsa	Santen OY	EU/1/19/1400/001	Eye drops, solution	-NETARSUDIL MESILATE -NETARSUDIL
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	-Human anti-D immunoglobulin
Riarify	Chiesi Farmaceutici S.p.A.	EU/1/18/1275/001-005	Pressurised inhalation, solution	-Beclometasone dipropionate -Formoterol fumarate dihydrate -GLYCLOPYRAMIDUM
Riastap 1 g Powder for Solution for Injection / Infusion	CSL Behring GmbH	PA0800/007/001	Powder for solution for injection/infusion	-Human fibrinogen

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Ridate Once a Week 35mg film-coated tablets	Rowex Ltd	PA0711/189/001	Film-coated tablet	-Risedronate sodium
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	-Calcium carbonate -Cholecalciferol -Risedronate sodium
Ridonex 10 mg orodispersible tablets	Clonmel Healthcare Ltd	PA0126/291/001	Orodispersible tablet	-Domperidone
Rifadin 100 mg/5 ml Oral Suspension	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/066/004	Oral suspension	-Rifampicin
Rifadin 150mg Capsules	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/066/001	Capsule, hard	-Rifampicin
Rifadin 300mg Capsules	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/066/002	Capsule, hard	-Rifampicin
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	-Rifampicin
Rifater 50 mg/300 mg/120 mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/067/001	Tablet	-Isoniazid -Pyrazinamide -Rifampicin
Rifaximin Alfasigma 550 mg film-coated tablets	Alfasigma S.p.A	PA2206/001/001	Film-coated tablet	-Rifaximin
Rifinah 150/100 mg Film- Coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/068/001	Film-coated tablet	-Rifampicin -Isoniazid
Rifinah 300 / 150 mg Film Coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/068/002	Film-coated tablet	-Rifampicin -Isoniazid
Riltrava Aerosphere	AstraZeneca AB	EU/1/21/1604/001-002	Pressurised inhalation, suspension	-Formoterol fumarate dihydrate -Glycopyrronium bromide -Budesonide
Rilutek	Sanofi Winthrop Industrie	EU/1/96/010/001	Tablet	-Riluzole
Riluzole Zentiva	Aventis Pharma S.A.	EU/1/12/768/001	Film-coated tablet	-Riluzole
Rimicorim 300mg Capsules	Brown & Burk IR Limited	PA23148/001/001	Capsule, hard	-Lymecycline
Ringer's Solution for Infusion, Viaflo container	Baxter Holding B.V.	PA2299/011/001	Solution for infusion	-Sodium chloride -Potassium chloride -Calcium chloride dihydrate
Rinozal 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/179/001	Film-coated tablet	-Levocetirizine dihydrochloride
Rinvoq	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1404/001-005	Prolonged-release tablet	-UPADACITINIB -Upadacitinib Hemihydrate
RINVOQ	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1404/006-009	Prolonged-release tablet	-Upadacitinib Hemihydrate
RINVOQ	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1404/010-011	Prolonged-release tablet	-Upadacitinib Hemihydrate
Risedronate Bluefish Once a Week 35 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/017/001	Film-coated tablet	-Risedronate sodium hemipentahydrate
Risedronate Sodium Accord Once A Week 35 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/140/003	Film-coated tablet	-Risedronate sodium
Risedronate Sodium Accord Once a Week 35 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/165/001	Film-coated tablet	-Risedronate sodium

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Risonate Once Weekly 35 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/064/001	Film-coated tablet	-Risedronate sodium
Risontel Once a week 35mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/197/001	Film-coated tablet	-Risedronate sodium
RISPERDAL 0.5 mg film-coated tablets	Janssen Sciences Ireland UC	PA22612/010/009	Film-coated tablet	-Risperidone
RISPERDAL 1 mg film-coated tablets	Janssen Sciences Ireland UC	PA22612/010/004	Film-coated tablet	-Risperidone
RISPERDAL 1 mg/ml oral solution	Janssen Sciences Ireland UC	PA22612/010/001	Oral solution	-Risperidone
RISPERDAL 1 mg/ml oral solution	Originalis B.V.	PPA2306/007/001	Oral solution	-Risperidone
RISPERDAL 2 mg film-coated tablets	Janssen Sciences Ireland UC	PA22612/010/005	Film-coated tablet	-Risperidone
RISPERDAL 3 mg film-coated tablets	Janssen Sciences Ireland UC	PA22612/010/006	Film-coated tablet	-Risperidone
RISPERDAL 4 mg film-coated tablets	Janssen Sciences Ireland UC	PA22612/010/007	Film-coated tablet	-Risperidone
RISPERDAL 6 mg film-coated tablets	Janssen Sciences Ireland UC	PA22612/010/002	Film-coated tablet	-Risperidone
RISPERDAL CONSTA 25 mg powder and solvent for prolonged-release suspension for injection	Janssen Sciences Ireland UC	PA22612/010/010	Powder and solvent for prolonged-release suspension for injection	-Risperidone
RISPERDAL CONSTA 37.5 mg powder and solvent for prolonged-release suspension for injection	Janssen Sciences Ireland UC	PA22612/010/011	Powder and solvent for prolonged-release suspension for injection	-Risperidone
RISPERDAL CONSTA 50 mg powder and solvent for prolonged-release suspension for injection	Janssen Sciences Ireland UC	PA22612/010/012	Powder and solvent for prolonged-release suspension for injection	-Risperidone
Risperidone 0.5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/175/001	Film-coated tablet	-Risperidone
Risperidone 1 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/175/002	Film-coated tablet	-Risperidone
Risperidone 1mg/ml Oral Solution	Pinewood Laboratories Ltd	PA0281/248/001	Oral solution	-Risperidone
Risperidone 1mg/ml Oral Solution	Chanelle Medical Unlimited Company	PA0688/006/008	Oral solution	-Risperidone
Risperidone 2 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/175/003	Film-coated tablet	-Risperidone
Risperidone 3 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/175/004	Film-coated tablet	-Risperidone
Risperidone 4 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/175/005	Film-coated tablet	-Risperidone
Risperidone 6 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/175/006	Film-coated tablet	-Risperidone
Risperidone Grindeks 0.5 mg film-coated tablets	AS Grindeks	PA22992/021/001	Film-coated tablet	-Risperidone
Risperidone Grindeks 1 mg film-coated tablets	AS Grindeks	PA22992/021/002	Film-coated tablet	-Risperidone
Risperidone Grindeks 2 mg film-coated tablets	AS Grindeks	PA22992/021/003	Film-coated tablet	-Risperidone
Risperidone Grindeks 3 mg film-coated tablets	AS Grindeks	PA22992/021/004	Film-coated tablet	-Risperidone

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Risperidone Grindeks 4 mg film-coated tablets	AS Grindeks	PA22992/021/005	Film-coated tablet	-Risperidone
Risperidone Grindeks 6 mg film-coated tablets	AS Grindeks	PA22992/021/006	Film-coated tablet	-Risperidone
Rispeva 0.5 mg film-coated tablets	Teva B.V.	PA1986/021/001	Film-coated tablet	-Risperidone
Rispeva 1 mg film-coated tablets	Teva Pharma B.V.	PA0749/049/007	Film-coated tablet	-Risperidone
Rispeva 2 mg film-coated tablets	Teva Pharma B.V.	PA0749/049/008	Film-coated tablet	-Risperidone
Rispeva 3 mg film-coated tablets	Teva Pharma B.V.	PA0749/049/009	Film-coated tablet	-Risperidone
Rispeva 4 mg film-coated tablets	Teva Pharma B.V.	PA0749/049/010	Film-coated tablet	-Risperidone
Risponse 0.5 mg film-coated tablets	Rowex Ltd	PA0711/106/002	Film-coated tablet	-Risperidone
Risponse 1 mg film-coated tablets	Rowex Ltd	PA0711/106/006	Film-coated tablet	-Risperidone
Risponse 1 mg/ml oral solution	Rowex Ltd	PA0711/106/001	Oral solution	-Risperidone
Risponse 2 mg film-coated tablets	Rowex Ltd	PA0711/106/007	Film-coated tablet	-Risperidone
Risponse 3 mg film-coated tablets	Rowex Ltd	PA0711/106/008	Film-coated tablet	-Risperidone
Ristaben 100 mg film-coated tablets	Merck Sharp & Dohme BV,	EU/1/10/621/13-18	Film-coated tablet	-Sitagliptin as monohydrate phosphate salt
Ristaben 25 mg film-coated tablets	Merck Sharp & Dohme BV	EU/1/10/621/1-6	Film-coated tablet	-Sitagliptin as monohydrate phosphate salt
Ristaben 50 mg film-coated tablets	Merck Sharp & Dohme BV,	EU/1/10/621/7-12	Film-coated tablet	-Sitagliptin as monohydrate phosphate salt
Ristfor	Merck Sharp & Dohme BV,	EU/1/10/620/009-016	Film-coated tablet	-Metformin Hydrochloride -Sitagliptin phosphate
Ristfor	Merck Sharp & Dohme BV	EU/1/10/620/1-8	Film-coated tablet	-Metformin Hydrochloride -Sitagliptin phosphate
Ristfor	Merck Sharp & Dohme BV,	EU/1/10/620/9-16	Film-coated tablet	-Metformin Hydrochloride -Sitagliptin phosphate
Ritalin 10mg Tablets	InfectoPharm Arzneimittel und Consilium GmbH	PA1972/002/001	Tablet	-Methylphenidate hydrochloride
Ritalin LA 20mg prolonged-release capsules	InfectoPharm Arzneimittel und Consilium GmbH	PA1972/002/002	Prolonged-release capsule, hard	-Methylphenidate hydrochloride
Ritalin LA 30mg prolonged-release capsules	InfectoPharm Arzneimittel und Consilium GmbH	PA1972/002/003	Prolonged-release capsule, hard	-Methylphenidate hydrochloride
Ritalin LA 40mg prolonged-release capsules	InfectoPharm Arzneimittel und Consilium GmbH	PA1972/002/004	Prolonged-release capsule, hard	-Methylphenidate hydrochloride
Ritonavir 100 mg film-coated tablet	Accord Healthcare Ireland Ltd.	PA2315/176/001	Film-coated tablet	-Ritonavir
Ritonavir Mylan (Previously Ritonavir JensonR+)	Mylan S.A.S.	EU/1/17/1242/001-003	Film-coated tablet	-Ritonavir
Rivaroxaban 10 mg film-coated tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/010/001	Film-coated tablet	-Rivaroxaban
Rivaroxaban 10 mg film-coated tablets	Flynn Pharma Limited	PA1226/016/002	Film-coated tablet	-Rivaroxaban

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Rivaroxaban 15 mg film-coated tablets	Flynn Pharma Limited	PA1226/016/003	Film-coated tablet	-Rivaroxaban
Rivaroxaban 15 mg film-coated tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/010/002	Film-coated tablet	-Rivaroxaban
Rivaroxaban 2.5 mg film-coated tablets	Flynn Pharma Limited	PA1226/016/001	Film-coated tablet	-Rivaroxaban
Rivaroxaban 20 mg film-coated tablets	Flynn Pharma Limited	PA1226/016/004	Film-coated tablet	-Rivaroxaban
Rivaroxaban 20 mg film-coated tablets	Renata Pharmaceuticals (Ireland) Limited	PA22865/010/003	Film-coated tablet	-Rivaroxaban
Rivaroxaban Accord	Accord Healthcare S.L.U.	EU/1/20/1488/001-011	Film-coated tablet	-Rivaroxaban
Rivaroxaban Accord	Accord Healthcare S.L.U.	EU/1/20/1488/012-023	Film-coated tablet	-Rivaroxaban
Rivaroxaban Accord	Accord Healthcare S.L.U.	EU/1/20/1488/024-039	Film-coated tablet	-Rivaroxaban
Rivaroxaban Accord	Accord Healthcare S.L.U.	EU/1/20/1488/040-053	Film-coated tablet	-Rivaroxaban
Rivaroxaban Clonmel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/035/002	Film-coated tablet	-Rivaroxaban
Rivaroxaban Clonmel 15 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/035/003	Film-coated tablet	-Rivaroxaban
Rivaroxaban Clonmel 15 mg film-coated tablets Rivaroxaban Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/035/005	Film-coated tablet	-Rivaroxaban -Rivaroxaban
Rivaroxaban Clonmel 15 mg hard capsules	Clonmel Healthcare Ltd	PA0126/353/001	Capsule, hard	-Rivaroxaban
Rivaroxaban Clonmel 15 mg hard capsules Rivaroxaban Clonmel 20 mg hard capsules	Clonmel Healthcare Ltd	PA0126/353/003	Capsule, hard	-Rivaroxaban -Rivaroxaban
Rivaroxaban Clonmel 2.5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/035/001	Film-coated tablet	-Rivaroxaban
Rivaroxaban Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/035/004	Film-coated tablet	-Rivaroxaban
Rivaroxaban Clonmel 20 mg hard capsules	Clonmel Healthcare Ltd	PA0126/353/002	Capsule, hard	-Rivaroxaban
Rivaroxaban Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/098/002	Film-coated tablet	-Rivaroxaban
Rivaroxaban Krka 15 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/098/003	Film-coated tablet	-Rivaroxaban
Rivaroxaban Krka 2.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/098/001	Film-coated tablet	-Rivaroxaban
Rivaroxaban Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/098/004	Film-coated tablet	-Rivaroxaban
Rivaroxaban Rowex 10 mg Film-coated tablets	Rowex Ltd	PA0711/275/001	Film-coated tablet	-Rivaroxaban
Rivaroxaban Rowex 15 mg Film-coated tablets	Rowex Ltd	PA0711/275/002	Film-coated tablet	-Rivaroxaban
Rivaroxaban Rowex 20 mg Film-coated tablets	Rowex Ltd	PA0711/275/003	Film-coated tablet	-Rivaroxaban
Rivaroxaban Teva 10 mg film-coated tablets	TEVA GmbH	PA22579/002/001	Film-coated tablet	-Rivaroxaban
Rivaroxaban Teva 15 mg film-coated tablets	TEVA GmbH	PA22579/002/002	Film-coated tablet	-Rivaroxaban

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Rivaroxaban Teva 20 mg film-coated tablets	TEVA GmbH	PA22579/002/003	Film-coated tablet	-Rivaroxaban
Rivaroxaban Viartis	Viartis Limited	EU/1/21/1588/001-014	Tablet	-Rivaroxaban
Rivaroxaban Viartis	Viartis Limited	EU/1/21/1588/015-025	Tablet	-Rivaroxaban
Rivaroxaban Viartis	Viartis Limited	EU/1/21/1588/026-040	Tablet	-Rivaroxaban
Rivaroxaban Viartis	Viartis Limited	EU/1/21/1588/041-055	Tablet	-Rivaroxaban
Rivastigmine - 1 A Pharma	1 A Pharma GmbH	EU/1/09/585/001-4	Capsule, hard	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine - 1 A Pharma	1 A Pharma GmbH	EU/1/09/585/005-8	Capsule, hard	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine - 1 A Pharma	1 A Pharma GmbH	EU/1/09/585/009-12	Capsule, hard	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine - 1 A Pharma	1 A Pharma GmbH	EU/1/09/585/013-16	Capsule, hard	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine 1 A Pharma (120ml)	1 A Pharma GmbH	EU/1/09/585/018	Oral solution	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine 1 A Pharma (50ml)	1 A Pharma GmbH	EU/1/09/585/017	Oral solution	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine Actavis	Actavis Group hf	EU/1/11/693/001-004	Capsule, hard	-Rivastigmine hydrogentartrate
Rivastigmine Actavis	Actavis Group hf	EU/1/11/693/005-008	Capsule, hard	-Rivastigmine hydrogentartrate
Rivastigmine Actavis	Actavis Group hf	EU/1/11/693/009-012	Capsule, hard	-Rivastigmine hydrogentartrate
Rivastigmine Actavis	Actavis Group hf	EU/1/11/693/013-016	Capsule, hard	-Rivastigmine hydrogentartrate
RIVASTIGMINE ACTAVIS	Actavis Group PTC ehf	EU/1/11/693/017-20	Transdermal Patch	-RIVASTIGMINE
RIVASTIGMINE ACTAVIS	Actavis Group PTC ehf	EU/1/11/693/021-24	Transdermal Patch	-RIVASTIGMINE
Rivastigmine Hexal	Hexal AG	EU/1/09/589/13-16	Capsule, hard	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine Hexal	Hexal AG	EU/1/09/589/1-4	Capsule, hard	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine Hexal	Hexal AG	EU/1/09/589/5-8	Capsule, hard	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine Hexal	Hexal AG	EU/1/09/589/9-12	Capsule, hard	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine Hexal (120 ml)	Hexal AG	EU/1/09/589/018	Oral solution	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine Hexal (50 ml)	Hexal AG	EU/1/09/589/017	Oral solution	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine Sandoz	Sandoz Pharmaceuticals GmbH	EU/1/09/599/13-16	Capsule, hard	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine Sandoz	Sandoz Pharmaceuticals GmbH	EU/1/09/599/1-4	Capsule, hard	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine Sandoz	Sandoz Pharmaceuticals GmbH	EU/1/09/599/5-8	Capsule, hard	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine Sandoz	Sandoz Pharmaceuticals GmbH	EU/1/09/599/9-12	Capsule, hard	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Rivastigmine Sandoz (120 ml)	Sandoz Pharmaceuticals GmbH	EU/1/09/599/018	Oral solution	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivastigmine Sandoz (50 ml)	Sandoz Pharmaceuticals GmbH	EU/1/09/599/017	Oral solution	-Sdz ena 713 hta (rivastigmine hydrogen tartrate)
Rivotril 0.5 mg Tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/020/001	Tablet	-Clonazepam
Rixathon	Sandoz GmbH	EU/1/17/1185/001-002	Concentrate for solution for infusion	-Rituximab
Rixathon	Sandoz GmbH	EU/1/17/1185/003-004	Concentrate for solution for infusion	-Rituximab
Riximyo	Sandoz GmbH	EU/1/17/1184/001-002	Concentrate for solution for infusion	-Rituximab
Riximyo	Sandoz GmbH	EU/1/17/1184/003-004	Concentrate for solution for infusion	-Rituximab
Rixubis	Baxter Innovations GmbH	EU/1/14/970/001	Powder and solvent for solution for injection	-Nonacog gamma
Rixubis	Baxter Innovations GmbH	EU/1/14/970/002	Powder and solvent for solution for injection	-Nonacog gamma
Rixubis	Baxter Innovations GmbH	EU/1/14/970/003	Powder and solvent for solution for injection	-Nonacog gamma
Rixubis	Baxter Innovations GmbH	EU/1/14/970/004	Powder and solvent for solution for injection	-Nonacog gamma
Rixubis	Baxter Innovations GmbH	EU/1/14/970/005	Powder and solvent for solution for injection	-Nonacog gamma
Rizadia 5 mg oral lyophilisate	Diapharm GmbH & Co. KG	PA1958/009/001	Orodispersible tablet	-Rizatriptan benzoate
Rizadia 5 mg Tablets	Diapharm GmbH & Co. KG	PA1958/009/002	Tablet	-Rizatriptan benzoate
RIZATRIPTAN MSD 10 mg oral lyophilisates	Organon Pharma (Ireland) Limited	PA23198/013/004	Oral lyophilisate	-Rizatriptan benzoate
RIZATRIPTAN MSD 10 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/013/002	Tablet	-Rizatriptan benzoate
RIZATRIPTAN MSD 5 mg oral lyophilisates	Organon Pharma (Ireland) Limited	PA23198/013/003	Oral lyophilisate	-Rizatriptan
RIZATRIPTAN MSD 5 mg Tablets	Organon Pharma (Ireland) Limited	PA23198/013/001	Tablet	-Rizatriptan
Rizmoic	Shionogi B.V.	EU/1/18/1291/001-003	Film-coated tablet	-Naldemedine tosilate
Roaccutane 10 mg soft capsules	Roche Products (Ireland) Ltd	PA2307/007/001	Capsule, soft	-Isotretinoin
Roaccutane 20 mg soft capsules	Roche Products (Ireland) Ltd	PA2307/007/002	Capsule, soft	-Isotretinoin
RoActemra	Roche Registration GmbH	EU/1/08/492/001-006	Concentrate for solution for infusion	-Tocilizumab
RoActemra	Roche Registration GmbH	EU/1/08/492/007	Solution for injection in pre-filled syringe	-Tocilizumab
Robitussin Dry Cough 7.5mg/5ml Oral Solution	Haleon Ireland Limited	PA0678/155/001	Oral solution	-Dextromethorphan hydrobromide
Robitussin Plus Oral Solution Guaifenesin 100 mg/5ml Pseudoephedrine HCl 30 mg/5ml	Haleon Ireland Limited	PA0678/154/001	Oral solution	-Guaifenesin -PSEUDOEPHEDRINE HYDROCHLORIDE
Rocephin 1 g powder and solvent for IM injection only	Roche Products (Ireland) Ltd	PA2307/008/002	Powder and solvent for solution for injection	-Ceftriaxone sodium -Lidocaine Hydrochloride Monohydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Rocephin 1 g powder for solution for injection/infusion	Roche Products (Ireland) Ltd	PA2307/008/003	Powder for solution for injection/infusion	-Ceftriaxone sodium
Roclanda	Santen OY	EU/1/20/1502/001	Eye drops, solution	-NETARSUDIL MESILATE -NETARSUDIL -Latanoprost
Roctavian	BioMarin International Limited	EU/1/22/1668/001	Solution for infusion	-Valoctocogene Roxaparvovec
Rocuronium 10 mg/ml solution for injection / infusion	Fresenius Kabi Deutschland GmbH	PA2059/018/001	Solution for injection/infusion	-Rocuronium bromide
Rocuronium 10 mg/ml solution for injection/infusion	B. Braun Melsungen AG	PA0736/029/001	Solution for injection/infusion	-Rocuronium bromide
Rocuronium bromide 10 mg / mL solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/015/001	Solution for injection in pre-filled syringe	-Rocuronium bromide
Rocuronium bromide 10 mg/ml solution for injection/infusion	AS Kalceks	PA2165/004/001	Solution for injection/infusion	-Rocuronium bromide
Rocuronium bromide 10 mg/mL Solution for injection/infusion	Noridem Enterprises Limited	PA1122/022/001	Solution for injection/infusion	-Rocuronium bromide
Rocuronium Bromide 10mg/ml solution for Injection/Infusion	Ibigen Srl	PA1862/001/001	Solution for injection/infusion	-Rocuronium bromide
Rolpryna SR 2 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/012/001	Prolonged-release tablet	-Ropinirole hydrochloride
Rolpryna SR 4 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/012/002	Prolonged-release tablet	-Ropinirole hydrochloride
Rolpryna SR 8 mg prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/012/003	Prolonged-release tablet	-Ropinirole hydrochloride
Rolufra Ellipta	GlaxoSmithKline Trading Services Limited	EU/1/17/1174/001-003	Inhalation powder, pre-dispensed	-Umeclidinium bromide
Rolyprexa 10 mg film-coated tablets	Rowex Ltd	PA0711/124/004	Film-coated tablet	-Olanzapine
Rolyprexa 2.5 mg film-coated tablets	Rowex Ltd	PA0711/124/001	Film-coated tablet	-Olanzapine
Rolyprexa 5 mg film-coated tablets	Rowex Ltd	PA0711/124/002	Film-coated tablet	-Olanzapine
Rolyprexa 7.5 mg film-coated tablets	Rowex Ltd	PA0711/124/003	Film-coated tablet	-Olanzapine
Romax Once Weekly 70mg Tablets	Aurobindo Pharma (Malta) Limited	PA1445/017/001	Tablet	-Alendronic acid
RONAPREVE	Roche Registration GmbH	EU/1/21/1601/001	Solution for injection/infusion	-casirivimab -imdevimab
RONAPREVE	Roche Registration GmbH	EU/1/21/1601/002	Solution for injection/infusion	-casirivimab -imdevimab
Ropivacaine 2 mg/ml solution for injection	Fresenius Kabi Deutschland GmbH	PA2059/021/001	Solution for injection	-Ropivacaine Hydrochloride
Ropivacaine 7.5 mg/ml solution for injection	Fresenius Kabi Deutschland GmbH	PA2059/021/002	Solution for injection	-Ropivacaine Hydrochloride
Ropivacaine Readyfusor 10 mg/h solution for infusion in administration system	BioQ Pharma B.V.	PA2284/001/001	Solution for infusion in administration system	-Ropivacaine hydrochloride monohydrate
Rosuva 10 mg film-coated tablets	Rowex Ltd	PA0711/176/002	Film-coated tablet	-Rosuvastatin
Rosuva 20 mg film-coated tablets	Rowex Ltd	PA0711/176/003	Film-coated tablet	-Rosuvastatin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Rosuva 40 mg film-coated tablets	Rowex Ltd	PA0711/176/004	Film-coated tablet	-Rosuvastatin
Rosuva 5 mg film-coated tablets	Rowex Ltd	PA0711/176/001	Film-coated tablet	-Rosuvastatin
Rosuvastatin 10 mg Film-coated Tablets	Brillpharma (Ireland) Limited	PA22749/017/002	Film-coated tablet	-Rosuvastatin
Rosuvastatin 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/068/002	Film-coated tablet	-Rosuvastatin calcium
Rosuvastatin 20 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/068/003	Film-coated tablet	-Rosuvastatin calcium
Rosuvastatin 20 mg Film-coated Tablets	Brillpharma (Ireland) Limited	PA22749/017/003	Film-coated tablet	-Rosuvastatin
Rosuvastatin 40 mg Film-coated Tablets	Brillpharma (Ireland) Limited	PA22749/017/004	Film-coated tablet	-Rosuvastatin
Rosuvastatin 40 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/068/004	Film-coated tablet	-Rosuvastatin calcium
Rosuvastatin 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/068/001	Film-coated tablet	-Rosuvastatin calcium
Rosuvastatin 5 mg Film-coated Tablets	Brillpharma (Ireland) Limited	PA22749/017/001	Film-coated tablet	-Rosuvastatin
Rosuvastatin Clonmel 10mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/261/002	Film-coated tablet	-Rosuvastatin
Rosuvastatin Clonmel 20mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/261/003	Film-coated tablet	-Rosuvastatin
Rosuvastatin Clonmel 40mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/261/004	Film-coated tablet	-Rosuvastatin
Rosuvastatin Clonmel 5mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/261/001	Film-coated tablet	-Rosuvastatin
Rosuvastatin Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/016/002	Film-coated tablet	-Rosuvastatin
Rosuvastatin Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/016/003	Film-coated tablet	-Rosuvastatin
Rosuvastatin Krka 40 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/016/004	Film-coated tablet	-Rosuvastatin
Rosuvastatin Krka 5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/016/001	Film-coated tablet	-Rosuvastatin
Rosuvastatin Pinewood 10 mg Film-coated Tablets	Pinewood Laboratories Ltd	PA0281/157/002	Film-coated tablet	-Rosuvastatin
Rosuvastatin Pinewood 20 mg Film-coated Tablets	Pinewood Laboratories Ltd	PA0281/157/003	Film-coated tablet	-Rosuvastatin
Rosuvastatin Pinewood 40 mg Film-coated Tablets	Pinewood Laboratories Ltd	PA0281/157/004	Film-coated tablet	-Rosuvastatin
Rosuvastatin Pinewood 5 mg Film-coated Tablets	Pinewood Laboratories Ltd	PA0281/157/001	Film-coated tablet	-Rosuvastatin
Rosuvastatin Rowa 10 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/093/002	Film-coated tablet	-Rosuvastatin
Rosuvastatin Rowa 20 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/093/003	Film-coated tablet	-Rosuvastatin
Rosuvastatin Rowa 40 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/093/004	Film-coated tablet	-Rosuvastatin
Rosuvastatin Rowa 5 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/093/001	Film-coated tablet	-Rosuvastatin
Rosuvastatin Teva Pharma 10 mg Film-coated Tablets	Teva B.V.	PA1986/024/002	Film-coated tablet	-Rosuvastatin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Rosuvastatin Teva Pharma 20 mg Film-coated Tablets	Teva B.V.	PA1986/024/003	Film-coated tablet	-Rosuvastatin
Rosuvastatin Teva Pharma 40 mg Film-coated Tablets	Teva B.V.	PA1986/024/004	Film-coated tablet	-Rosuvastatin
Rosuvastatin Teva Pharma 5 mg Film-coated Tablets	Teva B.V.	PA1986/024/001	Film-coated tablet	-Rosuvastatin
Rosuvastatin Viatris 10 mg film-coated tablets	Viatris Limited	PA23266/003/002	Film-coated tablet	-Rosuvastatin
Rosuvastatin Viatris 20 mg film-coated tablets	Viatris Limited	PA23266/003/003	Film-coated tablet	-Rosuvastatin
Rosuvastatin Viatris 40 mg film-coated tablets	Viatris Limited	PA23266/003/004	Film-coated tablet	-Rosuvastatin
Rosuvastatin Viatris 5 mg film-coated tablets	Viatris Limited	PA23266/003/001	Film-coated tablet	-Rosuvastatin
Rosuvastatin Zentiva 10 mg film-coated tablets	Zentiva k.s.	PA1701/005/002	Film-coated tablet	-Rosuvastatin calcium
Rosuvastatin Zentiva 20 mg film-coated tablets	Zentiva k.s.	PA1701/005/003	Film-coated tablet	-Rosuvastatin calcium
Rosuvastatin Zentiva 40 mg film-coated tablets	Zentiva k.s.	PA1701/005/004	Film-coated tablet	-Rosuvastatin calcium
Rosuvastatin Zentiva 5 mg film-coated tablets	Zentiva k.s.	PA1701/005/001	Film-coated tablet	-Rosuvastatin calcium
Rosuvastatin/Ezetimibe KRKA 10 mg/10 mg Film-Coated Tablets	KRKA, d.d., Novo mesto	PA1347/108/001	Film-coated tablet	-Rosuvastatin calcium -Ezetimibe
Rosuvastatin/Ezetimibe KRKA 20 mg/10 mg Film-Coated Tablets	KRKA, d.d., Novo mesto	PA1347/108/002	Film-coated tablet	-Rosuvastatin calcium -Ezetimibe
Rotarix	GlaxoSmithKline Biologicals S.A.	EU/1/05/330/1-4	Powder and solvent for oral suspension	-Rotavirus live attenuated, rix4414 strain, human
Rotarix	GlaxoSmithKline Biologicals S.A.	EU/1/05/330/5-11	Powder and solvent for oral suspension	-Human rotavirus, live attenuated
RotaTeq	Merck Sharp & Dohme BV,	EU/1/06/348/01	Oral solution	-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
Roteas	Berlin-Chemie AG	EU/1/16/1152/001-002	Film-coated tablet	-Edoxaban tosilate
Roteas	Berlin-Chemie AG	EU/1/16/1152/003-015	Film-coated tablet	-Edoxaban tosilate
Roteas	Berlin-Chemie AG	EU/1/16/1152/016-028	Film-coated tablet	-Edoxaban tosilate
Rowachol Gastro-resistant Capsules, Soft	Rowa Pharmaceuticals Limited	PA0074/008/001	Gastro-resistant capsule, soft	-Menthol -Menthone -Alpha pinene -Borneol -Cineole -Camphene -Beta pinene

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Rowachol Oral Drops, Solution	Rowa Pharmaceuticals Limited	PA0074/008/002	Oral drops, solution	-Alpha pinene -Borneol -Menthol -Beta pinene -Menthone -Camphene -Cineole
Rowatanal Cream	Rowa Pharmaceuticals Limited	PA0074/016/001	Cream	-Levomenthol -Bismuth subgallate -Zinc oxide
Rowatinex Gastro-resistant Capsules, Soft	Rowa Pharmaceuticals Limited	PA0074/009/001	Gastro-resistant capsule, soft	-Beta pinene -Cineole -Camphene -Alpha pinene -Fenchone -Anethole -Borneol
Rowatinex Oral Drops, Solution	Rowa Pharmaceuticals Limited	PA0074/009/002	Oral drops, solution	-Anethol -Alpha pinene -Borneol -Fenchone -Camphene -Cineole -Beta pinene
Rozex 7.5 mg/g Cream	Galderma International	PA22743/013/002	Cream	-Metronidazole
Rozex 7.5 mg/g Gel	Galderma International	PA22743/013/001	Gel	-Metronidazole
Rozex 7.5 mg/g Gel	PCO Manufacturing Ltd.	PPA0465/222/001	Gel	-Metronidazol
Rozex 7.5 mg/g Gel	IMED Healthcare Ltd.	PPA1463/184/001	Gel	-Metronidazole
Rozex 7.5 mg/g Gel	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/011/001	Gel	-Metronidazole
Rozlytrek	Roche Registration GmbH	EU/1/20/1460/001	Capsule, hard	-Entrectinib
Rozlytrek	Roche Registration GmbH	EU/1/20/1460/002	Capsule, hard	-Entrectinib
Rubraca	zr pharma& GmbH	EU/1/17/1250/001	Film-coated tablet	-Rucaparib camsylate
Rubraca	zr pharma& GmbH	EU/1/17/1250/002	Film-coated tablet	-Rucaparib camsylate
Rubraca	zr pharma& GmbH	EU/1/17/1250/003	Film-coated tablet	-Rucaparib camsylate
Ruconest	Pharming Group N.V.	EU/1/10/641/001	Powder for solution for injection	-Conestat alfa
Ruconest	Pharming Group N.V.	EU/1/10/641/002	Powder and solvent for solution for injection	-Conestat alfa
Rukobia	ViiV Healthcare BV	EU/1/20/1518/001	Prolonged-release tablet	-Fostemsavir -Tromethamine
Rupafin 1 mg/ml oral solution	J. Uriach y Compania S.A.	PA1129/001/002	Oral solution	-Rupatadine (as fumarate)
Rupafin 10mg tablets	J. Uriach y Compania S.A.	PA1129/001/001	Tablet	-Rupatadine (as fumarate)
Ruxience	Pfizer Europe MA EEIG	EU/1/20/1431/001	Concentrate for solution for infusion	-Rituximab
Ruxience	Pfizer Europe MA EEIG	EU/1/20/1431/002	Concentrate for solution for infusion	-Rituximab
RXULTI	Otsuka Pharmaceutical Netherlands B.V.	EU/1/18/1294/001	Film-coated tablet	-Brexpiprazole
RXULTI	Otsuka Pharmaceutical Netherlands B.V.	EU/1/18/1294/002	Film-coated tablet	-Brexpiprazole
RXULTI	Otsuka Pharmaceutical Netherlands B.V.	EU/1/18/1294/003-004	Film-coated tablet	-Brexpiprazole

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
RXULTI	Otsuka Pharmaceutical Netherlands B.V.	EU/1/18/1294/005	Film-coated tablet	-Brexpiprazole
RXULTI	Otsuka Pharmaceutical Netherlands B.V.	EU/1/18/1294/006	Film-coated tablet	-Brexpiprazole
RXULTI	Otsuka Pharmaceutical Netherlands B.V.	EU/1/18/1294/007	Film-coated tablet	-Brexpiprazole
Ryaltris 25 microgram/actuation + 600 microgram/actuation nasal spray, suspension	Glenmark Pharmaceuticals s.r.o.	PA1543/002/001	Nasal spray, suspension	-Mometasone furoate -Olopatadine
Rybelsus	Novo Nordisk A/S	EU/1/20/1430/001-004	Tablet	-Semaglutide
Rybelsus	Novo Nordisk A/S	EU/1/20/1430/005-007	Tablet	-Semaglutide
Rybelsus	Novo Nordisk A/S	EU/1/20/1430/008-010	Tablet	-Semaglutide
Rybrevant	Janssen-Cilag International NV	EU/1/21/1594/001	Concentrate for solution for infusion	-Amivantamab
Rybrila 160 micrograms/ml Oral Solution	Clinigen Healthcare B.V.	PA22701/001/001	Oral solution	-Glycopyrronium bromide
Rydapt	Novartis Europharm Limited	EU/1/17/1218/001	Capsule, soft	-Midostaurin
Ryeqo	Gedeon Richter Plc	EU/1/21/1565/001-002	Film-coated tablet	-Relugolix -Estradiol hemihydrate -Norethisterone acetate
Ryzodeg	Novo Nordisk A/S	EU/1/12/806/1,4,5,7,8	Solution for injection	-Insulin degludec (ideg) -Insulin aspart (iasp)
Sabril 500 mg film-coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/023/001	Film-coated tablet	-Vigabatrin
Sabril 500 mg Granules for Oral Solution	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/023/002	Granules for oral solution	-Vigabatrin
Saflutan 15 micrograms/ml eye drops, solution	Santen OY	PA0879/008/001	Eye drops, solution	-Tafluprost
Saflutan 15 micrograms/ml, eye drops, solution in single-dose container	Santen OY	PA0879/006/001	Eye drops, solution in single-dose container	-Tafluprost
Saflutan 15 micrograms/ml, eye drops, solution in single-dose container	PCO Manufacturing Ltd.	PPA0465/324/001	Eye drops, solution in single-dose container	-Tafluprost
Saizen 5.83 mg/ml solution for injection in cartridge	Merck Serono (Ireland) Limited	PA2286/006/001	Solution for injection in cartridge	-Somatropin
Saizen 8 mg/ml solution for injection in cartridge	Merck Serono (Ireland) Limited	PA2286/006/002	Solution for injection in cartridge	-Somatropin
Salactol Collodion	Dermal Laboratories (Ireland) Limited	PA23128/003/001	Collodion	-Salicylic acid -Lactic acid
Salamol CFC-Free Inhaler 100 micrograms pressurised inhalation, suspension	Norton Waterford	PA0436/032/001	Pressurised inhalation, suspension	-SALBUTAMOL SULFATE
Salamol Easi-Breathe CFC-Free Inhaler 100 micrograms Pressurised Inhalation, Suspension	Norton Waterford	PA0436/032/002	Pressurised inhalation, suspension	-SALBUTAMOL SULFATE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Salamol Steri-Neb 2.5 mg/2.5 ml nebuliser solution	Teva B.V.	PA1986/086/001	Nebuliser solution	-SALBUTAMOL SULFATE
Salamol Steri-Neb 5 mg/2.5 ml Nebuliser Solution	Teva B.V.	PA1986/086/002	Nebuliser solution	-Salbutamol
Salatac Gel Salicylic Acid 12.0% w/w Lactic Acid 4.0% w/w	Dermal Laboratories (Ireland) Limited	PA23128/007/001	Gel	-Salicylic acid -Lactic acid
Salazopyrin EN Tabs 500 mg Gastro-resistant tablets	PCO Manufacturing Ltd.	PPA0465/160/001	Gastro-resistant tablet	-Sulfasalazine
Salazopyrin EN Tabs 500 mg gastro-resistant tablets	IMED Healthcare Ltd.	PPA1463/059/001	Gastro-resistant tablet	-Sulfasalazine
Salazopyrin® 500 mg Tablets	Pfizer Healthcare Ireland	PA0822/196/002	Tablet	-Sulfasalazine
Salazopyrin® EN Tabs 500 mg Gastro-resistant tablets	Pfizer Healthcare Ireland	PA0822/196/001	Gastro-resistant tablet	-Sulfasalazine
Salbutamol CFC-Free Inhaler 100 micrograms per metered dose, pressurised inhalation, suspension	Valeas SPA Industria Chimica e Farmaceutica	PA1987/001/001	Pressurised inhalation, suspension	-Salbutamol
Salbutamol Neutec 2.5 mg/2.5 ml nebuliser solution	Neutec Inhaler Ireland Limited	PA23030/002/001	Nebuliser solution	-SALBUTAMOL SULFATE
Saline Steri-Neb 0.9% w/v Nebuliser Solution	Teva B.V.	PA1986/087/001	Nebuliser solution	-Sodium chloride
Salofalk 1.5g prolonged-release granules	Dr. Falk Pharma GmbH	PA0573/003/007	Prolonged-release granules	-Mesalazine
Salofalk 1000mg prolonged-release granules	Dr. Falk Pharma GmbH	PA0573/003/002	Prolonged-release granules	-Mesalazine
Salofalk 1g Suppositories	Dr. Falk Pharma GmbH	PA0573/004/004	Suppository	-Mesalazine
Salofalk 1g Suppositories	IMED Healthcare Ltd.	PPA1463/212/001	Suppository	-Mesalazine
Salofalk 1g/Actuation Rectal Foam	Dr. Falk Pharma GmbH	PA0573/004/005	Rectal foam	-Mesalazine
Salofalk 250 mg Suppositories	Dr. Falk Pharma GmbH	PA0573/004/002	Suppository	-Mesalazine
Salofalk 250mg Gastro-Resistant Tablets	Dr. Falk Pharma GmbH	PA0573/004/003	Gastro-resistant tablet	-Mesalazine
Salofalk 3g prolonged-release granules	Dr. Falk Pharma GmbH	PA0573/003/006	Prolonged-release granules	-Mesalazine
Salofalk 4g/60ml Enema	Dr. Falk Pharma GmbH	PA0573/004/001	Rectal suspension	-Mesalazine
Salofalk 500 mg prolonged-release granules	Dr. Falk Pharma GmbH	PA0573/003/001	Prolonged-release granules	-Mesalazine
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	-Triptorelin
Sametec Airmaster 50 microgram/ 100 microgram/ dose, inhalation powder, pre-dispensed	Clonmel Healthcare Ltd	PA0126/342/001	Inhalation powder, pre-dispensed	-SALMETEROL XINAFOATE -Fluticasone propionate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Sametec Airmaster 50 microgram/ 250 microgram/ dose, inhalation powder, pre-dispensed	Clonmel Healthcare Ltd	PA0126/342/002	Inhalation powder, pre-dispensed	-SALMETEROL XINAFOATE -Fluticasone propionate
Sametec Airmaster 50 microgram/ 500 microgram/ dose, inhalation powder, pre-dispensed	Clonmel Healthcare Ltd	PA0126/342/003	Inhalation powder, pre-dispensed	-SALMETEROL XINAFOATE -Fluticasone propionate
Samsca	Otsuka Pharmaceutical Netherlands B.V.	EU/1/09/539/005-006	Tablet	-Tolvaptan (opc-41061)
Samsca	Otsuka Pharmaceutical Netherlands B.V.	EU/1/09/539/1-2	Tablet	-Tolvaptan
Samsca	Otsuka Pharmaceutical Netherlands B.V.	EU/1/09/539/3-4	Tablet	-Tolvaptan
Sancuso	Kyowa Kirin Holdings B.V.	EU/1/12/766/001	Transdermal patch	-Granisetron
Sandimmun 100 mg/ml concentrate for oral solution	Novartis Ireland Limited	PA0896/027/001	Concentrate for oral solution	-Ciclosporin
Sandimmun 100mg Soft Capsules	Novartis Ireland Limited	PA0896/027/004	Capsule, soft	-Ciclosporin
Sandimmun 25mg Soft Capsules	Novartis Ireland Limited	PA0896/027/003	Capsule, soft	-Ciclosporin
Sandimmun 50 mg/ml Concentrate for Solution for Infusion	Novartis Ireland Limited	PA0896/027/002	Concentrate for solution for infusion	-Ciclosporin
Sandimmun 50mg Soft Capsules	Novartis Ireland Limited	PA0896/027/005	Capsule, soft	-Ciclosporin
SANDOSTATIN 100 microgram/1ml, solution for injection/infusion	Novartis Ireland Limited	PA0896/028/002	Solution for injection/infusion	-Octreotide
SANDOSTATIN 50 microgram/1 ml, solution for injection/infusion	Novartis Ireland Limited	PA0896/028/001	Solution for injection/infusion	-Octreotide
SANDOSTATIN 500 microgram/1 ml, solution for injection/infusion	Novartis Ireland Limited	PA0896/028/003	Solution for injection/infusion	-Octreotide
Sandostatin LAR 10 mg powder and solvent for suspension for injection	Novartis Ireland Limited	PA0896/028/004	Powder and solvent for suspension for injection	-Octreotide
Sandostatin LAR 20 mg powder and solvent for suspension for injection	Novartis Ireland Limited	PA0896/028/005	Powder and solvent for suspension for injection	-Octreotide
Sandostatin LAR 30 mg powder and solvent for suspension for injection	Novartis Ireland Limited	PA0896/028/006	Powder and solvent for suspension for injection	-Octreotide
Sanomigran 1.5mg Tablets	Phoenix Labs	PA1113/012/002	Coated tablet	-Pizotifen
Sanomigran 500 microgram Tablets	Phoenix Labs	PA1113/012/001	Coated tablet	-Pizotifen
Saphnelo	AstraZeneca AB	EU/1/21/1623/001	Concentrate for solution for infusion	-Anifrolumab
Sapropterin Dipharma	Dipharma Arzneimittel GmbH	EU/1/21/1620/001-003	Powder for oral solution	-Sapropterin hydrochloride
Sapropterin Dipharma	Dipharma Arzneimittel GmbH	EU/1/21/1620/004	Powder for oral solution	-Sapropterin hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Sapvit-D3 400 IU/drop oral drops, solution	Fresenius Kabi Austria GmbH	PA0773/006/001	Oral drops, solution	-Cholecalciferol
Sarclisa	Sanofi Winthrop Industrie	EU/1/20/1435/001-003	Concentrate for solution for infusion	-Isatuximab
Sastravi 100mg/25mg/200mg Film-coated Tablets	Teva B.V.	PA1986/120/003	Film-coated tablet	-Levodopa -Carbidopa -Entacapone
Sastravi 125mg/31.25mg/200mg Film-coated Tablets	Teva B.V.	PA1986/120/004	Film-coated tablet	-Levodopa -Carbidopa -Entacapone
Sastravi 150mg/37.5mg/200mg Film-coated Tablets	Teva B.V.	PA1986/120/005	Film-coated tablet	-Levodopa -Carbidopa -Entacapone
Sastravi 175mg/43.75mg/200mg Film-coated Tablets	Teva B.V.	PA1986/120/006	Film-coated tablet	-Levodopa -Carbidopa -Entacapone
Sastravi 200mg/50mg/200mg Film-coated Tablets	Teva B.V.	PA1986/120/007	Film-coated tablet	-Levodopa -Carbidopa -Entacapone
Sastravi 50mg/12.5mg/200mg Film-coated Tablets	Teva B.V.	PA1986/120/001	Film-coated tablet	-Levodopa -Carbidopa -Entacapone
Sastravi 75mg/18.75mg/200mg Film-coated Tablets	Teva B.V.	PA1986/120/002	Film-coated tablet	-Levodopa -Carbidopa -Entacapone
Sativex Oromucosal Spray	Jazz Pharmaceuticals Ireland Limited	PA23494/001/001	Oromucosal spray, solution	-Delta-9-tetrahydrocannabinol botanical drug substance (thc bds) -Cannabidiol botanical drug substance (cbd bds)
Savene	Clinigen Healthcare B.V.	EU/1/06/350/001	Powder and solvent for concentrate for solution for infusion	-Dexrazoxane
Saxenda	Novo Nordisk A/S	EU/1/15/992/001-003	Solution for injection in pre-filled pen	-Liraglutide
Scandonest 3% w/v Solution for Injection	Septodont	PA0196/015/001	Solution for injection	-Mepivacaine hydrochloride
Scemblix	Novartis Europharm Limited	EU/1/22/1670/001-002	Film-coated tablet	-Asciminib hydrochloride
Scemblix	Novartis Europharm Limited	EU/1/22/1670/003-004	Film-coated tablet	-Asciminib hydrochloride
Scenesse	Clinuvel Europe Limited	EU/1/14/969/001	Implant	-Afamelanotide
Scheriproct 1.5mg/g + 5mg/g rectal ointment	KARO PHARMA AB	PA22650/005/001	Rectal ointment	-PREDNISOLONE CAPROATE -Cinchocaine hydrochloride
Scheriproct 1mg + 1mg suppositories	KARO PHARMA AB	PA22650/005/002	Suppository	-Prednisolone Hydrochloride -Cinchocaine Hydrochloride
Scintimun	CIS bio International	EU/1/09/602/1-2	Kit for radiopharmaceutical preparation	-Besilesomab
Sedaconda 100% V/V inhalation vapour, liquid	Sedana Medical AB	PA23141/001/001	Inhalation vapour, liquid	-Isoflurane
Seebri Breezhaler	Novartis Europharm Limited	EU/1/12/788/001-006	Inhalation powder, hard capsule	-Glycopyrronium bromide
Seffalair Spiromax	Teva B.V.	EU/1/21/1533/001-002	Inhalation powder	-SALMETEROL XINAFOATE -Fluticasone propionate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Seffalair Spiromax	Teva B.V.	EU/1/21/1533/003-004	Inhalation powder	-SALMETEROL XINAFOATE -Fluticasone propionate
Segluromet	Merck Sharp & Dohme BV	EU/1/18/1265/001-007	Film-coated tablet	-Metformin Hydrochloride -Ertugliflozin l- pyroglutamic acid
Segluromet	Merck Sharp & Dohme BV	EU/1/18/1265/008-014	Film-coated tablet	-Ertugliflozin l- pyroglutamic acid -Metformin Hydrochloride
Segluromet	Merck Sharp & Dohme BV	EU/1/18/1265/015-021	Film-coated tablet	-Ertugliflozin l- pyroglutamic acid -Metformin Hydrochloride
Segluromet	Merck Sharp & Dohme BV	EU/1/18/1265/022-028	Film-coated tablet	-Ertugliflozin l- pyroglutamic acid -Metformin Hydrochloride
SeHCAT 370kBq capsules	GE Healthcare Buchler GmbH & Co KG	PA22661/001/001	Capsule, hard	-Tauroselcholic acid
Selesyn 100 micrograms/2 ml, oral solution (50 micrograms/ml)	biosyn Arzneimittel GmbH	PA1131/001/001	Oral solution	-Selenium
Selesyn 100 micrograms/2 ml, solution for injection (50 micrograms/ml)	biosyn Arzneimittel GmbH	PA1131/001/003	Solution for injection	-Selenium
Selesyn 500 micrograms/10 ml, oral solution (50 micrograms/ml)	biosyn Arzneimittel GmbH	PA1131/001/002	Oral solution	-Selenium
Selesyn 500 micrograms/10 ml, solution for injection (50 micrograms/ml)	biosyn Arzneimittel GmbH	PA1131/001/004	Solution for injection	-Selenium
Selincro	H. Lundbeck A/S	EU/1/12/815/001-005	Film-coated tablet	-Nalmefene
Selsun Shampoo 2.5% w/v	Opella Healthcare France SAS T/A Sanofi	PA23180/013/001	Shampoo	-Selenium disulfide
Semglee	Biosimilar Collaborations Ireland Limited	EU/1/18/1270/001-004	Solution for injection in pre-filled pen	-Insulin glargine
Senokot 7.5 mg/5 ml Syrup	Reckitt Benckiser Ireland Ltd	PA0979/016/003	Syrup	-Sennoside b
Senokot 7.5mg Tablets	Reckitt Benckiser Ireland Ltd	PA0979/016/002	Tablet	-Senna pods powdered
Senshio	Shionogi B.V.	EU/1/14/978/001-002	Film-coated tablet	-Ospemifene
Septabene 1.5 mg/ml + 5.0 mg/ml oromucosal spray, solution	KRKA, d.d., Novo mesto	PA1347/049/001	Oromucosal spray, solution	-BENZYDAMINE HYDROCHLORIDE -Cetylpyridinium chloride
Septabene eucalyptus 3 mg/1 mg lozenges	KRKA, d.d., Novo mesto	PA1347/063/001	Lozenge	-BENZYDAMINE HYDROCHLORIDE -Cetylpyridinium chloride
Septabene lemon and elderflower 3 mg /1 mg lozenges	KRKA, d.d., Novo mesto	PA1347/063/003	Lozenge	-BENZYDAMINE HYDROCHLORIDE -Cetylpyridinium chloride
Septabene Lemon and Honey 3 mg/1 mg lozenges	KRKA, d.d., Novo mesto	PA1347/063/002	Lozenge	-BENZYDAMINE HYDROCHLORIDE -Cetylpyridinium chloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Septanazal 1 mg/ 50 mg in 1 ml nasal spray solution	KRKA, d.d., Novo mesto	PA1347/058/002	Nasal spray, solution	-Xylometazoline hydrochloride -Dexpanthenol
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	-Xylometazoline hydrochloride -Dexpanthenol
Septanest 40 mg/ml + 10 micrograms/ml, solution for injection	Septodont	PA0196/017/002	Solution for injection	-Articaine hydrochloride -Adrenaline tartrate
Septtrin 80 mg/400 mg per ampoule, concentrate for solution for infusion	Aspen Pharma Trading Limited	PA1691/010/005	Concentrate for solution for infusion	-Sulfamethoxazole -Trimethoprim
Septtrin 80 mg/400 mg Tablets	Aspen Pharma Trading Limited	PA1691/010/001	Tablet	-Sulfamethoxazole -Trimethoprim
Septtrin Adult 80 mg/400 mg per 5 ml Oral Suspension	Aspen Pharma Trading Limited	PA1691/010/004	Oral suspension	-Sulphamethoxazole -Trimethoprim
Septtrin Forte 160 mg/800 mg Tablets	Aspen Pharma Trading Limited	PA1691/010/002	Tablet	-Sulphamethoxazole -Trimethoprim
Septtrin Paediatric 40 mg/200 mg per 5 ml Oral Suspension	Aspen Pharma Trading Limited	PA1691/010/003	Oral suspension	-Sulphamethoxazole -Trimethoprim
Serc 16 mg tablets	PCO Manufacturing Ltd.	PPA0465/482/001	Tablet	-Betahistine dihydrochloride
Serc 16mg Tablets	Viartis Healthcare Limited	PA23355/014/002	Tablet	-BETAHISTINE HYDROCHLORIDE
Serc 8mg Tablets	Viartis Healthcare Limited	PA23355/014/001	Tablet	-BETAHISTINE HYDROCHLORIDE
Sereflo 25 microgram/125 microgram per actuation pressurised inhalation, suspension	Cipla Europe NV	PA1963/013/001	Pressurised inhalation, suspension	-SALMETEROL XINAFOATE -Fluticasone propionate
Sereflo 25 microgram/250 microgram per actuation pressurised inhalation, suspension	Cipla Europe NV	PA1963/013/002	Pressurised inhalation, suspension	-Fluticasone propionate -SALMETEROL XINAFOATE
Seretide 100 Diskus 50 microgram/100 microgram / dose inhalation powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/046/001	Inhalation powder, pre-dispensed	-SALMETEROL XINAFOATE -Fluticasone propionate
Seretide 100 Diskus 50 microgram/100 microgram/dose inhalation powder, pre-dispensed	PCO Manufacturing Ltd.	PPA0465/091/001	Inhalation powder, pre-dispensed	-Fluticasone propionate -Salmeterol
Seretide 100 Diskus 50 microgram/100 microgram/dose inhalation powder, pre-dispensed	IMED Healthcare Ltd.	PPA1463/006/003	Inhalation powder, pre-dispensed	-Salmeterol -Fluticasone propionate
Seretide 125 Evohaler 25 microgram/125 microgram/dose pressurised inhalation, suspension	PCO Manufacturing Ltd.	PPA0465/091/005	Pressurised inhalation, suspension	-Fluticasone propionate -SALMETEROL XINAFOATE
Seretide 125 Evohaler 25 microgram/125 microgram/dose pressurised inhalation, suspension	GlaxoSmithKline (Ireland) Limited	PA1077/046/005	Pressurised inhalation, suspension	-SALMETEROL XINAFOATE -Fluticasone propionate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Seretide 250 Diskus 50 microgram/250 microgram/dose inhalation powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/046/002	Inhalation powder, pre-dispensed	-SALMETEROL XINAFOATE -Fluticasone propionate
Seretide 250 Diskus 50 microgram/250 microgram/dose inhalation powder, pre-dispensed	IMED Healthcare Ltd.	PPA1463/006/002	Inhalation powder, pre-dispensed	-Fluticasone propionate -Salmeterol
Seretide 250 Diskus 50 microgram/250 microgram/dose inhalation powder, pre-dispensed	Merit Pharmaceuticals Limited	PPA23080/028/001	Inhalation powder, pre-dispensed	-Salmeterol -Fluticasone propionate
Seretide 250 Diskus, 50 microgram/250 microgram/dose inhalation powder, pre-dispensed	PCO Manufacturing Ltd.	PPA0465/091/002	Inhalation powder, pre-dispensed	-Salmeterol -Fluticasone propionate
Seretide 250 Evohaler 25 microgram/250 microgram/dose pressurised inhalation, suspension	PCO Manufacturing Ltd.	PPA0465/091/006	Pressurised inhalation, suspension	-SALMETEROL XINAFOATE -Fluticasone propionate
Seretide 250 Evohaler 25 microgram/250 microgram/dose pressurised inhalation, suspension	GlaxoSmithKline (Ireland) Limited	PA1077/046/006	Pressurised inhalation, suspension	-SALMETEROL XINAFOATE -Fluticasone propionate
Seretide 50 Evohaler 25 microgram/50 microgram/dose pressurised inhalation, suspension	GlaxoSmithKline (Ireland) Limited	PA1077/046/004	Pressurised inhalation, suspension	-SALMETEROL XINAFOATE -Fluticasone propionate
Seretide 500 Diskus 50 microgram/500 microgram/dose inhalation powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/046/003	Inhalation powder, pre-dispensed	-SALMETEROL XINAFOATE -Fluticasone propionate
Seretide 500 Diskus 50 microgram/500 microgram/dose inhalation powder, pre-dispensed	Merit Pharmaceuticals Limited	PPA23080/028/002	Inhalation powder, pre-dispensed	-Salmeterol -Fluticasone propionate
Seretide 500 Diskus 50 microgram/500 microgram/dose inhalation powder, pre-dispensed	IMED Healthcare Ltd.	PPA1463/006/001	Inhalation powder, pre-dispensed	-Fluticasone propionate -Salmeterol
Seretide 500 Diskus, 50 microgram/500 microgram/dose inhalation powder, pre-dispensed	PCO Manufacturing Ltd.	PPA0465/091/003	Inhalation powder, pre-dispensed	-Salmeterol -Fluticasone propionate
Sertral 100 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/023/002	Film-coated tablet	-Sertraline
Sertral 50 mg film-coated tablets	Teva Pharma B.V.	PA0749/023/001	Film-coated tablet	-Sertraline
Serevent Diskus, 50 micrograms per metered dose, inhalation powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/047/003	Inhalation powder, pre-dispensed	-Salmeterol

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Serevent Evohaler 25 micrograms per actuation pressurised inhalation suspension	GlaxoSmithKline (Ireland) Limited	PA1077/047/005	Pressurised inhalation, suspension	-Salmeterol
Serevent Evohaler 25 micrograms per actuation pressurised inhalation suspension	PCO Manufacturing Ltd.	PPA0465/503/001	Pressurised inhalation, suspension	-Salmeterol
Serevent Evohaler 25 micrograms per actuation pressurised inhalation suspension	IMED Healthcare Ltd.	PPA1463/204/001	Pressurised inhalation, suspension	-Salmeterol
Serimel 100 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/135/002	Film-coated tablet	-Sertraline
Serimel 50 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/135/001	Film-coated tablet	-Sertraline
Serlan 100 mg Film-Coated Tablet	Rowex Ltd	PA0711/065/002	Film-coated tablet	-Sertraline
Serlan 50 mg film-coated tablets	Rowex Ltd	PA0711/065/001	Film-coated tablet	-Sertraline
Seropia 100 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/185/002	Film-coated tablet	-Quetiapine fumarate
Seropia 200 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/185/003	Film-coated tablet	-Quetiapine fumarate
Seropia 25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/185/001	Film-coated tablet	-Quetiapine fumarate
Seropia 300 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/185/004	Film-coated tablet	-Quetiapine fumarate
Seropia XR 150 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/275/002	Prolonged-release tablet	-Quetiapine
Seropia XR 200 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/275/003	Prolonged-release tablet	-Quetiapine
Seropia XR 300 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/275/004	Prolonged-release tablet	-Quetiapine
Seropia XR 400 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/275/005	Prolonged-release tablet	-Quetiapine
Seropia XR 50 mg prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/275/001	Prolonged-release tablet	-Quetiapine
Seroquel 100 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/182/002	Film-coated tablet	-Quetiapine
Seroquel 100 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/438/006	Film-coated tablet	-Quetiapine
Seroquel 100 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/002	Film-coated tablet	-Quetiapine
Seroquel 200 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/003	Film-coated tablet	-Quetiapine
Seroquel 25 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/001	Film-coated tablet	-Quetiapine
Seroquel 25 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/438/005	Film-coated tablet	-Quetiapine
Seroquel 25 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/182/001	Film-coated tablet	-Quetiapine
Seroquel 300 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/004	Film-coated tablet	-Quetiapine
Seroquel XR 150 mg prolonged-release tablets	Originalis B.V.	PPA2306/011/002	Prolonged-release tablet	-Quetiapine
Seroquel XR 150 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/438/002	Prolonged-release tablet	-Quetiapine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Seroquel XR 150mg prolonged-release tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/006	Prolonged-release tablet	-Quetiapine
Seroquel XR 200 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/438/003	Prolonged-release tablet	-Quetiapine
Seroquel XR 200mg prolonged-release tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/007	Prolonged-release tablet	-Quetiapine
Seroquel XR 300 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/438/004	Prolonged-release tablet	-Quetiapine
Seroquel XR 300mg prolonged-release tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/008	Prolonged-release tablet	-Quetiapine
Seroquel XR 400 mg prolonged-release tablets	Originalis B.V.	PPA2306/011/001	Prolonged-release tablet	-Quetiapine
Seroquel XR 400mg prolonged-release tablets.	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/009	Prolonged-release tablet	-Quetiapine
Seroquel XR 50 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/438/001	Prolonged-release tablet	-Quetiapine
Seroquel XR 50mg prolonged-release tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/022/005	Prolonged-release tablet	-Quetiapine
Seroxat 10 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/097/004	Film-coated tablet	-Paroxetine hydrochloride hemihydrate
Seroxat 20 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/097/002	Film-coated tablet	-Paroxetine hydrochloride hemihydrate
Seroxat 20 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/483/001	Film-coated tablet	-Paroxetine
Seroxat 30 mg film-coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/097/003	Film-coated tablet	-Paroxetine hydrochloride hemihydrate
Sertraline 100 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/177/002	Film-coated tablet	-Sertraline
Sertraline 50 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/177/001	Film-coated tablet	-Sertraline
Sertraline Bluefish 100 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/021/002	Film-coated tablet	-Sertraline hydrochloride
Sertraline Bluefish 50 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/021/001	Film-coated tablet	-Sertraline hydrochloride
Sertraline Krka 100 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/019/002	Film-coated tablet	-Sertraline
Sertraline Krka 50 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/019/001	Film-coated tablet	-Sertraline
Sevelamer Carbonate 800 mg film coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/205/001	Film-coated tablet	-Sevelamer carbonate
Sevelamer carbonate Genthon 800 mg, film-coated tablets	Genthon B.V.	PA0740/014/001	Film-coated tablet	-Sevelamer carbonate
Sevelamer carbonate Zentiva	Genzyme Europe B.V.	EU/1/14/952/001	Film-coated tablet	-Sevelamer carbonate
Sevelamer carbonate Zentiva	Genzyme Europe B.V.	EU/1/14/952/002-003	Powder for oral suspension	-Sevelamer carbonate
Sevelamer carbonate Zentiva	Genzyme Europe B.V.	EU/1/14/952/005	Powder for oral suspension	-Sevelamer carbonate
Sevelamer Hydrochloride Waymade 800 mg film-coated tablets	Waymade B.V.	PA22879/001/002	Film-coated tablet	-Sevelamer hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
SEVELAMER HYDROCHLORIDE ZENTIVA	Genzyme Europe B.V.	EU/1/14/953/001	Film-coated tablet	-SEVELAMER HYDROCHLORIDE
Sevoflurane 100% inhalation vapour, liquid	Chanelle Medical Unlimited Company	PA0688/036/001	Inhalation vapour, liquid	-Sevoflurane
Sevoflurane 100% Inhalation Vapour, liquid	Piramal Critical Care B.V.	PA22583/003/001	Inhalation vapour, liquid	-Sevoflurane
Sevoflurane Baxter, 100%, inhalation vapour, liquid	Baxter Holding B.V.	PA2299/031/001	Inhalation vapour, liquid	-Sevoflurane
Sevorane 100% v/v Inhalation Gas	AbbVie Limited	PA1824/004/001	Inhalation vapour, liquid	-Sevoflurane
Sevredol 10mg Film- Coated Tablets	Mundipharma Pharmaceuticals Limited	PA1688/009/001	Film-coated tablet	-Morphine sulfate
Sevredol 20 mg Film- Coated Tablets	Mundipharma Pharmaceuticals Limited	PA1688/009/002	Film-coated tablet	-Morphine sulfate
Shingrix	GlaxoSmithKline Biologicals S.A.	EU/1/18/1272/001-002	Powder and suspension for suspension for injection	-Recombinant varicella zoster virus surface glycoprotein e
Sialanar 320 micrograms/ml oral solution	Proveca Pharma Limited	EU/1/16/1135/001	Oral solution	-Glycopyrronium bromide
Sibnaya	Advicenne Pharma SA	EU/1/20/1517/001-006	Prolonged-release granules	-Potassium citrate -Potassium hydrogen carbonate
Sibnaya	Advicenne Pharma SA	EU/1/20/1517/007-012	Prolonged-release granules	-Potassium citrate -Potassium hydrogen carbonate
Sildenafil 100 mg tablets	Rowex Ltd	PA0711/170/003	Tablet	-Sildenafil
Sildenafil 25 mg tablets	Rowex Ltd	PA0711/170/001	Tablet	-Sildenafil
Sildenafil 50 mg Tablets	Rowex Ltd	PA0711/170/002	Tablet	-Sildenafil
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/001	Tablet	-Pramipexole dihydrochloride monohydrate
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/003	Tablet	-Pramipexole dihydrochloride monohydrate
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/005	Tablet	-Pramipexole dihydrochloride monohydrate
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/011	Tablet	-Pramipexole dihydrochloride monohydrate
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/028-30	Prolonged-release tablet	-Pramipexole dihydrochloride monohydrate, milled
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/031-33	Prolonged-release tablet	-Pramipexole dihydrochloride monohydrate, milled
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/13-15	Prolonged-release tablet	-Pramipexole dihydrochloride monohydrate, milled
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/16-18	Prolonged-release tablet	-Pramipexole dihydrochloride monohydrate, milled
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/19-21	Prolonged-release tablet	-Pramipexole dihydrochloride monohydrate, milled
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/22-24	Prolonged-release tablet	-Pramipexole dihydrochloride monohydrate, milled

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Sifrol	Boehringer Ingelheim International GmbH	EU/1/97/050/25-27	Prolonged-release tablet	-Pramipexole dihydrochloride monohydrate, milled
Signifor	Recordati Rare Diseases	EU/1/12/753/001-004	Solution for injection	-Pasireotide dispartate
Signifor	Recordati Rare Diseases	EU/1/12/753/005-008	Solution for injection	-Pasireotide dispartate
Signifor	Recordati Rare Diseases	EU/1/12/753/009-012	Solution for injection	-Pasireotide dispartate
Signifor	Recordati Rare Diseases	EU/1/12/753/013	Powder and solvent for suspension for injection	-Pasireotide pamoate
Signifor	Recordati Rare Diseases	EU/1/12/753/014-015	Powder and solvent for suspension for injection	-Pasireotide pamoate
Signifor	Recordati Rare Diseases	EU/1/12/753/016-017	Powder and solvent for suspension for injection	-Pasireotide pamoate
Signifor	Recordati Rare Diseases	EU/1/12/753/018	Powder and solvent for suspension for injection	-Pasireotide pamoate
Signifor	Recordati Rare Diseases	EU/1/12/753/019	Powder and solvent for suspension for injection	-Pasireotide pamoate
Siklos	Addmedica	EU/1/07/397/001	Film-coated tablet	-Hydroxycarbamide
Siklos	Addmedica	EU/1/07/397/002-004	Film-coated tablet	-Hydroxycarbamide
Silapo	Stada Arzneimittel AG	EU/1/07/432/1-6	Solution for injection in pre-filled syringe	-Epoetin zeta
Silapo	Stada Arzneimittel AG	EU/1/07/432/17-19	Solution for injection in pre-filled syringe	-Epoetin zeta
Silapo	Stada Arzneimittel AG	EU/1/07/432/7-16	Solution for injection in pre-filled syringe	-Epoetin zeta
Silcarfil 20 mg film-coated tablets	Rowex Ltd	PA0711/266/001	Film-coated tablet	-Sildenafil citrate
Sildenafil Accord 100 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/069/003	Film-coated tablet	-Sildenafil
Sildenafil Accord 25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/069/001	Film-coated tablet	-Sildenafil
Sildenafil Accord 50 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/069/002	Film-coated tablet	-Sildenafil
Sildenafil Actavis 100 mg film-coated tablets	Actavis Group hf	EU/1/09/595/11-15	Film-coated tablet	-Sildenafil
Sildenafil Actavis 25 mg film-coated tablets	Actavis Group hf	EU/1/09/595/1-5	Film-coated tablet	-Sildenafil
Sildenafil Actavis 50 mg film-coated tablets	Actavis Group hf	EU/1/09/595/6-10	Film-coated tablet	-Sildenafil
Sildenafil Clonmel 100 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/199/003	Film-coated tablet	-Sildenafil
Sildenafil Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/199/004	Film-coated tablet	-Sildenafil citrate
Sildenafil Clonmel 25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/199/001	Film-coated tablet	-Sildenafil
Sildenafil Clonmel 25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/382/001	Film-coated tablet	-Sildenafil citrate
Sildenafil Clonmel 50 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/382/002	Film-coated tablet	-Sildenafil citrate
Sildenafil Clonmel 50 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/199/002	Film-coated tablet	-Sildenafil
Sildenafil Mylan 100 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/141/003	Film-coated tablet	-Sildenafil
Sildenafil Mylan 25 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/141/001	Film-coated tablet	-Sildenafil

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Sildenafil Mylan 50 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/141/002	Film-coated tablet	-Sildenafil
Sildenafil ratiopharm 100 mg film-coated tablets	Ratiopharm GmbH	EU/1/09/603/9-12	Film-coated tablet	-Sildenafil
Sildenafil ratiopharm 25 mg film-coated tablets	Ratiopharm GmbH	EU/1/09/603/1-4	Film-coated tablet	-Sildenafil
Sildenafil ratiopharm 50 mg film-coated tablets	Ratiopharm GmbH	EU/1/09/603/5-8	Film-coated tablet	-Sildenafil
Sildenafil Teva 100 mg film-coated tablets	Teva B.V.	EU/1/09/584/13-18	Film-coated tablet	-Sildenafil
Sildenafil Teva 20 mg Film-coated Tablets	Teva B.V.	PA1986/031/001	Film-coated tablet	-Sildenafil
Sildenafil Teva 25 mg film-coated tablets	Teva B.V.	EU/1/09/584/1-6	Film-coated tablet	-Sildenafil
Sildenafil Teva 50 mg film-coated tablets	Teva B.V.	EU/1/09/584/7-12	Film-coated tablet	-Sildenafil
Sildenvia 50 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/261/001	Film-coated tablet	-Sildenafil
Silkis 3 micrograms per g ointment	Galderma International	PA22743/014/001	Ointment	-Calcitriol
Silodosin Recordati	Recordati Ireland Limited	EU/1/18/1343/001-006	Capsule, hard	-Silodosin
Silodosin Recordati	Recordati Ireland Limited	EU/1/18/1343/007-012	Capsule, hard	-Silodosin
Silodyx	Recordati Ireland Limited	EU/1/09/607/1-7	Capsule, hard	-Silodosin
Silodyx	Recordati Ireland Limited	EU/1/09/607/8-14	Capsule, hard	-Silodosin
SimAlvia 60mg/300mg, soft capsules	Laboratoires Galeniques Vernin	PA1927/001/001	Capsule, soft	-ALVERINE CITRATE -Simeticone
Simbrinza	Novartis Europharm Limited	EU/1/14/933/001-002	Eye drops, suspension	-Brinzolamide -Brimonidine tartrate
Simponi	Janssen Biologics B.V.	EU/1/09/546/005-008	Solution for injection	-Golimumab
Simponi	Janssen Biologics B.V.	EU/1/09/546/009	Solution for injection in pre-filled pen	-Golimumab
Simponi	Janssen Biologics B.V.	EU/1/09/546/1-4	Solution for injection	-Golimumab (cnto 148)
Simtan 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/125/002	Film-coated tablet	-Simvastatin
Simtan 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/125/003	Film-coated tablet	-Simvastatin
Simtan 40 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/125/004	Film-coated tablet	-Simvastatin
Simtan 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/125/001	Film-coated tablet	-Simvastatin
Simulect	Novartis Europharm Limited	EU/1/98/084/001	Powder and solvent for solution for injection/infusion	-Basiliximab
Simulect	Novartis Europharm Limited	EU/1/98/084/002	Powder and solvent for solution for injection/infusion	-Basiliximab
Simvastatin 10 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/054/001	Film-coated tablet	-Simvastatin
Simvastatin 20 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/054/002	Film-coated tablet	-Simvastatin
Simvastatin 20 mg film-coated tablets	Gentho B.V.	PA0740/003/003	Film-coated tablet	-Simvastatin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Simvastatin 40 mg film-coated tablets	Genthon B.V.	PA0740/003/004	Film-coated tablet	-Simvastatin
Simvastatin 40 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/054/003	Film-coated tablet	-Simvastatin
Simvastatin 80 mg Film-coated Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/054/004	Film-coated tablet	-Simvastatin
Simvastatin Bluefish 10 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/003/001	Film-coated tablet	-Simvastatin
Simvastatin Bluefish 20mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/003/002	Film-coated tablet	-Simvastatin
Simvastatin Bluefish 40mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/003/003	Film-coated tablet	-Simvastatin
Simvastatin Krka 10 mg Film-Coated Tablets	KRKA, d.d., Novo mesto	PA1347/028/001	Film-coated tablet	-Simvastatin
Simvastatin Krka 20 mg Film Coated Tablets	KRKA, d.d., Novo mesto	PA1347/028/002	Film-coated tablet	-Simvastatin
Simvastatin Krka 40 mg Film Coated Tablets	KRKA, d.d., Novo mesto	PA1347/028/003	Film-coated tablet	-Simvastatin
Simvastatin Teva 10 mg film-coated tablets	Teva Pharma B.V.	PA0749/052/002	Film-coated tablet	-Simvastatin
Simvastatin Teva 20 mg film-coated tablets	Teva Pharma B.V.	PA0749/052/003	Film-coated tablet	-Simvastatin
Simvastatin Teva 40 mg film-coated tablets	Teva Pharma B.V.	PA0749/052/004	Film-coated tablet	-Simvastatin
Sinemet 10 mg/100 mg tablets	Organon Pharma (Ireland) Limited	PA23198/004/002	Tablet	-Carbidopa -Levodopa
Sinemet 12.5 mg/50 mg tablets	Organon Pharma (Ireland) Limited	PA23198/004/001	Tablet	-Carbidopa -Levodopa
Sinemet 25 mg/250 mg tablets	Organon Pharma (Ireland) Limited	PA23198/004/004	Tablet	-Levodopa -Carbidopa
Sinemet CR 50 mg/200 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/468/002	Prolonged-release tablet	-Carbidopa -Levodopa
Sinemet CR 50mg/200 mg Prolonged-release Tablets	Organon Pharma (Ireland) Limited	PA23198/004/005	Prolonged-release tablet	-Levodopa -Carbidopa
Sinemet Plus 25 mg/100 mg tablets	Organon Pharma (Ireland) Limited	PA23198/004/003	Tablet	-Levodopa -Carbidopa
Sinemet Plus 25 mg/100 mg tablets	PCO Manufacturing Ltd.	PPA0465/468/001	Film-coated tablet	-Carbidopa -Levodopa
Singulair 10 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/064/003	Film-coated tablet	-Montelukast
Singulair 10 mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/014/004	Film-coated tablet	-Montelukast sodium
Singulair 10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/111/001	Film-coated tablet	-Montelukast
Singulair Paediatric 4 mg chewable tablets	Organon Pharma (Ireland) Limited	PA23198/014/001	Chewable tablet	-Montelukast
Singulair Paediatric 4 mg granules	Organon Pharma (Ireland) Limited	PA23198/014/002	Granules	-Montelukast sodium
Singulair Paediatric 5 mg chewable tablets	Organon Pharma (Ireland) Limited	PA23198/014/003	Chewable tablet	-Montelukast sodium
Singulair Paediatric 5 mg chewable tablets	PCO Manufacturing Ltd.	PPA0465/111/002	Chewable tablet	-Montelukast sodium
Singulair Paediatric 5 mg Chewable Tablets	IMED Healthcare Ltd.	PPA1463/064/002	Chewable tablet	-Montelukast
Sinora 0.08 mg/ml solution for infusion	Sintetica GmbH	PA22835/001/001	Solution for infusion	-NOREPINEPHRINE BITARTRATE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Sinora 0.1 mg/ml solution for infusion	Sintetica GmbH	PA22835/004/002	Solution for infusion	-Noradrenaline tartrate
Sinora 0.16 mg/ml solution for infusion	Sintetica GmbH	PA22835/001/002	Solution for infusion	-NOREPINEPHRINE BITARTRATE
Sinora 0.2 mg/ml solution for infusion	Sintetica GmbH	PA22835/004/003	Solution for infusion	-Noradrenaline tartrate
Sinora 1 mg/ml concentrate for solution for infusion	Sintetica GmbH	PA22835/004/001	Concentrate for solution for infusion	-Noradrenaline tartrate
Sirdupla 25 microgram/125 microgram per metered dose pressurised inhalation, suspension	Viartis Limited	PA23266/020/001	Pressurised inhalation, suspension	-SALMETEROL XINAFOATE -Fluticasone propionate
Sirdupla 25 microgram/250 microgram per metered dose pressurised inhalation, suspension	Viartis Limited	PA23266/020/002	Pressurised inhalation, suspension	-SALMETEROL XINAFOATE -Fluticasone propionate
Sirturo	Janssen-Cilag International NV	EU/1/13/901/001	Tablet	-Bedaquiline fumarate
Sirturo	Janssen-Cilag International NV	EU/1/13/901/003	Tablet	-Bedaquiline fumarate
Sitagliptin Grindeks 100 mg film-coated tablets	AS Grindeks	PA22992/005/003	Film-coated tablet	-Sitagliptin Hydrochloride Monohydrate
Sitagliptin Grindeks 25 mg film-coated tablets	AS Grindeks	PA22992/005/001	Film-coated tablet	-Sitagliptin Hydrochloride Monohydrate
Sitagliptin Grindeks 50 mg film-coated tablets	AS Grindeks	PA22992/005/002	Film-coated tablet	-Sitagliptin Hydrochloride Monohydrate
Sitagliptin Krka 100 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/094/003	Film-coated tablet	-Sitagliptin
Sitagliptin Krka 25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/094/001	Film-coated tablet	-Sitagliptin
Sitagliptin Krka 50 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/094/002	Film-coated tablet	-Sitagliptin
Sitagliptin Metformin Hydrochloride Mylan	Mylan Ireland Limited	EU/1/21/1619/001-008	Film-coated tablet	-Sitagliptin -Metformin Hydrochloride
Sitagliptin Metformin Hydrochloride Mylan	Mylan Ireland Limited	EU/1/21/1619/009-020	Film-coated tablet	-Metformin Hydrochloride -Sitagliptin
Sitagliptin Mylan 100 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/232/003	Film-coated tablet	-Sitagliptin
Sitagliptin Mylan 25 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/232/001	Film-coated tablet	-Sitagliptin
Sitagliptin Mylan 50 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/232/002	Film-coated tablet	-Sitagliptin
Sitagliptin Pinewood 100 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/219/003	Film-coated tablet	-Sitagliptin Hydrochloride
Sitagliptin Pinewood 25 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/219/001	Film-coated tablet	-Sitagliptin Hydrochloride
Sitagliptin Pinewood 50 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/219/002	Film-coated tablet	-Sitagliptin Hydrochloride
Sitagliptin Rowa 100 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/089/003	Film-coated tablet	-Sitagliptin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Sitagliptin Rowa 25 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/089/001	Film-coated tablet	-Sitagliptin
Sitagliptin Rowa 50 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/089/002	Film-coated tablet	-Sitagliptin
Sitagliptin SUN 100 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	EU/1/21/1598/009-012	Film-coated tablet	-Sitagliptin Fumarate
Sitagliptin SUN 25 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	EU/1/21/1598/001-004	Film-coated tablet	-Sitagliptin Fumarate
Sitagliptin SUN 50 mg film-coated tablets	Sun Pharmaceutical Industries Europe B.V.	EU/1/21/1598/005-008	Film-coated tablet	-Sitagliptin Fumarate
Sitagliptin Teva 100 mg film-coated tablets	Teva B.V.	PA1986/020/001	Film-coated tablet	-Sitagliptin
Sitagliptin/Metformin Clonmel 50 mg/1000 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/327/002	Film-coated tablet	-Sitagliptin -Metformin Hydrochloride
Sitagliptin/Metformin Clonmel 50 mg/850 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/327/001	Film-coated tablet	-Sitagliptin -Metformin Hydrochloride
Sitagliptin/Metformin Hydrochloride Accord	Accord Healthcare S.L.U.	EU/1/22/1661/017-032	Film-coated tablet	-Sitagliptin Hydrochloride Monohydrate -Metformin Hydrochloride
Sitagliptin/Metformin hydrochloride Grindeks 50 mg/1000 mg film-coated tablets	AS Grindeks	PA22992/006/002	Film-coated tablet	-Sitagliptin Hydrochloride Monohydrate -Metformin Hydrochloride
Sitagliptin/Metformin hydrochloride Grindeks 50 mg/850 mg film-coated tablets	AS Grindeks	PA22992/006/001	Film-coated tablet	-Metformin Hydrochloride -Sitagliptin Hydrochloride Monohydrate
Sitagliptin/Metformin hydrochloride Krka 50 mg/1000 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/100/002	Film-coated tablet	-Sitagliptin -Metformin Hydrochloride
Sitagliptin/Metformin hydrochloride Krka 50 mg/850 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/100/001	Film-coated tablet	-Sitagliptin -Metformin Hydrochloride
Sitagliptin/Metformin Hydrochloride Pinewood 50 mg/1000 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/220/002	Film-coated tablet	-Sitagliptin hydrochloride -Metformin Hydrochloride
Sitagliptin/Metformin Hydrochloride Pinewood 50 mg/850 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/220/001	Film-coated tablet	-Sitagliptin hydrochloride -Metformin Hydrochloride
Sitagliptin/Metformin hydrochloride Rowa 50 mg/1000 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/090/002	Film-coated tablet	-Sitagliptin Hydrochloride Monohydrate -Metformin Hydrochloride
Sitagliptin/Metformin hydrochloride Rowa 50 mg/850 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/090/001	Film-coated tablet	-Sitagliptin Hydrochloride Monohydrate -Metformin Hydrochloride
Sitagliptin/Metformin hydrochloride SUN	Sun Pharmaceutical Industries Europe B.V.	EU/1/23/1720/001-003	Film-coated tablet	-Sitagliptin Fumarate
Sitagliptin/Metformin hydrochloride SUN	Sun Pharmaceutical Industries Europe B.V.	EU/1/23/1720/004-006	Film-coated tablet	-Sitagliptin Fumarate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Sitagliptin/Metformin hydrochloride Teva 50 mg/1000 mg film-coated tablets	Norton Waterford	PA0436/051/002	Film-coated tablet	-Sitagliptin Hydrochloride Monohydrate -Metformin Hydrochloride
Sitagliptin/Metformin hydrochloride Teva 50 mg/850 mg film-coated tablets	Norton Waterford	PA0436/051/001	Film-coated tablet	-Sitagliptin Hydrochloride Monohydrate -Metformin Hydrochloride
Sivatin 10 mg film-coated tablets	Rowex Ltd	PA0711/050/001	Film-coated tablet	-Simvastatin
Sivatin 20 mg film-coated tablets	Rowex Ltd	PA0711/050/002	Film-coated tablet	-Simvastatin
Sivatin 40 mg film-coated tablets	Rowex Ltd	PA0711/050/003	Film-coated tablet	-Simvastatin
Sivextro	Merck Sharp & Dohme BV	EU/1/15/991/001	Film-coated tablet	-Tedizolid phosphate
Sivextro	Merck Sharp & Dohme BV	EU/1/15/991/002-003	Powder for concentrate for solution for infusion	-Tedizolid phosphate
Sixmo 74.2 mg implant	FGK Representative Service GmbH	EU/1/19/1369/001	Implant	-Buprenorphine hydrochloride
Skilarence	Almirall, S.A.	EU/1/17/1201/001	Gastro-resistant tablet	-Dimethyl Fumarate
Skilarence	Almirall, S.A.	EU/1/17/1201/002-011	Gastro-resistant tablet	-Dimethyl Fumarate
Skinoren 15% Gel	LEO Pharma A/S	PA1025/009/001	Gel	-Azelaic acid
Skudexa 75 mg/25 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/020/001	Film-coated tablet	-Dexketoprofen -Tramadol hydrochloride
Skudexa 75 mg/25 mg granules for oral solution in sachet	Menarini International Operations Luxembourg S.A.	PA0865/020/003	Granules for oral solution in sachet	-Tramadol hydrochloride -Dexketoprofen
Skyrizi	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1361/001	Solution for injection in pre-filled syringe	-RISANKIZUMAB
Skyrizi	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1361/002	Solution for injection in pre-filled pen	-RISANKIZUMAB
Skyrizi	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1361/003	Solution for injection in pre-filled syringe	-RISANKIZUMAB
Skyrizi	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1361/004	Concentrate for solution for infusion	-RISANKIZUMAB
Skyrizi	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1361/005	Solution for injection in cartridge	-RISANKIZUMAB
Skyrizi	AbbVie Deutschland GmbH & Co. KG	EU/1/19/1361/006	Solution for injection in pre-filled syringe	-RISANKIZUMAB
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/001	Powder and solvent for solution for injection	-Lonapegsomatropin -Somatropin
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/002	Powder and solvent for solution for injection	-Lonapegsomatropin -Somatropin
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/003	Powder and solvent for solution for injection	-Lonapegsomatropin -Somatropin
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/004	Powder and solvent for solution for injection	-Lonapegsomatropin -Somatropin
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/005	Powder and solvent for solution for injection	-Lonapegsomatropin -Somatropin
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/006	Powder and solvent for solution for injection	-Lonapegsomatropin -Somatropin
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/007	Powder and solvent for solution for injection	-Lonapegsomatropin -Somatropin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/008	Powder and solvent for solution for injection	-Lonapegsomatropin -Somatropin
Skytrofa	Ascendis Pharma Endocrinology Division A/S	EU/1/21/1607/009	Powder and solvent for solution for injection	-Lonapegsomatropin -Somatropin
Slentyto	RAD Neurim Pharmaceuticals EEC SARL	EU/1/18/1318/001-002	Prolonged-release tablet	-Melatonin
Slentyto	RAD Neurim Pharmaceuticals EEC SARL	EU/1/18/1318/003-004	Prolonged-release tablet	-Melatonin
Slow K 600mg Prolonged-release Coated Tablets	Essential Pharma (M) Limited	PA22644/002/001	Prolonged-release tablet	-Potassium chloride
Slyndy 4 mg film-coated tablets	Exeltis healthcare S.L.	PA22998/002/001	Film-coated tablet	-Drospirenone
SmofKabiven Central emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/058/002	Emulsion for infusion	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
SmofKabiven Central emulsion for infusion, Excel bags	Fresenius Kabi Deutschland GmbH	PA2059/058/001	Emulsion for infusion	-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 glycerophosphate 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
SmofKabiven Electrolyte Free Central emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/059/002	Emulsion for infusion	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
SmofKabiven extra Nitrogen Electrolyte free, emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/060/002	Emulsion for infusion	-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
SmofKabiven extra Nitrogen, emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/060/001	Emulsion for infusion	-Alanine -Arginine -Glycine -Histidine -Isoleucine -Leucine -Lysine acetate -Methionine -Phenylalanine -Proline -Serine -Taurine -Tryptophan -Tyrosine -Valine -Calcium chloride dihydrate -Sodium glycerophosphate 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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
SmofKabiven Low Osmo Peripheral emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/022/001	Emulsion for infusion	-Alanine -Arginine -Glycine -Histidine -Isoleucine -Leucine -Lysine acetate -Methionine -Phenylalanine -Proline -Serine -Taurine -Threonine -Tryptophan -Tyrosine -Valine -Calcium chloride dihydrate -Sodium glycerophosphate 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
SmofKabiven Nutribase emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/058/003	Emulsion for infusion	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
SmofKabiven Peripheral, emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/061/002	Emulsion for infusion	-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 glycerophosphate hydrate -Magnesium sulphate heptahydrate -Potassium chloride -Sodium acetate trihydrate -Zinc sulphate heptahydrate -Glucose monohydrate
SMOfIipid 200 mg/ml emulsion for infusion, excel bag	Fresenius Kabi Deutschland GmbH	PA2059/062/002	Emulsion for infusion	-Soya bean oil -Medium chain triglycerides -Refined olive oil -Purified fish oil
SMOfIipid 200 mg/ml emulsion for infusion, glass bottle	Fresenius Kabi Deutschland GmbH	PA2059/062/001	Emulsion for infusion	-Soybean oil -Triglycerides, medium chain -Refined olive oil -Purified fish oil
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	-Sodium chloride -Glucose
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	-Sodium chloride -Glucose
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	-Sodium chloride -Glucose
Sodium Chloride 0.45% w/v Solution for Infusio	Baxter Holding B.V.	PA2299/002/002	Solution for infusion	-Sodium chloride
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	-Sodium chloride -Glucose

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Sodium Chloride 0.9 % w/v solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/063/003	Solution for infusion	-Sodium chloride
Sodium Chloride 0.9% w/v Injection BP	Noridem Enterprises Limited	PA1122/002/001	Solvent for parenteral use	-Sodium chloride
Sodium Chloride 0.9% w/v Intravenous Infusion BP	Baxter Holding B.V.	PA2299/002/001	Solution for infusion	-Sodium chloride
Sodium Chloride 0.9% w/v Intravenous Infusion BP Solution for Infusion	B. Braun Melsungen AG	PA0736/003/001	Solution for infusion	-Sodium chloride
Sodium Chloride 0.9% w/v Solution for Infusio	Fresenius Kabi Deutschland GmbH	PA2059/063/004	Solution for infusion	-Sodium chloride
Sodium Chloride 0.9% w/v Solution for Infusio	Fresenius Kabi Deutschland GmbH	PA2059/063/002	Solution for infusion	-Sodium chloride
Sodium Chloride 0.9% w/v Solution for Infusion, polyethylene bottle	Fresenius Kabi Deutschland GmbH	PA2059/063/005	Solution for infusion	-Sodium chloride
Sodium chloride 0.9% w/v solvent for parenteral use	Fresenius Kabi Deutschland GmbH	PA2059/063/006	Solvent for parenteral use	-Sodium chloride
Sodium Chloride 0.9%w/v Solution for Infusion	Fresenius Kabi Deutschland GmbH	PA2059/063/001	Solution for infusion	-Sodium chloride
Sodium chloride 5 mmol/ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/015/001	Oral solution	-Sodium chloride
Sodium Chloride Intravenous Infusion BP 0.9% w/v (viaflex container)	Baxter Holding B.V.	PA2299/002/003	Solution for infusion	-Sodium chloride
Sodium Chloride Intravenous Infusion BP 0.9% w/v Solution for Infusion	B. Braun Medical Limited	PA0179/002/007	Solution for infusion	-Sodium chloride
Sodium Chloride Intravenous Infusion BP 0.9% w/v Solution for Infusion, Ecobag	B. Braun Medical Limited	PA0179/002/031	Solution for infusion	-Sodium chloride
Sodium Iodide (I131) Capsule T 37-7400 MBq hard capsule	Curium Netherlands B.V.	PA0690/006/002	Capsule, hard	-Sodium iodide (131 i)
Sodium Nitrite Hope Pharmaceuticals 30 mg/mL Solution for Injection	Hope Pharmaceuticals Ltd	PA22874/001/001	Solution for injection	-SODIUM NITRITE
Sodium oxybate 500 mg/ml oral solution	AS Kalceks	PA2165/007/001	Oral solution	-Sodium Oxybate
Sodium Thiosulfate Hope Pharmaceuticals 250 mg/mL Solution for Injection	Hope Pharmaceuticals Ltd	PA22874/002/001	Solution for injection	-Sodium thiosulfate
Sogroya	Novo Nordisk A/S	EU/1/20/1501/001-002	Solution for injection in pre-filled pen	-Somapacitan
Sogroya	Novo Nordisk A/S	EU/1/20/1501/003-004	Solution for injection in pre-filled pen	-Somapacitan
Sogroya	Novo Nordisk A/S	EU/1/20/1501/005-006	Solution for injection in pre-filled pen	-Somapacitan
Solaraze 3% gel	PCO Manufacturing Ltd.	PPA0465/488/001	Gel	-Diclofenac sodium
Solaraze 3% gel	IMED Healthcare Ltd.	PPA1463/205/001	Gel	-Diclofenac sodium

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Solaraze 3% gel	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/021/001	Gel	-Diclofenac sodium
Solaraze 3% gel	Almirall, S.A.	PA0968/004/001	Gel	-Diclofenac sodium
Solferol 1,000 IU Soft Capsules	Windzor Pharma Ireland Limited	PA23126/001/003	Capsule, soft	-Colecalciferol
Solferol 10,000 IU Soft Capsules	Windzor Pharma Ireland Limited	PA23126/001/004	Capsule, soft	-Colecalciferol
Solferol 20,000 IU Soft Capsules	Windzor Pharma Ireland Limited	PA23126/002/001	Capsule, soft	-Colecalciferol
Solferol 400 IU Soft Capsules	Windzor Pharma Ireland Limited	PA23126/001/001	Capsule, soft	-Colecalciferol
Solferol 800 IU Soft Capsules	Windzor Pharma Ireland Limited	PA23126/001/002	Capsule, soft	-Colecalciferol
Solian 100mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/158/002	Tablet	-Amisulpride
Solian 200mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/158/003	Tablet	-Amisulpride
Solian 400 mg film-coated tablets	Originalis B.V.	PPA2306/019/001	Film-coated tablet	-Amisulpride
Solian 400mg Film-coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/158/004	Film-coated tablet	-Amisulpride
Solian 50mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/158/001	Tablet	-Amisulpride
Solifenacin Clonmel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/288/002	Film-coated tablet	-Solifenacin succinate
Solifenacin Clonmel 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/288/001	Film-coated tablet	-Solifenacin succinate
Solifenacin succinate 10 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/206/002	Film-coated tablet	-Solifenacin succinate
Solifenacin succinate 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/118/002	Film-coated tablet	-Solifenacin succinate
Solifenacin succinate 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/118/001	Film-coated tablet	-Solifenacin succinate
Solifenacin succinate 5 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/206/001	Film-coated tablet	-Solifenacin succinate
Solifenacin succinate Aristo 10 mg film-coated tablets	Aristo Pharma GmbH	PA1983/006/002	Film-coated tablet	-Solifenacin succinate
Solifenacin succinate Aristo 5 mg film-coated tablets	Aristo Pharma GmbH	PA1983/006/001	Film-coated tablet	-Solifenacin succinate
Solifenacin succinate Rowex 10 mg film-coated tablets	Rowex Ltd	PA0711/280/002	Film-coated tablet	-Solifenacin succinate
Solifenacin succinate Rowex 5 mg film-coated tablets	Rowex Ltd	PA0711/280/001	Film-coated tablet	-Solifenacin succinate
Solifenacin succinate Vivanta 10 mg film-coated tablets	Vivanta Generics s.r.o.	PA2265/001/002	Film-coated tablet	-Solifenacin succinate
Solifenacin succinate Vivanta 5 mg film-coated tablets	Vivanta Generics s.r.o.	PA2265/001/001	Film-coated tablet	-Solifenacin succinate
Solifenacin succinate/Tamsulosin hydrochloride Clonmel 6 mg/0.4 mg modified-release tablets	Clonmel Healthcare Ltd	PA0126/351/001	Modified-release tablet	-Solifenacin succinate -Tamsulosin hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Solifenacin succinate/Tamsulosin hydrochloride Rowex 6 mg/0.4 mg modified-release tablets	Rowex Ltd	PA0711/317/001	Modified-release tablet	-Solifenacin succinate -Tamsulosin hydrochloride
Solifenacin TAD 10 mg film-coated tablets	TAD Pharma GmbH	PA0876/008/002	Film-coated tablet	-Solifenacin succinate
Solifenacin TAD 5 mg film-coated tablets	TAD Pharma GmbH	PA0876/008/001	Film-coated tablet	-Solifenacin succinate
Soliris	Alexion Europe SAS	EU/1/07/393/001	Concentrate for solution for infusion	-Eculizumab
Solivito N powder for concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/064/001	Powder for concentrate for solution for infusion	-Thiamine nitrate -Riboflavin sodium phosphate -Nicotinamide -Pyridoxine hydrochloride -Sodium pantothenate -Sodium ascorbate -Biotin -Folic acid -Cyanocobalamin
Solpa Cold & Flu Multi-Relief Capsules Paracetamol 500mg, Guaifenesin 100mg, Phenylephrine hydrochloride 6.1 mg	Chefaro Ireland DAC	PA1186/021/002	Capsule, hard	-Paracetamol -Guaifenesin -Phenylephrine hydrochloride
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	-Paracetamol -Guaifenesin -Phenylephrine hydrochloride
Solpadeine Capsules, Paracetamol 500mg, Codeine Phosphate Hemihydrate 8mg, Caffeine 30mg	Chefaro Ireland DAC	PA1186/011/002	Capsule, hard	-Paracetamol -Codeine phosphate hemihydrate -Caffeine
Solpadeine Soluble Tablets Paracetamol 500mg Codeine Phosphate Hemihydrate 8mg Caffeine 30mg	Chefaro Ireland DAC	PA1186/011/001	Effervescent tablet	-Paracetamol -Codeine phosphate hemihydrate -Caffeine
Solpadeine Tablets Paracetamol 500mg, Codeine Phosphate Hemihydrate 8mg, Caffeine 30mg	Chefaro Ireland DAC	PA1186/011/003	Tablet	-Paracetamol -Codeine phosphate hemihydrate -Caffeine
Solpadol 500 mg/30 mg Effervescent Tablets	Phoenix Labs	PA1113/027/002	Effervescent tablet	-Paracetamol -Codeine phosphate hemihydrate
Solpadol Caplets 500 mg/30 mg Tablets	Phoenix Labs	PA1113/027/001	Tablet	-Paracetamol -Codeine phosphate hemihydrate
Solpa-Extra 500 mg/65 mg Soluble Tablets	Chefaro Ireland DAC	PA1186/017/001	Soluble tablet	-Caffeine -Paracetamol
Solpa-Extra Tablets Paracetamol 500 mg Caffeine 65 mg	Chefaro Ireland DAC	PA1186/026/001	Tablet	-Paracetamol -Caffeine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Solpa-Plus Tablets Paracetamol 500 mg Codeine Phosphate Hemihydrate 12.8 mg	Chefaro Ireland DAC	PA1186/011/005	Film-coated tablet	-Paracetamol -Codeine phosphate hemihydrate
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	-Paracetamol -Codeine phosphate hemihydrate -Caffeine
Solpa-Sinus Film- coated Tablets Paracetamol 500mg Pseudoephedrine Hydrochloride 30mg	Chefaro Ireland DAC	PA1186/012/001	Film-coated tablet	-Paracetamol -PSEUDOEPHEDRINE HYDROCHLORIDE
Solu-Cortef Powder for Solution for Injection or Infusion 100mg	Pfizer Healthcare Ireland	PA0822/137/001	Powder and solvent for solution for injection/infusion	-HYDROCORTISONE PH. EUR.
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	-Methylprednisolone hydrogen succinate ph. eur.
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	-Methylprednisolone
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	-Methylprednisolone hydrogen succinate ph. eur.
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	-Methylprednisolone hydrogen succinate ph. eur.
SoluPrep 2% w/v / 70% v/v cutaneous solution	3M Deutschland GmbH	PA1762/002/001	Cutaneous solution	-Chlorhexidine gluconate -Isopropyl alcohol
SoluPrep with tint 2%w/v/70%v/v cutaneous solution	3M Deutschland GmbH	PA1762/002/002	Cutaneous solution	-Chlorhexidine gluconate -Isopropyl alcohol
Soluprick Negative control, Solution for skin prick test	ALK-Abello A/S	PA1255/003/002	Solution for skin-prick test	
Soluprick Positive control, 10 mg/ml, Solution for skin-prick test	ALK-Abello A/S	PA1255/003/001	Solution for skin-prick test	-Histamine dihydrochloride
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	-Phleum pratense
Somac Control	Takeda GmbH	EU/1/09/516/001	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate
Somac Control	Takeda GmbH	EU/1/09/516/001-004	Gastro-resistant tablet	-Pantoprazole sodium sesquihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
SomaKit TOC	Advanced Accelerator Applications	EU/1/16/1141/001	Kit for radiopharmaceutical preparation	-Edoteotide
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	-Lanreotide acetate
Somatuline Autogel 120mg, solution for injection in a pre-filled syringe	Originalis B.V.	PPA2306/026/002	Solution for injection in pre-filled syringe	-Lanreotide
Somatuline Autogel 120mg, solution for injection in a pre-filled syringe	Ipsen Pharmaceuticals Limited	PA0869/004/004	Solution for injection in pre-filled syringe	-Lanreotide acetate
Somatuline Autogel 60 mg, solution for injection in a prefilled syringe	Ipsen Pharmaceuticals Limited	PA0869/004/002	Solution for injection in pre-filled syringe	-Lanreotide acetate
Somatuline Autogel 60 mg, solution for injection in a prefilled syringe	Originalis B.V.	PPA2306/026/001	Solution for injection in pre-filled syringe	-Lanreotide
Somatuline Autogel 90mg, solution for injection in a pre-filled syringe	Ipsen Pharmaceuticals Limited	PA0869/004/003	Solution for injection in pre-filled syringe	-Lanreotide acetate
Somavert	Pfizer Europe MA EEIG	EU/1/02/240/009-010	Powder and solvent for solution for injection	-Pegvisomant
Somavert	Pfizer Europe MA EEIG	EU/1/02/240/011-012	Powder and solvent for solution for injection	-Pegvisomant
Somavert	Pfizer Europe MA EEIG	EU/1/02/240/1-3	Powder and solvent for solution for injection	-Pegvisomant
Sondelbay	Accord Healthcare S.L.U.	EU/1/22/1628/001-002	Solution for injection in pre-filled pen	-Teriparatide
SonoVue	Bracco International B.V.	EU/1/01/177/002	Powder and solvent for solution for infusion	-Sulphur hexafluoride
Soolantra 10 mg/g Cream	PCO Manufacturing Ltd.	PPA0465/498/001	Cream	-Ivermectin
Soolantra 10mg/g Cream	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/014/001	Cream	-Ivermectin
Soolantra 10mg/g Cream	Galderma International	PA22743/015/001	Cream	-Ivermectin
Sorafenib Accord	Accord Healthcare S.L.U.	EU/1/22/1696/001	Film-coated tablet	-Sorafenib Tosilate
Sorafenib Bluefish 200 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/038/001	Film-coated tablet	-Sorafenib Tosilate
Sormon 60 mg Prolonged-release Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/202/001	Prolonged-release tablet	-Isosorbide-5-mononitrate
Sotoger 80mg Tablets	Viartis Limited	PA23266/014/001	Tablet	-SOTALOL HYDROCHLORIDE
SOTYKTU	Bristol-Myers Squibb Pharma EEIG	EU/1/23/1718/001-008	Film-coated tablet	-Deucravacitinib
Sovaldi	Gilead Sciences Ireland UC	EU/1/13/894/001-002	Film-coated tablet	-Sofosbuvir
Sovaldi	Gilead Sciences Ireland UC	EU/1/13/894/003	Film-coated tablet	-Sofosbuvir
Sovaldi	Gilead Sciences Ireland UC	EU/1/13/894/004	Granules	-Sofosbuvir
Sovaldi	Gilead Sciences Ireland UC	EU/1/13/894/005	Granules	-Sofosbuvir

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Spasmalvex 60 mg/300 mg, soft capsules	Laboratoires Galeniques Vernin	PA1927/002/001	Capsule, soft	-ALVERINE CITRATE -Simeticone
Spasmonal 60mg hard Capsules	Mylan IRE Healthcare Limited	PA2010/043/001	Capsule, hard	-ALVERINE CITRATE
Spasmonal Forte 120mg Hard Capsules	Mylan IRE Healthcare Limited	PA2010/043/002	Capsule, hard	-ALVERINE CITRATE
Spectrila	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/15/1072/001-002	Powder for concentrate for solution for infusion	-Recombinant I-asparaginase
Spedra	Menarini International Operations Luxembourg S.A.	EU/1/13/841/001-003	Tablet	-Avanafil
Spedra	Menarini International Operations Luxembourg S.A.	EU/1/13/841/004-007	Tablet	-Avanafil
Spedra	Menarini International Operations Luxembourg S.A.	EU/1/13/841/008-010	Tablet	-Avanafil
Sperizak 25 mg powder and solvent for prolonged-release suspension for injection	Accord Healthcare Ireland Ltd.	PA2315/248/001	Powder and solvent for prolonged-release suspension for injection	-Risperidone
Sperizak 37.5 mg powder and solvent for prolonged-release suspension for injection	Accord Healthcare Ireland Ltd.	PA2315/248/002	Powder and solvent for prolonged-release suspension for injection	-Risperidone
Sperizak 50 mg powder and solvent for prolonged-release suspension for injection	Accord Healthcare Ireland Ltd.	PA2315/248/003	Powder and solvent for prolonged-release suspension for injection	-Risperidone
Spevigo	Boehringer Ingelheim International GmbH	EU/1/22/1688/001	Concentrate and solvent for solution for infusion	-Spesolimab
Spexotras	Novartis Europharm Limited	EU/1/23/1781/001	Powder for oral solution	-Dabrafenib Mesylate
Spherox 10-70 spheroids/ cm2 implantation suspension	Rejuvenate GmbH	EU/1/17/1181/001-002	Implantation suspension	-Spheroids of human autologous matrix-associated chondrocytes
Spikevax	MODERNA BIOTECH SPAIN, S.L	EU/1/20/1507/001	Dispersion for injection	-mRNA-1273
Spikevax	Moderna Biotech Spain S.L.	EU/1/20/1507/002	Dispersion for injection	-Elasomeran
Spikevax	Moderna Biotech Spain S.L.	EU/1/20/1507/003	Dispersion for injection	-Elasomeran
Spikevax bivalent Original/Omicron BA.1	Moderna Biotech Spain S.L.	EU/1/20/1507/004-005	Dispersion for injection	-Elasomeran
Spikevax bivalent Original/Omicron BA.1	Moderna Biotech Spain S.L.	EU/1/20/1507/007-008	Dispersion for injection	-Elasomeran
Spikevax bivalent Original/Omicron BA4-5	Moderna Biotech Spain S.L.	EU/1/20/1507/006	Dispersion for injection	-Elasomeran
Spinraza	Biogen Netherlands B.V.	EU/1/17/1188/001	Solution for injection	-Nusinersen
Spolto Respimat 2.5 microgram/2.5 microgram, inhalation solution	Boehringer Ingelheim International GmbH	PA0775/009/001	Inhalation solution	-Tiotropium -Olodaterol
Spolto Respimat 2.5 microgram/2.5 microgram, inhalation solution	PCO Manufacturing Ltd.	PPA0465/463/001	Inhalation solution	-Tiotropium -Olodaterol

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Spiolto Respimat 2.5 microgram/2.5 microgram, inhalation solution	IMED Healthcare Ltd.	PPA1463/185/001	Inhalation solution	-Olodaterol -Tiotropium
Spiriva 18 microgram inhalation powder, hard capsule	Merit Pharmaceuticals Limited	PPA23080/007/001	Inhalation powder, hard capsule	-Tiotropium bromide
SPIRIVA 18 microgram, inhalation powder, hard capsule	Boehringer Ingelheim International GmbH	PA0775/002/001	Inhalation powder, hard capsule	-Tiotropium
Spiriva Respimat 2.5 microgram inhalation solution	Boehringer Ingelheim International GmbH	PA0775/002/002	Inhalation solution	-Tiotropium
Spiriva Respimat 2.5 microgram inhalation solution	IMED Healthcare Ltd.	PPA1463/142/002	Inhalation solution	-Tiotropium
Spiriva Respimat 2.5 microgram, inhalation solution	PCO Manufacturing Ltd.	PPA0465/286/001	Inhalation solution	-Tiotropium
Spironolactone 100 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/119/003	Film-coated tablet	-Spironolactone
Spironolactone 25 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/119/001	Film-coated tablet	-Spironolactone
Spironolactone 50 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/119/002	Film-coated tablet	-Spironolactone
Sporanox 10 mg/mL oral solution	Janssen Sciences Ireland UC	PA22612/012/001	Oral solution	-Itraconazole
Sporanox 100 mg Capsules	PCO Manufacturing Ltd.	PPA0465/400/001	Capsule, hard	-Itraconazole
Sporanox 100 mg Capsules	IMED Healthcare Ltd.	PPA1463/188/001	Capsule	-Itraconazole
Sporanox 100mg Capsules	Janssen Sciences Ireland UC	PA22612/012/002	Capsule, hard	-Itraconazole
Spravato	Janssen-Cilag International NV	EU/1/19/1410/001-004	Nasal spray, solution	-ESKETAMINE HYDROCHLORIDE -Esketamine
Sprilon 12.5 % Zinc Oxide and 1.04 % Dimeticone Cutaneous Spray, Suspension	Ayrton Saunders (Ireland) Limited	PA22906/001/001	Cutaneous spray, suspension	-Dimeticone 350 -Zinc oxide
Sprycel	Bristol-Myers Squibb Pharma EEIG	EU/1/06/363/010-11	Film-coated tablet	-Dasatinib
Sprycel	Bristol-Myers Squibb Pharma EEIG	EU/1/06/363/012-013	Film-coated tablet	-Dasatinib
Sprycel	Bristol-Myers Squibb Pharma EEIG	EU/1/06/363/014-015	Film-coated tablet	-Dasatinib
Sprycel	Bristol-Myers Squibb Pharma EEIG	EU/1/06/363/016	Powder for oral suspension	-Dasatinib
Sprycel	Bristol-Myers Squibb Pharma EEIG	EU/1/06/363/1-4-7	Film-coated tablet	-Dasatinib
Sprycel	Bristol-Myers Squibb Pharma EEIG	EU/1/06/363/2-5-8	Film-coated tablet	-Dasatinib
Sprycel	Bristol-Myers Squibb Pharma EEIG	EU/1/06/363/3-6-9	Film-coated tablet	-Dasatinib
Staglipitin Accord 100 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/22/1633/011-015	Film-coated tablet	-Sitagliptin Hydrochloride Monohydrate
Staglipitin Accord 25 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/22/1633/001-005	Film-coated tablet	-Sitagliptin Hydrochloride Monohydrate
Staglipitin Accord 50 mg film-coated tablets	Accord Healthcare S.L.U.	EU/1/22/1633/006-010	Film-coated tablet	-Sitagliptin Hydrochloride Monohydrate
Stalevo	Orion Corporation	EU/1/03/260/001-004,13,16	Film-coated tablet	-Carbidopa -Entacapone -Levodopa

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Stalevo	Orion Corporation	EU/1/03/260/005-008,14,17	Not assigned	
Stalevo	Orion Corporation	EU/1/03/260/009-012,15,18	Not assigned	
Stalevo	Orion Corporation	EU/1/03/260/034-038	Film-coated tablet	-Carbidopa -Entacapone -Levodopa
Stalevo	Orion Corporation	EU/1/03/260/19-23	Film-coated tablet	-Carbidopa -Entacapone -Levodopa
Stalevo	Orion Corporation	EU/1/03/260/24-28	Film-coated tablet	-Carbidopa monohydrate -Levodopa -Entacapone
Stalevo	Orion Corporation	EU/1/03/260/29-33	Film-coated tablet	-Carbidopa monohydrate -Entacapone -Levodopa
Stalplex 50 microgram/500 microgram/dose inhalation powder, pre-dispensed	Glenmark Pharmaceuticals Nordic AB	PA22815/001/001	Inhalation powder, pre-dispensed	-Salmeterol -Fluticasone propionate
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	-Yellow fever virus 17 d-204 strain
STAMICIS 1mg kit for radiopharmaceutical preparation	CIS bio International	PA0677/018/001	Kit for radiopharmaceutical preparation	-Tetrakis (2-methoxy isobutyl isonitrile) copper (i) tetrafluoroborate
Stayveer	Janssen Pharmaceutica NV	EU/1/13/832/001	Film-coated tablet	-Bosentan monohydrate
Stayveer	Janssen Pharmaceutica NV	EU/1/13/832/002	Film-coated tablet	-Bosentan monohydrate
Steglatro	Merck Sharp & Dohme BV	EU/1/18/1267/001-006	Film-coated tablet	-Ertugliflozin l-pyroglutamic acid
Steglatro	Merck Sharp & Dohme BV	EU/1/18/1267/007-012	Film-coated tablet	-Ertugliflozin l-pyroglutamic acid
Steglujan	Merck Sharp & Dohme BV	EU/1/18/1266/001-006	Film-coated tablet	-Ertugliflozin l-pyroglutamic acid -Sitagliptin phosphate monohydrate
Steglujan	Merck Sharp & Dohme BV	EU/1/18/1266/007-012	Film-coated tablet	-Ertugliflozin l-pyroglutamic acid -Sitagliptin phosphate monohydrate
STELARA	Janssen-Cilag International NV	EU/1/08/494/001	Solution for injection	-Ustekinumab
STELARA	Janssen-Cilag International NV	EU/1/08/494/002	Solution for injection	-Ustekinumab
STELARA	Janssen-Cilag International NV	EU/1/08/494/003	Solution for injection in pre-filled syringe	-Ustekinumab
STELARA	Janssen-Cilag International NV	EU/1/08/494/004	Solution for injection in pre-filled syringe	-Ustekinumab
STELARA	Janssen-Cilag International NV	EU/1/08/494/005	Concentrate for solution for infusion	-Ustekinumab
Stelazine 1mg Film-coated Tablets	Amdipharm Limited	PA1142/037/001	Film-coated tablet	-Trifluoperazine
Stelazine 5 mg film-coated tablets	Amdipharm Limited	PA1142/037/002	Film-coated tablet	-Trifluoperazine
Stemetil 12.5 mg/ml solution for injection - 1 ml Ampoule	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/127/002	Solution for injection	- PROCHLORPERAZINE MESILATE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Stemetil 5mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/127/005	Tablet	-Prochlorperazine maleate
Sterile Dopamine Concentrate BP 160mg/ml, 5ml	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/108/002	Concentrate for solution for infusion	-DOPAMINE HYDROCHLORIDE
Sterile Dopamine Concentrate BP 40mg/ml	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/108/001	Concentrate for solution for infusion	-DOPAMINE HYDROCHLORIDE
Stesolid rectal solution 10mg	Accord Healthcare Ireland Ltd.	PA2315/137/002	Rectal solution	-Diazepam
Stesolid rectal solution 5mg	Accord Healthcare Ireland Ltd.	PA2315/137/001	Rectal solution	-Diazepam
Stieprox 15 mg/g Shampoo	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/055/001	Shampoo	-CICLOPIROX OLAMINE
Stieprox 15 mg/g Shampoo	GlaxoSmithKline (Ireland) Limited	PA1077/130/001	Shampoo	-CICLOPIROX OLAMINE
Stilnoct 10 mg Film-coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/160/002	Film-coated tablet	-Zolpidem tartrate
Stilnoct 5 mg Film Coated Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/160/001	Film-coated tablet	-Zolpidem tartrate
Stimufend	Fresenius Kabi Deutschland GmbH	EU/1/22/1632/001	Solution for injection in pre-filled syringe	-Pegfilgrastim
Stirlescent 250mg Effervescent Tablets	Stirling Anglian Pharmaceuticals Ireland Limited	PA23138/002/001	Effervescent tablet	-Naproxen
Stivarga	Bayer Pharma AG	EU/1/13/858/001-002	Film-coated tablet	-Regorafenib
STOCRIN	Merck Sharp & Dohme BV,	EU/1/99/111/001	Capsule	-Efavirenz
STOCRIN	Merck Sharp & Dohme BV,	EU/1/99/111/002	Capsule	-Efavirenz
Stocrin	Merck Sharp & Dohme BV,	EU/1/99/111/003	Capsule	-Efavirenz
Stocrin	Merck Sharp & Dohme BV,	EU/1/99/111/004	Capsule	-Efavirenz
Stocrin	Merck Sharp & Dohme BV,	EU/1/99/111/005	Oral solution	-Efavirenz
Stocrin	Merck Sharp & Dohme BV,	EU/1/99/111/010	Film-coated tablet	-Efavirenz
Stocrin	Merck Sharp & Dohme BV,	EU/1/99/111/011	Film-coated tablet	-Efavirenz
Stocrin Film-Coated	Merck Sharp & Dohme BV,	EU/1/99/111/6-7	Film-coated tablet	-Efavirenz
Stocrin Film-Coated	Merck Sharp & Dohme BV,	EU/1/99/111/8-9	Film-coated tablet	-Efavirenz
Strattera 4 mg/mL oral solution	Eli Lilly Nederland B.V.	PA2276/007/008	Oral solution	-ATOMOXETINE
Strengiq	Alexion Europe SAS	EU/1/15/1015/001-002	Solution for injection	-Asfotase alfa
Strengiq	Alexion Europe SAS	EU/1/15/1015/003-004	Solution for injection	-Asfotase alfa
Strepsils +Plus Anaesthetic Lozenges Amylmetacresol 0.6mg 2,4-Dichlorobenzyl Alcohol 1.2mg Lidocaine Hydrochloride 10mg	Reckitt Benckiser Ireland Ltd	PA0979/040/001	Lozenge	-Amylmetacresol -2, 4-dichlorobenzyl alcohol -Lidocaine Hydrochloride Ph. Eur.
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	-Amylmetacresol -2,4-Dichlorobenzyl alcohol -Lidocaine
Strepsils Intensive 8.75 mg Lozenges	Reckitt Benckiser Ireland Ltd	PA0979/041/001	Lozenge	-Flurbiprofen

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Strepsils Intensive Cherry & Mint 8.75mg/dose Oromucosal Spray	Reckitt Benckiser Ireland Ltd	PA0979/041/005	Oromucosal spray, solution	-Flurbiprofen
Strepsils Intensive Honey & Eucalyptus Sugar Free 8.75 mg lozenges	Reckitt Benckiser Ireland Ltd	PA0979/080/001	Lozenge	-Flurbiprofen
Strepsils Intensive Honey and Lemon 8.75mg/dose Oromucosal Spray	Reckitt Benckiser Ireland Ltd	PA0979/072/001	Oromucosal spray, solution	-Flurbiprofen
Strepsils Intensive Orange Sugar Free 8.75mg Lozenges	Reckitt Benckiser Ireland Ltd	PA0979/041/004	Lozenge	-Flurbiprofen
Strepsils Intensive Sugar-Free 8.75 mg Lozenges	Reckitt Benckiser Ireland Ltd	PA0979/041/006	Lozenge	-Flurbiprofen
STRIASCAN	CIS bio International	EU/1/19/1372/001-002	Solution for injection	-IOFLUPANE (1231)
Stribild	Gilead Sciences Ireland UC	EU/1/13/830/001	Film-coated tablet	-Emtricitabine -Tenofovir disoproxil -Cobicistat -Elvitegravir
Strimvelis	Orchard Therapeutics (Netherlands) B.V.	EU/1/16/1097/001	Dispersion for infusion	-Autologous cd34+ enriched cell fraction
Striverdi Respimat 2.5 microgram inhalation solution	Boehringer Ingelheim International GmbH	PA0775/006/001	Inhalation solution	-Olodaterol
Stugeron 15 mg Tablets	JNTL Consumer Health I (Ireland) Limited	PA23490/024/001	Tablet	-Cinnarizine
Sublimaze 50 micrograms/ml solution for injection	Piramal Critical Care B.V.	PA22583/002/001	Solution for injection	-FENTANYL CITRATE
Suboxone	Indivior Europe Limited	EU/1/06/359/005-006	Sublingual tablet	-Buprenorphine hydrochloride -Naloxone hydrochloride dihydrate
Suboxone	Indivior Europe Limited	EU/1/06/359/007-009	Sublingual film	-Buprenorphine hydrochloride -Naloxone hydrochloride dihydrate
Suboxone	Indivior Europe Limited	EU/1/06/359/010-012	Sublingual film	-Buprenorphine hydrochloride -Naloxone hydrochloride dihydrate
Suboxone	Indivior Europe Limited	EU/1/06/359/01-02	Sublingual tablet	-Naloxone -Buprenorphine
Suboxone	Indivior Europe Limited	EU/1/06/359/013-015	Sublingual film	-Buprenorphine hydrochloride -Naloxone hydrochloride dihydrate
Suboxone	Indivior Europe Limited	EU/1/06/359/016-018	Sublingual film	-Buprenorphine hydrochloride -Naloxone hydrochloride dihydrate
Suboxone	Indivior Europe Limited	EU/1/06/359/03-04	Sublingual tablet	-Buprenorphine hydrochloride -NALOXONE HYDROCHLORIDE
Subutex 0.4 mg sublingual tablets	Indivior Europe Limited	PA22617/001/001	Sublingual tablet	-Buprenorphine hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Subutex 2 mg sublingual tablets	Indivior Europe Limited	PA22617/001/002	Sublingual tablet	-Buprenorphine hydrochloride
Subutex 8 mg sublingual Tablets	Indivior Europe Limited	PA22617/001/003	Sublingual tablet	-Buprenorphine hydrochloride
Sudafed 0.1% w/v Nasal spray solution	Johnson & Johnson (Ireland) Limited	PA0330/027/001	Nasal spray, solution	-Xylometazoline hydrochloride
Sugammadex	Juta Pharma GmbH	PA22716/002/001	Solution for injection	-Sugammadex sodium
Sugammadex – Amomed®	AOP Orphan Pharmaceuticals AG	EU/1/22/1708/001	Solution for injection	-Sugammadex sodium
Sugammadex 10 mg/ml solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/016/001	Solution for injection in pre-filled syringe	-Sugammadex sodium
Sugammadex 100 mg/ml Solution for injection	Noridem Enterprises Limited	PA1122/032/001	Solution for injection	-Sugammadex sodium
Sugammadex 100 mg/ml solution for injection	Flynn Pharma Limited	PA1226/015/001	Solution for injection	-Sugammadex sodium
Sugammadex 100 mg/ml solution for injection	AS Kalceks	PA2165/022/001	Solution for injection	-Sugammadex sodium
Sugammadex 100 mg/ml solution for injection	Reddy Holding GmbH	PA23092/006/001	Solution for injection	-Sugammadex
Sugammadex 100 mg/ml Solution for Injection	Baxter Holding B.V.	PA2299/058/001	Solution for injection	-Sugammadex sodium
Sugammadex 100 mg/mL solution for injection	MSN Labs Europe Limited	PA23250/012/001	Solution for injection	-Sugammadex sodium
Sugammadex 50 mg/ml solution for injection in pre-filled syringe	Laboratoire AGUETTANT	PA1968/016/002	Solution for injection in pre-filled syringe	-Sugammadex sodium
Sugammadex Adroiq	Extrovis EU Kft.	EU/1/23/1733/001-002	Solution for injection	-Sugammadex sodium
Sugammadex Aspen 100 mg/mL solution for injection	Aspen Pharma Trading Limited	PA1691/036/001	Solution for injection	-Sugammadex sodium
Sugammadex Clonmel 100 mg/ml solution for injection	Clonmel Healthcare Ltd	PA0126/352/001	Solution for injection	-Sugammadex sodium
Sugammadex Fresenius Kabi	Fresenius Kabi Deutschland GmbH	EU/1/22/1663/001-003	Solution for injection	-Sugammadex
Sugammadex Mylan	Mylan IRE Healthcare Limited	EU/1/21/1583/001-004	Solution for injection	-Sugammadex sodium
Sugammadex Orion 100 mg/ml solution for injection	Orion Corporation	PA1327/020/001	Solution for injection	-Sugammadex sodium
Sugammadex Piramal	Piramal Critical Care B.V.	EU/1/23/1739/001-002	Solution for injection	-Sugammadex sodium
Sugammadex Teva 100 mg/ml solution for injection	Teva B.V.	PA1986/102/001	Solution for injection	-Sugammadex sodium
Suliqua	Sanofi-Aventis Groupe	EU/1/16/1157/001-002	Solution for injection in pre-filled pen	-Insulin glargine -Lixisenatide
Suliqua	Sanofi-Aventis Groupe	EU/1/16/1157/003-004	Solution for injection in pre-filled pen	-Lixisenatide -Insulin glargine
Sulpiride Grindeks 100 mg tablets	AS Grindeks	PA22992/009/002	Tablet	-Sulpiride
Sulpiride Grindeks 200 mg tablets	AS Grindeks	PA22992/009/003	Tablet	-Sulpiride
Sulpiride Grindeks 50 mg tablets	AS Grindeks	PA22992/009/001	Tablet	-Sulpiride
SUMATRAN 100 mg tablets	Rowex Ltd	PA0711/081/002	Tablet	-Sumatriptan

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
SUMATRAN 50 mg tablets	Rowex Ltd	PA0711/081/001	Tablet	-Sumatriptan
Sumatran Relief 50mg tablets	Rowex Ltd	PA0711/272/001	Tablet	-Sumatriptan
Sumatriptan 100 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/070/002	Film-coated tablet	-Sumatriptan
Sumatriptan 50 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/070/001	Film-coated tablet	-Sumatriptan
Sunitinib Accord	Accord Healthcare S.L.U.	EU/1/20/1511/001-003	Capsule, hard	-Sunitinib
Sunitinib Accord	Accord Healthcare S.L.U.	EU/1/20/1511/004-006	Capsule, hard	-Sunitinib
Sunitinib Accord	Accord Healthcare S.L.U.	EU/1/20/1511/007-009	Capsule, hard	-Sunitinib
Sunitinib Accord	Accord Healthcare S.L.U.	EU/1/20/1511/010-012	Capsule, hard	-Sunitinib
Sunitinib Bluefish 12.5 mg hard capsules	Bluefish Pharmaceuticals AB	PA1436/041/001	Capsule, hard	-Sunitinib
Sunitinib Bluefish 25 mg hard capsules	Bluefish Pharmaceuticals AB	PA1436/041/002	Capsule, hard	-Sunitinib
Sunitinib Bluefish 50 mg hard capsules	Bluefish Pharmaceuticals AB	PA1436/041/003	Capsule, hard	-Sunitinib
Sunitinib Krka 12.5 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/104/001	Capsule, hard	-Sunitinib
Sunitinib Krka 25 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/104/002	Capsule, hard	-Sunitinib
Sunitinib Krka 50 mg hard capsules	KRKA, d.d., Novo mesto	PA1347/104/003	Capsule, hard	-Sunitinib
Sunitinib Rowex 12.5 mg hard capsules	Rowex Ltd	PA0711/289/001	Capsule, hard	-Sunitinib
Sunitinib Rowex 25 mg hard capsules	Rowex Ltd	PA0711/289/002	Capsule, hard	-Sunitinib
Sunitinib Rowex 50 mg hard capsules	Rowex Ltd	PA0711/289/003	Capsule, hard	-Sunitinib
Sunlenca	Gilead Sciences Ireland UC	EU/1/22/1671/01	Film-coated tablet	-Lenacapavir sodium
Sunlenca	Gilead Sciences Ireland UC	EU/1/22/1671/02	Solution for injection	-Lenacapavir sodium
Sunosi	Atnahs Pharma Netherlands B.V.	EU/1/19/1408/001-005	Film-coated tablet	-Solriamfetol Hydrochloride
Sunosi	Atnahs Pharma Netherlands B.V.	EU/1/19/1408/006-010	Film-coated tablet	-Solriamfetol Hydrochloride
Supemtek	Sanofi Pasteur	EU/1/20/1484/001-006	Solution for injection in pre-filled syringe	-A/(H1N1)-LIKE VIRUS ANTIGEN
Suprane Inhalation vapour, solution	Baxter Holding B.V.	PA2299/023/001	Inhalation vapour, solution	-Desflurane
Suprax 200 mg Film-coated Tablets	Amdipharm Limited	PA1142/042/001	Film-coated tablet	-CEFIXIME TRIHYDRATE
Surmontil 25mg film-coated Tablets	Neuraxpharm Ireland Limited	PA23229/009/002	Film-coated tablet	-Trimipramine
Surmontil 50mg hard Capsules	Neuraxpharm Ireland Limited	PA23229/009/001	Capsule, hard	-Trimipramine maleate
SUSTIVA	Bristol-Myers Squibb Pharma EEIG	EU/1/99/110/001	Capsule, hard	-Efavirenz
Sustiva	Bristol-Myers Squibb Pharma EEIG	EU/1/99/110/002	Capsule, hard	-Efavirenz
Sustiva	Bristol-Myers Squibb Pharma EEIG	EU/1/99/110/003	Capsule, hard	-Efavirenz
Sustiva	Bristol-Myers Squibb Pharma EEIG	EU/1/99/110/004	Capsule, hard	-Efavirenz
Sustiva	Bristol-Myers Squibb Pharma EEIG	EU/1/99/110/005	Oral solution	-Efavirenz
Sustiva	Bristol-Myers Squibb Pharma EEIG	EU/1/99/110/006	Film-coated tablet	-Efavirenz
Sustiva	Bristol-Myers Squibb Pharma	EU/1/99/110/007	Film-coated tablet	-Efavirenz

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Sustiva	Bristol-Myers Squibb Pharma EEIG	EU/1/99/110/008	Film-coated tablet	-Efavirenz
Sustiva	Bristol-Myers Squibb Pharma	EU/1/99/110/009	Film-coated tablet	-Efavirenz
Sutent	Pfizer Europe MA EEIG	EU/1/06/347/001	Capsule, hard	-Sunitinib malate
Sutent	Pfizer Europe MA EEIG	EU/1/06/347/002	Capsule, hard	-Sunitinib malate
Sutent	Pfizer Europe MA EEIG	EU/1/06/347/003	Capsule, hard	-Sunitinib malate
Sutent	Pfizer Europe MA EEIG	EU/1/06/347/7-8	Capsule, hard	-Sunitinib malate
Suvezen 10 mg/10 mg film-coated tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/193/001	Film-coated tablet	-Rosuvastatin -Ezetimibe
Suvezen 20 mg/10 mg film-coated tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/193/002	Film-coated tablet	-Rosuvastatin -Ezetimibe
Suvezen 40 mg/10 mg film-coated tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/193/003	Film-coated tablet	-Rosuvastatin -Ezetimibe
Suxamethonium Chloride 50 mg/ml solution for injection/infusion	Ethypharm	PA0549/014/001	Solution for injection	-Suxamethonium chloride
Suxamethonium Chloride 50mg/ml Solution for Injection	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/110/001	Solution for injection	-Suxamethonium chloride
Sycrest	NV Organon	EU/1/10/640/001-003	Sublingual tablet	-Asenapine maleate
Sycrest	NV Organon	EU/1/10/640/004-006	Sublingual tablet	-Asenapine maleate
Sylvant	EUSA Pharma (Netherlands) B.V.	EU/1/14/928/001	Powder for concentrate for solution for infusion	-Siltuximab
Sylvant	EUSA Pharma (Netherlands) B.V.	EU/1/14/928/002	Powder for concentrate for solution for infusion	-Siltuximab
Symbicort Turbohaler 100 micrograms/6 micrograms/inhalation inhalation powder	IMED Healthcare Ltd.	PPA1463/051/002	Inhalation powder	-Budesonide -Formoterol fumarate dihydrate
Symbicort Turbohaler 200 micrograms/6 micrograms/inhalation inhalation powder	IMED Healthcare Ltd.	PPA1463/051/001	Inhalation powder	-Formoterol fumarate dihydrate -Budesonide
Symbicort Turbohaler 200 micrograms/6 micrograms/inhalation, inhalation powder	Merit Pharmaceuticals Limited	PPA23080/021/001	Inhalation powder	-Budesonide -Formoterol fumarate dihydrate
Symbicort Turbohaler 400 micrograms/12 micrograms/inhalation inhalation powder	IMED Healthcare Ltd.	PPA1463/051/003	Inhalation powder	-Formoterol fumarate dihydrate -Budesonide
Symbicort Turbohaler, 100 micrograms /6 micrograms/inhalation, inhalation powder	AstraZeneca AB	PA1019/020/001	Inhalation powder	-Budesonide -Formoterol fumarate dihydrate
Symbicort Turbohaler, 200 micrograms/6 micrograms/inhalation, inhalation powder	PCO Manufacturing Ltd.	PPA0465/225/001	Inhalation powder	-Budesonide -Formoterol fumarate dihydrate
Symbicort Turbohaler, 400 micrograms/12 micrograms/inhalation, inhalation powder	PCO Manufacturing Ltd.	PPA0465/225/002	Inhalation powder	-Formoterol fumarate dihydrate -Budesonide
Symbicort Turbohaler, 400 micrograms/12 micrograms/inhalation, inhalation powder	Merit Pharmaceuticals Limited	PPA23080/021/002	Inhalation powder	-Budesonide dihydrate -Formoterol fumarate dihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Symbicort Turbohaler, 400 micrograms/12 micrograms/inhalation, inhalation powder	AstraZeneca AB	PA1019/020/003	Inhalation powder	-Budesonide -Formoterol fumarate dihydrate
Symbicort, 200 micrograms/6 micrograms per inhalation, pressurised inhalation, suspension	AstraZeneca AB	PA1019/020/004	Pressurised inhalation, suspension	-Budesonide micronised -Formoterol fumarate dihydrate (micronised)
Symbicort® Turbohaler; 200 micrograms/6 micrograms/inhalation, inhalation powder	AstraZeneca AB	PA1019/020/002	Inhalation powder	-Budesonide -Formoterol fumarate dihydrate
Symkevi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/18/1306/001	Film-coated tablet	-TEZACAFITOR -Ivacaftor
Symkevi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/18/1306/002	Film-coated tablet	-TEZACAFITOR -Ivacaftor
Symkevi	Vertex Pharmaceuticals (Ireland) Limited	EU/1/18/1036/001	Film-coated tablet	-TEZACAFITOR -Ivacaftor
Symtuza	Janssen-Cilag International NV	EU/1/17/1225/001	Film-coated tablet	-Tenofovir alafenamide -Darunavir ethanolate -Emtricitabine -Cobicistat
Synacthen 250 micrograms/ml solution for injection	Alfasigma S.p.A	PA2206/002/001	Solution for injection	-Tetracosactide acetate
Synagis	AstraZeneca AB	EU/1/99/117/003-004	Solution for injection	-Palivizumab
Synarel 200 micrograms/dose Nasal Spray Solution	Pfizer Healthcare Ireland	PA0822/138/001	Nasal spray, solution	-Nafarelin
Synflorix	GlaxoSmithKline Biologicals S.A.	EU/1/09/508/1-13	Suspension for injectio	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Synflorix	GlaxoSmithKline Biologicals S.A.	EU/1/09/508/1-9	Suspension for injectio	-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
Synjardy	Boehringer Ingelheim International GmbH	EU/1/15/1003/001-009	Film-coated tablet	-Empagliflozin -Metformin Hydrochloride
Synjardy	Boehringer Ingelheim International GmbH	EU/1/15/1003/010-018	Film-coated tablet	-Empagliflozin -Metformin Hydrochloride
Synjardy	Boehringer Ingelheim International GmbH	EU/1/15/1003/019-027	Film-coated tablet	-Empagliflozin -Metformin Hydrochloride
Synjardy	Boehringer Ingelheim International GmbH	EU/1/15/1003/028-036	Film-coated tablet	-Empagliflozin -Metformin Hydrochloride
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	-Oxytocin
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	-Oxytocin
Syntometrine 500 micrograms/5 IU solution for injection	Alliance Pharma (Ireland) Limited	PA2325/014/001	Solution for injection	-ERGOMETRINE MALEATE -Oxytocin
Syrisal 1mmol/ml oral solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/016/001	Oral solution	-Sodium chloride
Tabrecta	Novartis Europharm Limited	EU/1/22/1650/001-002	Film-coated tablet	-Capmatinib dihydrochloride monohydrate
Tabrecta	Novartis Europharm Limited	EU/1/22/1650/003-004	Film-coated tablet	-Capmatinib dihydrochloride monohydrate
Tacforius	Teva B.V.	EU/1/17/1244/001-006	Prolonged-release capsule, hard	-Tacrolimus monohydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Tacforius	Teva B.V.	EU/1/17/1244/007-014	Prolonged-release capsule, hard	-Tacrolimus monohydrate
Tacforius	Teva B.V.	EU/1/17/1244/015-020	Prolonged-release capsule, hard	-Tacrolimus monohydrate
Tacforius	Teva B.V.	EU/1/17/1244/021-026	Prolonged-release capsule, hard	-Tacrolimus monohydrate
TACHOSIL	Corza Medical GmbH	EU/1/04/277/1-4	Sealant matrix	-Fibrinogen
Tacrolimus 0.03% ointment	Accord Healthcare Ireland Ltd.	PA2315/269/001	Ointment	-Tacrolimus
Tacrolimus 0.1% Ointment	Accord Healthcare Ireland Ltd.	PA2315/120/001	Ointment	-Tacrolimus
Tadalafil 10mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/071/002	Film-coated tablet	-Tadalafil
Tadalafil 10mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/020/003	Film-coated tablet	-Tadalafil
Tadalafil 2.5mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/020/001	Film-coated tablet	-Tadalafil
Tadalafil 20 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/071/003	Film-coated tablet	-Tadalafil
Tadalafil 20mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/020/004	Film-coated tablet	-Tadalafil
Tadalafil 5mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/020/002	Film-coated tablet	-Tadalafil
Tadalafil Clonmel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/311/001	Film-coated tablet	-Tadalafil
Tadalafil Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/311/002	Film-coated tablet	-Tadalafil
Tadalafil Generics ((previously known Tadalafil Mylan Pharma))	Viartis Limited	EU/1/16/1153/001-004	Film-coated tablet	-Tadalafil
Tadalafil Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/071/003	Film-coated tablet	-Tadalafil
Tadalafil Krka 2.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/071/001	Film-coated tablet	-Tadalafil
Tadalafil Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/071/004	Film-coated tablet	-Tadalafil
Tadalafil Krka 5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/071/002	Film-coated tablet	-Tadalafil
Tadalafil Lilly	Eli Lilly Nederland B.V.	EU/1/17/1177/001	Film-coated tablet	-Tadalafil
Tadalafil Lilly	Eli Lilly Nederland B.V.	EU/1/17/1177/002-004	Film-coated tablet	-Tadalafil
Tadalafil Lilly	Eli Lilly Nederland B.V.	EU/1/17/1177/005	Film-coated tablet	-Tadalafil
Tadalafil Lilly	Eli Lilly Nederland B.V.	EU/1/17/1177/006-009	Film-coated tablet	-Tadalafil
Tadalafil Mylan	Mylan Pharmaceuticals Limited	EU/1/14/961/001	Film-coated tablet	-Tadalafil
Tadalafil Mylan	Mylan Pharmaceuticals Limited	EU/1/14/961/003-006	Film-coated tablet	-Tadalafil
Tadalafil Mylan	Mylan Pharmaceuticals Limited	EU/1/14/961/008-009	Film-coated tablet	-Tadalafil
Tadalafil Mylan	Mylan Pharmaceuticals Limited	EU/1/14/961/012-016	Film-coated tablet	-Tadalafil
Tafinlar 50 mg hard capsules	Novartis Europharm Limited	EU/1/13/865/001-002	Capsule, hard	-Dabrafenib
Tafinlar 75 mg hard capsules	Novartis Europharm Limited	EU/1/13/865/003-004	Capsule, hard	-Dabrafenib
Tagrisso	AstraZeneca AB	EU/1/16/1086/001	Film-coated tablet	-Osimertinib mesylate
Tagrisso	AstraZeneca AB	EU/1/16/1086/002	Film-coated tablet	-Osimertinib mesylate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
TAKHZYRO	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/18/1340/001	Solution for injection	-LANADELUMAB
Takhzyro	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/18/1340/007-009	Solution for injection	-LANADELUMAB
Taltz	Eli Lilly and Company (Ireland) Limited	EU/1/15/1085/001-003	Solution for injection in pre-filled pen	-Ixekizumab
Taltz	Eli Lilly and Company (Ireland) Limited	EU/1/15/1085/004-006	Solution for injection in pre-filled syringe	-Ixekizumab
Talvey	Janssen-Cilag International NV	EU/1/23/1748/001	Solution for injection	-Talquetamab
Talvey	Janssen-Cilag International NV	EU/1/23/1748/002	Solution for injection	-Talquetamab
Talzenna	Pfizer Europe MA EEIG	EU/1/19/1377/001-004	Capsule, hard	-TALAZOPARIB TOSYLATE
Talzenna	Pfizer Europe MA EEIG	EU/1/19/1377/005-006	Capsule, hard	-TALAZOPARIB TOSYLATE
Talzenna	Pfizer Europe MA EEIG	EU/1/19/1377/007	Capsule, hard	-TALAZOPARIB TOSYLATE
Tambocor 10 mg/ml Solution for Injection or Infusion	Mylan IRE Healthcare Limited	PA2010/026/001	Solution for injection/infusion	-Flecainide acetate
Tambocor 100 mg Tablets	Mylan IRE Healthcare Limited	PA2010/026/003	Tablet	-Flecainide acetate
Tambocor 50 mg Tablets	Mylan IRE Healthcare Limited	PA2010/026/002	Tablet	-Flecainide acetate
Tamiflu	Roche Registration GmbH	EU/1/02/222/001	Capsule, hard	-Oseltamivir phosphate
Tamiflu	Roche Registration GmbH	EU/1/02/222/003	Capsule, hard	-Oseltamivir
Tamiflu	Roche Registration GmbH	EU/1/02/222/004	Capsule, hard	-Oseltamivir
Tamiflu	Roche Registration GmbH	EU/1/02/222/005	Powder for oral suspension	-Oseltamivir phosphate
Tamnexyl XL 400 micrograms prolonged-release tablets	Clonmel Healthcare Ltd	PA0126/224/001	Prolonged-release tablet	-Tamsulosin hydrochloride
Tamnic 400 micrograms Modified-release Capsules, hard	Clonmel Healthcare Ltd	PA0126/151/001	Modified-release capsule, hard	-Tamsulosin hydrochloride
Tamox 10 mg Film-coated tablets	Rowex Ltd	PA0711/022/001	Film-coated tablet	-Tamoxifen
Tamox 20 mg Film-coated tablets	Rowex Ltd	PA0711/022/002	Film-coated tablet	-Tamoxifen
Tamoxifen 20 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/207/001	Tablet	-Tamoxifen citrate
TAMSU 400 micrograms modified-release capsules, hard	Rowex Ltd	PA0711/079/001	Modified-release capsule, hard	-Tamsulosin hydrochloride
Tamsulosin 400 micrograms Modified-release Capsules, Hard	Viartis Limited	PA23266/016/001	Modified-release capsule, hard	-Tamsulosin hydrochloride
Tamsulosin Hydrochloride 400 micrograms Modified-release Capsules, hard	Synthon BV	PA0840/013/001	Modified-release capsule, hard	-Tamsulosin hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Tamzeltos 400 micrograms prolonged-release tablets	KRKA, d.d., Novo mesto	PA1347/087/001	Prolonged-release tablet	-Tamsulosin hydrochloride
Tandemact	CHEPLAPHARM Arzneimittel GmbH	EU/1/06/366/005-16	Tablet	-Glimepiride -Pioglitazone
Tandemact	CHEPLAPHARM Arzneimittel GmbH	EU/1/06/366/1-2	Tablet	-Pioglitazone -Glimepiride
Tandemact	CHEPLAPHARM Arzneimittel GmbH	EU/1/06/366/17-22	Tablet	-Glimepiride -Pioglitazone hydrochloride
TANYZ 400 micrograms hard modified-release capsules	KRKA, d.d., Novo mesto	PA1347/086/001	Modified-release capsule, hard	-Tamsulosin hydrochloride
Tapentadol Liconsa 100 mg prolonged-release tablets	Laboratorios LICONSA, S.A.	PA1239/029/003	Prolonged-release tablet	-Tapentadol Tartrate
Tapentadol Liconsa 150 mg prolonged-release tablets	Laboratorios LICONSA, S.A.	PA1239/029/004	Prolonged-release tablet	-Tapentadol Tartrate
Tapentadol Liconsa 200 mg prolonged-release tablets	Laboratorios LICONSA, S.A.	PA1239/029/005	Prolonged-release tablet	-Tapentadol Tartrate
Tapentadol Liconsa 25 mg prolonged-release tablets	Laboratorios LICONSA, S.A.	PA1239/029/001	Prolonged-release tablet	-Tapentadol Tartrate
Tapentadol Liconsa 250 mg prolonged-release tablets	Laboratorios LICONSA, S.A.	PA1239/029/006	Prolonged-release tablet	-Tapentadol Tartrate
Tapentadol Liconsa 50 mg prolonged-release tablets	Laboratorios LICONSA, S.A.	PA1239/029/002	Prolonged-release tablet	-Tapentadol Tartrate
Tapimio 100 mg prolonged-release tablets	Neuraxpharm Ireland Limited	PA23229/005/003	Prolonged-release tablet	-Tapentadol Phosphate
Tapimio 150 mg prolonged-release tablets	Neuraxpharm Ireland Limited	PA23229/005/004	Prolonged-release tablet	-Tapentadol Phosphate
Tapimio 200 mg prolonged-release tablets	Neuraxpharm Ireland Limited	PA23229/005/005	Prolonged-release tablet	-Tapentadol Phosphate
Tapimio 25 mg prolonged-release tablets	Neuraxpharm Ireland Limited	PA23229/005/001	Prolonged-release tablet	-Tapentadol Phosphate
Tapimio 250 mg prolonged-release tablets	Neuraxpharm Ireland Limited	PA23229/005/006	Prolonged-release tablet	-Tapentadol Phosphate
Tapimio 50 mg prolonged-release tablets	Neuraxpharm Ireland Limited	PA23229/005/002	Prolonged-release tablet	-Tapentadol Phosphate
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	-Tafluprost -Timolol
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	-Tafluprost -Timolol
Tarceva	Roche Registration GmbH	EU/1/05/311/01-3	Film-coated tablet	-ERLOTINIB HYDROCHLORIDE
Targaxan 550 mg film-coated tablets	Norgine B.V.	PA1336/009/001	Film-coated tablet	-Rifaximin

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Targin 10mg/5mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/002	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE -Naloxone hydrochloride dihydrate
Targin 15 mg/7.5 mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/006	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE -NALOXONE HYDROCHLORIDE
Targin 20mg/10mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/003	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE -Naloxone hydrochloride dihydrate
Targin 30 mg/15 mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/007	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE -NALOXONE HYDROCHLORIDE
Targin 40 mg/20 mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/004	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE -Naloxone hydrochloride dihydrate
Targin 5 mg/2.5 mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/001	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE -Naloxone hydrochloride dihydrate
Targin 60 mg/30 mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/008	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE -NALOXONE HYDROCHLORIDE
Targin 80 mg/40 mg prolonged-release tablets	Mundipharma Pharmaceuticals Limited	PA1688/010/009	Prolonged-release tablet	-OXYCODONE HYDROCHLORIDE -NALOXONE HYDROCHLORIDE
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	-Teicoplanin
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	-Teicoplanin
Targretin	Eisai GmbH	EU/1/01/178/001	Capsule, soft	-Bexarotene
Tasigna	Novartis Europharm Limited	EU/1/07/422/001-004	Capsule, hard	-Nilotinib
Tasigna	Novartis Europharm Limited	EU/1/07/422/005-006	Capsule, hard	-Nilotinib (as hydrochloride monohydrate)
Tasigna	Novartis Europharm Limited	EU/1/07/422/015	Capsule, hard	-Nilotinib (as hydrochloride monohydrate)
Tasmar	Viartis Healthcare Limited	EU/1/97/044/001	Film-coated tablet	-Tolcapone
Tasmar	Viartis Healthcare Limited	EU/1/97/044/002	Film-coated tablet	-Tolcapone
Tasmar	Viartis Healthcare Limited	EU/1/97/044/003	Film-coated tablet	-Tolcapone
Tasmar	Viartis Healthcare Limited	EU/1/97/044/004	Film-coated tablet	-Tolcapone
Tasmar	Viartis Healthcare Limited	EU/1/97/044/005	Film-coated tablet	-Tolcapone
Tasmar	Viartis Healthcare Limited	EU/1/97/044/006	Film-coated tablet	-Tolcapone

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Taurolin 2% w/v solution for intraperitoneal lavage after dilution or solution for instillation	Elara Pharmservices Europe Limited	PA22637/005/001	Intraperitoneal solution	-Taurolidine
Tavager 500 mg film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/104/002	Film-coated tablet	-Levofloxacin
Tavanic 5 mg/ml solution for infusion	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/077/001	Solution for infusion	-Levofloxacin
Tavanic 500 mg film-coated tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/077/003	Film-coated tablet	-Levofloxacin
Tavanic 500 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/302/001	Film-coated tablet	-Levofloxacin
Tavlesse	Rigel Pharmaceuticals B.V.	EU/1/19/1408/001	Film-coated tablet	-FOSTAMATINIB
Tavlesse	Instituto Grifols S.A.	EU/1/19/1405/002	Film-coated tablet	-FOSTAMATINIB
Tavneos	Vifor Fresenius Medical Care Renal Pharma France	EU/1/21/1605/001-002	Capsule, hard	-Avacopan
TAXOTERE	Sanofi Winthrop Industrie	EU/1/95/002/001	Concentrate for solution for infusion	-Docetaxel trihydrate
Taxotere	Sanofi Winthrop Industrie	EU/1/95/002/002	Concentrate and solvent for solution for infusion	-Docetaxel trihydrate
Taxotere	Sanofi Winthrop Industrie	EU/1/95/002/003	Concentrate and solvent for solution for infusion	-Docetaxel trihydrate
Taxotere	Sanofi Winthrop Industrie	EU/1/95/002/004	Concentrate and solvent for solution for infusion	-Docetaxel trihydrate
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	-Diphtheria toxoid, purified -Tetanus toxoid, purified -Pertussis toxoid
Tecartus	Kite Pharma EU B.V.	EU/1/20/1492/001	Dispersion for infusion	-Autologous Peripheral Blood T Cells CD4 and CD8 selected and CD3 and CD28 Activated Transduced with Retroviral
Tecentriq	Roche Registration GmbH	EU/1/17/1220/001	Concentrate for solution for infusion	-Atezolizumab
Tecentriq	Roche Registration GmbH	EU/1/17/1220/002	Concentrate for solution for infusion	-Atezolizumab
Tecentriq	Roche Registration GmbH	EU/1/17/1220/003	Solution for injection	-Atezolizumab
Tecfidera	Biogen Netherlands B.V.	EU/1/13/837/001	Gastro-resistant capsule, hard	-Dimethyl Fumarate
Tecfidera	Biogen Netherlands B.V.	EU/1/13/837/002	Gastro-resistant capsule, hard	-Dimethyl Fumarate
Technescan DMSA 1.2 mg kit for radiopharmaceutical preparation	Curium Netherlands B.V.	PA0690/011/001	Kit for radiopharmaceutical preparation	-Succimer
TechneScan DTPA 20.8 mg kit for radiopharmaceutical preparation	Curium Netherlands B.V.	PA0690/015/001	Kit for radiopharmaceutical preparation	-PENTETIC ACID

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
TechneScan HDP 3mg, kit for radiopharmaceutical preparation	Curium Netherlands B.V.	PA0690/004/001	Kit for radiopharmaceutical preparation	-Oxidronate disodium
TechneScan MAG3, powder for solution for injection	Curium Netherlands B.V.	PA0690/018/001	Powder for solution for injection	-Betiatide
Technescan MIBI 1mg kit for radiopharmaceutical preparation	Curium Netherlands B.V.	PA0690/020/001	Kit for radiopharmaceutical preparation	-Tetrakis (2-methylpropyl-isocyanide) copper (i) tetrafluoroborate
Technescan PYP 20 mg kit for radiopharmaceutical preparation	Curium Netherlands B.V.	PA0690/010/001	Kit for radiopharmaceutical preparation	-Sodium pyrophosphate decahydrate
Tecovirimat SIGA 200 mg hard capsules	SIGA Technologies Netherlands B.V.	EU/1/21/1600/001	Capsule, hard	-Tecovirimat Monohydrate
Tecvayli	Janssen-Cilag International NV	EU/1/22/1675/001	Solution for injection	-Teclistamab
Teedex Oral Solution Paracetamol 120 mg/5 ml Diphenhydramine Hydrochloride 12.5 mg/5 ml	Phoenix Healthcare Ltd	PA1721/004/001	Oral solution	-Diphenhydramine hydrochloride -Paracetamol
Tefin 150 mg Suppositories	Clonmel Healthcare Ltd	PA0126/330/002	Suppository	-Ibuprofen
Tefin 75 mg Suppositories	Clonmel Healthcare Ltd	PA0126/330/001	Suppository	-Ibuprofen
Tegretol 100mg Tablets	Novartis Ireland Limited	PA0896/030/002	Tablet	-Carbamazepine
Tegretol 100mg/5ml Oral Suspension	Novartis Ireland Limited	PA0896/030/001	Oral suspension	-Carbamazepine
Tegretol 200mg Tablets	Novartis Ireland Limited	PA0896/030/003	Tablet	-Carbamazepine
Tegretol 400mg Tablets	Novartis Ireland Limited	PA0896/030/004	Tablet	-Carbamazepine
Tegretol SR 200mg prolonged release tablets	Novartis Ireland Limited	PA0896/030/005	Prolonged-release tablet	-Carbamazepine
Tegretol SR 400mg prolonged release tablets	Novartis Ireland Limited	PA0896/030/006	Prolonged-release tablet	-Carbamazepine
Tegsedi (Inotersen-lonis)	Akcea Therapeutics Ireland Ltd	EU/1/18/1296/001-002	Solution for injection in pre-filled syringe	-INOTERSEN
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	-Teicoplanin
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	-Teicoplanin
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	-Teicoplanin
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	-Teicoplanin
Tekcis 2-50 GBq radionuclide generator	CIS bio International	PA0677/020/001	Radionuclide generator	-Sodium pertechnetate (99m tc)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Telfast 120 mg film-coated tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/003/002	Film-coated tablet	-Fexofenadine hydrochloride
Telfast 180 mg film-coated tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/003/003	Film-coated tablet	-Fexofenadine hydrochloride
Telfast 30 mg film-coated tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/003/001	Film-coated tablet	-Fexofenadine hydrochloride
Telfast Allergy 120 mg film-coated tablets	Opella Healthcare France SAS T/A Sanofi	PA23180/014/001	Film-coated tablet	-Fexofenadine hydrochloride
Telfast Allergy 120 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/500/001	Film-coated tablet	-Fexofenadine hydrochloride
Telmisartan 20 mg tablets	Brillpharma (Ireland) Limited	PA22749/012/001	Tablet	-Telmisartan
Telmisartan 20 mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/014/001	Tablet	-Telmisartan
Telmisartan 40 mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/014/002	Tablet	-Telmisartan
Telmisartan 40 mg tablets	Brillpharma (Ireland) Limited	PA22749/012/002	Tablet	-Telmisartan
Telmisartan 80 mg tablets	Brillpharma (Ireland) Limited	PA22749/012/003	Tablet	-Telmisartan
Telmisartan 80 mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/014/003	Tablet	-Telmisartan
Telmisartan Actavis 20 mg tablets	Actavis Group hf	EU/1/10/639/001-010	Tablet	-Telmisartan
Telmisartan Actavis 40 mg tablets	Actavis Group hf	EU/1/10/639/011-020	Tablet	-Telmisartan
Telmisartan Actavis 80 mg tablets	Actavis Group hf	EU/1/10/639/021-030	Tablet	-Telmisartan
Telmisartan Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/228/001	Film-coated tablet	-Telmisartan
Telmisartan Clonmel 40 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/228/002	Film-coated tablet	-Telmisartan
Telmisartan Clonmel 80 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/228/003	Film-coated tablet	-Telmisartan
Telmisartan Fair-Med 20 mg Tablets	Fair-Med Healthcare GmbH	PA1789/008/001	Tablet	-Telmisartan
Telmisartan Fair-Med 40 mg Tablets	Fairmed Healthcare GmbH	PA1789/008/002	Tablet	-Telmisartan
Telmisartan Fair-Med 80 mg Tablets	Fairmed Healthcare GmbH	PA1789/008/003	Tablet	-Telmisartan
Telmisartan Mylan 20 mg tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/135/001	Tablet	-Telmisartan
Telmisartan Mylan 40 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/135/002	Tablet	-Telmisartan
Telmisartan Mylan 80 mg Tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/135/003	Tablet	-Telmisartan
Telmisartan Rowa 20 mg tablets	Rowa Pharmaceuticals Limited	PA0074/078/001	Tablet	-Telmisartan
Telmisartan Rowa 40 mg tablets	Rowa Pharmaceuticals Limited	PA0074/078/002	Tablet	-Telmisartan
Telmisartan Rowa 80 mg tablets	Rowa Pharmaceuticals Limited	PA0074/078/003	Tablet	-Telmisartan
Telmisartan Teva Pharma 20 mg tablets	Teva B.V.	EU/1/11/719/001-020	Tablet	-Telmisartan

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Telmisartan Teva Pharma 40 mg tablets	Teva B.V.	EU/1/11/719/021-040	Tablet	-Telmisartan
Telmisartan Teva Pharma 80 mg tablets	Teva B.V.	EU/1/11/719/041-060	Tablet	-Telmisartan
Telmisartan/Hydrochlorothiazide 40 mg/12.5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/107/001	Tablet	-Telmisartan -Hydrochlorothiazide
Telmisartan/Hydrochlorothiazide 80 mg/12.5 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/107/002	Tablet	-Telmisartan -Hydrochlorothiazide
Telmisartan/Hydrochlorothiazide 80 mg/25 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/107/003	Tablet	-Telmisartan -Hydrochlorothiazide
Telmisartan/Hydrochlorothiazide Clonmel 40 mg/12.5 mg tablets	Clonmel Healthcare Ltd	PA0126/259/001	Tablet	-Telmisartan -Hydrochlorothiazide
Telmisartan/Hydrochlorothiazide Clonmel 80 mg/12.5 mg tablets	Clonmel Healthcare Ltd	PA0126/259/002	Tablet	-Telmisartan -Hydrochlorothiazide
Telmisartan/Hydrochlorothiazide Clonmel 80 mg/25 mg tablets	Clonmel Healthcare Ltd	PA0126/259/003	Tablet	-Telmisartan -Hydrochlorothiazide
Telmisartan/Hydrochlorothiazide Liconsa 40 mg/12.5 mg tablets	Laboratorios LICONSA, S.A.	PA1239/025/001	Tablet	-Telmisartan -Hydrochlorothiazide
Telmisartan/Hydrochlorothiazide Liconsa 80 mg/12.5 mg tablets	Laboratorios LICONSA, S.A.	PA1239/025/002	Tablet	-Telmisartan -Hydrochlorothiazide
Telmisartan/Hydrochlorothiazide Liconsa 80 mg/25 mg tablets	Laboratorios LICONSA, S.A.	PA1239/025/003	Tablet	-Telmisartan -Hydrochlorothiazide
Telmisartan/Hydrochlorothiazide Rowa 40 mg/12.5 mg tablets	Rowa Pharmaceuticals Limited	PA0074/081/001	Tablet	-Telmisartan -Hydrochlorothiazide
Telmisartan/Hydrochlorothiazide Rowa 80 mg/12.5 mg tablets	Rowa Pharmaceuticals Limited	PA0074/081/002	Tablet	-Telmisartan -Hydrochlorothiazide
Telmisartan/Hydrochlorothiazide Rowa 80 mg/25 mg tablets	Rowa Pharmaceuticals Limited	PA0074/081/003	Tablet	-Hydrochlorothiazide -Telmisartan
TELZIR	ViiV Healthcare BV	EU/1/04/282/1-2	Film-coated tablet	-Fosamprenavir calcium
Temgesic 200 microgram Sublingual Tablets	Eumedica Pharmaceuticals GmbH	PA23460/001/001	Sublingual tablet	-Buprenorphine hydrochloride
Temgesic 300 micrograms/ml, solution for injection	Eumedica Pharmaceuticals GmbH	PA23460/001/002	Solution for injection	-Buprenorphine hydrochloride
Temodal	Merck Sharp & Dohme BV	EU/1/98/096/001-002	Capsule, hard	-Temozolomide
Temodal	Merck Sharp & Dohme BV	EU/1/98/096/003-004	Capsule, hard	-Temozolomide
Temodal	Merck Sharp & Dohme BV,	EU/1/98/096/005-006	Capsule, hard	-Temozolomide
Temodal	Merck Sharp & Dohme BV,	EU/1/98/096/007-008	Capsule, hard	-Temozolomide
Temodal	Merck Sharp & Dohme BV	EU/1/98/096/009-010	Capsule, hard	-Temozolomide
Temodal	Merck Sharp & Dohme BV	EU/1/98/096/011-012	Capsule, hard	-Temozolomide
Temodal	Merck Sharp & Dohme BV	EU/1/98/096/023	Powder for solution for infusion	-Temozolomide
TEMOMEDAC	Medac Gesellschaft für Klinische Spezialpräparate mbH	EU/1/09/605/11-12	Capsule, hard	-TEMOZOLOMIDE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
TEMOMEDAC	Medac Gesellschaft fur Klinische Spezialpräparate mbH	EU/1/09/605/1-2	Capsule, hard	-TEMOZOLOMIDE
TEMOMEDAC	Medac Gesellschaft fur Klinische Spezialpräparate mbH	EU/1/09/605/3-4	Capsule, hard	-TEMOZOLOMIDE
TEMOMEDAC	Medac Gesellschaft fur Klinische Spezialpräparate mbH	EU/1/09/605/5-6	Capsule, hard	-TEMOZOLOMIDE
TEMOMEDAC	Medac Gesellschaft fur Klinische Spezialpräparate mbH	EU/1/09/605/7-8	Capsule, hard	-TEMOZOLOMIDE
TEMOMEDAC	Medac Gesellschaft fur Klinische Spezialpräparate mbH	EU/1/09/605/9-10	Capsule, hard	-TEMOZOLOMIDE
Temozolomide Accord	Accord Healthcare S.L.U.	EU/1/10/615/001-002	Capsule, hard	-Temozolomide
Temozolomide Accord	Accord Healthcare S.L.U.	EU/1/10/615/005-006	Capsule, hard	-Temozolomide
Temozolomide Accord	Accord Healthcare S.L.U.	EU/1/10/615/009-010	Capsule, hard	-Temozolomide
Temozolomide Accord	Accord Healthcare S.L.U.	EU/1/10/615/013-014	Capsule, hard	-Temozolomide
Temozolomide Accord	Accord Healthcare S.L.U.	EU/1/10/615/017-018	Capsule, hard	-Temozolomide
Temozolomide Accord	Accord Healthcare S.L.U.	EU/1/10/615/021-022	Capsule, hard	-Temozolomide
Temozolomide Clonmel 100mg hard capsules	Clonmel Healthcare Ltd	PA0126/188/003	Capsule, hard	-Temozolomide
Temozolomide Clonmel 140mg hard capsules	Clonmel Healthcare Ltd	PA0126/188/004	Capsule, hard	-Temozolomide
Temozolomide Clonmel 180 mg hard capsules	Clonmel Healthcare Ltd	PA0126/188/005	Capsule, hard	-Temozolomide
Temozolomide Clonmel 20 mg hard capsules	Clonmel Healthcare Ltd	PA0126/188/002	Capsule, hard	-Temozolomide
Temozolomide Clonmel 250 mg hard capsules	Clonmel Healthcare Ltd	PA0126/188/006	Capsule, hard	-Temozolomide
Temozolomide Clonmel 5mg hard capsules	Clonmel Healthcare Ltd	PA0126/188/001	Capsule, hard	-Temozolomide
Temozolomide FAIR-MED 100 mg hard capsules	Fairmed Healthcare GmbH	PA1789/005/003	Capsule, hard	-Temozolomide
Temozolomide FAIR-MED 140 mg hard capsules	Fairmed Healthcare GmbH	PA1789/005/004	Capsule, hard	-Temozolomide
Temozolomide FAIR-MED 180 mg hard capsules	Fairmed Healthcare GmbH	PA1789/005/005	Capsule, hard	-Temozolomide
Temozolomide FAIR-MED 20 mg hard capsules	Fairmed Healthcare GmbH	PA1789/005/002	Capsule, hard	-Temozolomide
Temozolomide FAIR-MED 250 mg hard capsules	Fairmed Healthcare GmbH	PA1789/005/006	Capsule, hard	-Temozolomide
Temozolomide FAIR-MED 5 mg hard capsules	Fairmed Healthcare GmbH	PA1789/005/001	Capsule, hard	-Temozolomide
TEMOZOLOMIDE SUN	Sun Pharmaceutical Industries Europe B.V.	EU/1/11/697/001-002	Capsule, hard	-TEMOZOLOMIDE
TEMOZOLOMIDE SUN	Sun Pharmaceutical Industries Europe B.V.	EU/1/11/697/003-004	Capsule, hard	-TEMOZOLOMIDE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
TEMOZOLOMIDE SUN	Sun Pharmaceutical Industries Europe B.V.	EU/1/11/697/005-006	Capsule, hard	-TEMOZOLOMIDE
TEMOZOLOMIDE SUN	Sun Pharmaceutical Industries Europe B.V.	EU/1/11/697/007-008	Capsule, hard	-TEMOZOLOMIDE
TEMOZOLOMIDE SUN	Sun Pharmaceutical Industries Europe B.V.	EU/1/11/697/009-010	Capsule, hard	-TEMOZOLOMIDE
TEMOZOLOMIDE SUN	Sun Pharmaceutical Industries Europe B.V.	EU/1/11/697/011-012	Capsule, hard	-TEMOZOLOMIDE
Temozolomide Teva	Teva B.V.	EU/1/09/606/001-002	Capsule, hard	-Temozolomide
Temozolomide Teva	Teva B.V.	EU/1/09/606/003-004	Capsule, hard	-Temozolomide
Temozolomide Teva	Teva B.V.	EU/1/09/606/005-006	Capsule, hard	-Temozolomide
Temozolomide Teva	Teva B.V.	EU/1/09/606/007-008	Capsule, hard	-Temozolomide
Temozolomide Teva	Teva B.V.	EU/1/09/606/009-010	Capsule, hard	-Temozolomide
Temozolomide Teva	Teva B.V.	EU/1/09/606/011-012	Capsule, hard	-Temozolomide
Tendrotil SR 2 mg Prolonged-Release Capsules, Hard	Accord Healthcare Ireland Ltd.	PA2315/134/001	Prolonged-release capsule, hard	-Tolterodine tartrate
Tendrotil SR 4 mg Prolonged-Release Capsules, Hard	Accord Healthcare Ireland Ltd.	PA2315/134/002	Prolonged-release capsule, hard	-Tolterodine tartrate
Tenkasi	Menarini International Operations Luxembourg S.A.	EU/1/15/989/001	Powder for concentrate for solution for infusion	-Oritavancin
Tenkasi	Menarini International Operations Luxembourg S.A.	EU/1/15/989/002	Powder for concentrate for solution for infusion	-Oritavancin
Tenofovir disoproxil Accordpharma 245 mg Film-coated Tablets.	Accord Healthcare Ireland Ltd.	PA2315/022/001	Film-coated tablet	-Tenofovir disoproxil fumarate
Tenofovir disoproxil Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1129/001	Film-coated tablet	-Tenofovir disoproxil
Tenofovir Disoproxil Teva 245 mg Film-coated Tablets	Teva B.V.	PA1986/003/001	Film-coated tablet	-Tenofovir disoproxil
Tenofovir disoproxil Zentiva	Zentiva k.s.	EU/1/16/1127/001-002	Film-coated tablet	-Tenofovir disoproxil phosphate
Tepadina	Adienne S.r.l.	EU/1/10/622/001	Powder for concentrate for solution for infusion	-Thiotepa
Tepadina	Adienne S.r.l.	EU/1/10/622/002	Powder for concentrate for solution for infusion	-Thiotepa
Tepadina	Adienne S.r.l. S.U.	EU/1/10/622/003	Powder and solvent for solution for infusion	-Thiotepa
Tepkinly	AbbVie Deutschland GmbH & Co. KG	EU/1/23/1759/001	Concentrate for solution for injection	-Epcoritamab
Tepkinly	AbbVie Deutschland GmbH & Co. KG	EU/1/23/1759/002	Solution for injection	-Epcoritamab
Tepmetko	Merck Europe B.V.	EU/1/21/1596/001	Film-coated tablet	-Tepotinib hydrochloride monohydrate
Terbasil 250mg Tablets	Accord Healthcare Ireland Ltd.	PA2315/099/001	Tablet	-Terbinafine
Terbinafine Rowa 250 mg Tablets	Rowa Pharmaceuticals Limited	PA0074/084/001	Tablet	-Terbinafine hydrochloride
Teriflunomide Accord	Accord Healthcare S.L.U.	EU/1/22/1693/001-004	Film-coated tablet	-Teriflunomide
Teriflunomide Clonmel 14 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/375/001	Film-coated tablet	-Teriflunomide
Teriflunomide Mylan	Mylan Pharmaceuticals Limited	EU/1/22/1698/001-007	Film-coated tablet	-Teriflunomide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Teriparatide SUN	Sun Phamaceutical Industries Europe B.V.	EU/1/22/1697/001-002	Solution for injection in pre-filled pen	-Teriparatide
Terlipressin acetate EVER Pharma 0.2 mg/ml solution for injection	EVER Valinject GmbH	PA1774/007/001	Solution for injection	-Terlipressin acetate
Terrosa	Gedeon Richter Plc	EU/1/16/1159/001-002	Solution for injection	-Teriparatide
Tesavel 100 mg film-coated tablets	Merck Sharp & Dohme BV	EU/1/07/435/13-18	Film-coated tablet	-Sitagliptin as monohydrate phosphate salt
Tesavel 25 mg film-coated tablets	Merck Sharp & Dohme BV,	EU/1/07/435/1-6	Film-coated tablet	-Sitagliptin as monohydrate phosphate salt
Tesavel 50 mg film-coated tablets	Merck Sharp & Dohme BV	EU/1/07/435/7-12	Film-coated tablet	-Sitagliptin as monohydrate phosphate salt
Testarzon 20 mg/g Transdermal gel	The Simple Pharma Company Limited	PA23202/001/001	Transdermal gel	-Testosterone
Testogel 16.2 mg/g, gel	Laboratoires Besins International	PA1054/002/004	Gel	-Testosterone
Testogel 25 mg transdermal gel in sachet	Laboratoires Besins International	PA1054/002/001	Transdermal gel in sachet	-Testosterone
Testogel 40.5 mg transdermal gel in sachet	Laboratoires Besins International	PA1054/002/005	Transdermal gel in sachet	-Testosterone
Testogel 50 mg transdermal gel in sachet	Laboratoires Besins International	PA1054/002/002	Transdermal gel in sachet	-Testosterone
Testosterone Besins 1000 mg/4 ml solution for injection	Besins Healthcare Ireland Limited	PA22624/002/001	Solution for injection	-Testosterone Undecanoate
Tetagam P, prefilled syringeSolution for injection for intramuscular use	CSL Behring GmbH	PA0800/009/002	Solution for injection	-Human plasma protein
Tetrabenazine 25 mg Tablets	Aop Orphan Pharmaceuticals GmbH	PA0934/004/001	Tablet	-Tetrabenazine
Tetralysal 300 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/256/001	Capsule, hard	-Lymecycline
Tetralysal 300 mg hard capsules	IMED Healthcare Ltd.	PPA1463/133/001	Capsule, hard	-Tetracycline
Tetralysal 300mg Hard Capsules	Galderma International	PA22743/016/001	Capsule, hard	-Tetracycline
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	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Teriparatide
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
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	-Enoxaparin sodium
Tevagrastim	Teva Generics GmbH	EU/1/08/445/1-4	Solution for injection/infusion	-Filgrastim
Tevagrastim 48 MIU/0.8 ml solution for injection o	Teva Generics GmbH	EU/1/08/445/5-8	Solution for injection/infusion	-Filgrastim
Tevanate Once Weekly 70mg Tablets	Teva Pharma B.V.	PA0749/016/001	Tablet	-Alendronic acid
Tevaquel 100 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/060/002	Film-coated tablet	-Quetiapine fumarate
Tevaquel 200 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/060/004	Film-coated tablet	-Quetiapine
Tevaquel 25 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/060/001	Film-coated tablet	-Quetiapine fumarate
Tevaquel 300 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/060/005	Film-coated tablet	-Quetiapine
Tevaquel XL 200 mg Prolonged-release tablets	Teva Pharma B.V.	PA0749/060/007	Prolonged-release tablet	-Quetiapine
Tevaquel XL 300 mg Prolonged-release tablets	Teva Pharma B.V.	PA0749/060/008	Prolonged-release tablet	-Quetiapine fumarate
Tevaquel XL 400 mg Prolonged-release tablets	Teva Pharma B.V.	PA0749/060/009	Prolonged-release tablet	-Quetiapine
Tevaquel XL 50 mg Prolonged-release tablets	Teva Pharma B.V.	PA0749/060/006	Prolonged-release tablet	-Quetiapine
TEVETEN 400 mg, film-coated tablets	Mylan IRE Healthcare Limited	PA2010/017/001	Film-coated tablet	-Eprosartan mesylate
Teveten 600 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/469/001	Film-coated tablet	-Eprosartan
Teveten 600 mg, film-coated tablets	IMED Healthcare Ltd.	PPA1463/091/001	Film-coated tablet	-Eprosartan
Teveten 600 mg, film-coated tablets	Mylan IRE Healthcare Limited	PA2010/017/002	Film-coated tablet	-Eprosartan mesylate
Teveten Plus 600 mg/12.5 mg film-coated tablets	Mylan IRE Healthcare Limited	PA2010/018/001	Film-coated tablet	-Eprosartan -Hydrochlorothiazide
Teveten Plus 600 mg/12.5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/448/001	Film-coated tablet	-Hydrochlorothiazide -Eprosartan

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Tevimbra	BeiGene Ireland Limited	EU/1/23/1758/001-002	Concentrate for solution for infusion	-Tislelizumab
Teysuno	Nordic Group B.V.	EU/1/11/669/001-002	Capsule, hard	-Tegafur -Gimeracil -Oteracil (as monopotassium salt)
Teysuno	Nordic Group B.V.	EU/1/11/669/003-004	Capsule, hard	-Gimeracil -Oteracil (as monopotassium salt) -Tegafur
TEZSPIRE	AstraZeneca AB	EU/1/22/1677/001-002	Solution for injection	-Tezepelumab
Thalidomide BMS	Bristol-Myers Squibb Pharmaceuticals uc	EU/1/08/443/1	Capsule, hard	-Thalidomide
Thalidomide Lipomed	Lipomed GmbH	EU/1/22/1676/001	Coated tablet	-Thalidomide
Thallos (TI201) chloride injection 37 MBq/ml solution for injection	Curium Netherlands B.V.	PA0690/016/001	Solution for injection	-Thallos chloride (201 tl)
Thamicarb 84mg/ml Oral Solution	Syri Pharma Limited t/a Thame Laboratories	PA22697/017/001	Oral solution	-Sodium hydrogen carbonate
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	-Thiotepa
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	-Thiotepa
Thiotepa Riemser	Riemser Pharma GmbH	EU/1/21/1536/001	Powder for concentrate for solution for infusion	-Thiotepa
Thiotepa Riemser	Riemser Pharma GmbH	EU/1/21/1536/002	Powder for concentrate for solution for infusion	-Thiotepa
THORENS 10 000 I.U./ml oral drops, solution	Galen Pharma Ireland Limited	PA22680/005/001	Oral drops, solution	-Cholecalciferol
THORENS 25 000 I.U./2.5 ml oral solution	Galen Pharma Ireland Limited	PA22680/005/002	Oral solution	-Cholecalciferol
Thorens 25 000 I.U. capsules, hard	Galen Pharma Ireland Limited	PA22680/005/003	Capsule, hard	-Colecalciferol
Thorinane	Techdow Pharma Netherlands B.V	EU/1/16/1131/001-002	Solution for injection in pre-filled syringe	-Enoxaparin sodium
Thorinane	Pharmathen S.A.	EU/1/16/1131/003-004	Solution for injection in pre-filled syringe	-Enoxaparin sodium
Thorinane	Pharmathen S.A.	EU/1/16/1131/005-006	Solution for injection in pre-filled syringe	-Enoxaparin sodium
Thorinane	Pharmathen S.A.	EU/1/16/1131/007-008	Solution for injection in pre-filled syringe	-Enoxaparin sodium
Thorinane	Pharmathen S.A.	EU/1/16/1131/009-010	Solution for injection in pre-filled syringe	-Enoxaparin sodium
Thwart 26% w/w Cutaneous Solution	Alliance Pharma (Ireland) Limited	PA2325/015/001	Cutaneous solution	-Salicylic acid
Thymoglobuline 25 mg powder for solution for infusion	Genzyme Europe B.V.	PA0611/003/001	Powder for solution for infusion	-Rabbit anti-human thymocyte immunoglobulin
THYROGEN	Genzyme Europe B.V.	EU/1/99/122/001	Powder for solution for injection	-Thyrotropin alfa
THYROGEN	Genzyme Europe B.V.	EU/1/99/122/002	Powder for solution for injection	-Thyrotropin alfa
Tibolone Aristo 2.5 mg tablets	Aristo Pharma GmbH	PA1983/003/001	Tablet	-Tibolone
Tibsovo	Les Laboratoires Servier	EU/1/23/1728/001	Film-coated tablet	-Ivosidenib
Ticagrelor Krka 60 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/102/001	Film-coated tablet	-Ticagrelor

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Ticagrelor Krka 90 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/102/002	Film-coated tablet	-Ticagrelor
Ticagrelor Pinewood 90 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/258/001	Film-coated tablet	-Ticagrelor
Ticagrelor Rowex 90 mg Film-coated tablets	Rowex Ltd	PA0711/299/001	Film-coated tablet	-Ticagrelor
Ticagrelor Teva 90 mg Film-coated Tablets	Teva B.V.	PA1986/123/001	Film-coated tablet	-Ticagrelor
Ticagrelor Viatriis 60 mg film-coated tablets	Viatriis Limited	PA23266/008/001	Film-coated tablet	-Ticagrelor
Ticagrelor Viatriis 90 mg film-coated tablets	Viatriis Limited	PA23266/008/002	Film-coated tablet	-Ticagrelor
TicoVac 0.5 ml Suspension for injection in a pre-filled syringe Tick-Borne Encephalitis Vaccine (whole Virus, inactivated)	Pfizer Healthcare Ireland	PA0822/184/001	Suspension for injection in pre-filled syringe	-Tbe virus antigen
TicoVac Junior 0.25 ml Suspension for injection in a pre-filled syringe Tick-Borne Encephalitis Vaccine (whole Virus, inactivated)	Pfizer Healthcare Ireland	PA0822/184/002	Suspension for injection in pre-filled syringe	-TICK-BORNE ENCEPHALITIS VIRUS (INACTIVATED) NEUDOERFL
Tidimaz 20 mg/ml + 5 mg/ml eye drops, solution	Farmaprojects S.A.	PA1391/004/001	Eye drops, solution	-Dorzolamide hydrochloride -Timolol Maleate
Tigecycline 50 mg powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/070/001	Powder for solution for infusion	-Tigecycline
Tigecycline Accord	Accord Healthcare S.L.U.	EU/1/19/1394/001-002	Powder for solution for infusion	-Tigecycline
Timlatan 50 micrograms/ml + 5 mg/ml eye drops, solution	Bausch + Lomb Ireland Limited	PA23259/001/001	Eye drops, solution	-Latanoprost -Timolol Maleate
Timofluid 1 mg/g eye gel in single-dose container	Laboratoires Thea	PA1107/003/001	Eye gel in single-dose container	-Timolol Maleate
Timolol 0.25% w/v Eye Drops, Solution	Brown & Burk IR Limited	PA23148/003/001	Eye drops, solution	-Timolol Maleate
Timolol 0.5% w/v Eye Drops, Solution	Brown & Burk IR Limited	PA23148/003/002	Eye drops, solution	-Timolol Maleate
Tiogiva, 18 microgram, inhalation powder, hard capsule	Glenmark Pharmaceuticals Nordic AB	PA22815/002/001	Inhalation powder, hard capsule	-Tiotropium
Tiotropium Viatriis 18 microgram, inhalation powder, hard capsule	Viatriis Limited	PA23266/007/001	Inhalation powder, hard capsule	-Tiotropium
Tipol 125 mg suppositories	Clonmel Healthcare Ltd	PA0126/331/002	Suppository	-Paracetamol
Tipol 250 mg suppositories	Clonmel Healthcare Ltd	PA0126/331/003	Suppository	-Paracetamol
Tipol 500 mg suppositories	Clonmel Healthcare Ltd	PA0126/331/004	Suppository	-Paracetamol
Tipol 75 mg suppositories	Clonmel Healthcare Ltd	PA0126/331/001	Suppository	-Paracetamol
Tipol Max 1000 mg suppositories	Clonmel Healthcare Ltd	PA0126/331/005	Suppository	-Paracetamol
Tipuric 100 mg Tablets	Clonmel Healthcare Ltd	PA0126/038/001	Tablet	-Allopurinol
Tipuric 300 mg Tablets	Clonmel Healthcare Ltd	PA0126/038/002	Tablet	-Allopurinol

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
TISSEEL Lyo Powder and Solvent for Sealant	Baxter Holding B.V.	PA2299/025/002	Powder and solvent for sealant	-Human fibrinogen -Human factor xiii -Aprotinin -Human thrombin -Calcium chloride
TISSEEL Ready to use Solutions for Sealant	Baxter Holding B.V.	PA2299/025/001	Solution for sealant	-Human fibrinogen -Aprotinin -Human factor xiii -Human thrombin -Calcium chloride
Tivicay	ViiV Healthcare BV	EU/1/13/892/001-002	Film-coated tablet	-Dolutegravir
Tivicay	ViiV Healthcare BV	EU/1/13/892/003-004	Film-coated tablet	-Dolutegravir
Tivicay	ViiV Healthcare BV	EU/1/13/892/005-006	Film-coated tablet	-Dolutegravir
Tivicay	ViiV Healthcare BV	EU/1/13/892/007	Dispersible tablet	-Dolutegravir sodium
TOBI 300 mg/5 mL Nebuliser Solution Tobramycin 300 mg/5 ml Nebuliser Solution	Mylan IRE Healthcare Limited	PA2010/063/001	Nebuliser solution	-Tobramycin
Tobi Podhaler	Viartis Limited	EU/1/10/652/001-003	Inhalation powder, hard capsule	-Tobramycin
Tobramycin 40 mg/ml Solution for Injection	Pfizer Healthcare Ireland	PA0822/207/001	Solution for injection	-Tobramycin
Tobramycin PARI	PARI Pharma GmbH	EU/1/18/1350/001	Nebuliser solution	-Tobramycin
Tolterodine Tartrate 1 mg Film-coated Tablet	Accord Healthcare Ireland Ltd.	PA2315/041/001	Film-coated tablet	-Tolterodine tartrate
Tolterodine Tartrate 2 mg Film-coated Tablet	Accord Healthcare Ireland Ltd.	PA2315/041/002	Film-coated tablet	-Tolterodine tartrate
Toltertan SR 2 mg Prolonged-Release Capsules, Hard	Clonmel Healthcare Ltd	PA0126/231/001	Prolonged-release capsule, hard	-Tolterodine tartrate
Toltertan SR 4 mg Prolonged-Release Capsules, Hard	Clonmel Healthcare Ltd	PA0126/231/002	Prolonged-release capsule, hard	-Tolterodine tartrate
Tolucombi 40 mg/12.5 mg tablets	KRKA, d.d., Novo mesto	EU/1/13/821/001-010	Tablet	-Telmisartan -Hydrochlorothiazide
Tolucombi 80 mg/12.5 mg tablets	KRKA, d.d., Novo mesto	EU/1/13/821/011-020	Tablet	-Telmisartan -Hydrochlorothiazide
Tolucombi 80 mg/25 mg tablets	KRKA, d.d., Novo mesto	EU/1/13/821/021-030	Tablet	-Telmisartan -Hydrochlorothiazide
Tolura 20 mg tablets	KRKA, d.d., Novo mesto	EU/1/10/632/001-7	Tablet	-Telmisartan
Tolura 40 mg tablets	KRKA, d.d., Novo mesto	EU/1/10/632/008-14	Tablet	-Telmisartan
Tolura 80 mg tablets	KRKA, d.d., Novo mesto	EU/1/10/632/015-21	Tablet	-Telmisartan
Tolvaptan Accord	Accord Healthcare S.L.U.	EU/1/23/1719/001-004	Tablet	-Tolvaptan
Tolvaptan Ascend 7.5 mg tablets	Ascend GmbH	PA23429/006/001	Tablet	-Tolvaptan
Tookad	STEBA Biotech S.A.	EU/1/17/1228/001	Powder for solution for injection	-Padeliporfin
Tookad	STEBA Biotech S.A.	EU/1/17/1228/002	Powder for solution for injection	-Padeliporfin
Topamax 100 mg Film-Coated Tablets	PCO Manufacturing Ltd.	PPA0465/196/003	Film-coated tablet	-Topiramate
Topamax 100 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/136/001	Film-coated tablet	-Topiramate
Topamax 100 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/001/001	Film-coated tablet	-Topiramate
TOPAMAX 100 mg Film-coated Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/001/002	Film-coated tablet	-Topiramate
Topamax 100 mg film-coated tablets	Merit Pharmaceuticals Limited	PPA23080/016/003	Film-coated tablet	-Topiramate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
TOPAMAX 100 mg Film-coated Tablets	Janssen Sciences Ireland UC	PA22612/013/003	Film-coated tablet	-Topiramate
Topamax 200 mg Film-coated Tablets	IMED Healthcare Ltd.	PPA1463/136/004	Film-coated tablet	-Topiramate
Topamax 200 mg film-coated tablets	Originalis B.V.	PPA2306/003/001	Film-coated tablet	-Topiramate
Topamax 200 mg Film-Coated Tablets	PCO Manufacturing Ltd.	PPA0465/196/004	Film-coated tablet	-Topiramate
TOPAMAX 200mg Film-coated Tablets	Janssen Sciences Ireland UC	PA22612/013/004	Film-coated tablet	-Topiramate
Topamax 25 mg Film-Coated Tablets	PCO Manufacturing Ltd.	PPA0465/196/001	Film-coated tablet	-Topiramate
Topamax 25 mg Film-coated Tablets	IMED Healthcare Ltd.	PPA1463/136/002	Film-coated tablet	-Topiramate
Topamax 25 mg film-coated tablets	Merit Pharmaceuticals Limited	PPA23080/016/001	Film-coated tablet	-Topiramate
TOPAMAX 25mg Film-coated Tablets	Janssen Sciences Ireland UC	PA22612/013/001	Film-coated tablet	-Topiramate
Topamax 50 mg film-coated tablets	Merit Pharmaceuticals Limited	PPA23080/016/002	Film-coated tablet	-Topiramate
Topamax 50 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/136/003	Film-coated tablet	-Topiramate
Topamax 50 mg Film-Coated Tablets	PCO Manufacturing Ltd.	PPA0465/196/002	Film-coated tablet	-Topiramate
TOPAMAX 50mg Film-coated Tablets	Janssen Sciences Ireland UC	PA22612/013/002	Film-coated tablet	-Topiramate
Topamax Sprinkle 15 mg Hard Capsules	Janssen Sciences Ireland UC	PA22612/013/007	Capsule, hard	-Topiramate
Topamax Sprinkle 25 mg Hard Capsules	Janssen Sciences Ireland UC	PA22612/013/008	Capsule, hard	-Topiramate
Topotecan Accord 1mg/ml concentrate for solution for infusion	Accord Healthcare Ireland Ltd.	PA2315/121/001	Concentrate for solution for infusion	-Topotecan (as hydrochloride)
Topotecan Hospira	Pfizer Europe MA EEIG	EU/1/10/633/001-2	Concentrate for solution for infusion	-Topotecan (as hydrochloride)
Torisel	Pfizer Europe MA EEIG	EU/1/07/424/001	Concentrate and solvent for solution for infusion	-Temozolomide
Tostran 2% Gel	Advanz Pharma Limite	PA23450/002/001	Gel	-Testosterone
Toujeo	Sanofi-Aventis Deutschland GmbH	EU/1/00/133/033-035	Solution for injection in pre-filled pen	-Insulin glargine
Tovanor Breezhaler	Novartis Europharm Limited	EU/1/12/790/001-006	Inhalation powder, hard capsule	-Glycopyrronium bromide
TOVIAZ 4 mg prolonged-release tablets	Pfizer Europe MA EEIG	EU/1/07/386/1-5	Prolonged-release tablet	-Fesoterodine fumarate
TOVIAZ 8 mg prolonged-release tablets	Pfizer Europe MA EEIG	EU/1/07/386/6-10	Prolonged-release tablet	-Fesoterodine fumarate
Tracleer	Janssen-Cilag International NV	EU/1/02/220/001	Film-coated tablet	-Bosentan
Tracleer	Janssen-Cilag International NV	EU/1/02/220/002	Film-coated tablet	-Bosentan
Tracleer	Janssen-Cilag International NV	EU/1/02/220/003	Film-coated tablet	-Bosentan
Tracleer	Janssen-Cilag International NV	EU/1/02/220/004	Film-coated tablet	-Bosentan
Tracleer	Janssen-Cilag International NV	EU/1/02/220/005	Film-coated tablet	-Bosentan
Tracleer	Janssen-Cilag International NV	EU/1/02/220/006	Dispersible tablet	-Bosentan
Tracrium 10 mg/ml, Solution for injection or infusion, vials	Aspen Pharma Trading Limited	PA1691/029/002	Solution for injection/infusion	-Atracurium besilate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Tracrium 10mg/ml, solution for injection or infusion, ampoules	Aspen Pharma Trading Limited	PA1691/029/001	Solution for injection/infusion	-Atracurium besilate
TRACTOCILE	Ferring AB	EU/1/99/124/001	Solution for injection	-Atosiban acetate
Tractocile	Ferring AB	EU/1/99/124/002	Solution for injection	-Atosiban acetate
Tradol 50 mg Effervescent tablets	Rowa Pharmaceuticals Limited	PA0074/094/001	Effervescent tablet	-Tramadol hydrochloride
Tradol 50mg Hard Capsules	Rowex Ltd	PA0711/029/001	Capsule, hard	-Tramadol hydrochloride
Tradol 50mg/ml Solution for Injection or Infusion	Rowex Ltd	PA0711/029/003	Solution for injection/infusion	-Tramadol hydrochloride
Tradol SR 100 mg Prolonged release tablets	Rowex Ltd	PA0711/029/005	Prolonged-release tablet	-Tramadol hydrochloride
Tradol SR 150 mg Prolonged release tablets	Rowex Ltd	PA0711/029/006	Prolonged-release tablet	-Tramadol hydrochloride
Tradol SR 200 mg Prolonged release tablets	Rowex Ltd	PA0711/029/007	Prolonged-release tablet	-Tramadol hydrochloride
Trajenta	Boehringer Ingelheim International GmbH	EU/1/11/707/001-011	Film-coated tablet	-Linagliptin
Tramadol /Paracetamol Rowa 37.5 mg/325 mg Film-coated Tablets	Rowa Pharmaceuticals Limited	PA0074/070/001	Film-coated tablet	-Tramadol hydrochloride -Paracetamol
Tramadol hydrochloride 50 mg Hard Capsules	Accord Healthcare Ireland Ltd.	PA2315/214/001	Capsule, hard	-Tramadol hydrochloride
Tramadol Hydrochloride/Paracetamol 37.5 mg/325 mg Film-Coated Tablets	Athlone Pharmaceuticals Limited	PA1418/009/001	Film-coated tablet	-Tramadol hydrochloride -Paracetamol
Tramadol Krka 50mg hard capsules	KRKA, d.d., Novo mesto	PA1347/079/001	Capsule, hard	-Tramadol hydrochloride
Tramadol/Paracetamol 37.5 mg/325 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/143/001	Film-coated tablet	-Tramadol hydrochloride -Paracetamol
Tramadol/Paracetamol Krka 37.5mg/325mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/052/001	Film-coated tablet	-Paracetamol -Tramadol hydrochloride
Trandate 100mg Film-Coated Tablets	RPH Pharmaceuticals AB	PA1638/006/002	Film-coated tablet	-Labetalol hydrochloride
Trandate 200mg Film-coated Tablets	RPH Pharmaceuticals AB	PA1638/006/003	Film-coated tablet	-Labetalol hydrochloride
Trandate 5mg/ml Solution for Injection	RPH Pharmaceuticals AB	PA1638/006/001	Solution for injection	-Labetalol hydrochloride
Tranexamic acid 100 mg/ml Solution for Injection	Accord Healthcare Ireland Ltd.	PA2315/178/001	Solution for injection	-Tranexamic acid
Tranexamic acid 100 mg/mL solution for injection/infusion	Baxter Holding B.V.	PA2299/048/001	Solution for injection/infusion	-TRANEXAMIC ACID PH. EUR.
Tranexamic Acid 100 mg/ml solution for injection/infusion	Ibigen Srl	PA1862/002/001	Solution for injection/infusion	-Tranexamic acid
Transiderm-Nitro 10milligram/24 hours Transdermal Patch	Sandoz Pharmaceuticals d.d.	PA23311/005/002	Transdermal patch	-Glyceryl trinitrate
Transiderm-Nitro 15milligrams/24 hours Transdermal Patch	Sandoz Pharmaceuticals d.d.	PA23311/005/003	Transdermal patch	-Glyceryl trinitrate
Transiderm-Nitro 5milligrams/24 hours Transdermal Patch	Sandoz Pharmaceuticals d.d.	PA23311/005/001	Transdermal patch	-Glyceryl trinitrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Tranisoft 8.5 g powder for oral solution in sachet	Laboratoires Mayoly Spindler	PA1993/002/001	Powder for oral solution in sachet	-Macrogol 3350
Translarna	PTC Therapeutics International Limited	EU/1/13/902/001	Granules for oral suspension	-Ataluren
Translarna	PTC Therapeutics International Limited	EU/1/13/902/002	Granules for oral suspension	-Ataluren
Translarna	PTC Therapeutics International Limited	EU/1/13/902/003	Granules for oral suspension	-Ataluren
Transtec 35 micrograms/h Transdermal Patch	Grünenthal GmbH	PA1032/001/001	Transdermal patch	-Buprenorphine
Transtec 52.5 micrograms/h Transdermal Patch	Grünenthal GmbH	PA1032/001/002	Transdermal patch	-Buprenorphine
Transtec 70 micrograms/h Transdermal Patch	Grünenthal GmbH	PA1032/001/003	Transdermal patch	-Buprenorphine
Trasylol 10,000 KIU/ml, solution for injection or infusion	Nordic Group B.V.	PA2252/001/001	Solution for injection/infusion	-APROTININ CONCENTRATED SOLUTION
Travatan	Novartis Europharm Limited	EU/1/01/199/001	Eye drops, solution	-Travoprost
Travatan	Novartis Europharm Limited	EU/1/01/199/002	Eye drops, solution	-Travoprost
Travocort® 0.1 + 1% w/w Cream	LEO Pharma A/S	PA1025/012/001	Cream	-DIFLUCORTOLONE VALERATE -Isoconazole nitrate
Traxam 3 %w/w Gel	Amdipharm Limited	PA1142/025/001	Gel	-Felbinac
Trazimera	Pfizer Europe MA EEIG	EU/1/18/1295/001	Concentrate for solution for infusion	-Trastuzumab
Trazodone hydrochloride 100 mg Capsules, Hard	Brillpharma (Ireland) Limited	PA22749/010/002	Capsule, hard	-Trazodone hydrochloride
Trazodone Hydrochloride 100 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/122/002	Tablet	-Trazodone hydrochloride
Trazodone hydrochloride 150 mg film-coated tablets	Brillpharma (Ireland) Limited	PA22749/010/003	Film-coated tablet	-Trazodone hydrochloride
Trazodone Hydrochloride 150 mg Film-Coated Tablets	Azure Pharmaceuticals Ltd.	PA22871/015/001	Film-coated tablet	-Trazodone hydrochloride
Trazodone Hydrochloride 150 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/122/003	Tablet	-Trazodone hydrochloride
Trazodone hydrochloride 50 mg Capsules, Hard	Brillpharma (Ireland) Limited	PA22749/010/001	Capsule, hard	-Trazodone hydrochloride
Trazodone Hydrochloride 50 mg tablets	Accord Healthcare Ireland Ltd.	PA2315/122/001	Tablet	-Trazodone hydrochloride
Trazodone Hydrochloride 50mg/5ml Oral Solution	Lexon Pharmaceuticals (Ireland) Limited	PA23176/005/001	Oral solution	-Trazodone hydrochloride
Trazodone Hydrochloride Azure 100 mg Hard Capsules	Azure Pharmaceuticals Ltd.	PA22871/018/002	Capsule, hard	-Trazodone hydrochloride
Trazodone Hydrochloride Azure 50 mg Hard Capsules	Azure Pharmaceuticals Ltd.	PA22871/018/001	Capsule, hard	-Trazodone hydrochloride
Trebon 600 mg powder for oral solution	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	PA1732/003/001	Powder for oral solution	-Acetylcysteine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Treclin 10 mg/g + 0.25 mg/g Gel	Mylan IRE Healthcare Limited	PA2010/044/001	Gel	-Clindamycin -Tretinoin
Trecondi	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/18/1351/001-002	Powder for solution for infusion	
Trecondi	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/18/1351/003-004	Powder for solution for infusion	
Trelegy Ellipta	GlaxoSmithKline Trading Services Limited	EU/1/17/1236/001-003	Inhalation powder, pre-dispensed	-Fluticasone furoate -Umeclidinium bromide -Vilanterol
Tremelimumab AstraZeneca	AstraZeneca AB	EU/1/22/1712/001-002	Concentrate for solution for infusion	-Tremelimumab
Tremfya	Janssen-Cilag International NV	EU/1/17/1234/001	Solution for injection in pre-filled syringe	-Guselkumab
Treosulfan Tillomed 5 g powder for solution for infusion	Laboratorios Tillomed Spain, S.L.U.	PA2321/003/001	Powder for solution for infusion	-Treosulfan
Treposuvi 1 mg/ml solution for infusion	Orpha-Devel Handels und Vertriebs GmbH	PA1353/006/001	Solution for infusion	-Treprostnil
Treposuvi 10 mg/ml solution for infusion	Orpha-Devel Handels und Vertriebs GmbH	PA1353/006/004	Solution for infusion	-Treprostnil
Treposuvi 2.5 mg/ml solution for infusion	Orpha-Devel Handels und Vertriebs GmbH	PA1353/006/002	Solution for infusion	-Treprostnil
Treposuvi 5 mg/ml solution for infusion	Orpha-Devel Handels und Vertriebs GmbH	PA1353/006/003	Solution for infusion	-Treprostnil
Treprostnil 1 mg/ml solution for infusion	Reddy Holding GmbH	PA23092/002/001	Solution for infusion	-Treprostnil
Treprostnil 10 mg/ml solution for infusion	Reddy Holding GmbH	PA23092/002/004	Solution for infusion	-Treprostnil
Treprostnil 2.5 mg/ml solution for infusion	Reddy Holding GmbH	PA23092/002/002	Solution for infusion	-Treprostnil
Treprostnil 5 mg/ml solution for infusion	Reddy Holding GmbH	PA23092/002/003	Solution for infusion	-Treprostnil
Treprostnil Tillomed 1 mg/ml solution for infusion	Tillomed Pharma GmbH	PA22720/011/001	Solution for infusion	-Treprostnil
Treprostnil Tillomed 10 mg/ml solution for infusion	Tillomed Pharma GmbH	PA22720/011/004	Solution for infusion	-Treprostnil
Treprostnil Tillomed 2.5 mg/ml solution for infusion	Tillomed Pharma GmbH	PA22720/011/002	Solution for infusion	-Treprostnil
Treprostnil Tillomed 5 mg/ml solution for infusion	Tillomed Pharma GmbH	PA22720/011/003	Solution for infusion	-Treprostnil
Trepulmix	Scipharm S.à.r.l.	EU/1/19/1419/001	Solution for infusion	-Treprostnil sodium
Trepulmix	Scipharm S.à.r.l.	EU/1/19/1419/002	Solution for infusion	-Treprostnil sodium
Trepulmix	Scipharm S.à.r.l.	EU/1/19/1419/003	Solution for infusion	-Treprostnil sodium
Trepulmix	Scipharm S.à.r.l.	EU/1/19/1419/004	Solution for infusion	-Treprostnil sodium
Tresiba	Novo Nordisk A/S	EU/1/12/807/1,4,5,7,8	Solution for injection	-Insulin degludec (ideg)
Tresiba	Novo Nordisk A/S	EU/1/12/807/9,12,13,15	Solution for injection in pre-filled pen	-Insulin degludec (ideg)
TREVICTA	Janssen-Cilag International NV	EU/1/14/971/007	Prolonged-release suspension for injection	-Paliperidone palmitate (r092670)
TREVICTA	Janssen-Cilag International NV	EU/1/14/971/008	Prolonged-release suspension for injection	-Paliperidone palmitate (r092670)
TREVICTA	Janssen-Cilag International NV	EU/1/14/971/009	Prolonged-release suspension for injection	-Paliperidone palmitate (r092670)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
TREVICTA	Janssen-Cilag International NV	EU/1/14/971/010	Prolonged-release suspension for injection	-Paliperidone palmitate (r092670)
Triapin 2.5mg/2.5mg prolonged release tablet	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/082/001	Prolonged-release tablet	-Felodipine -Ramipril
Triapin 5 mg/5 mg prolonged release tablets	IMED Healthcare Ltd.	PPA1463/098/001	Prolonged-release tablet	-Felodipine -Ramipril
Triapin 5 mg/5 mg, prolonged release tablets	Merit Pharmaceuticals Limited	PPA23080/015/001	Prolonged-release tablet	-Felodipine -Ramipril
Triapin 5mg/5mg prolonged release tablet	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/082/002	Prolonged-release tablet	-Felodipine -Ramipril
Triaxis, suspension for injection in a pre-filled syringe Diphtheria, Tetanus, Pertussis (acellular component) Vaccine (adsorbed, reduced antigen(s) content)	Sanofi Pasteur	PA2131/010/002	Suspension for injection in pre-filled syringe	-Diphtheria toxoid -Tetanus toxoid -Pertussis toxoid -Filamentous haemagglutinin -Pertactin (prn) -Fimbriae types 2 and 3
Trientine 167 mg hard capsules	Tillomed Pharma GmbH	PA22720/010/001	Capsule, hard	-TRIENTINE DIHYDROCHLORIDE
Trileptal 150 mg Film-coated tablets	Novartis Ireland Limited	PA0896/033/001	Film-coated tablet	-Oxcarbazepine
Trileptal 300 mg Film-coated tablets	Novartis Ireland Limited	PA0896/033/002	Film-coated tablet	-Oxcarbazepine
Trileptal 300 mg film-coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/018/002	Film-coated tablet	-Oxcarbazepine
Trileptal 300 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/154/002	Film-coated tablet	-Oxcarbazepine
Trileptal 300 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/308/001	Film-coated tablet	-Oxcarbazepine
Trileptal 60 mg/ml Oral Suspension	IMED Healthcare Ltd.	PPA1463/154/001	Oral suspension	-Oxcarbazepine
Trileptal 60 mg/ml Oral Suspension	Originalis B.V.	PPA2306/004/001	Oral suspension	-Oxcarbazepine
Trileptal 60 mg/ml Oral Suspension	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/018/001	Oral suspension	-Oxcarbazepine
Trileptal 60 mg/ml Oral Suspension	Novartis Ireland Limited	PA0896/033/004	Oral suspension	-Oxcarbazepine
Trileptal 60 mg/ml oral suspension.	PCO Manufacturing Ltd.	PPA0465/308/003	Oral suspension	-Oxcarbazepine
Trileptal 600 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/308/002	Film-coated tablet	-Oxcarbazepine
Trileptal 600 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/154/003	Film-coated tablet	-Oxcarbazepine
Trileptal 600 mg Film-coated tablets	Novartis Ireland Limited	PA0896/033/003	Film-coated tablet	-Oxcarbazepine
Trimbow	Chiesi Farmaceutici S.p.A.	EU/1/17/1208/001-003	Pressurised inhalation, solution	-Beclometasone dipropionate anhydrous -Formoterol fumarate dihydrate -Glycopyrronium bromide
Trimbow	Chiesi Farmaceutici S.p.A.	EU/1/17/1208/004	Pressurised inhalation, solution	-Glycopyrronium bromide -Formoterol fumarate dihydrate -Beclometasone dipropionate anhydrous

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Trimbow	Chiesi Farmaceutici S.p.A.	EU/1/17/1208/005	Pressurised inhalation, solution	-Beclometasone dipropionate anhydrous -Glycopyrronium bromide -Formoterol fumarate dihydrate
Trimbow	Chiesi Farmaceutici S.p.A.	EU/1/17/1208/006-009	Pressurised inhalation, solution	-Beclometasone dipropionate -Formoterol fumarate dihydrate -Glycopyrronium bromide
Trimbow	Chiesi Farmaceutici S.p.A.	EU/1/17/1208/010-012	Inhalation powder	-Beclometasone dipropionate -Formoterol fumarate dihydrate -GLYCOPYRRONIUM -Glycopyrronium bromide
Trimega 1000 mg Capsules	Clonmel Healthcare Ltd	PA0126/236/001	Capsule, soft	-Omega-3-acid ethyl esters 90
Trimethoprim 10mg/ml Oral Suspension	Athlone Pharmaceuticals Limited	PA1418/005/001	Oral suspension	-Trimethoprim
Tri-Minulet Coated* Tablets	Pfizer Healthcare Ireland	PA0822/099/001	Coated tablet	-Ethinylestradiol -Gestodene -Ethinylestradiol -Gestodene -Ethinylestradiol -Gestodene
Trimoptin Tablets 100 mg	Athlone Pharmaceuticals Limited	PA1418/008/001	Tablet	-Trimethoprim
Trimoptin Tablets 200 mg	Athlone Pharmaceuticals Limited	PA1418/008/002	Tablet	-Trimethoprim
Trinomia 100 mg/20 mg/10 mg hard capsules	Ferrer Internacional, S.A	PA1744/002/003	Capsule, hard	-Acetylsalicylic acid -Atorvastatin -Ramipril
Trinomia 100 mg/20 mg/2.5 mg hard capsules	Ferrer Internacional, S.A	PA1744/002/001	Capsule, hard	-Acetylsalicylic acid -Atorvastatin -Ramipril
Trinomia 100 mg/20 mg/5 mg hard capsules	Ferrer Internacional, S.A	PA1744/002/002	Capsule, hard	-Acetylsalicylic acid -Atorvastatin -Ramipril
Trinomia 100 mg/40 mg/10 mg hard capsules	Ferrer Internacional, S.A	PA1744/002/006	Capsule, hard	-Acetylsalicylic acid -Ramipril -Atorvastatin
Trinomia 100 mg/40 mg/2.5 mg hard capsules	Ferrer Internacional, S.A	PA1744/002/004	Capsule, hard	-Acetylsalicylic acid -Ramipril -Atorvastatin
Trinomia 100 mg/40 mg/5 mg hard capsules	Ferrer Internacional, S.A	PA1744/002/005	Capsule, hard	-Acetylsalicylic acid -Ramipril -Atorvastatin
Trinordiol Tablets	Pfizer Healthcare Ireland	PA0822/100/001	Coated tablet	-Levonorgestrel -Ethinylestradiol -Levonorgestrel -Ethinylestradiol -Levonorgestrel -Ethinylestradiol

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
TRIOMEL 12 g/l nitrogen 950 kcal/l with electrolytes, emulsion for infusion	Baxter Holding B.V.	PA2299/043/007	Emulsion for infusion	-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 glycerophosphate hydrate -Glucose monohydrate -Calcium chloride dihydrate -Olive oil, refined -Soya Bean Oil, Refined Ph.Eur
TRIOMEL 12 g/l nitrogen 950 kcal/l, emulsion for infusion	Baxter Holding B.V.	PA2299/043/008	Emulsion for infusion	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Triomel 5g/L nitrogen 990kcal/L with electrolytes, emulsion for infusion	Baxter Holding B.V.	PA2299/029/002	Emulsion for infusion	-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
Triomel 7g/L nitrogen 1140kcal/L emulsion for infusion	Baxter Holding B.V.	PA2299/029/004	Emulsion for infusion	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Triomel 7g/L nitrogen 1140kcal/L with electrolytes emulsion for infusion	Baxter Holding B.V.	PA2299/029/003	Emulsion for infusion	-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
Triomel 9g/L nitrogen 1070kcal/L emulsion for infusion	Baxter Holding B.V.	PA2299/029/006	Emulsion for infusion	-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

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Triomel 9g/L nitrogen 1070kcal/L with electrolytes emulsion for infusion	Baxter Holding B.V.	PA2299/029/005	Emulsion for infusion	-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
Triomel Peripheral 4g/L nitrogen 700kcal/L with electrolytes emulsion for infusion	Baxter Holding B.V.	PA2299/029/001	Emulsion for infusion	-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
Triregol coated tablets	Gedeon Richter Plc	PA1330/016/001	Coated tablet	-Ethinylloestradiol -Levonorgestrel -Levonorgestrel -Ethinylestradiol -Levonorgestrel -Ethinylestradiol
Trisenox	Teva B.V.	EU/1/02/204/001	Concentrate for solution for infusion	-Arsenic trioxide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Trisenox	Teva B.V.	EU/1/02/204/002	Concentrate for solution for infusion	-Arsenic trioxide
Trisequens film-coated tablets	Novo Nordisk A/S	PA0218/008/001	Film-coated tablet	-Estradiol -Estradiol -Norethisterone acetate -Estradiol
TRITACE 1.25 mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/084/005	Tablet	-Ramipril
Tritace 10 mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/084/008	Tablet	-Ramipril
Tritace 2.5 mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/084/006	Tablet	-Ramipril
Tritace 5 mg Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/084/007	Tablet	-Ramipril
TRIUMEQ	ViiV Healthcare BV	EU/1/14/940/001-002	Film-coated tablet	-Dolutegravir -Abacavir -Lamivudine
Triumeq	ViiV Healthcare BV	EU/1/14/940/001-003	Film-coated tablet	-Dolutegravir sodium -Lamivudine -Abacavir sulfate
Trixeo Aerosphere	AstraZeneca AB	EU/1/20/1498/002-003	Pressurised inhalation, suspension	-Budesonide micronised -Glycopyrronium bromide -Formoterol fumarate dihydrate (micronised)
Trizivir	ViiV Healthcare BV	EU/1/00/156/001	Film-coated tablet	-Lamivudine -Abacavir sulfate -Zidovudine
Trizivir	ViiV Healthcare BV	EU/1/00/156/002	Film-coated tablet	-Abacavir sulfate -Zidovudine -Lamivudine
Trizivir	ViiV Healthcare BV	EU/1/00/156/003-4	Film-coated tablet	-Abacavir sulfate -Zidovudine -Lamivudine
Trodelyv	Gilead Sciences Ireland UC	EU/1/21/1592/001	Powder for concentrate for solution for infusion	-Sacituzumab Govitecan
Tropex 5% w/v Ear Drops Solution	Rowa Pharmaceuticals Limited	PA0074/002/001	Ear drops, solution	-Phenazone
Trosyl 283 mg/ml Nail Solution	Pfizer Healthcare Ireland	PA0822/197/001	Cutaneous solution	-Tioconazole
Trosyl 283 mg/ml Nail Solution	IMED Healthcare Ltd.	PPA1463/169/001	Cutaneous solution	-Tioconazole
Trosyl 283 mg/ml Nail Solution	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/030/001	Cutaneous solution	-Tioconazole
Trosyl 283 mg/ml Nail Solution	PCO Manufacturing Ltd.	PPA0465/247/001	Cutaneous solution	-Tioconazole
Trulicity	Eli Lilly Nederland B.V.	EU/1/14/956/001-005	Solution for injection	-Dulaglutide
Trulicity	Eli Lilly Nederland B.V.	EU/1/14/956/006-010	Solution for injection	-Dulaglutide
Trulicity	Eli Lilly Nederland B.V.	EU/1/14/956/011-0013	Solution for injection in pre-filled pen	-Dulaglutide
Trumenba	Pfizer Europe MA EEIG	EU/1/17/1187/001-006	Suspension for injection in pre-filled syringe	-Neisseria meningitidis serogroup b recombinant lipoprotein (rlp2086; sub family a) -Neisseria meningitidis serogroup b recombinant lipoprotein (rlp2086; sub family b)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Truoxin I.V. 200mg/100ml solution for infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/002/001	Solution for infusion	-Ciprofloxacin
Truoxin I.V. 400 mg/200 ml solution for infusion	Hikma Farmacêutica (Portugal) S.A.	PA1217/002/002	Solution for infusion	-Ciprofloxacin
Trusitev SR 2 mg Prolonged-release Capsules, hard	Teva Pharma B.V.	PA0749/191/001	Prolonged-release capsule, hard	-Tolterodine tartrate
Trusitev SR 4 mg Prolonged-release Capsules, hard	Teva Pharma B.V.	PA0749/191/002	Prolonged-release capsule, hard	-Tolterodine tartrate
TRUSOPT 20 mg/ml eye drops, solution	Santen OY	PA0879/004/001	Eye drops, solution	-Dorzolamide hydrochloride
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	-Dorzolamide
Truvada 200 mg/245 mg film-coated tablets	Gilead Sciences Ireland UC	EU/1/04/305/001-002	Film-coated tablet	-Emtricitabine -Tenofovir disoproxil
Truvelog Mix 30	Sanofi Winthrop Industrie	EU/1/22/1639/001-005	Suspension for injectio	-Insulin aspart
Truxima	Celltrion Healthcare Hungary Kft.	EU/1/16/1167/001	Concentrate for solution for infusion	-Rituximab
Truxima	Celltrion Healthcare Hungary Kft.	EU/1/16/1167/002	Concentrate for solution for infusion	
Trydonis	Chiesi Farmaceutici S.p.A.	EU/1/18/1274/001-005	Pressurised inhalation, solution	-Beclometasone dipropionate -Formoterol fumarate dihydrate -GLYCOPYRRONIUM
Trydonis	Chiesi Farmaceutici S.p.A.	EU/1/18/1274/006-008	Inhalation powder	-Beclometasone dipropionate -Formoterol fumarate dihydrate -Glycopyrronium bromide
Tuberculin PPD RT23 AJV 2 T.U./0.1 mL, solution for injection	AJ Vaccines A/S	PA2160/004/001	Solution for injection	-Tuberculin ppd
Tukysa	Seagen Netherlands B.V.	EU/1/20/1526/001	Film-coated tablet	-Tucatinib
Tukysa	Seagen Netherlands B.V.	EU/1/20/1526/002	Film-coated tablet	-Tucatinib
TUXERDIV 1.5 mg film- coated tablets	Adamed Pharma S.A.	PA23514/001/001	Film-coated tablet	-Cytisinicline
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/001	Suspension for injection in pre-filled syringe	-Hepatitis a vaccine -Hepatitis b surface antigen, recominant
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/002	Suspension for injection in pre-filled syringe	-Hepatitis a vaccine -Hepatitis b surface antigen, recominant
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/003	Suspension for injection in pre-filled syringe	-Hepatitis a vaccine -Hepatitis b surface antigen, recominant
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/004	Suspension for injectio	-Hepatitis a vaccine -Hepatitis b surface antigen, recominant
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/005	Suspension for injectio	-Hepatitis a vaccine -Hepatitis b surface antigen, recominant
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/006	Suspension for injectio	-Hepatitis a vaccine -Hepatitis b surface antigen, recominant

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/007	Suspension for injection in pre-filled syringe	-Hepatitis a vaccine -Hepatitis b surface antigen, recominant
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/008	Suspension for injection in pre-filled syringe	-Hepatitis a vaccine -Hepatitis b surface antigen, recominant
Twinrix Adult	SmithKline Beecham Biologicals	EU/1/96/020/009	Suspension for injection in pre-filled syringe	-Hepatitis a vaccine -Hepatitis b surface antigen, recominant
Twinrix Paediatric	SmithKline Beecham Biologicals	EU/1/97/029/001	Suspension for injection in pre-filled syringe	-Hepatitis b surface antigen, recominant -Hepatitis a vaccine
Twinrix Paediatric	SmithKline Beecham Biologicals	EU/1/97/029/002	Suspension for injection in pre-filled syringe	-Hepatitis b surface antigen, recominant -Hepatitis a vaccine
Twinrix Paediatric	SmithKline Beecham Biologicals	EU/1/97/029/003	Suspension for injection in pre-filled syringe	-Hepatitis b surface antigen, recominant -Hepatitis a vaccine
Twinrix Paediatric	SmithKline Beecham Biologicals	EU/1/97/029/004	Suspension for injection in pre-filled syringe	-Hepatitis b surface antigen, recominant -Hepatitis a vaccine
Twinrix Paediatric	SmithKline Beecham Biologicals	EU/1/97/029/005	Suspension for injection in pre-filled syringe	-Hepatitis b surface antigen, recominant -Hepatitis a vaccine
Twinrix Paediatric	SmithKline Beecham Biologicals	EU/1/97/029/006	Suspension for injection in pre-filled syringe	-Hepatitis b surface antigen, recominant -Hepatitis a vaccine
Twinrix Paediatric	SmithKline Beecham Biologicals	EU/1/97/029/007	Suspension for injection in pre-filled syringe	-Hepatitis b surface antigen, recominant -Hepatitis a vaccine
Twynsta	Boehringer Ingelheim International GmbH	EU/1/10/648/001-007	Tablet	-Telmisartan -Amlodipine besilate
Twynsta	Boehringer Ingelheim International GmbH	EU/1/10/648/008-014	Tablet	-Amlodipine besilate -Telmisartan
Twynsta	Boehringer Ingelheim International GmbH	EU/1/10/648/015-021	Tablet	-Telmisartan -Amlodipine besilate
Twynsta	Boehringer Ingelheim International GmbH	EU/1/10/648/022-028	Tablet	-Telmisartan -Amlodipine besilate
Tybost	Gilead Sciences Ireland UC	EU/1/13/872/001-002	Film-coated tablet	-Cobicistat on silicon dioxide
Tyedra 1500 micrograms tablet	Laboratorios Leon Farma, S.A.	PA1474/013/001	Tablet	-Levonorgestrel micronized
Tyenne	Fresenius Kabi Deutschland GmbH	EU/1/23/1754/001-006	Concentrate for solution for infusion	-Tocilizumab
Tyenne	Fresenius Kabi Deutschland GmbH	EU/1/23/1754/007-009	Solution for injection in pre-filled syringe	-Tocilizumab
Tyenne	Fresenius Kabi Deutschland GmbH	EU/1/23/1754/010-012	Solution for injection in pre-filled pen	-Tocilizumab
Tygacil	Pfizer Europe MA EEIG	EU/1/06/336/01	Powder for solution for infusion	-Tigecycline
Tylox 30 mg / 500 mg Hard Capsules	UCB (Pharma) Ireland Limited	PA0891/014/001	Capsule, hard	-Codeine phosphate hemihydrate -Paracetamol
Tymbrineb 300 mg/5 ml Nebuliser Solution	Teva Pharma B.V.	PA0749/117/001	Nebuliser solution	-Tobramycin
Typhim Vi Solution for Injection Typhoid Polysaccharide Vaccin	Sanofi Pasteur	PA2131/011/001	Solution for injection	-Salmonella typhi, vi antigen
Tyruko	Polpharma Biologics S.A.	EU/1/23/1745/001	Concentrate for solution for infusion	-Natalizumab
Tysabri	Biogen Netherlands B.V.	EU/1/06/346/001	Concentrate for solution for infusion	-Natalizumab
Tysabri	Biogen Netherlands B.V.	EU/1/06/346/002	Solution for injection	-Natalizumab

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Tyvens 20mg Capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/005/001	Capsule, hard	-Lisdexamfetamine dimesylate
Tyvens 30 mg Capsules, Hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/005/002	Capsule, hard	-Lisdexamfetamine dimesylate
Tyvens 40mg Capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/005/003	Capsule, hard	-Lisdexamfetamine dimesylate
Tyvens 50 mg Capsules, Hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/005/004	Capsule, hard	-Lisdexamfetamine dimesylate
Tyvens 60mg Capsules, hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/005/005	Capsule, hard	-Lisdexamfetamine dimesylate
Tyvens 70 mg Capsules, Hard	Takeda Pharmaceuticals International AG Ireland Branch	PA23211/005/006	Capsule, hard	-Lisdexamfetamine dimesylate
Tyverb	Novartis Europharm Limited	EU/1/07/440/1-2	Film-coated tablet	-Lapatinib ditosylate monohydrate
Ucedane	Eurocept International BV	EU/1/17/1202/001-002	Dispersible tablet	-Carglumic acid
Ulipristal Acetate Rowex 30 mg Film-coated Tablets	Rowex Ltd	PA0711/292/001	Film-coated tablet	-Ulipristal acetate
Ultibro Breezhaler	Novartis Europharm Limited	EU/1/13/862/001-006	Inhalation powder, hard capsule	-Indacaterol maleate -Glycopyrronium bromide
Ultiva 1 mg Powder for Concentrate for Solution for Infusion	Aspen Pharma Trading Limited	PA1691/032/001	Powder for concentrate for solution for infusion	-Remifentanil hydrochloride
Ultiva 2 mg Powder for Concentrate for Solution for Infusion	Aspen Pharma Trading Limited	PA1691/032/002	Powder for concentrate for solution for infusion	-Remifentanil hydrochloride
Ultiva 5 mg Powder for Concentrate for Solution for Infusion	Aspen Pharma Trading Limited	PA1691/032/003	Powder for concentrate for solution for infusion	-Remifentanil hydrochloride
Ultomiris	Alexion Europe SAS	EU/1/19/1371/001	Concentrate for solution for infusion	-RAVULIZUMAB
Ultomiris	Alexion Europe S.A.S.	EU/1/19/1371/002	Concentrate for solution for infusion	-RAVULIZUMAB
Ultomiris	Alexion Europe S.A.S.	EU/1/19/1371/003	Concentrate for solution for infusion	-RAVULIZUMAB
Ultomiris	Alexion Europe S.A.S.	EU/1/19/1371/004	Solution for injection	-RAVULIZUMAB
Ultraproct 0.92mg/g + 0.95mg/g + 5mg/g Rectal Ointment	Karo Pharma AB	PA22650/004/001	Rectal ointment	-FLUOCORTOLONE PIVALATE -Fluocortolone caproate -Cinchocaine Hydrochloride
Ultra-TechneKow FM 2.15-43.00 GBq radionuclide generator	Curium Netherlands B.V.	PA0690/017/001	Radionuclide generator	-Sodium Molybdate. ⁹⁹ Mo
Ulunar Breezhaler	Novartis Europharm Limited	EU/1/14/917/001-006	Inhalation powder, hard capsule	-Indacaterol maleate -Glycopyrronium bromide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Uniflu Plus with Vitamin C Tablets	Phoenix Labs	PA1113/006/001	Film-coated tablet + tablet	-Paracetamol -Codeine phosphate hemihydrate -Diphenhydramine hydrochloride -Phenylephrine hydrochloride -Caffeine -Ascorbic acid
Uniflu with Vitamin C Tablets	Phoenix Labs	PA1113/005/001	Film-coated tablet + tablet	-Caffeine -Diphenhydramine hydrochloride -Paracetamol -Phenylephrine hydrochloride -Ascorbic acid
UNIPHYLLIN Continus 200 mg Prolonged-Release Tablets	Ennogen Healthcare (Europe) Limited	PA23369/003/001	Prolonged-release tablet	-Theophylline
UNIPHYLLIN Continus 300 mg Prolonged-Release Tablets	Ennogen Healthcare (Europe) Limited	PA23369/003/002	Prolonged-release tablet	-Theophylline
UNIPHYLLIN Continus 400 mg Prolonged-Release Tablets	Ennogen Healthcare (Europe) Limited	PA23369/003/003	Prolonged-release tablet	-Theophylline
Uplizna	Horizon Therapeutics Ireland Designated Activity Company	EU/1/21/1602/001	Concentrate for solution for infusion	-Inebilizumab
Upstaza	PTC Therapeutics International Limited	EU/1/22/1653/001	Solution for infusion	-Eladocagene Exuparovec
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/001-003	Film-coated tablet	-Selexipag
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/004	Film-coated tablet	-Selexipag
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/005	Film-coated tablet	-Selexipag
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/006	Film-coated tablet	-Selexipag
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/007	Film-coated tablet	-Selexipag
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/008	Film-coated tablet	-Selexipag
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/009	Film-coated tablet	-Selexipag
Uptravi	Janssen-Cilag International NV	EU/1/15/1083/010	Film-coated tablet	-Selexipag
Urispas 200 mg Film-coated Tablets	Recordati Ireland Limited	PA1404/001/001	Film-coated tablet	-Flavoxate hydrochloride
Urografin 30 %w/v Solution for infusion	Bayer Limited	PA1410/012/001	Solution for infusion	-Meglumine -Sodium hydroxide -Sodium amidotrizoate
Uromitexan 100mg/ml Solution for Injection or Infusion	Baxter Holding B.V.	PA2299/024/001	Solution for injection/infusion	-Mesna
Uromitexan Tablets 400mg	Baxter Holding B.V.	PA2299/024/002	Film-coated tablet	-Mesna
Uromitexan Tablets 600mg	Baxter Holding B.V.	PA2299/024/003	Film-coated tablet	-Mesna
Urorec	Recordati Ireland Limited	EU/1/09/608/1-7	Capsule, hard	-Silodosin
Urorec	Recordati Ireland Limited	EU/1/09/608/8-14	Capsule, hard	-Silodosin
Ursodeoxycholic Acid 250 mg capsules, hard	Amdipharm Limited	PA1142/018/001	Capsule, hard	-Ursodeoxycholic acid
Ursodeoxycholic acid Strides 250 mg Hard Capsules	Strides Pharma (Cyprus) Limited	PA22639/001/001	Capsule, hard	-Ursodeoxycholic acid

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Ursofalk 250 mg hard capsules	PCO Manufacturing Ltd.	PPA0465/183/001	Capsule, hard	-Ursodeoxycholic acid
Ursofalk 250 mg Hard Capsules	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/006/001	Capsule, hard	-Ursodeoxycholic acid
Ursofalk 250 mg Hard Capsules	IMED Healthcare Ltd.	PPA1463/144/001	Capsule, hard	-Ursodeoxycholic acid
Ursofalk 250 mg hard capsules	Primecrown 2010 Limited	PPA1633/016/001	Capsule, hard	-Ursodeoxycholic acid
Ursofalk 250 mg/5 ml Suspension	Dr. Falk Pharma GmbH	PA0573/005/002	Oral suspension	-Ursodeoxycholic acid
Ursofalk 500 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/183/002	Film-coated tablet	-Ursodeoxycholic acid
Ursofalk 500mg film-coated tablets	Dr. Falk Pharma GmbH	PA0573/005/003	Film-coated tablet	-Ursodeoxycholic acid
Ursofalk® 250 mg Hard Capsules	Dr. Falk Pharma GmbH	PA0573/005/001	Capsule, hard	-Ursodeoxycholic acid
Ursogrix 250 mg hard capsules	AS Grindeks	PA22992/002/001	Capsule, hard	-Ursodeoxycholic acid
Utrogestan 100 mg capsules, soft	Laboratoires Besins International	PA1054/003/001	Capsule, soft	-Progesterone
Utrogestan Vaginal 200 mg vaginal capsule, soft	Besins Healthcare Ireland Limited	PA22624/001/001	Vaginal capsule, soft	-PROGESTERONE, MICRONISED
Utrogestan Vaginal 300 mg Vaginal Capsules, soft	Besins Healthcare Ireland Limited	PA22624/001/002	Vaginal capsule, soft	-Progesterone
Vaborem	Menarini International Operations Luxembourg S.A.	EU/1/18/1334/001	Powder for concentrate for solution for infusion	-VABORBACTAM -Meropenem -Meropenem Trihydrate
Vabysmo	Roche Registration GmbH	EU/1/22/1683/001	Solution for injection	-Faricimab
Vafseo	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/23/1725/001-002	Film-coated tablet	-Vadadustat
Vafseo	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/23/1725/003-004	Film-coated tablet	-Vadadustat
Vafseo	Medice Arzneimittel Putter GmbH & Co. K.G	EU/1/23/1725/005-006	Film-coated tablet	-Vadadustat
Vagifem 10 micrograms vaginal tablets	Novo Nordisk A/S	PA0218/030/002	Vaginal tablet	-Estradiol
Vagirux 10 microgram vaginal tablets	Gedeon Richter Plc	PA1330/028/001	Vaginal tablet	-Estradiol
Valaciclovir 500 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/102/001	Film-coated tablet	-Valaciclovir
Valaciclovir Bluefish 500 mg film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/005/001	Film-coated tablet	-Valaciclovir
Valaciclovir Teva 500 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/036/001	Film-coated tablet	-Valaciclovir
Valcyte 450 mg film-coated tablets	CHEPLAPHARM Arzneimittel GmbH	PA2239/023/001	Film-coated tablet	-Valganciclovir
Valcyte 50 mg/ml powder for oral solution	CHEPLAPHARM Arzneimittel GmbH	PA2239/023/002	Powder for oral solution	-Valganciclovir hydrochloride
Valdoxan 25 mg film-coated tablets	Les Laboratoires Servier	EU/1/08/499/1-8	Film-coated tablet	-Agomelatine
Valganciclovir Accord 450 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/179/001	Film-coated tablet	-Valganciclovir
Valoid 50 mg Tablets	Amdipharm Limited	PA1142/001/002	Tablet	-CYCLIZINE HYDROCHLORIDE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Valoid 50 mg/ml Solution for Injection	Amdipharm Limited	PA1142/001/001	Solution for injection	-Cyclizine
Valotix 500mg film-coated tablets	Rowex Ltd	PA0711/173/001	Film-coated tablet	-Valaciclovir
Valsartan / Hydrochlorothiazide Teva 160 mg/25 mg Film-coated tablets	Teva Pharma B.V.	PA0749/047/002	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Valsartan / Hydrochlorothiazide Teva 80 mg/12.5 mg Film-coated tablets	Teva Pharma B.V.	PA0749/047/001	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Valsartan 160 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/188/003	Film-coated tablet	-Valsartan
Valsartan 40 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/188/001	Film-coated tablet	-Valsartan
Valsartan 80 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/188/002	Film-coated tablet	-Valsartan
Valsartan Krka 160 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/010/008	Film-coated tablet	-Valsartan
Valsartan Krka 320 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/010/009	Film-coated tablet	-Valsartan
Valsartan Krka 40 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/010/006	Film-coated tablet	-Valsartan
Valsartan Krka 80 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/010/007	Film-coated tablet	-Valsartan
Valsartan Rowa 160 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/083/003	Film-coated tablet	-Valsartan
Valsartan Rowa 320 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/083/004	Film-coated tablet	-Valsartan
Valsartan Rowa 40 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/083/001	Film-coated tablet	-Valsartan
Valsartan Rowa 80 mg film-coated tablets	Rowa Pharmaceuticals Limited	PA0074/083/002	Film-coated tablet	-Valsartan
Valsartan Teva 160 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/084/003	Film-coated tablet	-Valsartan
Valsartan Teva 40 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/084/001	Film-coated tablet	-Valsartan
Valsartan Teva 80 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/084/002	Film-coated tablet	-Valsartan
Valsartan Viatrix 160 mg Film-coated Tablets	Viatrix Limited	PA23266/006/003	Film-coated tablet	-Valsartan
Valsartan Viatrix 320 mg Film-coated Tablets	Viatrix Limited	PA23266/006/004	Film-coated tablet	-Valsartan
Valsartan Viatrix 40 mg Film-coated Tablets	Viatrix Limited	PA23266/006/001	Film-coated tablet	-Valsartan
Valsartan Viatrix 80 mg Film-coated Tablets	Viatrix Limited	PA23266/006/002	Film-coated tablet	-Valsartan
Valsartan/Hydrochlorothiazide 160 mg/ 12.5 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/181/002	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Valsartan/Hydrochlorothiazide 160 mg/ 25 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/181/003	Film-coated tablet	-Valsartan -Hydrochlorothiazide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Valsartan/Hydrochlorot hiazide 80 mg/ 12.5 mg Film-coated Tablets	Accord Healthcare Ireland Ltd.	PA2315/181/001	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Valsartan/hydrochlorot hiazide Krka 160 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/004/002	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Valsartan/hydrochlorot hiazide Krka 160 mg/25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/004/003	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Valsartan/hydrochlorot hiazide Krka 320 mg/12.5 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/004/004	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Valsartan/hydrochlorot hiazide Krka 320 mg/25 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/004/005	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Valsartan/hydrochlorot hiazide Krka 80 mg/12.5 mg Film- coated Tablets	KRKA, d.d., Novo mesto	PA1347/004/001	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Valsartan/Hydrochlorot hiazide Teva 160 mg/12.5 mg Film- coated Tablets	Teva Pharma B.V.	PA0749/047/003	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Valsol plus 160 mg/25 mg film-coated tablets	Laboratorios LICONSA, S.A.	PA1239/007/003	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Valsol plus 80 mg/12.5 mg film-coated tablets	Laboratorios LICONSA, S.A.	PA1239/007/001	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Valtan 160 mg film- coated tablets	Clonmel Healthcare Ltd	PA0126/211/003	Film-coated tablet	-Valsartan
Valtan 40 mg film- coated tablets	Clonmel Healthcare Ltd	PA0126/211/001	Film-coated tablet	-Valsartan
Valtan 80 mg film- coated tablets	Clonmel Healthcare Ltd	PA0126/211/002	Film-coated tablet	-Valsartan
Valtan Comp 80mg/12.5mg Film- coated tablets	Clonmel Healthcare Ltd	PA0126/216/001	Film-coated tablet	-Valsartan -Hydrochlorothiazide
Valtrex 250 mg Film- Coated Tablets	GlaxoSmithKline (Ireland) Limited	PA1077/082/001	Film-coated tablet	-Valaciclovir
Valtrex 500 mg Film- coated tablets	IMED Healthcare Ltd.	PPA1463/173/001	Film-coated tablet	-Valaciclovir
Valtrex 500 mg film- coated tablets	PCO Manufacturing Ltd.	PPA0465/459/001	Film-coated tablet	-Valaciclovir
Valtrex 500 mg film- coated tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/026/001	Film-coated tablet	-Valaciclovir
Valtrex 500mg Film- coated tablets	GlaxoSmithKline (Ireland) Limited	PA1077/082/002	Film-coated tablet	-Valaciclovir

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Vaminolact solution for infusion, 100 ml bottle	Fresenius Kabi Deutschland GmbH	PA2059/065/001	Solution for infusion	-Alanine -Arginine -Aspartic Acid -Cysteine -Glutamic acid -Glycine -Histidine -Isoleucine -Leucine -Lysine -Methionine -Phenylalanine -Proline -Serine -Threonine -Tryptophan -Tyrosine -Valine -Taurine
Vaminolact solution for infusion, 500 ml bottle	Fresenius Kabi Deutschland GmbH	PA2059/065/002	Solution for infusion	-Alanine -Arginine -Cysteine -Glutamic acid -Glycine -Histidine -Isoleucine -Leucine -Lysine -Methionine -Phenylalanine -Proline -Serine -Threonine -Tryptophan -Tyrosine -Valine -Taurine
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	-Vancomycin
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	-Vancomycin
Vancocin Matrigel 125mg Hard Capsules	Flynn Pharma Limited	PA1226/005/001	Capsule, hard	-VANCOMYCIN HYDROCHLORIDE
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	-VANCOMYCIN HYDROCHLORIDE
Vancomycin 1000 mg powder for concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/066/002	Powder for concentrate for solution for infusion	-VANCOMYCIN HYDROCHLORIDE
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	-VANCOMYCIN HYDROCHLORIDE
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	-VANCOMYCIN HYDROCHLORIDE

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-VANCOMYCIN HYDROCHLORIDE
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	-VANCOMYCIN HYDROCHLORIDE
Vancomycin 500 mg powder for concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/066/001	Powder for concentrate for solution for infusion	-VANCOMYCIN HYDROCHLORIDE
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	-VANCOMYCIN HYDROCHLORIDE
Vancomycin Viatrix 1000 mg, powder for solution for infusion	Viatrix Limited	PA23266/004/002	Powder for solution for infusion	-Vancomycin
Vancomycin Viatrix 500 mg, powder for solution for infusion	Viatrix Limited	PA23266/004/001	Powder for solution for infusion	-Vancomycin
Vanflyta	Daiichi Sankyo Europe GmbH	EU/1/23/1768/001-002	Film-coated tablet	-QUIZARTINIB DIHYDROCHLORIDE
Vanflyta	Daiichi Sankyo Europe GmbH	EU/1/23/1768/003-005	Film-coated tablet	-QUIZARTINIB DIHYDROCHLORIDE
Vaniqa 11.5%	Almirall, S.A.	EU/1/01/173/001	Cream	-Eflornithine
Vaniqa 11.5%	Almirall, S.A.	EU/1/01/173/002	Cream	-Eflornithine
Vaniqa 11.5%	Almirall, S.A.	EU/1/01/173/003	Cream	-Eflornithine
VANTAVO 70 mg/2800 IU tablets	N.V. Organon	EU/1/09/572/001-005	Tablet	-Alendronic acid -Vitamin D3
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	-Strain cr 326f hepatitis a virus, inactivated 50 u
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	-Strain cr 326f hepatitis a virus, inactivated 50 u
Vardenafil Accord 10 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/123/002	Film-coated tablet	-VARDENAFIL HYDROCHLORIDE TRIHYDRATE
Vardenafil Accord 20 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/123/003	Film-coated tablet	-Vardenafil
Vardenafil Accord 5 mg film-coated tablets	Accord Healthcare Ireland Ltd.	PA2315/123/001	Film-coated tablet	-Vardenafil
Vardenafil Chanelle 10 mg Orodispersible Tablets	Chanelle Medical Unlimited Company	PA0688/051/001	Orodispersible tablet	-VARDENAFIL HYDROCHLORIDE TRIHYDRATE
Vardenafil Krka 10 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/073/002	Film-coated tablet	-VARDENAFIL HYDROCHLORIDE TRIHYDRATE
Vardenafil Krka 20 mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/073/003	Film-coated tablet	-VARDENAFIL HYDROCHLORIDE TRIHYDRATE
Vardenafil Krka 5mg film-coated tablets	KRKA, d.d., Novo mesto	PA1347/073/001	Film-coated tablet	-VARDENAFIL HYDROCHLORIDE TRIHYDRATE
Vargatef	Boehringer Ingelheim International GmbH	EU/1/14/954/001-003	Capsule, soft	-Nintedanib

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Vargatef	Boehringer Ingelheim International GmbH	EU/1/14/954/004	Capsule, soft	-Nintedanib
VARIVAX powder and solvent for suspension for injection in a pre-filled syringe Varicella Vaccine (live)	Merck Sharp & Dohme Ireland (Human Health) Limited	PA1286/057/001	Powder and solvent for suspension for injection	-Varicella virus (oka strain) live attenuated
Vastarel 20 mg Film-coated Tablets	Les Laboratoires Servier	PA0568/033/001	Film-coated tablet	-Trimetazidine dihydrochloride
Vatan 160 mg Film-coated Tablets	Rowex Ltd	PA0711/183/003	Film-coated tablet	-Valsartan
Vatan 40 mg Film-coated Tablets	Rowex Ltd	PA0711/183/001	Film-coated tablet	-Valsartan
Vatan 80 mg Film-coated Tablets	Rowex Ltd	PA0711/183/002	Film-coated tablet	-Valsartan
Vaxchora	Bavarian Nordic A/S	EU/1/20/1423/001	Effervescent powder and suspension for oral suspension	-V.Chloerae CVD 103-HGR
Vaxelis	MCM Vaccine B.V.	EU/1/15/1079/001-007	Suspension for injectio	-Diphtheria toxoid adsorbed -Tetanus toxoid adsorbed

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Vaxneuvance	Merck Sharp & Dohme BV,	EU/1/21/1591/001-006	Solution for injection in pre-filled syringe	-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
Supply through pharmacy only.				Page 402 of 429

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Vaxzevria	AstraZeneca AB	EU/1/21/1529/001-002	Suspension for injectio	-Chimpanzee Adenovirus encoding the SARS-CoV 2-Spike glycoprotein (ChAdOx1-S)
Vazkepa	Amarin Pharmaceuticals Ireland Limited	EU/1/20/1524/001-002	Capsule, soft	-Icosapent ethyl
Vectavir Cold Sore Cream	Chefaro Ireland DAC	PA1186/020/001	Cream	-Penciclovir
Vectibix	Amgen Europe B.V.	EU/1/07/423/001-003	Concentrate for solution for infusion	-Panitumumab
Vedixal 37.5mg Tablets	Rowex Ltd	PA0711/161/002	Tablet	-Venlafaxine
Vedixal 75mg Tablets	Rowex Ltd	PA0711/161/004	Tablet	-Venlafaxine
Vedixal XL 150mg Prolonged release capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/016/002	Prolonged-release capsule, hard	-Venlafaxine hydrochloride
Vedixal XL 75 mg prolonged release capsules, hard	Aurobindo Pharma (Malta) Limited	PA1445/016/001	Prolonged-release capsule, hard	-Venlafaxine hydrochloride
Vedrop	Recordati Rare Diseases	EU/1/09/533/1-3	Oral solution	-Tocofersolan d-alpha tocopheryl polyethylene glycol 1000 succinate
Veganin Plus Tablets	Chefaro Ireland DAC	PA1186/006/001	Film-coated tablet	-Paracetamol -Caffeine -Codeine phosphate hemihydrate
Vegzelma	Celltrion Healthcare Hungary Kft.	EU/1/22/1667/001-004	Concentrate for solution for infusion	-Bevacizumab
Veklury	Gilead Sciences Ireland UC	EU/1/20/1459/001-002	Powder for concentrate for solution for infusion	-Remdesivir
VELCADE	Janssen-Cilag International NV	EU/1/04/274/001	Powder for solution for injection	-Bortezomib
Velcade	Janssen-Cilag International NV	EU/1/04/274/002	Powder for solution for injection	-Ps-341 as boronic acid (bortezomib)
Veletri 0.5 Milligram Powder for Solution for Infusion	Janssen-Cilag International NV	PA0885/001/001	Powder for solution for infusion	-Epoprostenol
Veletri 1.5 Milligram Powder for Solution for Infusion	Janssen-Cilag International NV	PA0885/001/002	Powder for solution for infusion	-Epoprostenol
Velmetia	Merck Sharp & Dohme BV,	EU/1/08/456/1-7	Film-coated tablet	-Sitagliptin phosphate -Metformin Hydrochloride
Velmetia	Merck Sharp & Dohme BV	EU/1/08/456/8-14	Film-coated tablet	-Sitagliptin phosphate -Metformin Hydrochloride
Velphoro	Vifor Fresenius Medical Care Renal Pharma France	EU/1/14/943/005	Oral powder in sachet	-Sucroferric Oxyhydroxide
Velphoro	Vifor Fresenius Medical Care Renal Pharma France	EU/1/14/943/001-004	Chewable tablet	-Mixture of iron(iii)-oxyhydroxide, sucrose, starches
Velsipity	Pfizer Europe MA EEIG	EU/1/23/1790/001-003	Film-coated tablet	-Etrasimod arginine
Veltassa	Vifor Fresenius Medical Care Renal Pharma France	EU/1/17/1179/001-003	Powder for oral suspension	-Patiomer sorbitex calcium
Veltassa	Vifor Fresenius Medical Care Renal Pharma France	EU/1/17/1179/004-006	Powder for oral suspension	-Patiomer sorbitex calcium
Veltassa	Vifor Fresenius Medical Care Renal Pharma France	EU/1/17/1179/007-008	Powder for oral suspension	-Patiomer sorbitex calcium

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Veltassa	Vifor Fresenius Medical Care Renal Pharma France	EU/1/17/1179/011	Powder for oral suspension	-Patiromer sorbitex calcium
Vemlidy (formerly Tenofovir alafenamide)	Gilead Sciences Ireland UC	EU/1/16/1154/001-002	Film-coated tablet	-Tenofovir alafenamide
Venclyxto	AbbVie Deutschland GmbH & Co. KG	EU/1/16/1138/001-002	Film-coated tablet	-Venetoclax
Venclyxto	AbbVie Deutschland GmbH & Co. KG	EU/1/16/1138/003-004	Film-coated tablet	-Venetoclax
Venclyxto	AbbVie Deutschland GmbH & Co. KG	EU/1/16/1138/005-007	Film-coated tablet	-Venetoclax
Venex XL 150 mg Prolonged-release Capsules, hard	Clonmel Healthcare Ltd	PA0126/285/003	Prolonged-release capsule, hard	-Venlafaxine
Venex XL 37.5 mg Prolonged-release Capsules, hard	Clonmel Healthcare Ltd	PA0126/285/001	Prolonged-release capsule, hard	-Venlafaxine
Venex XL 75 mg prolonged-release capsules, hard	Clonmel Healthcare Ltd	PA0126/285/002	Prolonged-release capsule, hard	-Venlafaxine
Venlablue XL 150mg Prolonged Release Capsules, Hard	Bluefish Pharmaceuticals AB	PA1436/006/002	Prolonged-release capsule, hard	-Venlafaxine hydrochloride
Venlablue XL 75 mg prolonged-release capsules, hard	Bluefish Pharmaceuticals AB	PA1436/006/001	Prolonged-release capsule, hard	-Venlafaxine hydrochloride
Venlafex XL 150 mg prolonged-release capsules, hard	KRKA, d.d., Novo mesto	PA1347/036/003	Prolonged-release capsule, hard	-Venlafaxine hydrochloride
Venlafex XL 37.5 mg prolonged-release capsules, hard	KRKA, d.d., Novo mesto	PA1347/036/001	Prolonged-release capsule, hard	-Venlafaxine hydrochloride
Venlafex XL 75 mg prolonged-release capsules, hard	KRKA, d.d., Novo mesto	PA1347/036/002	Prolonged-release capsule, hard	-Venlafaxine hydrochloride
Venlatev 150 mg hard prolonged-release capsules	Teva B.V.	PA1986/099/003	Prolonged-release capsule, hard	-Venlafaxine
Venlatev 37.5 mg hard prolonged-release capsules	Teva B.V.	PA1986/099/001	Prolonged-release capsule, hard	-Venlafaxine
Venlatev 75 mg hard prolonged-release capsules	Teva B.V.	PA1986/099/002	Prolonged-release capsule, hard	-Venlafaxine
Venlofex 150 mg prolonged-release hard capsules	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/100/002	Prolonged-release capsule, hard	-Venlafaxine hydrochloride
Venlofex 75 mg prolonged-release hard capsules	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/100/001	Prolonged-release capsule, hard	-Venlafaxine hydrochloride
Venofer 20 mg iron/mL solution for injection or concentrate for solution for infusion, ampoule	Vifor France	PA0949/001/001	Solution for injection/infusion	-IRON (III)
Venofer 20 mg iron/mL solution for injection or concentrate for solution for infusion, vial	Vifor France	PA0949/001/002	Solution for injection/infusion	-Iron (iii) - hydroxide sucrose complex
Vensir XL 150 mg prolonged-release hard capsules	Morningside Healthcare (Malta) Limited	PA23142/002/002	Prolonged-release capsule, hard	-Venlafaxine hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Vensir XL 75 mg prolonged-release hard capsules	Morningside Healthcare (Malta) Limited	PA23142/002/001	Prolonged-release capsule, hard	-Venlafaxine hydrochloride
Ventavis	Bayer Pharma AG	EU/1/03/255/009-010,012	Nebuliser solution	-Iloprost trometanol
Ventavis	Bayer AG	EU/1/03/255/1-3	Nebuliser solution	-Iloprost trometanol
Ventizolve 1.26 mg nasal spray, solution in single-dose container	DNE Pharma AS	PA22993/001/001	Nasal spray, solution in single-dose container	-Naloxone
Ventolin 1mg/ml Concentrate for Solution for Intravenous Infusion	GlaxoSmithKline (Ireland) Limited	PA1077/049/002	Concentrate for solution for infusion	-Salbutamol
Ventolin 2mg/5ml Oral Solution	GlaxoSmithKline (Ireland) Limited	PA1077/049/012	Oral solution	-SALBUTAMOL SULFATE
Ventolin 500 micrograms/ml Solution for Injection	GlaxoSmithKline (Ireland) Limited	PA1077/049/001	Solution for injection	-Salbutamol
Ventolin Diskus 200 micrograms Inhalation Powder, pre-dispensed	GlaxoSmithKline (Ireland) Limited	PA1077/049/011	Inhalation powder, pre-dispensed	-Salbutamol
Ventolin Evohaler 100 micrograms pressurised inhalation, suspension	GlaxoSmithKline (Ireland) Limited	PA1077/049/010	Pressurised inhalation, suspension	-Salbutamol
Ventolin Evohaler 100 micrograms Pressurised Inhalation, Suspension	PCO Manufacturing Ltd.	PPA0465/064/001	Pressurised inhalation, suspension	-Salbutamol
VEPESID 100 mg capsule, soft	CHEPLAPHARM Arzneimittel GmbH	PA2239/006/002	Capsule, soft	-Etoposide
VEPESID 50 mg capsule, soft	CHEPLAPHARM Arzneimittel GmbH	PA2239/006/001	Capsule, soft	-Etoposide
Verap 120mg Prolonged Release Tablets	Rowex Ltd	PA0711/016/004	Prolonged-release tablet	-Verapamil hydrochloride
Verap 240mg prolonged release tablets	Rowex Ltd	PA0711/016/005	Prolonged-release tablet	-Verapamil hydrochloride
VeraSeal	Instituto Grifols S.A.	EU/1/17/1239/001-002	Solution for sealant	-Human fibrinogen
VeraSeal	Instituto Grifols S.A.	EU/1/17/1239/003-004	Solution for sealant	-Human fibrinogen
Verdye 5 mg/ml powder for solution for injection	Diagnostic Green Limited	PA23409/001/001	Powder for solution for injection	-Indocyanine green
Verkazia	Santen OY	EU/1/17/1219/001-004	Eye drops, emulsion	-Ciclosporin
Vermox 100 mg tablets	Johnson & Johnson (Ireland) Limited	PA0330/046/002	Tablet	-Mebendazole
Vermox 100 mg Tablet	PCO Manufacturing Ltd.	PPA0465/440/001	Tablet	-Mebendazole
Vermox 100mg/5ml Oral Suspension	JNTL Consumer Health I (Ireland) Limited	PA23490/026/001	Oral suspension	-Mebendazole
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	-Rabies virus (inactivated) strain wistar (PM/WI 38-1503-3M)
Verquvo	Bayer AG	EU/1/21/1561/001-011	Film-coated tablet	-Vericiguat
Verquvo	Bayer AG	EU/1/21/1561/012-022	Film-coated tablet	-Vericiguat
Verquvo	Bayer AG	EU/1/21/1561/023-025	Film-coated tablet	-Vericiguat
Versatis 700 mg medicated plaster	PCO Manufacturing Ltd.	PPA0465/299/001	Medicated plaster	-Lidocaine
Versatis 700 mg medicated plaster	Merit Pharmaceuticals Limited	PPA23080/013/001	Medicated plaster	-Lidocaine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Versatis 700 mg medicated plaster	IMED Healthcare Ltd.	PPA1463/135/001	Medicated plaster	-Lidocaine
Versatis 700 mg medicated plaster	Grunenthal Pharma Ltd	PA2242/007/001	Medicated plaster	-Lidocaine
Vertigon 16 mg tablets	Aurobindo Pharma (Malta) Limited	PA1445/023/002	Tablet	-Betahistine dihydrochloride
Vertigon 8 mg tablets	Aurobindo Pharma (Malta) Limited	PA1445/023/001	Tablet	-Betahistine dihydrochloride
VERZENIOS	Eli Lilly Nederland B.V.	EU/1/18/1307/001-003	Film-coated tablet	-ABEMACICLIB
VERZENIOS	Eli Lilly Nederland B.V.	EU/1/18/1307/004-006	Film-coated tablet	-ABEMACICLIB
VERZENIOS	Eli Lilly Nederland B.V.	EU/1/18/1307/007-009	Film-coated tablet	-ABEMACICLIB
Vesanoid 10 mg soft capsules	Cheplapharm Arzneimittel GmbH	PA1868/001/001	Capsule, soft	-Tretinoin
Vesitirim 1 mg/ml oral suspension	Astellas Pharma Co. Limited	PA1241/009/003	Oral suspension	-Solifenacin succinate
Vesitirim 10 mg film-coated tablets	Astellas Pharma Co. Limited	PA1241/009/002	Film-coated tablet	-Solifenacin succinate
Vesitirim 10 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/130/002	Film-coated tablet	-Solifenacin succinate
Vesitirim 10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/262/002	Film-coated tablet	-Solifenacin succinate
Vesitirim 5 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/262/001	Film-coated tablet	-Solifenacin succinate
Vesitirim 5 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/130/001	Film-coated tablet	-Solifenacin succinate
Vesitirim 5 mg film-coated tablets	Astellas Pharma Co. Limited	PA1241/009/001	Film-coated tablet	-Solifenacin succinate
Vesomni 6 mg/0.4 mg modified-release tablet	Astellas Pharma Co. Limited	PA1241/016/001	Modified-release tablet	-Solifenacin succinate -Tamsulosin hydrochloride
Vesomni 6 mg/0.4 mg modified-release tablet	PCO Manufacturing Ltd.	PPA0465/452/001	Modified-release tablet	-Solifenacin succinate -Tamsulosin hydrochloride
Vesomni 6 mg/0.4 mg modified-release tablet	IMED Healthcare Ltd.	PPA1463/139/001	Modified-release tablet	-Solifenacin succinate -Tamsulosin hydrochloride
Vesomni 6 mg/0.4 mg modified-release tablet	Merit Pharmaceuticals Limited	PPA23080/033/001	Modified-release tablet	-Solifenacin succinate -Tamsulosin hydrochloride
Vesomni 6 mg/0.4 mg modified-release tablet	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/012/001	Modified-release tablet	-Solifenacin succinate -Tamsulosin hydrochloride
Veyann 0.02 mg/3 mg Film-coated tablets	Theramex Ireland Limited	PA22668/005/001	Film-coated tablet	-Drospirenone -Ethinyl estradiol
VEYVONDI	Baxalta Innovations GmbH	EU/1/18/1298/001	Powder and solvent for solution for injection	-VONICOG ALFA
VEYVONDI	Baxalta Innovations GmbH	EU/1/18/1298/002	Powder and solvent for solution for injection	-VONICOG ALFA
Vfend	Pfizer Europe MA EEIG	EU/1/02/212/001-009	Film-coated tablet	-Voriconazole
Vfend	Pfizer Europe MA EEIG	EU/1/02/212/013-021	Film-coated tablet	-Voriconazole
Vfend	Pfizer Europe MA EEIG	EU/1/02/212/025	Powder for solution for infusion	-Voriconazole
VFEND	Pfizer Europe MA EEIG	EU/1/02/212/026	Powder for oral suspension	-Voriconazole
Viacoram 3.5mg/2.5mg Tablets	Les Laboratoires Servier	PA0568/027/001	Tablet	-Perindopril arginine -Amlodipine
Viacoram 7mg/5mg Tablets	Les Laboratoires Servier	PA0568/027/002	Tablet	-Perindopril arginine -Amlodipine
Viagra	Upjohn EESV	EU/1/98/077/020-023	Orodispersible tablet	-Sildenafil citrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Viagra	Upjohn EESV	EU/1/98/077/026-029	Orodispersible film	-Sildenafil
Viagra 100 mg film-coated tablets	Upjohn EESV	EU/1/98/077/10-11	Film-coated tablet	-Sildenafil
Viagra 25 mg film-coated tablets	Upjohn EESV	EU/1/98/077/2-4	Film-coated tablet	-Sildenafil
Viagra 50 mg film-coated tablets	Upjohn EESV	EU/1/98/077/6-8	Film-coated tablet	-Sildenafil
Viagra Connect 50 mg Film-Coated Tablet	Upjohn EESV	PA23055/016/001	Film-coated tablet	-Sildenafil
Viaredin 25 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/373/001	Film-coated tablet	-Sildenafil citrate
Viaredin 50 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/373/002	Film-coated tablet	-Sildenafil citrate
Viartil 1500 mg Powder for Oral Solution	Rottapharm Ltd	PA0868/005/001	Powder for oral solution	-Glucosamine sulphate sodium chloride
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	-Vi polysaccharide of salmonella typhi -Hepatitis a virus
Vibramycin Capsules 100 mg	Pfizer Healthcare Ireland	PA0822/193/001	Capsule, hard	-Doxycycline
Vicks Sinex Micromist 0.05% w/v Nasal Spray, Solution	WICK Pharma - Zweigniederlassung der Procter & Gamble GmbH	PA2294/004/001	Nasal spray, solution	-Oxymetazoline hydrochloride
Victoza	Novo Nordisk A/S	EU/1/09/529/1-5	Solution for injection in pre-filled pen	-Liraglutide
Vidaza	Bristol-Myers Squibb Pharma EEIG	EU/1/08/488/001	Powder for suspension for injection	-Azacitidine
Videne 10% w/w Alcoholic Tincture	Ecolab Deutschland GmbH	PA1843/002/003	Cutaneous solution	-Iodinated povidone
Videne 7.5% w/w Surgical Scrub	Ecolab Deutschland GmbH	PA1843/002/001	Cutaneous solution	-Iodinated povidone
Videne Antiseptic Solution 10% w/w Cutaneous Solution	Ecolab Deutschland GmbH	PA1843/002/002	Cutaneous solution	-Iodinated povidone
Vidiscic 0.2 % w/w eye gel	Bausch + Lomb Ireland Limited	PA23259/008/001	Eye gel	-Carbomer
Vidiscic Preservative Free Single Dose Unit	Bausch + Lomb Ireland Limited	PA23259/008/002	Eye gel	-Carbomer
VidPrevtyl Beta	Sanofi Pasteur	EU/1/21/1580/001	Emulsion for injection	-SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Viekirax	AbbVie Deutschland GmbH & Co. KG	EU/1/14/982/001	Film-coated tablet	-Ombitasvir -Paritaprevir -Ritonavir
Vihuma	Octapharma AB	EU/1/16/1168/001	Powder and solvent for solution for injection	-Simoctocog alfa
Vihuma	Octapharma AB	EU/1/16/1168/002	Powder and solvent for solution for injection	-Simoctocog alfa
Vihuma	Octapharma AB	EU/1/16/1168/003	Powder and solvent for solution for injection	-Simoctocog alfa
Vihuma	Octapharma AB	EU/1/16/1168/004	Powder and solvent for solution for injection	-Simoctocog alfa

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Vihuma	Octapharma AB	EU/1/16/1168/004-005	Powder and solvent for solution for injection	-Simoctocog alfa
Vihuma	Octapharma AB	EU/1/16/1168/006	Powder and solvent for solution for injection	-Simoctocog alfa
Vihuma	Octapharma AB	EU/1/16/1168/007	Powder and solvent for solution for injection	-Simoctocog alfa
Vildagliptin Krka 50 mg tablets	KRKA, d.d., Novo mesto	PA1347/076/001	Tablet	-Vildagliptin
Vildagliptin/Metformin hydrochloride Accord	Accord Healthcare S.L.U.	EU/1/21/1611/00-004	Film-coated tablet	-Vildagliptin -Metformin Hydrochloride
Vildagliptin/Metformin hydrochloride Accord	Accord Healthcare S.L.U.	EU/1/21/1611/001-002	Film-coated tablet	-Vildagliptin -Metformin Hydrochloride
Vimizim	BioMarin International Limited	EU/1/14/914/001	Concentrate for solution for infusion	-Rhgalns
VIMOVO 500 mg/20 mg modified-release tablets	PCO Manufacturing Ltd.	PPA0465/328/001	Modified-release tablet	-Naproxen -Esomeprazole
VIMOVO 500 mg/20 mg modified-release tablets	Merit Pharmaceuticals Limited	PPA23080/031/001	Modified-release tablet	-Naproxen -Esomeprazole
VIMOVO 500 mg/20 mg modified-release tablets	IMED Healthcare Ltd.	PPA1463/152/001	Modified-release tablet	-Esomeprazole -Naproxen
VIMOVO 500 mg/20 mg modified-release tablets	Grunenthal Pharma Ltd	PA2242/014/001	Modified-release tablet	-Naproxen -Esomeprazole magnesium trihydrate
Vimpat	UCB Pharma SA	EU/1/08/470/13	Film-coated tablet	-Lacosamide
Vimpat 10 mg/ml solution for infusion	UCB Pharma SA	EU/1/08/470/16	Solution for infusion	-Lacosamide
Vimpat 10 mg/ml syrup	UCB Pharma SA	EU/1/08/470/018-019	Syrup	-Lacosamide
Vimpat 100 mg film-coated tablets	UCB Pharma SA	EU/1/08/470/4-6	Film-coated tablet	-Lacosamide
Vimpat 15 mg/ml syrup	UCB Pharma SA	EU/1/08/470/14-15	Syrup	-Lacosamide
Vimpat 150 mg film-coated tablets	UCB Pharma SA	EU/1/08/470/7-9	Film-coated tablet	-Lacosamide
Vimpat 200 mg film-coated tablets	UCB Pharma SA	EU/1/08/470/10-12	Film-coated tablet	-Lacosamide
Vimpat 50 mg film-coated tablets	UCB Pharma SA	EU/1/08/470/1-3	Film-coated tablet	-Lacosamide
Vinblastine Sulfate 1mg/ml Solution for Injection or Infusion	Pfizer Healthcare Ireland	PA0822/208/001	Solution for injection/infusion	-VINBLASTINE SULFATE
Vincristine Sulfate 1mg/ml Solution for Injection or Infusion	Pfizer Healthcare Ireland	PA0822/232/001	Solution for injection/infusion	-Vincristine sulfate
Vinorelbine Accord 20 mg soft capsules	Accord Healthcare Ireland Ltd.	PA2315/253/001	Capsule, soft	-Vinorelbine tartrate
Vinorelbine Accord 30 mg soft capsules	Accord Healthcare Ireland Ltd.	PA2315/253/002	Capsule, soft	-Vinorelbine tartrate
Violite 100/20 micrograms film-coated tablets	Gedeon Richter Plc	PA1330/030/001	Film-coated tablet	-Levonorgestrel -Ethinylestradiol
Vipdomet	Takeda Pharma A/S	EU/1/13/843/001-012	Film-coated tablet	-Metformin Hydrochloride -Alogliptin (as benzoate)
Vipdomet	Takeda Pharma A/S	EU/1/13/843/013-024	Film-coated tablet	-Alogliptin (as benzoate) -Metformin Hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Vipidia	Takeda Pharma A/S	EU/1/13/844/001-009	Film-coated tablet	-Alogliptin (as benzoate)
Vipidia	Takeda Pharma A/S	EU/1/13/844/010-018	Film-coated tablet	-Alogliptin (as benzoate)
Vipidia	Takeda Pharma A/S	EU/1/13/844/019-027	Film-coated tablet	-Alogliptin (as benzoate)
VIRAFERON	Schering Plough Europe	EU/1/99/128/015	Solution for Injection	-INTERFERON ALFA-2B
ViraferonPeg 0.5 ml 100mcg ampoule	Schering Plough Europe	EU/1/00/132/039	Powder and solvent for solution for injection	-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	-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	-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	-Peginterferon alfa-2b
ViraferonPeg 0.5ml 100 mcg ampoule	Schering Plough Europe	EU/1/00/132/042	Powder and solvent for solution for injection	-Peginterferon alfa-2b
ViraferonPeg 0.5ml 100 mcg ampoule	Schering Plough Europe	EU/1/00/132/040	Powder and solvent for solution for injection	-Peginterferon alfa-2b
ViraferonPeg 0.5ml 120 mcg ampoule	Schering Plough Europe	EU/1/00/132/045	Powder and solvent for solution for injection	-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	-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	-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	-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	-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	-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	-Peginterferon alfa-2b
ViraferonPeg0.5ml 100mcg ampoule	Schering Plough Europe	EU/1/00/132/041	Powder and solvent for suspension for injection	-Peginterferon alfa-2b
Viralief 50 mg/g Cream	Clonmel Healthcare Ltd	PA0126/201/001	Cream	-ACICLOVIR
Viramune	Boehringer Ingelheim International GmbH	EU/1/97/055/001	Tablet	-Nevirapine
VIRAMUNE	Boehringer Ingelheim International GmbH	EU/1/97/055/002	Oral suspension	-Nevirapine hemihydrate
Viramune	Boehringer Ingelheim International GmbH	EU/1/97/055/006	Prolonged-release tablet	-Nevirapine
Viramune	Boehringer Ingelheim International GmbH	EU/1/97/055/007-009	Prolonged-release tablet	-Nevirapine
VIREAD	Gilead Sciences Ireland UC	EU/1/01/200/001-002	Film-coated tablet	-Tenofovir disoproxil fumarate
Viread	Gilead Sciences Ireland UC	EU/1/01/200/003	Granules	-Tenofovir disoproxil fumarate
Viread	Gilead Sciences Ireland UC	EU/1/01/200/004-005	Film-coated tablet	-Tenofovir disoproxil fumarate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Viread	Gilead Sciences Ireland UC	EU/1/01/200/006-007	Film-coated tablet	-Tenofovir disoproxil fumarate
Viread	Gilead Sciences Ireland UC	EU/1/01/200/008-009	Film-coated tablet	-Tenofovir disoproxil fumarate
Viscolex Syrup 250 mg / 5 ml Oral Solution	Pinewood Laboratories Ltd	PA0281/070/001	Oral solution	-Carbocysteine
VISIPAQUE 270 mg l/ml Solution for Injection, glass container	GE Healthcare AS	PA0735/009/003	Solution for injection	-Iodixanol
VISIPAQUE 270 mg l/ml Solution for Injection, polypropylene container	GE Healthcare AS	PA0735/009/012	Solution for injection	-Iodixanol
VISIPAQUE 320 mg l/ml Solution for Injection, glass container	GE Healthcare AS	PA0735/009/007	Solution for injection	-Iodixanol
Visipaque 320 mg l/ml Solution for Injection, polypropylene container	GE Healthcare AS	PA0735/009/013	Solution for injection	-Iodixanol
VISTABEL, 4 Allergan Units/0.1ml, Powder for solution for injection	AbbVie Limited	PA1824/020/001	Powder for solution for injection	-Botulinum Toxin Type A
Visudyne	CHEPLAPHARM Arzneimittel GmbH	EU/1/00/140/001	Powder for solution for infusion	-Verteporfin
Vitafen 100mg Film-coated Tablets	Phoenix Labs	PA1113/009/001	Film-coated tablet	-Aceclofenac
Vitaros 2 mg/g cream	Recordati Ireland Limited	PA1404/003/001	Cream	-Alprostadil
Vitaros 3 mg/g cream	Recordati Ireland Limited	PA1404/003/002	Cream	-Alprostadil
Vitlipid N Adult concentrate for emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/067/001	Concentrate for emulsion for infusion	-Ergocalciferol -Phytomenadione -Retinol palmitate -Dl-alpha-tocopherol
Vitlipid N Infant concentrate for emulsion for infusion	Fresenius Kabi Deutschland GmbH	PA2059/067/002	Concentrate for emulsion for infusion	-Retinol palmitate -Ergocalciferol -Dl-alpha-tocopherol -Phytomenadione
VITRAKVI	Bayer AG	EU/1/19/1385/001	Capsule, hard	-LAROTRECTINIB -LAROTRECTINIB SULFATE
VITRAKVI	Bayer AG	EU/1/19/1385/002	Capsule, hard	-LAROTRECTINIB SULFATE -LAROTRECTINIB
Vivanza	Bayer Schering Pharma AG	EU/1/03/249/016	Orodispersible tablet	-Vardenafil hydrochloride trihydrate (micronized)
Vividrin Antiallergic Eye Drops, Solution 2% w/v	Bausch + Lomb Ireland Limited	PA23259/005/001	Eye drops, solution	-Sodium cromoglycate
Vividrin Preservative Free SDU 2% w/v Eye Drops solution	Bausch + Lomb Ireland Limited	PA23259/005/002	Eye drops, solution	-Sodium cromoglycate
Vizamyl	GE Healthcare AS	EU/1/14/941/001-002	Solution for injection	-Flutemetamol (18F)
Vizarsin	KRKA, d.d., Novo mesto	EU/1/09/551/013-017	Orodispersible tablet	-Sildenafil
Vizarsin	KRKA, d.d., Novo mesto	EU/1/09/551/018-022	Orodispersible tablet	-Sildenafil
Vizarsin	KRKA, d.d., Novo mesto	EU/1/09/551/023-027	Orodispersible tablet	-Sildenafil

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Vizarsin 100 mg film-coated tablets	KRKA, d.d., Novo mesto	EU/1/09/551/9-12	Film-coated tablet	-Sildenafil
Vizarsin 25 mg film-coated tablets	KRKA, d.d., Novo mesto	EU/1/09/551/1-4	Film-coated tablet	-Sildenafil
Vizarsin 50 mg film-coated tablets	KRKA, d.d., Novo mesto	EU/1/09/551/5-8	Film-coated tablet	-Sildenafil
Vizimpro	Pfizer Europe MA EEIG	EU/1/19/1354/001	Film-coated tablet	-DACOMITINIB MONOHYDRATE
Vizimpro	Pfizer Europe MA EEIG	EU/1/19/1354/002	Film-coated tablet	-DACOMITINIB MONOHYDRATE
Vizimpro	Pfizer Europe MA EEIG	EU/1/19/1354/003	Film-coated tablet	-DACOMITINIB MONOHYDRATE
VOCABRIA	ViiV Healthcare BV	EU/1/20/1481/001	Film-coated tablet	-cabotegravir
VOCABRIA	ViiV Healthcare BV	EU/1/20/1481/002	Prolonged-release suspension for injection	-cabotegravir
VOCABRIA	ViiV Healthcare BV	EU/1/20/1481/003	Prolonged-release suspension for injection	-cabotegravir
Vokanamet	Janssen-Cilag International NV	EU/1/14/918/001-003	Film-coated tablet	-Metformin Hydrochloride -Purified water -Croscarmellose sodium -Hypromellose 2910, 15 mpa.s -MICROCRYSTALLINE CELLULOSE -Canagliflozin
Vokanamet	Janssen-Cilag International NV	EU/1/14/918/004-006	Film-coated tablet	-Metformin Hydrochloride -MICROCRYSTALLINE CELLULOSE -Hypromellose 2910, 15 mpa.s -Purified water -Croscarmellose sodium -Canagliflozin
Vokanamet	Janssen-Cilag International NV	EU/1/14/918/007-009	Film-coated tablet	-MICROCRYSTALLINE CELLULOSE -Croscarmellose sodium -Canagliflozin -Purified water -Metformin Hydrochloride -Hypromellose 2910, 15 mpa.s
Vokanamet	Janssen-Cilag International NV	EU/1/14/918/010-012	Film-coated tablet	-Purified water -Hypromellose 2910, 15 mpa.s -Canagliflozin -Croscarmellose sodium -MICROCRYSTALLINE CELLULOSE -Metformin Hydrochloride
Volibris	GlaxoSmithKline (Ireland) Limited	EU/1/08/451/001-002	Film-coated tablet	-Ambrisentan
Volibris	GlaxoSmithKline (Ireland) Limited	EU/1/08/451/003-004	Film-coated tablet	-Ambrisentan

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Volibris	GlaxoSmithKline (Ireland) Limited	EU/1/08/451/005	Film-coated tablet	-Ambrisentan
Voltarol 1% w/w Gel	Haleon Ireland Limited	PA0678/140/001	Gel	-Diclofenac sodium
Voltarol 50 mg Gastro-Resistant Tablets	Novartis Ireland Limited	PA0896/034/001	Gastro-resistant tablet	-Diclofenac sodium
Voltarol Emulgel 1% w/w Gel	PCO Manufacturing Ltd.	PPA0465/442/001	Gel	-Diclofenac sodium
Voltarol Emulgel Extra Strength 2% w/w gel	PCO Manufacturing Ltd.	PPA0465/442/002	Gel	-Diclofenac sodium (as diclofenac diethylammonium)
Voltarol Emulgel Extra Strength 2% w/w gel	IMED Healthcare Ltd.	PPA1463/221/001	Gel	-Diclofenac sodium
Voltarol Emulgel Extra Strength 2% w/w gel	Haleon Ireland Limited	PA0678/140/003	Gel	-Diclofenac sodium
Voltarol Ophtha Multidose 1mg/ml Eye Drops Solution	Laboratoires Thea	PA1107/009/002	Eye drops, solution	-Diclofenac sodium
Voltarol Retard 100 mg Film-coated Prolonged Release Tablets	Novartis Ireland Limited	PA0896/034/002	Prolonged-release tablet	-Diclofenac sodium
Voltarol Retard 75 mg Film-coated Prolonged-release Tablets	Novartis Ireland Limited	PA0896/034/003	Prolonged-release tablet	-Diclofenac sodium
Voltfast Sachets 50mg Powder for Oral Solution	Wisdom Pharmaceutical Technology Co Limited	PA2308/001/001	Powder for oral solution	-Diclofenac potassium
Voncento	CSL Behring GmbH	EU/1/13/857/001	Powder and solvent for solution for injection/infusion	-Human coagulation factor viii -Von willebrand factor
Voncento	CSL Behring GmbH	EU/1/13/857/002	Powder and solvent for solution for injection/infusion	-Von willebrand factor -Human coagulation factor viii
Voncento	CSL Behring GmbH	EU/1/13/857/003	Powder and solvent for solution for injection/infusion	-Human coagulation factor viii -Von willebrand factor
Voncento	CSL Behring GmbH	EU/1/13/857/004	Powder and solvent for solution for injection/infusion	-Von willebrand factor -Human coagulation factor viii
Vonodiol 100 mcg / 20 mcg Film-coated Tablets	Theramex Ireland Limited	PA22668/004/001	Film-coated tablet	-Levonorgestrel -Ethinylestradiol
Voquily 1 mg/ml oral solution	Clinigen Healthcare B.V.	PA22701/002/001	Oral solution	-Melatonin
Voraxaze	Serb S.A.S.	EU/1/21/1586/001	Powder for solution for injection	-Glucarpidase
Voriconazole 200mg powder for solution for infusion	hameln pharma gmbh	PA2237/006/001	Powder for solution for infusion	-Voriconazole
Voriconazole 200mg powder for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/020/001	Powder for solution for infusion	-Voriconazole
Voriconazole Accord	Accord Healthcare S.L.U.	EU/1/13/835/001-009	Film-coated tablet	-Voriconazole
Voriconazole Accord	Accord Healthcare S.L.U.	EU/1/13/835/010-018	Film-coated tablet	-Voriconazole
Voriconazole Hospira	Hikma Farmacêutica (Portugal) S.A.	EU/1/15/1004/001-002	Powder for solution for infusion	-Voriconazole
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	-Voriconazole
Voriconazole Teva 200 mg Film-coated Tablets	Teva Pharma B.V.	PA0749/181/001	Film-coated tablet	-Voriconazole

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Vortioxetine Clonmel 10 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/385/002	Film-coated tablet	-Vortioxetine hydrobromide
Vortioxetine Clonmel 15 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/385/003	Film-coated tablet	-Vortioxetine hydrobromide
Vortioxetine Clonmel 20 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/385/004	Film-coated tablet	-Vortioxetine hydrobromide
Vortioxetine Clonmel 5 mg film-coated tablets	Clonmel Healthcare Ltd	PA0126/385/001	Film-coated tablet	-Vortioxetine hydrobromide
Vosevi	Gilead Sciences Ireland UC	EU/1/17/1223/001	Film-coated tablet	-Sofosbuvir -Velpatasvir -Voxilaprevir
Vosevi	Gilead Sciences Ireland UC	EU/1/17/1223/002	Film-coated tablet	-Sofosbuvir -Velpatasvir -Voxilaprevir
Votrient	Novartis Europharm Limited	EU/1/10/628/001-2	Film-coated tablet	-Pazopanib hydrochloride
Votrient	Novartis Europharm Limited	EU/1/10/628/003-4	Film-coated tablet	-Pazopanib hydrochloride
Votubia	Novartis Europharm Limited	EU/1/11/710/001-003	Tablet	-Rad n bht
Votubia	Novartis Europharm Limited	EU/1/11/710/004-005	Tablet	-Rad n bht
Votubia	Novartis Europharm Limited	EU/1/11/710/006-007	Tablet	-Rad n bht
Votubia	Novartis Europharm Limited	EU/1/11/710/009-011	Dispersible tablet	-Rad n bht
Votubia	Novartis Europharm Limited	EU/1/11/710/012-013	Dispersible tablet	-Rad n bht
Votubia	Novartis Europharm Limited	EU/1/11/710/014-015	Dispersible tablet	-Rad n bht
Votubia	Novartis Europharm Limited	EU/1/11/710/016	Dispersible tablet	-Everolimus
Voxzogo	BioMarin International Limited	EU/1/21/1577/001	Powder and solvent for solution for injection	-Vosoritide
VPRIV	Shire Pharmaceuticals Ireland Limited	EU/1/10/646/002	Powder for solution for infusion	-Velaglucerase alfa
Vumerity	Biogen Netherlands B.V.	EU/1/21/1585/001-002	Gastro-resistant capsule, hard	-Diroximel Fumarate
Vydura	Biohaven Pharmaceutical Ireland DAC	EU/1/22/1645/001-002	Orodispersible tablet	-Rimegepant sulfat
Vydura	Pfizer Europe MA EEIG	EU/1/22/1645/001-003	Oral lyophilisate	-Rimegepant sulfat
Vyepti	H. Lundbeck A/S	EU/1/21/1599/001	Concentrate for solution for infusion	-Eptinezumab
Vyepti	H. Lundbeck A/S	EU/1/21/1599/003	Concentrate for solution for infusion	-Eptinezumab
Vyndaqel	Pfizer Europe MA EEIG	EU/1/11/717/001	Capsule, soft	-Tafamidis
Vyndaqel	Pfizer Europe MA EEIG	EU/1/11/717/003-004	Capsule, soft	-Tafamidis
Vyvgart	Argenx	EU/1/22/1674/001	Concentrate for solution for infusion	-Efgartigimod ALFA
Vyxeos	Jazz Pharmaceuticals Ireland Limited	EU/1/18/1308/001-003	Powder for concentrate for solution for infusion	-Cytarabine -DAUNOMYCIN HYDROCHLORIDE
Wakix	Bioprojet Pharma	EU/1/15/1068/001	Film-coated tablet	-Pitolisant hydrochloride
Wakix	Bioprojet Pharma	EU/1/15/1068/002	Film-coated tablet	-Pitolisant hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Warfant 1 mg Tablets	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/139/001	Tablet	-WARFARIN SODIUM
Warfant 3 mg Tablets	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/139/002	Tablet	-WARFARIN SODIUM
Warfant 5 mg Tablets	Mercury Pharmaceuticals (Ireland) Ltd	PA0073/139/003	Tablet	-WARFARIN SODIUM
Warfarin Teva 0.5mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/001	Tablet	-Warfarin sodium clathrate
Warfarin Teva 1 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/002	Tablet	-Warfarin sodium clathrate
Warfarin Teva 10 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/009	Tablet	-Warfarin sodium clathrate
Warfarin Teva 2 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/003	Tablet	-Warfarin sodium clathrate
Warfarin Teva 2.5 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/004	Tablet	-Warfarin sodium clathrate
Warfarin Teva 3 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/005	Tablet	-Warfarin sodium clathrate
Warfarin Teva 5 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/006	Tablet	-Warfarin sodium clathrate
Warfarin Teva 6 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/007	Tablet	-Warfarin sodium clathrate
Warfarin Teva 7.5 mg Tablets	Sun Pharmaceutical Industries Europe B.V.	PA2050/001/008	Tablet	-Warfarin sodium clathrate
Warticon 0.15% w/w Cream	Phoenix Labs	PA1113/017/001	Cream	-Podophyllotoxin
Water for Injections Ph Eur	Noridem Enterprises Limited	PA1122/001/001	Solvent for parenteral use	-Water for injections
Water for Injections Ph. Eur	B. Braun Medical Limited	PA0179/009/003	Solvent for parenteral use	-Water for injections
Water for Injections Ph. Eur., viaflo container	Baxter Holding B.V.	PA2299/013/001	Solvent for parenteral use	-Water for injection
Water for Injections solvent for parenteral use	CSL Behring GmbH	PA0800/011/001	Solvent for parenteral use	-Water for injection
Water for injections, solvent for parenteral use	Fresenius Kabi Deutschland GmbH	PA2059/035/001	Solvent for parenteral use	-Water for injections
WAXSOL 0.5% w/v Ear Drops Solution	Mylan IRE Healthcare Limited	PA2010/056/001	Ear drops, solution	-Docusate sodium
Waylivra	Akcea Therapeutics Ireland Ltd	EU/1/19/1360/001-002	Solution for injection in pre-filled syringe	-VOLANESORSEN SODIUM
Wecol 6.9 g powder for oral solution	Stirling Anglian Pharmaceuticals Ireland Limited	PA23138/001/001	Powder for oral solution	-Macrogol 3350 -Sodium chloride -Potassium chloride -Sodium hydrogen carbonate
Wecol Paediatric 6.9 g powder for oral solution	Stirling Anglian Pharmaceuticals Ireland Limited	PA23138/001/002	Powder for oral solution	-Macrogol 3350 -Sodium chloride -Potassium chloride -Sodium hydrogen carbonate
Wegovy	Novo Nordisk A/S	EU/1/21/1608/001	Solution for injection in pre-filled pen	-Semaglutide
Wegovy	Novo Nordisk A/S	EU/1/21/1608/002	Solution for injection in pre-filled pen	-Semaglutide
Wegovy	Novo Nordisk A/S	EU/1/21/1608/003	Solution for injection in pre-filled pen	-Semaglutide
Wegovy	Novo Nordisk A/S	EU/1/21/1608/004	Solution for injection in pre-filled pen	-Semaglutide
Wegovy	Novo Nordisk A/S	EU/1/21/1608/005	Solution for injection in pre-filled pen	-Semaglutide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Whitfield's Antifungal 3% w/w & 6% w/w Ointment	Ovelle Limited	PA0206/024/001	Ointment	-Salicylic acid -Benzoic acid
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	-Human factor viii -Von willebrand factor human
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	-Human factor viii -Von willebrand factor human
WILZIN	Recordati Rare Diseases	EU/1/04/286/1-2	Capsule, hard	-Zinc acetate dihydrate
Wynzora 50 micrograms/g + 0.5 mg/g cream	Almirall, S.A.	PA0968/006/001	Cream	-Calcipotriol -Betamethasone
Xadago	Zambon S.p.A.	EU/1/14/984/001-005	Film-coated tablet	-Safinamide methanesulfonate
Xadago	Zambon S.p.A.	EU/1/14/984/006-010	Film-coated tablet	-Safinamide methanesulfonate
XAGRID	Takeda Pharmaceuticals International AG Ireland Branch	EU/1/04/295/001	Capsule, hard	-Anagrelide hydrochloride
Xalacom 50 micrograms/mL + 5 mg/mL, eye drops, solution	Upjohn EESV	PA23055/008/001	Eye drops, solution	-Latanoprost -Timolol
Xalacom 50 micrograms/ml + 5 mg/ml, eye drops, solution	PCO Manufacturing Ltd.	PPA0465/406/001	Eye drops, solution	-Latanoprost -Timolol
Xalatan 50 micrograms/mL Eye drops, solution	Upjohn EESV	PA23055/009/001	Eye drops, solution	-Latanoprost
Xalkori	Pfizer Europe MA EEIG	EU/1/12/793/001-002	Capsule, hard	-Crizotinib
Xalkori	Pfizer Europe MA EEIG	EU/1/12/793/003-004	Capsule, hard	-Crizotinib
Xaluprine	Nova Laboratories Ireland Limited	EU/1/11/727/001	Oral suspension	-Mercaptopurine monohydrate
Xamiol 50 micrograms/g + 0.5 mg/g gel	LEO Pharma A/S	PA1025/003/001	Gel	-Calcipotriol -Betamethasone
Xanax 1 mg Tablets	Upjohn EESV	PA23055/010/001	Tablet	-Alprazolam
Xanax 250 microgram Tablets	Upjohn EESV	PA23055/010/002	Tablet	-Alprazolam
Xanax 500 microgram Tablets	Upjohn EESV	PA23055/010/003	Tablet	-Alprazolam
Xarelto	Bayer AG	EU/1/08/472/011-016	Film-coated tablet	-Rivaroxaban
Xarelto	Bayer AG	EU/1/08/472/017-021	Film-coated tablet	-Rivaroxaban
Xarelto	Bayer AG	EU/1/08/472/025-033	Film-coated tablet	-Rivaroxaban
Xarelto	Bayer AG	EU/1/08/472/1-8	Film-coated tablet	-Rivaroxaban
Xarelto 1 mg/ml granules for oral suspension	Bayer AG	EU/1/08/472/050-051	Granules for oral suspension	-Rivaroxaban
Xatger 10mg prolonged release tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/079/002	Prolonged-release tablet	-Alfuzosin hydrochloride
Xatral 10mg Prolonged Release Tablets	Sanofi-Aventis Ireland Limited T/A SANOFI	PA0540/162/003	Prolonged-release tablet	-Alfuzosin hydrochloride
Xelevia 100 mg film-coated tablets	Merck Sharp & Dohme BV	EU/1/07/382/13-18	Film-coated tablet	-Sitagliptin phosphate monohydrate
Xelevia 25 mg film-coated tablets	Merck Sharp & Dohme BV	EU/1/07/382/1-6	Film-coated tablet	-Sitagliptin phosphate monohydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Xelevia 50 mg film-coated tablets	Merck Sharp & Dohme BV	EU/1/07/382/7-12	Film-coated tablet	-Sitagliptin phosphate monohydrate
Xeljanz	Pfizer Europe MA EEIG	EU/1/17/1178/001-003	Film-coated tablet	-Tofacitinib citrate
XELJANZ	Pfizer Europe MA EEIG	EU/1/17/1178/005-009	Film-coated tablet	-Tofacitinib citrate
Xeljanz	Pfizer Europe MA EEIG	EU/1/17/1178/010-013	Prolonged-release tablet	-TOFACITINIB
Xeljanz	Pfizer Europe MA EEIG	EU/1/17/1178/015	Oral solution	-TOFACITINIB
Xeloda	Cheplapharm Arzneimittel GmbH	EU/1/00/163/001	Film-coated tablet	-Capecitabine
Xeloda	Cheplapharm Arzneimittel GmbH	EU/1/00/163/002	Film-coated tablet	-Capecitabine
Xenetix 250mg I/ml Solution for Injection	Guerbet	PA0686/002/001	Solution for injection	-lobitridol
Xenetix 300mg I/ml Solution for Injection	Guerbet	PA0686/002/002	Solution for injection	-lobitridol
Xenetix 300mg I/ml Solution for injection, polypropylene bag	Guerbet	PA0686/002/004	Solution for injection	-lobitridol
Xenetix 350mg I/ml Solution for Injection	Guerbet	PA0686/002/003	Solution for injection	-lobitridol
Xenetix 350mg I/ml Solution for injection, polypropylene bag	Guerbet	PA0686/002/005	Solution for injection	-lobitridol
Xenical	Cheplapharm Arzneimittel GmbH	EU/1/98/071/001	Capsule, hard	-Orlistat
Xenical	CHEPLAPHARM Arzneimittel GmbH	EU/1/98/071/002	Capsule, hard	-Orlistat
Xenical	Cheplapharm Arzneimittel GmbH	EU/1/98/071/003	Capsule, hard	-Orlistat
Xenical	Cheplapharm Arzneimittel GmbH	EU/1/98/071/004	Capsule, hard	-Orlistat
Xenical	Cheplapharm Arzneimittel GmbH	EU/1/98/071/005	Capsule, hard	-Orlistat
Xenical	Cheplapharm Arzneimittel GmbH	EU/1/98/071/006	Capsule, hard	-Orlistat
Xenleta	Nabriva Therapeutics Ireland DAC	EU/1/20/1457/001	Concentrate and solvent for solution for infusion	-Lefamulin
Xenleta	Nabriva Therapeutics Ireland DAC	EU/1/20/1457/002	Film-coated tablet	-Lefamulin
Xenpozyme	Genzyme Europe B.V.	EU/1/22/1659/001-004	Powder for concentrate for solution for infusion	-Olipudase Alfa
XEOMIN 100 units powder for solution for injection	Merz Pharmaceuticals GmbH	PA1907/001/002	Powder for solution for injection	-Clostridium botulinum neuro-toxin type a (150 kd), free from complexing proteins
XEOMIN 200 units powder for solution for injection	Merz Pharmaceuticals GmbH	PA1907/001/003	Powder for solution for injection	-Clostridium botulinum neuro-toxin type a (150 kd), free from complexing proteins
XEOMIN 50 units powder for solution for injection	Merz Pharmaceuticals GmbH	PA1907/001/001	Powder for solution for injection	-Clostridium botulinum neuro-toxin type a (150 kd), free from complexing proteins
Xeplion 100 mg prolonged-release suspension for injection	Janssen-Cilag International NV	EU/1/11/672/004	Prolonged-release suspension for injection	-Paliperidone palmitate (r092670)
Xeplion 150 mg prolonged-release suspension for injection	Janssen-Cilag International NV	EU/1/11/672/005-006	Prolonged-release suspension for injection	-Paliperidone palmitate (r092670)

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Xeplion 25 mg prolonged-release suspension for injection	Janssen-Cilag International NV	EU/1/11/672/001	Prolonged-release suspension for injection	-Paliperidone palmitate (r092670)
Xeplion 50 mg prolonged-release suspension for injection	Janssen-Cilag International NV	EU/1/11/672/002	Prolonged-release suspension for injection	-Paliperidone palmitate (r092670)
Xeplion 75 mg prolonged-release suspension for injection	Janssen-Cilag International NV	EU/1/11/672/003	Prolonged-release suspension for injection	-Paliperidone palmitate (r092670)
Xerava	Paion Deutschland GmbH	EU/1/18/1312/001	Powder for concentrate for solution for infusion	-ERAVACYCLINE
Xerava	Tetraphase Pharmaceuticals Ireland Limited	EU/1/18/1312/003-004	Powder for concentrate for solution for infusion	-ERAVACYCLINE
Xermelo	Serb S.A.S.	EU/1/17/1224/001-002	Film-coated tablet	-Telotristat etiprate
Xevudy	GlaxoSmithKline Trading Services Limited	EU/1/21/1562/001	Concentrate for solution for infusion	-Sotrovimab
XGEVA	Amgen Europe B.V.	EU/1/11/703/001-002	Solution for injection	-Denosumab
Xigduo	AstraZeneca AB	EU/1/13/900/001-006	Film-coated tablet	-Dapagliflozin propanediol monohydrate -Metformin Hydrochloride
Xigduo	AstraZeneca AB	EU/1/13/900/007-012	Film-coated tablet	-Metformin Hydrochloride -Dapagliflozin propanediol monohydrate
Xiliarx	Novartis Europharm Limited	EU/1/08/486/1-11	Tablet	-Vildagliptin
Xilmac 4 mg/ml Solution for injection	Macure Healthcare Limited	PA23314/001/001	Solution for injection	-Lorazepam
Ximluci	Stada Arzneimittel AG	EU/1/22/1691/001	Solution for injection	-Ranibizumab
Ximluci	Stada Arzneimittel AG	EU/1/22/1691/002	Solution for injection	-Ranibizumab
Xofigo	Bayer AG	EU/1/13/873/001	Solution for injection	-Radium-223 chloride
Xofluza	Roche Registration GmbH	EU/1/20/1500/001	Film-coated tablet	-Baloxavir Marboxil
Xofluza	Roche Registration GmbH	EU/1/20/1500/002	Film-coated tablet	-Baloxavir Marboxil
Xofluza	Roche Registration GmbH	EU/1/20/1500/003	Film-coated tablet	-Baloxavir Marboxil
Xofluza	Roche Registration GmbH	EU/1/20/1500/005	Granules for oral suspension	-Baloxavir Marboxil
Xolair	Novartis Europharm Limited	EU/1/05/319/001	Powder and solvent for solution for injection	-Omalizumab
Xolair	Novartis Europharm Limited	EU/1/05/319/002	Powder and solvent for solution for injection	-Omalizumab
Xolair	Novartis Europharm Limited	EU/1/05/319/012-014	Solution for injection in pre-filled syringe	-Omalizumab
Xolair	Novartis Europharm Limited	EU/1/05/319/015-017	Solution for injection in pre-filled pen	-Omalizumab
Xolair	Novartis Europharm Limited	EU/1/05/319/5-7	Solution for injection in pre-filled syringe	-Omalizumab
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	-Omalizumab
Xonvea 10 mg/10 mg gastro-resistant tablets	Exeltis healthcare S.L.	PA22998/006/001	Gastro-resistant tablet	-Doxylamine hydrogen succinate -Pyridoxine hydrochloride

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Xonvea MR 20 mg/20 mg modified-release tablets	Exeltis healthcare S.L.	PA22998/003/001	Modified-release tablet	-Doxylamine hydrogen succinate -Pyridoxine hydrochloride
XOSPATA	Astellas Pharma Europe B.V.	EU/1/19/1399/001	Film-coated tablet	-Gilteritinib Fumarate
Xoterna Breezhaler	Novartis Europharm Limited	EU/1/13/863/001-006	Inhalation powder, hard capsule	-Indacaterol maleate -Glycopyrronium bromide
Xromi	Nova Laboratories Ireland Limited	EU/1/19/1366/001	Oral solution	-Hydroxycarbamide
Xtandi	Astellas Pharma Europe BV	EU/1/13/846/001	Capsule, soft	-Enzalutamide
Xtandi	Astellas Pharma Europe B.V.	EU/1/13/846/002	Film-coated tablet	-Enzalutamide
Xtandi	Astellas Pharma Europe B.V.	EU/1/13/846/003	Film-coated tablet	-Enzalutamide
Xtex 250 mg /5 ml oral solution	Rowa Pharmaceuticals Limited	PA0074/071/001	Oral solution	-Carbocisteine
Xultophy	Novo Nordisk A/S	EU/1/14/947/001-004	Solution for injection	-Insulin degludec -Liraglutide
Xydalba	AbbVie Deutschland GmbH & Co. KG	EU/1/14/986/001	Powder for concentrate for solution for infusion	-Dalbavancin hcl
Xylocaine 10 mg/delivered dose Mucosal Spray	Aspen Pharma Trading Limited	PA1691/028/001	Oromucosal spray, solution	-Lidocaine
Xylocaine 2% w/v with Adrenaline (Epinephrine) 1:80,000 DENTAL Solution for Injection	DENTSPLY DeTrey GmbH	PA1045/003/001	Solution for injection	-Lidocaine hydrochloride -Adrenaline tartrate
Xylocaine 2% with Adrenaline (Epinephrine) (1:200,000) Solution for Injection	Aspen Pharma Trading Limited	PA1691/027/001	Solution for injection	-Adrenaline tartrate -Lidocaine hydrochloride
Xylonor, 50 mg/g + 1.5 mg/g, gingival gel	Septodont	PA0196/014/002	Gingival gel	-Lidocaine -Cetrimide
Xymel 50 mg Capsules	Clonmel Healthcare Ltd	PA0126/099/001	Capsule, hard	-Tramadol hydrochloride
Xymel Comp 37.5mg/325mg Film-Coated Tablets	Clonmel Healthcare Ltd	PA0126/244/001	Film-coated tablet	-Tramadol hydrochloride -Paracetamol
Xyrem	UCB Pharma SA	EU/1/05/312/001	Oral solution	-Sodium Oxybate
Xyzal 0.5 mg/ml oral solution	UCB (Pharma) Ireland Limited	PA0891/003/003	Oral solution	-Levocetirizine dihydrochloride
Xyzal 0.5 mg/ml oral solution	PCO Manufacturing Ltd.	PPA0465/169/002	Oral solution	-Levocetirizine dihydrochloride
Xyzal 0.5 mg/ml oral solution	IMED Healthcare Ltd.	PPA1463/170/001	Oral solution	-Levocetirizine dihydrochloride
Xyzal 5 mg film-coated tablets	UCB (Pharma) Ireland Limited	PA0891/003/001	Film-coated tablet	-Levocetirizine dihydrochloride
Xyzal 5 mg/ml oral drops, solution	UCB (Pharma) Ireland Limited	PA0891/003/002	Oral drops, solution	-Levocetirizine dihydrochloride
Yargesa	Piramal Critical Care B.V.	EU/1/17/1176/001	Capsule, hard	-Miglustat
Yasmin 0.03 mg / 3 mg film-coated tablets	Bayer Limited	PA1410/023/001	Film-coated tablet	-Drospirenone -Ethinylestradiol
Yasminelle 0.02 mg/3 mg film-coated tablets	Bayer Limited	PA1410/024/001	Film-coated tablet	-Ethinylestradiol -Drospirenone
Yaz 0.02 mg/3 mg film-coated tablets	Bayer Limited	PA1410/056/001	Film-coated tablet	-Ethinylestradiol -Drospirenone
Yellox	Bausch Health Ireland Limited	EU/1/11/692/001	Eye drops, solution	-Bromfenac sodium sesquihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Yentreve	Eli Lilly Nederland B.V.	EU/1/04/280/001	Gastro-resistant capsule, hard	-Duloxetine hydrochloride
Yentreve	Eli Lilly Nederland B.V.	EU/1/04/280/1-6	Gastro-resistant capsule, hard	-Duloxetine hydrochloride
Yervoy	Bristol-Myers Squibb Pharma EEIG	EU/1/11/698/001-002	Concentrate for solution for infusion	-Ipilimumab
Yesafili	Biosimilar Collaborations Ireland Limited	EU/1/23/1751/001-002	Solution for injection	-Aflibercept
YESCARTA	Kite Pharma EU B.V.	EU/1/18/1299/001	Dispersion for infusion	-AXICABTAGENE CILOLEUCEL
Yondelis	Pharma Mar S.A.	EU/1/07/417/1	Powder for concentrate for solution for infusion	-Trabectedin
Yondelis	Pharma Mar S.A.	EU/1/07/417/2	Powder for concentrate for solution for infusion	-Trabectedin
Yorvipath	Ascendis Pharma Bone Diseases A/S	EU/1/23/1766/001	Solution for injection in pre-filled pen	-Palopegteriparatide -Teriparatide
Yorvipath	Ascendis Pharma Bone Diseases A/S	EU/1/23/1766/002	Solution for injection in pre-filled pen	-Palopegteriparatide -Teriparatide
Yorvipath	Ascendis Pharma Bone Diseases A/S	EU/1/23/1766/003	Solution for injection in pre-filled pen	-Palopegteriparatide -Teriparatide
Yselty 100 mg film-coated tablets	Theramex Ireland Limited	EU/1/21/1606/001	Film-coated tablet	-Linzagolix Choline
Yselty 200 mg film-coated tablets	Theramex Ireland Limited	EU/1/21/1606/002	Film-coated tablet	-Linzagolix Choline
Yttriga	Eckert & Ziegler Radiopharm GmbH	EU/1/05/322/001	Radiopharmaceutical precursor, solution	-Yttrium (90 y)
Yuflyma	Celltrion Healthcare Hungary Kft.	EU/1/20/1513/001-012	Solution for injection	-Adalimumab
Yuflyma	Celltrion Healthcare Hungary Kft.	EU/1/20/1513/013-016	Solution for injection	-Adalimumab
Yuflyma	Celltrion Healthcare Hungary Kft.	EU/1/20/1513/017	Solution for injection	-Adalimumab
ZABDENO	Janssen-Cilag International NV	EU/1/20/1444/001	Suspension for injectio	-AD26.ZEBOV
Zacin 0.025% w/w Cream	Teva B.V.	PA1986/090/001	Cream	-Capsaicin
Zaditen 0.25 mg/ml, eye drops, solution	Laboratoires Thea	PA1107/010/001	Eye drops, solution	-KETOTIFEN FUMARATE
Zaditen 1 mg Tablets	Alfasigma S.p.A	PA2206/004/002	Tablet	-KETOTIFEN FUMARATE
Zaditen 1mg/5ml oral solution	Alfasigma S.p.A	PA2206/004/001	Oral solution	-KETOTIFEN FUMARATE
Zafrilla 2mg tablets	Gedeon Richter Plc	PA1330/023/001	Tablet	-Dienogest
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/006	Tablet	-Olanzapine
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/11-15	Tablet	-Olanzapine
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/1-5	Tablet	-Olanzapine
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/16-21	Tablet	-Olanzapine
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/22-26	Tablet	-Olanzapine
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/27-31	Tablet	-Olanzapine
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/32-36	Orodispersible tablet	-Olanzapine
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/37-41	Orodispersible tablet	-Olanzapine
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/42-46	Orodispersible tablet	-Olanzapine
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/47-51	Orodispersible tablet	-Olanzapine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Zalasta	KRKA, d.d., Novo mesto	EU/1/07/415/52-56	Orodispersible tablet	-Olanzapine
Zaltrap	Sanofi Winthrop Industrie	EU/1/12/814/001-003	Concentrate for solution for infusion	-Aflibercept
Zanaflex 2 mg Tablets	Teva Pharma B.V.	PA0749/054/001	Tablet	-Tizanidine
Zanaflex 2 mg Tablets	PCO Manufacturing Ltd.	PPA0465/474/001	Tablet	-Tizanidine
Zanaflex 4 mg Tablets	PCO Manufacturing Ltd.	PPA0465/474/002	Tablet	-Tizanidine
Zanaflex 4 mg Tablets	Teva Pharma B.V.	PA0749/054/002	Tablet	-Tizanidine
Zanidip 10 mg film-coated tablets	Recordati Industria Chimica e Farmaceutica SpA	PA0812/001/001	Film-coated tablet	-Lercanidipine hydrochloride
Zanidip 10 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/481/001	Film-coated tablet	-Lercanidipine hydrochloride
Zanidip 10 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/203/001	Film-coated tablet	-Lercanidipine hydrochloride
Zanidip 20 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/203/002	Film-coated tablet	-Lercanidipine hydrochloride
Zanidip 20 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/481/002	Film-coated tablet	-Lercanidipine hydrochloride
Zanidip 20mg film-coated tablets	Recordati Industria Chimica e Farmaceutica SpA	PA0812/001/002	Film-coated tablet	-Lercanidipine hydrochloride
Zarontin 250 mg/5 ml Syrup	PCO Manufacturing Ltd.	PPA0465/456/001	Syrup	-Ethosuximide
Zarontin 250 mg/5 ml Syrup	IMED Healthcare Ltd.	PPA1463/181/001	Syrup	-Ethosuximide
Zarontin 250 mg/5 ml Syrup	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/042/001	Syrup	-Ethosuximide
Zarontin 250mg/5ml Syrup	Originalis B.V.	PPA2306/031/001	Syrup	-Ethosuximide
Zarontin 250mg/5ml Syrup	Essential Pharma (M) Limited	PA22644/005/001	Syrup	-Ethosuximide
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	-Ep2006 (recombinant human granulocyte-colony stimulating factor)
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	-Ep2006 (recombinant human granulocyte-colony stimulating factor)
Zavedos 1mg/ml solution for injection	Pfizer Healthcare Ireland	PA0822/142/005	Solution for injection	-Idarubicin hydrochloride
Zavesca	Janssen-Cilag International NV	EU/1/02/238/001	Capsule, hard	-Miglustat
Zavicefta	Pfizer Ireland Pharmaceuticals	EU/1/16/1109/001	Powder for concentrate for solution for infusion	-Avibactam sodium -Ceftazidime pentahydrate
Zebinix	BIAL-Portela & Ca, S.A	EU/1/09/514/021-023	Tablet	-Eslicarbazepine acetate
Zebinix	BIAL-Portela & Ca, S.A	EU/1/09/514/024	Oral suspension	-Eslicarbazepine acetate
Zebinix	BIAL-Portela & Ca, S.A	EU/1/09/514/12-20	Tablet	-Eslicarbazepine acetate
Zebinix	BIAL-Portela & Ca, S.A	EU/1/09/514/1-6	Tablet	-Eslicarbazepine acetate
Zebinix	BIAL-Portela & Ca, S.A	EU/1/09/514/7-11	Tablet	-Eslicarbazepine acetate
Zedbac 500 mg powder for concentrate for solution for infusion	Morningside Healthcare (Malta) Limited	PA23142/010/001	Powder for concentrate for solution for infusion	-Azithromycin dihydrate
Zeffix	GlaxoSmithKline (Ireland) Limited	EU/1/99/114/001	Film-coated tablet	-Lamivudine

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Zeffix	GlaxoSmithKline (Ireland) Limited	EU/1/99/114/002	Film-coated tablet	-Lamivudine
Zeffix	GlaxoSmithKline (Ireland) Limited	EU/1/99/114/003	Oral solution	-Lamivudine
Zejula	GlaxoSmithKline (Ireland) Limited	EU/1/17/1235/001-003	Capsule, hard	-Niraparib tosylate monohydrate
Zejula	GlaxoSmithKline (Ireland) Limited	EU/1/17/1235/004-005	Film-coated tablet	-Niraparid tosylate monohydrate
Zelboraf	Roche Registration GmbH	EU/1/12/751/001	Film-coated tablet	-Vemurafenib
Zemplar 1 microgram capsules, soft	AbbVie Limited	PA1824/005/001	Capsule, soft	-Paricalcitol
Zemplar 2 micrograms capsules, soft	AbbVie Limited	PA1824/005/002	Capsule, soft	-Paricalcitol
Zemplar 5 micrograms/ml solution for injection	AbbVie Limited	PA1824/005/004	Solution for injection	-Paricalcitol
Zepatier	Merck Sharp & Dohme BV,	EU/1/16/1119/001	Film-coated tablet	-Grazoprevir -Elbasvir
Zeposia	Bristol-Myers Squibb Pharma EEIG	EU/1/20/1442/001	Capsule, hard	-OZANIMOD
Zeposia	Bristol-Myers Squibb Pharma EEIG	EU/1/20/1442/002-003	Capsule, hard	-OZANIMOD
Zerbaxa	Merck Sharp & Dohme BV,	EU/1/15/1032/001	Powder for concentrate for solution for infusion	-Ceftolozane sulfate -Tazobactam sodium
Zercepac	Accord Healthcare S.L.U.	EU/1/20/1456/001	Powder for concentrate for solution for infusion	-Trastuzumab
Zerlinda 4 mg/100 ml solution for infusion	Teva B.V.	PA1986/119/001	Solution for infusion	-Zoledronic acid
Zerseos 0.5 mg/2.5 mg per 2.5 ml nebuliser solution	Azure Pharmaceuticals Ltd	PA22871/011/001	Nebuliser solution	-Ipratropium bromide monohydrate -SALBUTAMOL SULFATE
Zessly	Sandoz GmbH	EU/1/18/1280/001-005	Powder for concentrate for solution for infusion	-Infliximab
Zestan 10 mg tablets	Clonmel Healthcare Ltd	PA0126/112/003	Tablet	-Lisinopril Dihydrate
Zestan 2.5mg Tablets	Clonmel Healthcare Ltd	PA0126/112/001	Tablet	-Lisinopril Dihydrate
Zestan 20 mg tablets	Clonmel Healthcare Ltd	PA0126/112/004	Tablet	-Lisinopril Dihydrate
Zestan 5mg Tablets	Clonmel Healthcare Ltd	PA0126/112/002	Tablet	-Lisinopril Dihydrate
Zestoretic 10 mg /12.5 mg Tablets	Atnahs Pharma Netherlands B.V.	PA23140/001/001	Tablet	-Lisinopril Dihydrate -Hydrochlorothiazide
Zestoretic 20 mg/12.5 mg Tablets	Atnahs Pharma Netherlands B.V.	PA23140/001/002	Tablet	-Hydrochlorothiazide -lisinopril anhydrous
Zestril 10 mg Tablets	Atnahs Pharma Netherlands B.V.	PA23140/002/002	Tablet	-Lisinopril
Zestril 20mg Tablets	Atnahs Pharma Netherlands B.V.	PA23140/002/003	Tablet	-Lisinopril
Zestril 5 mg Tablets	PCO Manufacturing Ltd.	PPA0465/066/005	Tablet	-Lisinopril
Zestril 5mg Tablets	Atnahs Pharma Netherlands B.V.	PA23140/002/001	Tablet	-Lisinopril
Zevalin	Ceft Biopharma s.r.o	EU/1/03/264/001	Kit for radiopharmaceutical preparation	-Ibritumomabum tiuxetan
Ziagen	ViiV Healthcare BV	EU/1/99/112/001	Film-coated tablet	-Abacavir sulfate
Ziagen	ViiV Healthcare BV	EU/1/99/112/002	Oral solution	-Abacavir sulfate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
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	-Bemiparin sodium
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	-Bemiparin sodium
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	-Bemiparin sodium
Ziextenzo	Sandoz GmbH	EU/1/18/1327/001	Solution for injection in pre-filled syringe	-Pegfilgrastim
Zilbrysq	UCB Pharma S.A.	EU/1/23/1764/001-002	Solution for injection in pre-filled syringe	-Zilucoplan
Zilbrysq	UCB Pharma S.A.	EU/1/23/1764/003-004	Solution for injection in pre-filled syringe	-Zilucoplan
Zilbrysq	UCB Pharma S.A.	EU/1/23/1764/005-006	Solution for injection in pre-filled syringe	-Zilucoplan
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	-Indacaterol acetate -Glycopyrronium bromide -Mometasone furoate
Zimoclone 7.5 mg film-coated tablets	Viartis Limited	PA23266/009/001	Film-coated tablet	-Zopiclone
Zimovane 7.5 mg Film-coated Tablets	Viartis Healthcare Limited	PA23355/017/001	Film-coated tablet	-Zopiclone
Zinacef 750 mg Powder for Solution or Suspension for Injection	Sandoz Pharmaceuticals d.d.	PA23311/002/002	Powder for solution for injection	-Cefuroxime Sodium
Zinacef 1.5 g Powder for Solution for Injection or Infusion	Sandoz Pharmaceuticals d.d.	PA23311/002/003	Powder for solution for injection/infusion	-Cefuroxime Sodium
Zinacef 250 mg Powder for Solution or Suspension for Injection	Sandoz Pharmaceuticals d.d.	PA23311/002/001	Powder for solution for injection	-Cefuroxime Sodium
Zinc 15% w/w Ointment	Ovelle Limited	PA0206/028/001	Ointment	-Zinc oxide
Zindaclin 1% Gel	Canute Pharma (Ireland) Limited	PA23139/001/001	Gel	-CLINDAMYCIN PHOSPHATE
Zineryt 40 mg + 12 mg powder and solvent for cutaneous solution	CHEPLAPHARM Arzneimittel GmbH	PA2239/018/001	Powder and solvent for cutaneous solution	-Erythromycin -Zinc acetate dihydrate
Zineryt 40 mg + 12 mg powder and solvent for cutaneous solution	IMED Healthcare Ltd.	PPA1463/067/001	Powder and solvent for cutaneous solution	-Erythromycin -Zinc acetate dihydrate
Zinforo	Pfizer Ireland Pharmaceuticals	EU/1/12/785/001	Powder for concentrate for solution for infusion	-Ceftaroline fosamil
Zinnat 125 mg film-coated tablets	Sandoz Pharmaceuticals d.d.	PA23311/003/002	Film-coated tablet	-Cefuroxime
Zinnat 125 mg/5 ml granules for oral suspension	Sandoz Pharmaceuticals d.d.	PA23311/003/005	Granules for oral suspension	-Cefuroxime axetil
Zinnat 250 mg film-coated tablets	Sandoz Pharmaceuticals d.d.	PA23311/003/003	Film-coated tablet	-Cefuroxime
Zinnat 250mg/5ml granules for oral suspension	Sandoz Pharmaceuticals d.d.	PA23311/003/001	Granules for oral suspension	-Cefuroxime axetil
Zinnat 500 mg film-coated tablets	Sandoz Pharmaceuticals d.d.	PA23311/003/004	Film-coated tablet	-Cefuroxime

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
ZINPLAVA (Formerly known Bezlotoxumab MSD))	Merck Sharp & Dohme BV	EU/1/16/1156/001	Concentrate for solution for infusion	-Bezlotoxumab
Zipzoc 20%, Impregnated Dressing	Evolan Pharma AB	PA2262/001/001	Impregnated dressing	-Zinc oxide
Zirabev	Pfizer Europe MA EEIG	EU/1/18/1344/001-002	Concentrate for solution for infusion	-Bevacizumab
Zirpine 1mg/ml Oral Solution	Pinewood Laboratories Ltd	PA0281/178/001	Oral solution	-Cetirizine dihydrochloride
Zirtek 1 mg/ml oral solution	PCO Manufacturing Ltd.	PPA0465/502/001	Oral solution	-Cetirizine dihydrochloride
Zirtek 1 mg/ml oral solution	IMED Healthcare Ltd.	PPA1463/214/001	Oral solution	-Cetirizine dihydrochloride
Zirtek 1 mg/ml oral solution	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/062/001	Oral solution	-Cetirizine dihydrochloride
Zirtek 1 mg/ml oral solution	UCB (Pharma) Ireland Limited	PA0891/008/003	Oral solution	-Cetirizine dihydrochloride
Zirtek 10 mg film-coated tablets	UCB (Pharma) Ireland Limited	PA0891/008/002	Film-coated tablet	-Cetirizine hydrochloride
Zirtek 10 mg/ml Oral Drops, Solution	UCB (Pharma) Ireland Limited	PA0891/008/004	Oral drops, solution	-Cetirizine dihydrochloride
Zirtek Allergy Relief 10 mg film-coated tablets	UCB (Pharma) Ireland Limited	PA0891/008/005	Film-coated tablet	-Cetirizine dihydrochloride
Zirtek Plus Decongestant 5mg/120mg Prolonged Release Tablet	UCB (Pharma) Ireland Limited	PA0891/008/001	Prolonged-release tablet	-PSEUDOEPHEDRINE HYDROCHLORIDE -Cetirizine dihydrochloride
Zirtene 10 mg film-coated tablets	Viartis Limited	PA23266/017/001	Film-coated tablet	-Cetirizine dihydrochloride
Zismirt 30mg Film-coated tablets	McDermott Laboratories Ltd., T/A Gerard Laboratories	PA0577/059/001	Film-coated tablet	-Mirtazapine
Zispin 15 mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/025/001	Film-coated tablet	-Mirtazapine
Zispin 30 mg film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/025/002	Film-coated tablet	-Mirtazapine
Zispin SolTab 15 mg orodispersible tablets	Organon Pharma (Ireland) Limited	PA23198/015/001	Orodispersible tablet	-Mirtazapine
Zispin SolTab 30 mg orodispersible tablets	Organon Pharma (Ireland) Limited	PA23198/015/002	Orodispersible tablet	-Mirtazapine
Zispin SolTab 45 mg orodispersible tablets	Organon Pharma (Ireland) Limited	PA23198/015/003	Orodispersible tablet	-Mirtazapine
Zithromax capsules 250 mg	Pfizer Healthcare Ireland	PA0822/191/001	Capsule, hard	-Azithromycin
Zithromax Powder for Oral Suspension 200mg/5ml	Pfizer Healthcare Ireland	PA0822/191/002	Powder for oral suspension	-Azithromycin
Zitrease Allergy 10 mg Film-coated tablets	Bluefish Pharmaceuticals AB	PA1436/042/001	Film-coated tablet	-Cetirizine hydrochloride
Zocor 10 mg, film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/008/001	Film-coated tablet	-Simvastatin
Zocor 20 mg, film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/008/002	Film-coated tablet	-Simvastatin
Zocor 40 mg, film-coated tablets	Organon Pharma (Ireland) Limited	PA23198/008/003	Film-coated tablet	-Simvastatin
Zoely	Theramex Ireland Limited	EU/1/11/690/001-002	Film-coated tablet	-NOMEGESTROL ACETATE -Estradiol hemihydrate
ZOFENIL 30 mg film-coated tablet	Menarini International Operations Luxembourg S.A.	PA0865/003/003	Film-coated tablet	-Zofenopril calcium
ZOFENIL 7.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/003/001	Film-coated tablet	-Zofenopril calcium

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Zofenil Plus 30 mg/12.5 mg film-coated tablets	Menarini International Operations Luxembourg S.A.	PA0865/012/001	Film-coated tablet	-Zofenopril calcium -Hydrochlorothiazide
Zofran 4 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/113/001	Film-coated tablet	-Ondansetron
Zofran 4 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/158/002	Film-coated tablet	-Ondansetron
Zofran 4 mg film-coated tablets	Rowex Ltd	PA0711/327/003	Film-coated tablet	-Ondansetron
Zofran 4 mg/5 ml syrup	Rowex Ltd	PA0711/327/002	Syrup	-Ondansetron
Zofran 4mg/2ml Solution for Injection or Infusion	Rowex Ltd	PA0711/327/001	Solution for injection/infusion	-Ondansetron hydrochloride dihydrate
Zofran 8 mg film-coated tablets	Rowex Ltd	PA0711/327/004	Film-coated tablet	-Ondansetron
Zofran 8 mg film-coated tablets	IMED Healthcare Ltd.	PPA1463/158/003	Film-coated tablet	-Ondansetron
Zofran 8 mg film-coated tablets	PCO Manufacturing Ltd.	PPA0465/113/002	Film-coated tablet	-Ondansetron
Zofran Zydis 4 mg oral lyophilisate	Originalis B.V.	PPA2306/006/001	Oral lyophilisate	-Ondansetron
Zofran Zydis 4 mg oral lyophilisate	PCO Manufacturing Ltd.	PPA0465/445/001	Oral lyophilisate	-Ondansetron
Zofran Zydis 4 mg oral lyophilisate	Rowex Ltd	PA0711/327/005	Oral lyophilisate	-Ondansetron
Zofran Zydis 8 mg oral lyophilisate	Rowex Ltd	PA0711/327/006	Oral lyophilisate	-Ondansetron
Zoftacot 3.35 mg/ml eye drops, solution in single-dose container	Laboratoires Thea	PA1107/013/001	Eye drops, solution in single-dose container	-Hydrocortisone sodium phosphate
Zokinvy	Eigerbio Europe Limited	EU/1/22/1660/001	Capsule, hard	-Lonafarnib
Zoladex 3.6 mg implant	AstraZeneca AB	PA1019/027/001	Implant	-Goserelin
Zoladex 3.6 mg implant	IMED Healthcare Ltd.	PPA1463/125/001	Implant	-Goserelin
Zoladex LA 10.8 mg implant	IMED Healthcare Ltd.	PPA1463/125/002	Implant	-Goserelin
Zoladex LA 10.8 mg Implant	Originalis B.V.	PPA2306/027/001	Implant	-Goserelin
Zoladex LA 10.8 mg implant	AstraZeneca AB	PA1019/027/002	Implant	-Goserelin
Zoledronic Acid 4 mg / 5 mL Concentrate for solution for infusion	Noridem Enterprises Limited	PA1122/016/001	Concentrate for solution for infusion	-Zoledronic acid
Zoledronic acid 4 mg/5 ml concentrate for solution for infusion	Fresenius Kabi Deutschland GmbH	PA2059/019/001	Concentrate for solution for infusion	-Zoledronic acid
Zoledronic Acid Accord	Accord Healthcare S.L.U.	EU/1/13/834/001-003	Concentrate for solution for infusion	-Zoledronic acid monohydrate
Zoledronic acid Actavis	Actavis Group hf	EU/1/12/759/001-003	Concentrate for solution for infusion	-Zoledronic acid monohydrate
Zoledronic Acid Hospir	Pfizer Europe MA EEIG	EU/1/12/800/001-002	Concentrate for solution for infusion	-Zoledronic acid monohydrate
Zoledronic Acid Hospir	Pfizer Europe MA EEIG	EU/1/12/800/003	Solution for infusion	-Zoledronic acid monohydrate
Zoledronic Acid Hospir	Pfizer Europe MA EEIG	EU/1/12/800/004	Solution for infusion	-Zoledronic acid monohydrate
Zoledronic acid medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/12/779/001-003	Concentrate for solution for infusion	-Zoledronic acid monohydrate
Zoledronic acid medac	medac Gesellschaft für klinische Spezialpräparate mbH	EU/1/12/779/004-006	Solution for infusion	-Zoledronic acid monohydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Zoledronic acid Mylan	Mylan Pharmaceuticals Limited	EU/1/12/786/001-003	Concentrate for solution for infusion	-Zoledronic acid monohydrate
ZOLEDRONIC ACID TEVA	Teva B.V.	EU/1/12/771/007-009	Solution for Infusion	-ZOLEDRONIC ACID TEVA
ZOLEDRONIC ACID TEVA PHARMA	Teva B.V.	EU/1/12/771/001-006	Solution for Infusion	-ZOLEDRONIC ACID
Zolepant 20 mg gastro-resistant tablets	Pinewood Laboratories Ltd	PA0281/140/001	Gastro-resistant tablet	-Pantoprazole
Zolepant 40 mg gastro-resistant tablets	Pinewood Laboratories Ltd	PA0281/140/002	Gastro-resistant tablet	-Pantoprazole
Zolmitriptan 2.5 mg Orodispersible Tablets	Accord Healthcare Ireland Ltd.	PA2315/232/001	Orodispersible tablet	-Zolmitriptan
Zolnod 10 mg film-coated tablets	Rowex Ltd	PA0711/039/001	Film-coated tablet	-Zolpidem tartrate
Zolpidem Tartrate Teva 10 mg film-coated tablets	Teva Pharma B.V.	PA0749/095/002	Film-coated tablet	-Zolpidem tartrate
Zolpidem Tartrate Teva 5 mg film-coated tablet	Teva Pharma B.V.	PA0749/095/001	Film-coated tablet	-Zolpidem tartrate
Zolsketil Pegylated Liposomal	Accord Healthcare S.L.U.	EU/1/22/1629/001-000	Concentrate for dispersion for infusion	-Doxorubicin Hydrochloride, Liposomal
Zomarist	Novartis Europharm Limited	EU/1/08/483/1-6	Film-coated tablet	
Zomarist	Novartis Europharm Limited	EU/1/08/483/7-18	Film-coated tablet	
Zomel 15 mg gastro-resistant capsule, hard	Clonmel Healthcare Ltd	PA0126/147/001	Gastro-resistant capsule, hard	-Lansoprazole
Zomel 30 mg gastro-resistant capsule, hard	Clonmel Healthcare Ltd	PA0126/147/002	Gastro-resistant capsule, hard	-Lansoprazole
Zometa	Phoenix Labs	EU/1/01/176/001	Powder and solvent for solution for infusion	-Zoledronic acid
Zometa	Phoenix Labs	EU/1/01/176/002	Powder and solvent for solution for injection	-Zoledronic acid
Zometa	Phoenix Labs	EU/1/01/176/003	Powder and solvent for solution for injection	-Zoledronic acid
Zometa	Phoenix Labs	EU/1/01/176/004	Concentrate for solution for infusion	-Zoledronic acid
Zometa	Phoenix Labs	EU/1/01/176/007-009	Powder and solvent for solution for infusion	-Zoledronic acid monohydrate
Zomig 2.5 mg Tablets	Grunenthal Pharma Ltd	PA2242/004/001	Film-coated tablet	-Zolmitriptan
Zomig 2.5 mg Tablets	IMED Healthcare Ltd.	PPA1463/168/001	Film-coated tablet	-Zolmitriptan
Zomig 2.5 mg tablets	PCO Manufacturing Ltd.	PPA0465/099/001	Film-coated tablet	-Zolmitriptan
Zomig Rapimelt 2.5 mg Orodispersible Tablets	PCO Manufacturing Ltd.	PPA0465/099/002	Orodispersible tablet	-Zolmitriptan
Zomig Rapimelt 2.5 mg orodispersible Tablets	IMED Healthcare Ltd.	PPA1463/168/002	Orodispersible tablet	-Zolmitriptan
Zomig Rapimelt 2.5 mg orodispersible Tablets	Grunenthal Pharma Ltd	PA2242/004/002	Orodispersible tablet	-Zolmitriptan
Zonegran	Amdipharm Limited	EU/1/04/307/003	Capsule, hard	-Zonisamide
Zonegran	Amdipharm Limited	EU/1/04/307/004	Capsule, hard	-Zonisamide
Zonegran	Amdipharm Limited	EU/1/04/307/1-4	Capsule, hard	-Zonisamide
Zonisamide Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1093/001-004	Capsule, hard	-Zonisamide

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Zonisamide Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1093/005-008	Capsule, hard	-Zonisamide
Zonisamide Mylan	Mylan Pharmaceuticals Limited	EU/1/16/1093/009-013	Capsule, hard	-Zonisamide
Zonisamide Neuraxpharm 100 mg tablets	Neuraxpharm Ireland Limited	PA23229/006/003	Tablet	-Zonisamide
Zonisamide Neuraxpharm 200 mg tablets	Neuraxpharm Ireland Limited	PA23229/006/004	Tablet	-Zonisamide
Zonisamide Neuraxpharm 25 mg tablets	Neuraxpharm Ireland Limited	PA23229/006/001	Tablet	-Zonisamide
Zonisamide Neuraxpharm 300 mg tablets	Neuraxpharm Ireland Limited	PA23229/006/005	Tablet	-Zonisamide
Zonisamide Neuraxpharm 50 mg tablets	Neuraxpharm Ireland Limited	PA23229/006/002	Tablet	-Zonisamide
Zonisamide Rowex 100 mg hard capsules	Rowex Ltd	PA0711/336/003	Capsule, hard	-Zonisamide
Zonisamide Rowex 25 mg hard capsules	Rowex Ltd	PA0711/336/001	Capsule, hard	-Zonisamide
Zonisamide Rowex 50 mg hard capsules	Rowex Ltd	PA0711/336/002	Capsule, hard	-Zonisamide
Zoonotic Influenza Vaccine Seqirus	Seqirus S.r.l.	EU/1/23/1761/001-002	Suspension for injectio	- A/TURKEY/TURKEY/1/05 (H5N1)-LIKE STRAIN (NIBRG-23)
Zopiclone Pinewood 3.75 mg film-coated tablets	Pinewood Laboratories Ltd	PA0281/257/002	Film-coated tablet	-Zopiclone
Zopiclone Pinewood 7.5 mg Film-Coated Tablets	Pinewood Laboratories Ltd	PA0281/257/001	Film-coated tablet	-Zopiclone
Zopitan 3.75 mg Film-Coated Tablet	Clonmel Healthcare Ltd	PA0126/104/001	Film-coated tablet	-Zopiclone
Zopitan 7.5 mg Film-Coated Tablet	Clonmel Healthcare Ltd	PA0126/104/002	Film-coated tablet	-Zopiclone
Zorclon 7.5 mg Film-Coated Tablets	Teva B.V.	PA1986/080/001	Film-coated tablet	-Zopiclone
Zoreeda 25 microgram/125 microgram per actuation pressurised inhalation, suspension	Cipla Europe NV	PA1963/009/001	Pressurised inhalation, suspension	-Fluticasone propionate -SALMETEROL XINAFOATE
Zoreeda 25 microgram/250 microgram per actuation pressurised inhalation, suspension	Cipla Europe NV	PA1963/009/002	Pressurised inhalation, suspension	-Fluticasone propionate -SALMETEROL XINAFOATE
Zostavax	Merck Sharp & Dohme BV,	EU/1/06/341/003	Powder and solvent for suspension for injection in pre-filled syringe	-Varicella-zoster virus, oka/merck strain (live attenuated)
Zostavax	Merck Sharp & Dohme BV,	EU/1/06/341/01-13	Powder and solvent for suspension for injection	-Varicella virus vaccine live (oka/merck)
Zoton FasTab 15 mg Oro-Dispersible Tablets	Pfizer Healthcare Ireland	PA0822/101/002	Orodispersible tablet	-Lansoprazole
Zoton FasTab 15 mg oro-dispersible tablets	Merit Pharmaceuticals Limited	PPA23080/004/001	Orodispersible tablet	-Lansoprazole
Zoton FasTab 30 mg oro-dispersible tablets	Pfizer Healthcare Ireland	PA0822/101/003	Orodispersible tablet	-Lansoprazole

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Zoton FasTab 30mg oro-dispersible tablets	Merit Pharmaceuticals Limited	PPA23080/004/002	Orodispersible tablet	-Lansoprazole
Zovirax 200 mg Dispersible Tablets	IMED Healthcare Ltd.	PPA1463/199/001	Dispersible tablet	-Aciclovir
Zovirax 200 mg dispersible tablets	PCO Manufacturing Ltd.	PPA0465/038/005	Dispersible tablet	-Acyclovir
Zovirax 200 mg Dispersible Tablets	GlaxoSmithKline (Ireland) Limited	PA1077/084/007	Dispersible tablet	-Aciclovir
Zovirax 200 mg/5 mL Oral Suspension	GlaxoSmithKline (Ireland) Limited	PA1077/084/005	Oral suspension	-Aciclovir
Zovirax 200 mg/5 mL oral suspension	PCO Manufacturing Ltd.	PPA0465/038/008	Oral suspension	-Aciclovir
Zovirax 200 mg/5 mL Oral Suspension	IMED Healthcare Ltd.	PPA1463/199/003	Oral suspension	-Aciclovir
Zovirax 5 % w/w Cream	GlaxoSmithKline (Ireland) Limited	PA1077/084/001	Cream	-Acyclovir
Zovirax 800 mg Dispersible Tablets	GlaxoSmithKline (Ireland) Limited	PA1077/084/009	Dispersible tablet	-Aciclovir
Zovirax 800 mg Dispersible Tablets	IMED Healthcare Ltd.	PPA1463/199/002	Dispersible tablet	-Aciclovir
Zovirax 800 mg Dispersible Tablets	Originalis B.V.	PPA2306/030/001	Dispersible tablet	-Aciclovir
Zovirax 800 mg Dispersible Tablets	Merit Pharmaceuticals Limited	PPA23080/029/001	Dispersible tablet	-Aciclovir
Zovirax 800 mg Dispersible Tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/058/001	Dispersible tablet	-Aciclovir
Zovirax 800 mg Dispersible Tablets	PCO Manufacturing Ltd.	PPA0465/038/007	Dispersible tablet	-Aciclovir
Zovirax Double Strength 400 mg/5 mL Oral Suspension	GlaxoSmithKline (Ireland) Limited	PA1077/084/006	Oral suspension	-Acyclovir
Zovirax Duo 50 mg/g and 10 mg/g Cream	Haleon Ireland Limited	PA0678/143/001	Cream	-ACICLOVIR PH. EUR. -HYDROCORTISONE PH. EUR.
Zovirax IV for Infusion 250 mg, Powder for solution for infusion	GlaxoSmithKline (Ireland) Limited	PA1077/084/003	Powder for solution for infusion	-Aciclovir
ZTALMY	Marinus Pharmaceuticals Emerald Limited	EU/1/23/1743/001-002	Oral suspension	-Ganaxolone
Zubsolv	Accord Healthcare S.L.U.	EU/1/17/1233/001	Sublingual tablet	-Buprenorphine hydrochloride -Naloxone hydrochloride dihydrate
Zubsolv	Accord Healthcare S.L.U.	EU/1/17/1233/002	Sublingual tablet	-Buprenorphine hydrochloride -Naloxone hydrochloride dihydrate
Zubsolv	Accord Healthcare S.L.U.	EU/1/17/1233/003	Sublingual tablet	-Naloxone hydrochloride dihydrate -Buprenorphine hydrochloride
Zubsolv	Accord Healthcare S.L.U.	EU/1/17/1233/004	Sublingual tablet	-Naloxone hydrochloride dihydrate -Buprenorphine hydrochloride
Zubsolv	Accord Healthcare S.L.U.	EU/1/17/1233/005	Sublingual tablet	-Buprenorphine hydrochloride -Naloxone hydrochloride dihydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Zubsolv	Accord Healthcare S.L.U.	EU/1/17/1233/006	Sublingual tablet	-Naloxone hydrochloride dihydrate -Buprenorphine hydrochloride
Zutectra	Biotest Pharma GmbH	EU/1/09/600/001	Solution for injection in pre-filled syringe	-Human plasma protein >96% immunoglobulins -Hbs antibodies
Zyban 150 mg prolonged release tablets	GlaxoSmithKline (Ireland) Limited	PA1077/017/001	Prolonged-release tablet	-BUPROPION HYDROCHLORIDE
Zyban 150 mg prolonged release tablets	Lexon Pharmaceuticals (Ireland) Limited	PPA23176/047/001	Prolonged-release tablet	-BUPROPION HYDROCHLORIDE
Zyban 150 mg prolonged release tablets	Originalis B.V.	PPA2306/005/001	Prolonged-release tablet	-Bupropion hydrochloride
Zyban 150 mg prolonged-release tablets	PCO Manufacturing Ltd.	PPA0465/496/001	Prolonged-release tablet	-BUPROPION HYDROCHLORIDE
Zyclara	Viartis Healthcare Limited	EU/1/12/783/001-003	Cream	-Imiquimod
Zydelig	Gilead Sciences Ireland UC	EU/1/14/938/001	Film-coated tablet	-Idelalisib
Zydelig	Gilead Sciences Ireland UC	EU/1/14/938/002	Film-coated tablet	-Idelalisib
ZYDOL 50 mg Hard Capsules	Grunenthal Pharma Ltd	PA2242/005/001	Capsule, hard	-Tramadol hydrochloride
ZYDOL SR 100 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/005/003	Prolonged-release tablet	-Tramadol hydrochloride
ZYDOL SR 150 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/005/004	Prolonged-release tablet	-Tramadol hydrochloride
ZYDOL SR 200 mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/005/005	Prolonged-release tablet	-Tramadol hydrochloride
ZYDOL SR 50mg prolonged-release tablets	Grunenthal Pharma Ltd	PA2242/005/006	Prolonged-release tablet	-Tramadol hydrochloride
Zykadia	Novartis Europharm Limited	EU/1/15/999/001	Capsule, hard	-Ceritinib
Zykadia	Novartis Europharm Limited	EU/1/15/999/002-003	Film-coated tablet	-Ceritinib
ZYLLT	Krka d.d., Novo mesto	EU/1/09/553/001-10	Film-coated tablet	-CLOPIDOGREL HYDROGEN SULPHATE
Zyloric 100 mg Tablets	Aspen Pharma Trading Limited	PA1691/002/001	Tablet	-Allopurinol
Zyloric 300 mg Tablets	Aspen Pharma Trading Limited	PA1691/002/002	Tablet	-Allopurinol
Zynlonta	Swedish Orphan Biovitrum AB	EU/1/22/1695/001	Powder for concentrate for solution for infusion	-Loncastuximab Tesirine
Zynrelief	Heron Therapeutics B.V.	EU/1/20/1478/001	Prolonged-release wound solution	-Bupivacaine
Zynrelief	Heron Therapeutics B.V.	EU/1/20/1478/002	Prolonged-release wound solution	-Bupivacaine
Zynrelief	Heron Therapeutics B.V.	EU/1/20/1478/003	Prolonged-release wound solution	-Bupivacaine
Zypadhera	Eli Lilly Nederland B.V.	EU/1/08/479/001	Powder and solvent for prolonged-release suspension for injection	-Olanzapine pamoate monohydrate

Trade Name	Licence Holder	Licence Number	Dosage Form	Active Ingredients
Zypadhera	Eli Lilly Nederland B.V.	EU/1/08/479/002	Powder and solvent for prolonged-release suspension for injection	-Olanzapine pamoate monohydrate
Zypadhera	Eli Lilly Nederland B.V.	EU/1/08/479/003	Powder and solvent for prolonged-release suspension for injection	-Olanzapine pamoate monohydrate
Zyprexa	Eli Lilly Nederland B.V.	EU/1/96/022/002	Coated tablet	-Olanzapine
Zyprexa	Eli Lilly Nederland B.V.	EU/1/96/022/004	Coated tablet	-Olanzapine
Zyprexa	Eli Lilly Nederland B.V.	EU/1/96/022/006	Coated tablet	-Olanzapine
Zyprexa	Eli Lilly Nederland B.V.	EU/1/96/022/009	Coated tablet	-Olanzapine
Zyprexa	Eli Lilly Nederland B.V.	EU/1/96/022/012	Coated tablet	-Olanzapine
Zyprexa	Eli Lilly Nederland B.V.	EU/1/96/022/014	Coated tablet	-Olanzapine
Zyprexa	Eli Lilly Nederland B.V.	EU/1/96/022/016	Powder for solution for injection	-Olanzapine
ZYPREXA VELOTAB	Eli Lilly Nederland B.V.	EU/1/99/125/001	Orodispersible tablet	-Olanzapine
Zyprexa Velotab	Eli Lilly Nederland B.V.	EU/1/99/125/002	Orodispersible tablet	-Olanzapine
Zyprexa Velotab	Eli Lilly Nederland B.V.	EU/1/99/125/003	Orodispersible tablet	-Olanzapine
Zyprexa Velotab	Eli Lilly Nederland B.V.	EU/1/99/125/004	Orodispersible tablet	-Olanzapine
Zytiga	Janssen-Cilag International NV	EU/1/11/714/001	Tablet	-Abiraterone acetate
Zytiga	Janssen-Cilag International NV	EU/1/11/714/002-003	Film-coated tablet	-Abiraterone acetate
Zyvox 100 mg/5 ml granules for oral suspension	Pfizer Healthcare Ireland	PA0822/143/001	Granules for oral suspension	-Linezolid
Zyvox 2 mg/ml solution for infusion	Pfizer Healthcare Ireland	PA0822/143/002	Solution for infusion	-Linezolid
Zyvox 600 mg Film-Coated Tablets	Pfizer Healthcare Ireland	PA0822/143/004	Film-coated tablet	-Linezolid