

Package leaflet: Information for the user  
**LIPITOR® 10 mg, 20 mg, 40 mg and 80 mg**  
**Film-coated Tablets**

Atorvastatin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Lipitor tablets marketed in Ireland are normally white, oval shaped marked 10,20,40 or 80 on one side and 'PD155', 'PD156', 'PD157' or 'PD158' on the other side. Lipitor tablets imported from the UK are white with a circular shape, marked 10, 20, 40 or 80 on one side and 'ATV' on the other. Despite these minor differences in appearance, the Irish and UK products are equivalent.

**What is in this leaflet:**

1. What Lipitor is and what it is used for
2. What you need to know before you take Lipitor
3. How to take Lipitor
4. Possible side effects
5. How to store Lipitor
6. Contents of the pack and other information

**1. What Lipitor is and what it is used for**

Lipitor belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

Lipitor is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed.

If you are at an increased risk of heart disease, Lipitor can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.

**2. What you need to know before you take Lipitor**

**Do not take Lipitor**

- if you are allergic to atorvastatin or to any similar medicines used to lower blood lipids or to any of the other ingredients of this medicine (listed in section 6)
- if you have or have ever had a disease which affects the liver
- if you have had any unexplained abnormal blood tests for liver function
- if you are a woman able to have children and not using reliable contraception
- if you are pregnant or trying to become pregnant
- if you are breast-feeding.

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Lipitor.

The following are reasons why Lipitor may not be suitable for you:

- if you have had a previous stroke with bleeding into the brain, or have small pockets of fluid in the brain from previous strokes
- if you have kidney problems
- if you have an under-active thyroid gland (hypothyroidism)
- if you have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems
- if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other '-statin' or '-fibrate' medicines)
- if you regularly drink a large amount of alcohol
- if you have a history of liver disease
- if you are older than 70 years

**Check with your doctor or pharmacist before taking Lipitor**

- if you have severe respiratory failure .

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your Lipitor treatment to predict your risk of muscle related side effects. The risk of muscle related side effects e.g rhabdomyolysis is known to increase when certain medicines are taken at the same time (see section 2 "Other medicines and Lipitor").

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

**Other medicines and Lipitor**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There are some medicines that may change the effect of Lipitor or their effect may be changed by Lipitor. This type of

interaction could make one or both of the medicines less effective.

Alternatively it could increase the risk or severity of side-effects, including the important muscle wasting condition known as rhabdomyolysis described in section 4:

- Medicines used to alter the way your immune system works, e.g. ciclosporin
- Certain antibiotics or antifungal medicines, e.g. erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampin, fusidic acid
- Other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol
- Some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine, diltiazem,; medicines to regulate your heart rhythm e.g. digoxin, verapamil, amiodarone
- Medicines used in the treatment of HIV e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, the combination of tipranavir/ritonavir etc.
- Some medicines used in the treatment of hepatitis C e.g. telaprevir
- Other medicines known to interact with Lipitor include ezetimibe (which lowers cholesterol), warfarin (which reduces blood clotting), oral contraceptives, stiripentol (an anti-convulsant for epilepsy), cimetidine (used for heartburn and peptic ulcers), phenazone (a painkiller), colchicine (used to treat gout), antacids (indigestion products containing aluminium or magnesium) and boceprevir (used to treat liver disease such as hepatitis C)
- Medicines obtained without a prescription: St John's Wort

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Lipitor with food and drink**

See section 3 for instructions on how to take Lipitor. Please note the following:

*Grapefruit juice*

Do not take more than one or two small glasses of grapefruit juice per day because large quantities of grapefruit juice can change the effects of Lipitor.

*Alcohol*

Avoid drinking too much alcohol while taking this medicine. See section 2 "Warnings and precautions" for details

**Pregnancy and breast-feeding**

Do not take Lipitor if you are pregnant, or if you are trying to become pregnant.

Do not take Lipitor if you are able to become pregnant unless you use reliable contraceptive measures.

Do not take Lipitor if you are breast-feeding.

The safety of Lipitor during pregnancy and breast-feeding has not yet been proven. Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

Normally this medicine does not affect your ability to drive or operate machines. However, do not drive if this medicine affects your ability to drive. Do not use any tools or machines if your ability to use them is affected by this medicine.

**Lipitor contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**3. How to take Lipitor**

Before starting treatment, your doctor will place you on a low-cholesterol diet, which you should maintain also during therapy with Lipitor.

The usual starting dose of Lipitor is 10 mg once a day in adults and children aged 10 years or older. This may be increased if necessary by your doctor until you are taking the amount you need. Your doctor will adapt the dose at intervals of 4 weeks or more. The maximum dose of Lipitor is 80 mg once daily for adults and 20 mg once daily for children.

Lipitor tablets should be swallowed whole with a drink of water, and can be taken at any time of day, with or without food. However, try to take your tablet at the same time every day.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**The duration of treatment with Lipitor is determined by your doctor.**

Please ask your doctor if you think that the effect of Lipitor is too strong or too weak.

**If you take more Lipitor than you should**

If you accidentally take too many Lipitor tablets (more than your usual daily dose), contact your doctor or nearest hospital for advice.

**If you forget to take Lipitor**

If you forget to take a dose, just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Lipitor**

If you have any further questions on the use of this medicine or wish to stop your treatment, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you experience any of the following serious side effects, stop taking your tablets and tell your doctor immediately or go to the nearest hospital accident and emergency department.**

Rare: may affect up to 1 in 1,000 people

- Serious allergic reaction which causes swelling of the face, tongue and throat that can cause great difficulty in breathing.
- Serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever. Skin rash with pink-red blotches especially on palms of hands or soles of feet which may blister.
- Muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown. The abnormal muscle breakdown does not always go away, even after you have stopped taking atorvastatin, and it can be life-threatening and lead to kidney problems.

Very rare: may affect up to 1 in 10,000 people

- If you experience problems with unexpected or unusual bleeding or bruising, this may be suggestive of a liver complaint. You should consult your doctor as soon as possible.

#### Other possible side effects with Lipitor:

Common side effects (may affect up to 1 in 10 people) include:

- inflammation of the nasal passages, pain in the throat, nose bleed
- allergic reactions
- increases in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels), increase in blood creatine kinase
- headache
- nausea, constipation, wind, indigestion, diarrhoea
- joint pain, muscle pain and back pain
- blood test results that show your liver function can become abnormal

Uncommon side effects (may affect up to 1 in 100 people) include:

- anorexia (loss of appetite), weight gain, decreases in blood sugar levels (if you have diabetes you should continue careful monitoring of your blood sugar levels)
- having nightmares, insomnia
- dizziness, numbness or tingling in the fingers and toes, reductions of sensation to pain or touch, change in sense of taste, loss of memory
- blurred vision
- ringing in the ears and/or head
- vomiting, belching, abdominal pain upper and lower, pancreatitis (inflammation of the pancreas leading to stomach pain)
- hepatitis (liver inflammation)
- rash, skin rash and itching, hives, hair loss
- neck pain, muscle fatigue
- fatigue, feeling unwell, weakness, chest pain, swelling especially in the ankles (oedema), raised temperature
- urine tests that are positive for white blood cells

Rare side effects (may affect up to 1 in 1,000 people) include:

- visual disturbance
- unexpected bleeding or bruising
- cholestasis (yellowing of the skin and whites of the eyes)
- tendon injury

Very rare side effects (may affect up to 1 in 10,000 people) include:

- an allergic reaction - symptoms may include sudden wheezing and chest pain or tightness, swelling of the eyelids, face, lips, mouth, tongue or throat, difficulty breathing, collapse
- hearing loss
- gynecomastia (breast enlargement in men).

Side effects of unknown frequency:

- Muscle weakness that is constant.

Possible side effects reported with some statins (medicines of the same type):

- Sexual difficulties
- Depression
- Breathing problems including persistent cough and/or shortness of breath or fever
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Lipitor

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the container and outer packaging after {EXP}. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

##### What Lipitor contains

- The active substance is atorvastatin.
- Each film-coated tablet contains 10mg, 20mg, 40mg or 80mg of atorvastatin (as atorvastatin calcium trihydrate).
- The other ingredients of Lipitor are: calcium carbonate, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, polysorbate 80, hydroxypropyl cellulose and magnesium stearate.
- The coating of Lipitor film-coated tablets contains hypromellose, macrogol 8000, titanium dioxide, talc, simeticone, macrogol stearate and sorbic acid.
- The circular-shaped 10, 20, 40 and 80 mg tablets also contain stearate emulsifiers, thickeners, and benzoic acid.
- The elliptical shaped 10, 20 and 40 mg tablets also contain candelilla wax.

##### What Lipitor looks like and contents of the pack

Lipitor 10 mg Film-Coated Tablets are white with an oval shape. They are marked with 10 on one side and PD155 on the other side OR white with a round shape marked with 10 on one side and ATV on the other side.

Lipitor 20 mg Film-Coated Tablets are white with an oval shape. They are marked with 20 on one side and PD156 on the other side. OR white with a round shape marked with 20 on one side and ATV on the other side.

Lipitor 40 mg Film-Coated Tablets are white with an oval shape. They are marked with 40 on one side and PD157 on the other side. OR white with a round shape marked with 40 on one side and ATV on the other side.

Lipitor 80 mg Film-Coated Tablets are white with an oval shape. They are marked with 80 on one side and PD158 on the other side. OR white with a round shape marked with 80 on one side and ATV on the other side.

Each strength of Lipitor is supplied in blister packs of 28 tablets.

##### Procured from within the EU by the Parallel Product Authorisation

**Holder:** Clear Pharmacy, 157-173 Roden Street, Belfast, BT12 5QA, UK

##### Manufacturer

Goedecke GmbH, Mooswaldallee 1, D-79090 Freiburg, Germany

##### Repackager

Cast Healthcare Ltd, 5-7 Tobermore Road, Draperstown, BT45 7AG, UK.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria, Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia	Sortis
Belgium, Cyprus, Finland, Greece, Ireland, Luxembourg, Malta, Netherlands, Norway, Sweden, United Kingdom	Lipitor
Denmark, Iceland, Portugal, Spain	Zarator
France	Tahor
Germany	Atorvastatin Pfizer,
Italy	Xarator

**Leaflet date: DECEMBER 2015**

20160322

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- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Lipitor tablets marketed in Ireland are normally white, oval shaped marked 10,20,40 or 80 on one side and 'PD155', 'PD156', 'PD157' or 'PD158' on the other side. Lipitor tablets imported from the UK are white with a circular shape, marked 10, 20, 40 or 80 on one side and 'ATV' on the other. Despite these minor differences in appearance, the Irish and UK products are equivalent.

**What is in this leaflet:**

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6. Contents of the pack and other information

**1. What Lipitor is and what it is used for**

Lipitor belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

Lipitor is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed.

If you are at an increased risk of heart disease, Lipitor can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.

**2. What you need to know before you take Lipitor**

**Do not take Lipitor**

- if you are allergic to atorvastatin or to any similar medicines used to lower blood lipids or to any of the other ingredients of this medicine (listed in section 6)
- if you have or have ever had a disease which affects the liver
- if you have had any unexplained abnormal blood tests for liver function
- if you are a woman able to have children and not using reliable contraception
- if you are pregnant or trying to become pregnant
- if you are breast-feeding.

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Lipitor.

The following are reasons why Lipitor may not be suitable for you:

- if you have had a previous stroke with bleeding into the brain, or have small pockets of fluid in the brain from previous strokes
- if you have kidney problems
- if you have an under-active thyroid gland (hypothyroidism)
- if you have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems
- if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other '-statin' or '-fibrate' medicines)
- if you regularly drink a large amount of alcohol
- if you have a history of liver disease
- if you are older than 70 years

**Check with your doctor or pharmacist before taking Lipitor**

- if you have severe respiratory failure .

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your Lipitor treatment to predict your risk of muscle related side effects. The risk of muscle related side effects e.g rhabdomyolysis is known to increase when certain medicines are taken at the same time (see section 2 "Other medicines and Lipitor").

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

**Other medicines and Lipitor**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There are some medicines that may change the effect of Lipitor or their effect may be changed by Lipitor. This type of

interaction could make one or both of the medicines less effective. Alternatively it could increase the risk or severity of side-effects, including the important muscle wasting condition known as rhabdomyolysis described in section 4:

- Medicines used to alter the way your immune system works, e.g. ciclosporin
- Certain antibiotics or antifungal medicines, e.g. erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampin, fusidic acid
- Other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol
- Some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine, diltiazem,; medicines to regulate your heart rhythm e.g. digoxin, verapamil, amiodarone
- Medicines used in the treatment of HIV e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, the combination of tipranavir/ritonavir etc.
- Some medicines used in the treatment of hepatitis C e.g. telaprevir
- Other medicines known to interact with Lipitor include ezetimibe (which lowers cholesterol), warfarin (which reduces blood clotting), oral contraceptives, stiripentol (an anti-convulsant for epilepsy), cimetidine (used for heartburn and peptic ulcers), phenazone (a painkiller), colchicine (used to treat gout), antacids (indigestion products containing aluminium or magnesium) and boceprevir (used to treat liver disease such as hepatitis C)
- Medicines obtained without a prescription: St John's Wort

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Lipitor with food and drink**

See section 3 for instructions on how to take Lipitor. Please note the following:

*Grapefruit juice*

Do not take more than one or two small glasses of grapefruit juice per day because large quantities of grapefruit juice can change the effects of Lipitor.

*Alcohol*

Avoid drinking too much alcohol while taking this medicine. See section 2 "Warnings and precautions" for details

**Pregnancy and breast-feeding**

Do not take Lipitor if you are pregnant, or if you are trying to become pregnant.

Do not take Lipitor if you are able to become pregnant unless you use reliable contraceptive measures.

Do not take Lipitor if you are breast-feeding.

The safety of Lipitor during pregnancy and breast-feeding has not yet been proven. Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

Normally this medicine does not affect your ability to drive or operate machines. However, do not drive if this medicine affects your ability to drive. Do not use any tools or machines if your ability to use them is affected by this medicine.

**Lipitor contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**3. How to take Lipitor**

Before starting treatment, your doctor will place you on a low-cholesterol diet, which you should maintain also during therapy with Lipitor.

The usual starting dose of Lipitor is 10 mg once a day in adults and children aged 10 years or older. This may be increased if necessary by your doctor until you are taking the amount you need. Your doctor will adapt the dose at intervals of 4 weeks or more. The maximum dose of Lipitor is 80 mg once daily for adults and 20 mg once daily for children.

Lipitor tablets should be swallowed whole with a drink of water, and can be taken at any time of day, with or without food. However, try to take your tablet at the same time every day.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**The duration of treatment with Lipitor is determined by your doctor.**

Please ask your doctor if you think that the effect of Lipitor is too strong or too weak.

**If you take more Lipitor than you should**

If you accidentally take too many Lipitor tablets (more than your usual daily dose), contact your doctor or nearest hospital for advice.

**If you forget to take Lipitor**

If you forget to take a dose, just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Lipitor**

If you have any further questions on the use of this medicine or wish to stop your treatment, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you experience any of the following serious side effects, stop taking your tablets and tell your doctor immediately or go to the nearest hospital accident and emergency department.**

Rare: may affect up to 1 in 1,000 people

- Serious allergic reaction which causes swelling of the face, tongue and throat that can cause great difficulty in breathing.
- Serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever. Skin rash with pink-red blotches especially on palms of hands or soles of feet which may blister.
- Muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown. The abnormal muscle breakdown does not always go away, even after you have stopped taking atorvastatin, and it can be life-threatening and lead to kidney problems.

Very rare: may affect up to 1 in 10,000 people

- If you experience problems with unexpected or unusual bleeding or bruising, this may be suggestive of a liver complaint. You should consult your doctor as soon as possible.

#### Other possible side effects with Lipitor:

Common side effects (may affect up to 1 in 10 people) include:

- inflammation of the nasal passages, pain in the throat, nose bleed
- allergic reactions
- increases in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels), increase in blood creatine kinase
- headache
- nausea, constipation, wind, indigestion, diarrhoea
- joint pain, muscle pain and back pain
- blood test results that show your liver function can become abnormal

Uncommon side effects (may affect up to 1 in 100 people) include:

- anorexia (loss of appetite), weight gain, decreases in blood sugar levels (if you have diabetes you should continue careful monitoring of your blood sugar levels)
- having nightmares, insomnia
- dizziness, numbness or tingling in the fingers and toes, reductions of sensation to pain or touch, change in sense of taste, loss of memory
- blurred vision
- ringing in the ears and/or head
- vomiting, belching, abdominal pain upper and lower, pancreatitis (inflammation of the pancreas leading to stomach pain)
- hepatitis (liver inflammation)
- rash, skin rash and itching, hives, hair loss
- neck pain, muscle fatigue
- fatigue, feeling unwell, weakness, chest pain, swelling especially in the ankles (oedema), raised temperature
- urine tests that are positive for white blood cells

Rare side effects (may affect up to 1 in 1,000 people) include:

- visual disturbance
- unexpected bleeding or bruising
- cholestasis (yellowing of the skin and whites of the eyes)
- tendon injury

Very rare side effects (may affect up to 1 in 10,000 people) include:

- an allergic reaction - symptoms may include sudden wheezing and chest pain or tightness, swelling of the eyelids, face, lips, mouth, tongue or throat, difficulty breathing, collapse
- hearing loss
- gynaecomastia (breast enlargement in men).

Side effects of unknown frequency:

- Muscle weakness that is constant.

Possible side effects reported with some statins (medicines of the same type):

- Sexual difficulties
- Depression
- Breathing problems including persistent cough and/or shortness of breath or fever
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Lipitor

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the container and outer packaging after {EXP}. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

##### What Lipitor contains

- The active substance is atorvastatin.
- Each film-coated tablet contains 10mg, 20mg, 40mg or 80mg of atorvastatin (as atorvastatin calcium trihydrate).
- The other ingredients of Lipitor are: calcium carbonate, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, polysorbate 80, hydroxypropyl cellulose and magnesium stearate.
- The coating of Lipitor film-coated tablets contains hypromellose, macrogol 8000, titanium dioxide, talc, simeticone, macrogol stearate and sorbic acid.
- The circular-shaped 10, 20, 40 and 80 mg tablets also contain stearate emulsifiers, thickeners, and benzoic acid.
- The elliptical shaped 10, 20 and 40 mg tablets also contain candelilla wax.

##### What Lipitor looks like and contents of the pack

Lipitor 10 mg Film-Coated Tablets are white with an oval shape. They are marked with 10 on one side and PD155 on the other side OR white with a round shape marked with 10 on one side and ATV on the other side.

Lipitor 20 mg Film-Coated Tablets are white with an oval shape. They are marked with 20 on one side and PD156 on the other side. OR white with a round shape marked with 20 on one side and ATV on the other side.

Lipitor 40 mg Film-Coated Tablets are white with an oval shape. They are marked with 40 on one side and PD157 on the other side. OR white with a round shape marked with 40 on one side and ATV on the other side.

Lipitor 80 mg Film-Coated Tablets are white with an oval shape. They are marked with 80 on one side and PD158 on the other side. OR white with a round shape marked with 80 on one side and ATV on the other side.

Each strength of Lipitor is supplied in blister packs of 28 tablets.

##### Procured from within the EU by the Parallel Product Authorisation

**Holder:** Clear Pharmacy, 157-173 Roden Street, Belfast, BT12 5QA, UK

##### Manufacturer

Goedecke GmbH, Mooswaldallee 1, D-79090 Freiburg, Germany

##### Repackager

Pharmaram Ltd, Unit F4 Ivanhoe Business Park, Tom Bill Way, Ashby de la Zouch, Leicestershire LE65 2UY, UK.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria, Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia	Sortis
Belgium, Cyprus, Finland, Greece, Ireland, Luxembourg, Malta, Netherlands, Norway, Sweden, United Kingdom	Lipitor
Denmark, Iceland, Portugal, Spain	Zarator
France	Tahor
Germany	Atorvastatin Pfizer,
Italy	Xarator

**Leaflet date: DECEMBER 2015**


20160322

**PARALLEL IMPORT PACKAGE LEAFLET  
STATEMENT OF COMPLIANCE**

*To be submitted with an application for a parallel import licence, provided that the conditions for the package leaflet to be regarded as sufficiently similar to the leaflet on the Irish market outlined in Annex I of the HPRA guide to labels and leaflets are met.*

1. Name and address of the proposed parallel import licence holder: <b>Clear Pharmacy</b> <b>157-173 Roden Street</b> <b>BT12 5QA</b> <b>UK</b>	Name and address of the applicant, if different: <b>Megan Koritnik-Wright</b> <b>Freelance Regulatory</b>
2. Name of product to be marketed: <b>Lipitor</b>  Pharmaceutical form: <b>film-coated tablets</b>	Active substance(s): <b>atorvastatin</b>  Strength(s): <b>10, 20, 40, 80mg</b>
3. Leaflet to be printed:  Size of the finished leaflet (e.g. A4, A5):  Font and size used for body text:  Finished format:	Single-sided <input type="checkbox"/> Double-sided <input checked="" type="checkbox"/>  A4  Times New Roman 8pt  Flat sheet <input checked="" type="checkbox"/> Booklet <input type="checkbox"/> Other

The text of the leaflet exactly follows the text of the Irish leaflet except for product specific differences.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
A full-scale mock-up of the leaflet has been provided.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
List other previously approved leaflets for this product which satisfies the consultation requirement by similarity to the Irish leaflet:	<i>Include the PPA numbers:</i>

Signed: 

Date: 22/03/2016

Position: Freelance Regulatory on behalf of Clear Pharmacy

Package leaflet: Information for the user  
**LIPITOR® 10 mg, 20 mg and 40 mg**  
**Film-coated Tablets**

Atorvastatin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Lipitor tablets marketed in Ireland are normally white, oval shaped marked 10,20 or 40 on one side and 'PD155', 'PD156' or 'PD157' on the other side.

Lipitor tablets imported from Spain are white with a circular shape, marked 10, 20 or 40 on one side and 'ATV' on the other. Despite these minor differences in appearance, the Irish and Spanish products are equivalent

**What is in this leaflet:**

1. What Lipitor is and what it is used for
2. What you need to know before you take Lipitor
3. How to take Lipitor
4. Possible side effects
5. How to store Lipitor
6. Contents of the pack and other information

**1. What Lipitor is and what it is used for**

Lipitor belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

Lipitor is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed.

If you are at an increased risk of heart disease, Lipitor can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.

**2. What you need to know before you take Lipitor**

**Do not take Lipitor**

- if you are allergic to atorvastatin or to any similar medicines used to lower blood lipids or to any of the other ingredients of this medicine (listed in section 6)
- if you have or have ever had a disease which affects the liver
- if you have had any unexplained abnormal blood tests for liver function
- if you are a woman able to have children and not using reliable contraception
- if you are pregnant or trying to become pregnant
- if you are breast-feeding.

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Lipitor.

The following are reasons why Lipitor may not be suitable for you:

- if you have had a previous stroke with bleeding into the brain, or have small pockets of fluid in the brain from previous strokes
- if you have kidney problems
- if you have an under-active thyroid gland (hypothyroidism)
- if you have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems
- if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other '-statin' or '-fibrate' medicines)
- if you regularly drink a large amount of alcohol
- if you have a history of liver disease
- if you are older than 70 years

**Check with your doctor or pharmacist before taking Lipitor**

- if you have severe respiratory failure .

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your Lipitor treatment to predict your risk of muscle related side effects. The risk of muscle related side effects e.g rhabdomyolysis is known to increase when certain medicines are taken at the same time (see section 2 "Other medicines and Lipitor").

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

**Other medicines and Lipitor**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There are some medicines that may change the effect of Lipitor or their effect may be changed by Lipitor. This type of interaction could make one or both of the medicines less effective.

Alternatively it could increase the risk or severity of side-effects, including the important muscle wasting condition known as rhabdomyolysis described in section 4:

- Medicines used to alter the way your immune system works, e.g. ciclosporin
- Certain antibiotics or antifungal medicines, e.g. erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampin, fusidic acid
- Other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol
- Some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine, diltiazem.; medicines to regulate your heart rhythm e.g. digoxin, verapamil, amiodarone
- Medicines used in the treatment of HIV e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, the combination of tipranavir/ritonavir etc.
- Some medicines used in the treatment of hepatitis C e.g. telaprevir
- Other medicines known to interact with Lipitor include ezetimibe (which lowers cholesterol), warfarin (which reduces blood clotting), oral contraceptives, stiripentol (an anti-convulsant for epilepsy), cimetidine (used for heartburn and peptic ulcers), phenazone (a painkiller), colchicine (used to treat gout), antacids (indigestion products containing aluminium or magnesium) and boceprevir (used to treat liver disease such as hepatitis C)
- Medicines obtained without a prescription: St John's Wort

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Lipitor with food and drink**

See section 3 for instructions on how to take Lipitor. Please note the following:

*Grapefruit juice*

Do not take more than one or two small glasses of grapefruit juice per day because large quantities of grapefruit juice can change the effects of Lipitor.

*Alcohol*

Avoid drinking too much alcohol while taking this medicine. See section 2 "Warnings and precautions" for details

**Pregnancy and breast-feeding**

Do not take Lipitor if you are pregnant, or if you are trying to become pregnant.

Do not take Lipitor if you are able to become pregnant unless you use reliable contraceptive measures.

Do not take Lipitor if you are breast-feeding.

The safety of Lipitor during pregnancy and breast-feeding has not yet been proven. Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

Normally this medicine does not affect your ability to drive or operate machines. However, do not drive if this medicine affects your ability to drive. Do not use any tools or machines if your ability to use them is affected by this medicine.

**Lipitor contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**3. How to take Lipitor**

Before starting treatment, your doctor will place you on a low-cholesterol diet, which you should maintain also during therapy with Lipitor.

The usual starting dose of Lipitor is 10 mg once a day in adults and children aged 10 years or older. This may be increased if necessary by your doctor until you are taking the amount you need. Your doctor will adapt the dose at intervals of 4 weeks or more. The maximum dose of Lipitor is 80 mg once daily for adults and 20 mg once daily for children.

Lipitor tablets should be swallowed whole with a drink of water, and can be taken at any time of day, with or without food. However, try to take your tablet at the same time every day.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**The duration of treatment with Lipitor is determined by your doctor.**

Please ask your doctor if you think that the effect of Lipitor is too strong or too weak.

**If you take more Lipitor than you should**

If you accidentally take too many Lipitor tablets (more than your usual daily dose), contact your doctor or nearest hospital for advice.

**If you forget to take Lipitor**

If you forget to take a dose, just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Lipitor**

If you have any further questions on the use of this medicine or wish to stop your treatment, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you experience any of the following serious side effects, stop taking your tablets and tell your doctor immediately or go to the nearest hospital accident and emergency department.**

Rare: may affect up to 1 in 1,000 people

- Serious allergic reaction which causes swelling of the face, tongue and throat that can cause great difficulty in breathing.
- Serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever. Skin rash with pink-red blotches especially on palms of hands or soles of feet which may blister.
- Muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown. The abnormal muscle breakdown does not always go away, even after you have stopped taking atorvastatin, and it can be life-threatening and lead to kidney problems.

Very rare: may affect up to 1 in 10,000 people

- If you experience problems with unexpected or unusual bleeding or bruising, this may be suggestive of a liver complaint. You should consult your doctor as soon as possible.

#### Other possible side effects with Lipitor:

Common side effects (may affect up to 1 in 10 people) include:

- inflammation of the nasal passages, pain in the throat, nose bleed
- allergic reactions
- increases in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels), increase in blood creatine kinase
- headache
- nausea, constipation, wind, indigestion, diarrhoea
- joint pain, muscle pain and back pain
- blood test results that show your liver function can become abnormal

Uncommon side effects (may affect up to 1 in 100 people) include:

- anorexia (loss of appetite), weight gain, decreases in blood sugar levels (if you have diabetes you should continue careful monitoring of your blood sugar levels)
- having nightmares, insomnia
- dizziness, numbness or tingling in the fingers and toes, reductions of sensation to pain or touch, change in sense of taste, loss of memory
- blurred vision
- ringing in the ears and/or head
- vomiting, belching, abdominal pain upper and lower, pancreatitis (inflammation of the pancreas leading to stomach pain)
- hepatitis (liver inflammation)
- rash, skin rash and itching, hives, hair loss
- neck pain, muscle fatigue
- fatigue, feeling unwell, weakness, chest pain, swelling especially in the ankles (oedema), raised temperature
- urine tests that are positive for white blood cells

Rare side effects (may affect up to 1 in 1,000 people) include:

- visual disturbance
- unexpected bleeding or bruising
- cholestasis (yellowing of the skin and whites of the eyes)
- tendon injury

Very rare side effects (may affect up to 1 in 10,000 people) include:

- an allergic reaction - symptoms may include sudden wheezing and chest pain or tightness, swelling of the eyelids, face, lips, mouth, tongue or throat, difficulty breathing, collapse
- hearing loss
- gynaecomastia (breast enlargement in men).

Side effects of unknown frequency:

- Muscle weakness that is constant.

Possible side effects reported with some statins (medicines of the same type):

- Sexual difficulties
- Depression
- Breathing problems including persistent cough and/or shortness of breath or fever
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Lipitor

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the container and outer packaging after {EXP}. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

##### What Lipitor contains

- The active substance is atorvastatin.
- Each film-coated tablet contains 10mg, 20mg or 40mg of atorvastatin (as atorvastatin calcium trihydrate).
- The other ingredients of Lipitor are: calcium carbonate, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, polysorbate 80, hydroxypropyl cellulose and magnesium stearate.
- The coating of Lipitor film-coated tablets contains hypromellose, macrogol 8000, titanium dioxide, talc, simeticone, stearate emulsifier and sorbic acid.

##### What Lipitor looks like and contents of the pack

Lipitor 10 mg Film-Coated Tablets are white with an oval shape. They are marked with 10 on one side and PD155 on the other side OR white with a round shape marked with 10 on one side and ATV on the other side.

Lipitor 20 mg Film-Coated Tablets are white with an oval shape. They are marked with 20 on one side and PD156 on the other side. OR white with a round shape marked with 20 on one side and ATV on the other side.

Lipitor 40 mg Film-Coated Tablets are white with an oval shape. They are marked with 40 on one side and PD157 on the other side. OR white with a round shape marked with 40 on one side and ATV on the other side.

Each strength of Lipitor is supplied in blister packs of 28 tablets.

##### Procured from within the EU by the Parallel Product Authorisation

**Holder:** Clear Pharmacy, 157-173 Roden Street, Belfast, BT12 5QA, UK

##### Manufacturer

Industrias Farmacéuticas Almirall Prodesfarma, S.L.  
Ctra. Nacional II, KM. 593  
08740 Sant Andreu de la Barca  
Barcelona (España).

##### Repackager

Cast Healthcare Ltd, 5-7 Tobermore Road, Draperstown, BT45 7AG, UK.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria, Bulgaria, Czech Republic, Estonia , Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia	Sortis
Belgium, Cyprus, Finland, Greece, Ireland, Luxembourg, Malta, Netherlands, Norway, Sweden, United Kingdom	Lipitor
Denmark, Iceland, Portugal, Spain	Zarator
France	Tahor
Germany	Atorvastatin Pfizer,
Italy	Xarator

**Leaflet date: DECEMBER 2015**

20160322

Package leaflet: Information for the user  
**LIPITOR® 10 mg, 20 mg and 40 mg**  
**Film-coated Tablets**

Atorvastatin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Lipitor tablets marketed in Ireland are normally white, oval shaped marked 10,20 or 40 on one side and 'PD155', 'PD156' or 'PD157' on the other side.

Lipitor tablets imported from Spain are white with a circular shape, marked 10, 20 or 40 on one side and 'ATV' on the other. Despite these minor differences in appearance, the Irish and Spanish products are equivalent

**What is in this leaflet:**

1. What Lipitor is and what it is used for
2. What you need to know before you take Lipitor
3. How to take Lipitor
4. Possible side effects
5. How to store Lipitor
6. Contents of the pack and other information

### 1. What Lipitor is and what it is used for

Lipitor belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

Lipitor is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed.

If you are at an increased risk of heart disease, Lipitor can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.

### 2. What you need to know before you take Lipitor

**Do not take Lipitor**

- if you are allergic to atorvastatin or to any similar medicines used to lower blood lipids or to any of the other ingredients of this medicine (listed in section 6)
- if you have or have ever had a disease which affects the liver
- if you have had any unexplained abnormal blood tests for liver function
- if you are a woman able to have children and not using reliable contraception
- if you are pregnant or trying to become pregnant
- if you are breast-feeding.

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Lipitor.

The following are reasons why Lipitor may not be suitable for you:

- if you have had a previous stroke with bleeding into the brain, or have small pockets of fluid in the brain from previous strokes
- if you have kidney problems
- if you have an under-active thyroid gland (hypothyroidism)
- if you have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems
- if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other '-statin' or '-fibrate' medicines)
- if you regularly drink a large amount of alcohol
- if you have a history of liver disease
- if you are older than 70 years

**Check with your doctor or pharmacist before taking Lipitor**

- if you have severe respiratory failure .

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your Lipitor treatment to predict your risk of muscle related side effects. The risk of muscle related side effects e.g rhabdomyolysis is known to increase when certain medicines are taken at the same time (see section 2 "Other medicines and Lipitor").

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

**Other medicines and Lipitor**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There are some medicines that may change the effect of Lipitor or their effect may be changed by Lipitor. This type of interaction could make one or both of the medicines less effective.

Alternatively it could increase the risk or severity of side-effects, including the important muscle wasting condition known as rhabdomyolysis described in section 4:

- Medicines used to alter the way your immune system works, e.g. ciclosporin
- Certain antibiotics or antifungal medicines, e.g. erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampin, fusidic acid
- Other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol
- Some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine, diltiazem,; medicines to regulate your heart rhythm e.g. digoxin, verapamil, amiodarone
- Medicines used in the treatment of HIV e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, the combination of tipranavir/ritonavir etc.
- Some medicines used in the treatment of hepatitis C e.g. telaprevir
- Other medicines known to interact with Lipitor include ezetimibe (which lowers cholesterol), warfarin (which reduces blood clotting), oral contraceptives, stiripentol (an anti-convulsant for epilepsy), cimetidine (used for heartburn and peptic ulcers), phenazone (a painkiller), colchicine (used to treat gout), antacids (indigestion products containing aluminium or magnesium) and boceprevir (used to treat liver disease such as hepatitis C)
- Medicines obtained without a prescription: St John's Wort

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Lipitor with food and drink**

See section 3 for instructions on how to take Lipitor. Please note the following:

*Grapefruit juice*

Do not take more than one or two small glasses of grapefruit juice per day because large quantities of grapefruit juice can change the effects of Lipitor.

*Alcohol*

Avoid drinking too much alcohol while taking this medicine. See section 2 "Warnings and precautions" for details

**Pregnancy and breast-feeding**

Do not take Lipitor if you are pregnant, or if you are trying to become pregnant.

Do not take Lipitor if you are able to become pregnant unless you use reliable contraceptive measures.

Do not take Lipitor if you are breast-feeding.

The safety of Lipitor during pregnancy and breast-feeding has not yet been proven. Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

Normally this medicine does not affect your ability to drive or operate machines. However, do not drive if this medicine affects your ability to drive. Do not use any tools or machines if your ability to use them is affected by this medicine.

**Lipitor contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### 3. How to take Lipitor

Before starting treatment, your doctor will place you on a low-cholesterol diet, which you should maintain also during therapy with Lipitor.

The usual starting dose of Lipitor is 10 mg once a day in adults and children aged 10 years or older. This may be increased if necessary by your doctor until you are taking the amount you need. Your doctor will adapt the dose at intervals of 4 weeks or more. The maximum dose of Lipitor is 80 mg once daily for adults and 20 mg once daily for children.

Lipitor tablets should be swallowed whole with a drink of water, and can be taken at any time of day, with or without food. However, try to take your tablet at the same time every day.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**The duration of treatment with Lipitor is determined by your doctor.**

Please ask your doctor if you think that the effect of Lipitor is too strong or too weak.

**If you take more Lipitor than you should**

If you accidentally take too many Lipitor tablets (more than your usual daily dose), contact your doctor or nearest hospital for advice.

**If you forget to take Lipitor**

If you forget to take a dose, just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Lipitor**

If you have any further questions on the use of this medicine or wish to stop your treatment, ask your doctor or pharmacist.



#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you experience any of the following serious side effects, stop taking your tablets and tell your doctor immediately or go to the nearest hospital accident and emergency department.**

Rare: may affect up to 1 in 1,000 people

- Serious allergic reaction which causes swelling of the face, tongue and throat that can cause great difficulty in breathing.
- Serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever. Skin rash with pink-red blotches especially on palms of hands or soles of feet which may blister.
- Muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown. The abnormal muscle breakdown does not always go away, even after you have stopped taking atorvastatin, and it can be life-threatening and lead to kidney problems.

Very rare: may affect up to 1 in 10,000 people

- If you experience problems with unexpected or unusual bleeding or bruising, this may be suggestive of a liver complaint. You should consult your doctor as soon as possible.

#### Other possible side effects with Lipitor:

Common side effects (may affect up to 1 in 10 people) include:

- inflammation of the nasal passages, pain in the throat, nose bleed
- allergic reactions
- increases in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels), increase in blood creatine kinase
- headache
- nausea, constipation, wind, indigestion, diarrhoea
- joint pain, muscle pain and back pain
- blood test results that show your liver function can become abnormal

Uncommon side effects (may affect up to 1 in 100 people) include:

- anorexia (loss of appetite), weight gain, decreases in blood sugar levels (if you have diabetes you should continue careful monitoring of your blood sugar levels)
- having nightmares, insomnia
- dizziness, numbness or tingling in the fingers and toes, reductions of sensation to pain or touch, change in sense of taste, loss of memory
- blurred vision
- ringing in the ears and/or head
- vomiting, belching, abdominal pain upper and lower, pancreatitis (inflammation of the pancreas leading to stomach pain)
- hepatitis (liver inflammation)
- rash, skin rash and itching, hives, hair loss
- neck pain, muscle fatigue
- fatigue, feeling unwell, weakness, chest pain, swelling especially in the ankles (oedema), raised temperature
- urine tests that are positive for white blood cells

Rare side effects (may affect up to 1 in 1,000 people) include:

- visual disturbance
- unexpected bleeding or bruising
- cholestasis (yellowing of the skin and whites of the eyes)
- tendon injury

Very rare side effects (may affect up to 1 in 10,000 people) include:

- an allergic reaction - symptoms may include sudden wheezing and chest pain or tightness, swelling of the eyelids, face, lips, mouth, tongue or throat, difficulty breathing, collapse
- hearing loss
- gynaecomastia (breast enlargement in men).

Side effects of unknown frequency:

- Muscle weakness that is constant.

Possible side effects reported with some statins (medicines of the same type):

- Sexual difficulties
- Depression
- Breathing problems including persistent cough and/or shortness of breath or fever
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Lipitor

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the container and outer packaging after {EXP}. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

##### What Lipitor contains

- The active substance is atorvastatin.
- Each film-coated tablet contains 10mg, 20mg or 40mg of atorvastatin (as atorvastatin calcium trihydrate).
- The other ingredients of Lipitor are: calcium carbonate, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, polysorbate 80, hydroxypropyl cellulose and magnesium stearate.
- The coating of Lipitor film-coated tablets contains hypromellose, macrogol 8000, titanium dioxide, talc, simeticone, stearate emulsifier and sorbic acid.

##### What Lipitor looks like and contents of the pack

Lipitor 10 mg Film-Coated Tablets are white with an oval shape. They are marked with 10 on one side and PD155 on the other side OR white with a round shape marked with 10 on one side and ATV on the other side.

Lipitor 20 mg Film-Coated Tablets are white with an oval shape. They are marked with 20 on one side and PD156 on the other side. OR white with a round shape marked with 20 on one side and ATV on the other side.

Lipitor 40 mg Film-Coated Tablets are white with an oval shape. They are marked with 40 on one side and PD157 on the other side. OR white with a round shape marked with 40 on one side and ATV on the other side.

Each strength of Lipitor is supplied in blister packs of 28 tablets.

##### Procured from within the EU by the Parallel Product Authorisation

**Holder:** Clear Pharmacy, 157-173 Roden Street, Belfast, BT12 5QA, UK

##### Manufacturer

Industrias Farmacéuticas Almirall Prodesfarma, S.L.  
Ctra. Nacional II, KM. 593  
08740 Sant Andreu de la Barca  
Barcelona (España).

##### Repackager

Pharmaram Ltd, Unit F4 Ivanhoe Business Park, Tom Bill Way, Ashby de la Zouch, Leicestershire LE65 2UY, UK.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria, Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia	Sortis
Belgium, Cyprus, Finland, Greece, Ireland, Luxembourg, Malta, Netherlands, Norway, Sweden, United Kingdom	Lipitor
Denmark, Iceland, Portugal, Spain	Zarator
France	Tahor
Germany	Atorvastatin Pfizer,
Italy	Xarator

**Leaflet date: DECEMBER 2015**


20160322

**PARALLEL IMPORT PACKAGE LEAFLET  
STATEMENT OF COMPLIANCE**

*To be submitted with an application for a parallel import licence, provided that the conditions for the package leaflet to be regarded as sufficiently similar to the leaflet on the Irish market outlined in Annex I of the HPRA guide to labels and leaflets are met.*

1. Name and address of the proposed parallel import licence holder: <b>Clear Pharmacy</b> <b>157-173 Roden Street</b> <b>BT12 5QA</b> <b>UK</b>	Name and address of the applicant, if different: <b>Megan Koritnik-Wright</b> <b>Freelance Regulatory</b>
2. Name of product to be marketed: <b>Lipitor</b>  Pharmaceutical form: <b>film-coated tablets</b>	Active substance(s): <b>atorvastatin</b>  Strength(s): <b>10, 20, 40, 80mg</b>
3. Leaflet to be printed:  Size of the finished leaflet (e.g. A4, A5):  Font and size used for body text:  Finished format:	Single-sided <input type="checkbox"/> Double-sided <input checked="" type="checkbox"/>  A4  Times New Roman 8pt  Flat sheet <input checked="" type="checkbox"/> Booklet <input type="checkbox"/> Other

The text of the leaflet exactly follows the text of the Irish leaflet except for product specific differences.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
A full-scale mock-up of the leaflet has been provided.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
List other previously approved leaflets for this product which satisfies the consultation requirement by similarity to the Irish leaflet:	<i>Include the PPA numbers:</i>

Signed: 

Date: 22/03/2016

Position: Freelance Regulatory on behalf of Clear Pharmacy