

PACKAGE LEAFLET

Package leaflet: Information for the patient

Atorvastatin 10 mg film-coated tablets
Atorvastatin 20 mg film-coated tablets
Atorvastatin 40 mg film-coated tablets
Atorvastatin 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Atorvastatin is and what it is used for

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

Atorvastatin is used to lower lipids known as cholesterol and other fats (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, Atorvastatin 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 Atorvastatin

Do not take Atorvastatin:

- if you are allergic to atorvastatin or to any similar medicines used to lower blood lipids or any of the other ingredients of this medicine (listed in section 6).
- if you use the combination of glecaprevir/pibrentasvir in the treatment of hepatitis C.
- if you are allergic to peanut or soya, as it contains soya lecithin
- 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 or pharmacist before taking Atorvastatin:

- if you have severe respiratory failure

- if you have had a previous stroke or mini-stroke (also known as transient ischaemic attack ('TIA')), or a 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
- if you are taking or have taken in the last 7 days a medicine called fusidic acid (a medicine for bacterial infection), orally or by injection. The combination of fusidic acid and Atorvastatin Mylan can lead to serious muscle problems (rhabdomyolysis).

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your Atorvastatin 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 "Taking other medicines").

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.

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.

Other medicines and Atorvastatin

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

There are some medicines that may change the effect of atorvastatin or their effect may be changed by atorvastatin. 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
- Other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol, niacin,
- 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
- Letemovir, a medicine that helps stop you from getting ill from cytomegalovirus
- Medicines used in the treatment of HIV e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, delavirdine, efavirenz, saquinavir, the combination of tipranavir/ritonavir, nelfinavir, fosamprenavir etc.
- Some medicines used in the treatment of liver problems such as hepatitis C e.g. telaprevir, boceprevir and the combination of elbasvir/grazoprevir.
- Other medicines known to interact with atorvastatin include ezetimibe (which lowers cholesterol), warfarin (which reduces blood clotting), oral contraceptives, stiripentol (an anticonvulsant for epilepsy), cimetidine (used for heartburn and peptic ulcers), phenazone, (a painkiller), colchicine (used to treat gout) and antacids (indigestion products containing aluminium or magnesium)
- Medicines obtained without a prescription: St John's wort

If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart Atorvastatin. Taking Atorvastatin with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

Atorvastatin with drink and alcohol

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 Atorvastatin.

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 Atorvastatin if you are pregnant, or if you are trying to become pregnant. Do not take Atorvastatin if you are able to become pregnant unless you use reliable contraceptive measures.

Do not take Atorvastatin if you are breast-feeding.

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

Atorvastatin contains lactose and sodium

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Atorvastatin

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

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

The recommended starting dose of Atorvastatin 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 dosage at intervals of 4 weeks or more. The maximum dose of Atorvastatin is 80 mg once daily.

Atorvastatin 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 tablets at the same time every day.

The duration of treatment with Atorvastatin is determined by your doctor:

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

If you take more Atorvastatin than you should

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

If you forget to take Atorvastatin

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 Atorvastatin

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 or symptoms, stop taking your tablets and tell your doctor immediately or go to your nearest hospital accident and emergency department:

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

- pancreatitis (inflammation of the pancreas leading to severe stomach pain which may reach around to the back)
- hepatitis (liver inflammation)

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

- serious allergic reaction - symptoms may include sudden wheezing and chest pain or tightness, swelling of the eyelids, face, lips, mouth, tongue or throat, great difficulty in breathing, collapse.
- 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, pain, rupture or red-brown discolouration of urine and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown (rhabdomyolysis). 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.
- blockage of the bile duct (cholestasis) which may include signs such as yellowing of the skin or eyes, pain in the right upper part of the abdomen, loss of appetite.

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

- if you experience pain in the upper right abdomen, abdominal swelling, and yellowing of the skin and eyes, this may be suggestive of a liver complaint. You should consult your doctor as soon as possible.
- lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

Frequency not known (cannot be estimated from the available data):

- muscle weakness that is constant

Other possible side effects with Atorvastatin:**Common side effects** (may affect up to 1 in 10 people):

- 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, muscle spasm
- blood test results that show your liver function can become abnormal

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

- 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,
- 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):

- visual disturbance
- unexpected bleeding or bruising
- tendon injury

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

- hearing loss
- gynecomastia (breast enlargement in men).

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Atorvastatin

Keep this medicine out of the sight and reach of children.

OPA/Al/PVC/Al blisters and tablet containers: Store in the original package in order to protect from light and moisture.

PVC/Aclar blisters: Store in the original package in order to protect from moisture, keep the blister in the outer carton or inner carton (if multipack is used) in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton, container label and blister after EXP. The expiry date refers to the last day of that month.

Use within 3 months after the first opening of the tablet container.

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 Atorvastatin contains

The active substance is atorvastatin (as atorvastatin calcium trihydrate).

Each film-coated tablet contains 10mg, 20mg, 40mg or 80mg atorvastatin as atorvastatin calcium trihydrate.

The other ingredients of Atorvastatin are colloidal anhydrous silica, sodium carbonate, microcrystalline cellulose, L-arginine, lactose, croscarmellose sodium, hydroxypropyl cellulose (E463) and magnesium stearate. The film coat contains polyvinyl alcohol, titanium dioxide (E171), talc, soya lecithin (E322), xanthan gum (E415) and macrogol. See section 2 'Do not take Atorvastatin' and Atorvastatin contains lactose and sodium'.

What Atorvastatin looks like and contents of the pack

The film-coated tablets are oval and white. The 10 mg tablet is marked '10' on one side; the 20 mg tablet marked '20', the 40mg tablet marked '40' and the 80 mg tablet marked '80'. The 20 mg, 40 mg and 80 mg tablets have a score-line on one side to facilitate breaking for ease of swallowing and not to divide into equal doses.

Atorvastatin is available in opaque plastic tablet containers of 10, 14, 28, 30, 50, 56, 60, 90, 100, 200, 250 and 500 tablets.

Atorvastatin is also available in blister packs of 10, 14, 28, 30, 50, 56, 60, 84, 90, 98 and 100 tablets, calendar packs of 28 tablets and in a multipack of 98 comprising 2 cartons, each containing 49 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer

McDermott Laboratories Limited trading as Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

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