

PACKAGE LEAFLET: INFORMATION FOR THE USER

ATORVASTATIN

(atorvastatin)

10 mg film coated tablets

20 mg film coated tablets

40 mg film coated tablets

80 mg film coated tablets

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Atorvastatin is and what it is used for
2. Before you take Atorvastatin
3. How to take Atorvastatin
4. Possible side effects
5. How to store Atorvastatin
6. Further 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 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. BEFORE YOU TAKE ATORVASTATIN

Do not take Atorvastatin:

- If you are hypersensitive (allergic) to Atorvastatin or to any similar medicines used to lower blood lipids or to any of the other ingredients of the medicine – see Section 6 for details.
- 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.

Take special care with Atorvastatin

The following are reasons why Atorvastatin 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 Atorvastatin

- 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 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

Taking other medicines

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, 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, etc.
- Other medicines known to interact with Atorvastatin 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) and antacids (indigestion products containing aluminium or magnesium).
- Medicines obtained without a prescription: St John’s Wort.

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

Taking Atorvastatin with food and drink

See Section 3 for instructions on how to take Atorvastatin. 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 Atorvastatin.

Alcohol

Avoid drinking too much alcohol while taking this medicine. See Section 2 “Take special care with Atorvastatin” 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 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.

Important information about some of the ingredients of Atorvastatin

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

3. HOW TO TAKE ATORVASTATIN

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

The usual 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 dose at intervals of 4 weeks or more. The maximum dose of Atorvastatin is 80 mg once daily for adults and 20 mg once daily for children.

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 tablet at the same time every day.

Always take Atorvastatin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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, Atorvastatin 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: affects 1 to 10 users in 10,000:

- 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 which can be lifethreatening and lead to kidney problems.

Very rare: affect less than 1 user in 10,000:

- 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 Atorvastatin:

Common side effects (affects 1 to 10 users in 100) 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, diarrhea,
- joint pain, muscle pain and back pain,
- blood test results that show your liver function can become abnormal.

Uncommon side effects (affects 1 to 10 users in 1000) 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 (affects 1 to 10 users in 10,000) include:

- visual disturbance,

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

Very rare side effects (affects less than 1 user in 10,000) 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 and women).

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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ATORVASTATIN

Keep out of reach and sight of children.

Should be kept at temperature up to 25C, in original package.

Do not use after the last day of the month shown in the expiry date on the carton and blister.

6. FURTHER INFORMATION

What Atorvastatin contains

The active substance of Atorvastatin film coated tablets is atorvastatin. Each tablet contains 10 mg, 20 mg, 40 mg or 80 mg of atorvastatin as atorvastatin calcium trihydrate.

The other ingredients are: calcium carbonate powder, lactose monohydrate, cellulose microcrystalline, croscarmellose sodium, povidone, polyoxyethylene sorbitan fatty acid esters (polysorbate 60), silica colloidal anhydrous, talc, magnesium stearate, hypromellose 6 cP (HPMC 2910), titanium dioxide, macrogol (PEG 6000)

What Atorvastatin looks like and contents of the pack

Atorvastatin 10 mg are uniform, round, slightly biconvex, white film coated tablets.

Atorvastatin 20 mg are uniform, round, biconvex, white film coated tablets.

Atorvastatin 40 mg are uniform, oval, biconvex, white film coated tablets, with score line on one side.

Atorvastatin 80 mg are uniform, oval, biconvex, white film coated tablets, with score lines on both sides.

Pack size:

Box with 30 film coated tablets of 10 mg in blisters.

Box with 30 film coated tablets of 20 mg in blisters.

Box with 30 film coated tablets of 40 mg in blisters.

Box with 30 film coated tablets of 80 mg in blisters.

Dispensing status

Prescription only medicament.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

REPLEK FARM Ltd.-Skopje, 188 Kozle str., 1000 Skopje, Republic of Macedonia.

Manufacturer

REPLEK FARM Ltd.-Skopje, 188 Kozle str., 1000 Skopje, Republic of Macedonia.

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