

PACKAGE LEAFLET: INFORMATION FOR THE USER

Atorvastatin Pharmathen 10 mg film-coated tablets
Atorvastatin Pharmathen 20 mg film-coated tablets
Atorvastatin Pharmathen 40 mg film-coated tablets
Atorvastatin Pharmathen 80 mg film-coated tablets
Atorvastatin

Read all of these 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.

What is in this leaflet:

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

1. What Atorvastatin Pharmathen is and what it is used for

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

Atorvastatin Pharmathen 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 Pharmathen 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 Pharmathen

Do not take Atorvastatin Pharmathen:

- if you are hypersensitive to Atorvastatin, or to any similar medicines used to lower blood lipids, or to any of the other ingredients of the 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 a reliable contraception.
- if you are pregnant, or trying to become pregnant .
- If you are breast-feeding.

Warnings and precautions Atorvastatin Pharmathen

Talk to your doctor, pharmacist or nurse before taking Atorvastatin Pharmathen

- 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, 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 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 Pharmathen can lead to serious muscle problems (rhabdomyolysis).
- 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 Pharmathen if you:

- Have severe respiratory failure

If any of these apply to you, your doctor will need to carry out blood tests before and possibly during your Atorvastatin Pharmathen 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 Atorvastatin Pharmathen").

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 Atorvastatin Pharmathen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- **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 Pharmathen. Taking Atorvastatin Pharmathen with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

There are some medicines that may change the effect of Atorvastatin Pharmathen, or their effect may be changed by Atorvastatin Pharmathen . 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 Atorvastatin Pharmathen 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.

Taking Atorvastatin Pharmathen with food and drink

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

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 Pharmathen if you are pregnant, or if you are trying to become pregnant.

Do not take Atorvastatin Pharmathen if you are able to become pregnant unless you use reliable contraceptive measures. Do not take Atorvastatin Pharmathen if you are breast-feeding.

The safety of Atorvastatin Pharmathen 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.

Atorvastatin Pharmathen contains lactose

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 Pharmathen

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 also during therapy with Atorvastatin Pharmathen.

The recommended starting dose of Atorvastatin Pharmathen 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 is 80 mg once daily for adults and 20 mg once daily for children.

Atorvastatin Pharmathen 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.

Atorvastatin Pharmathen The duration of treatment with Atorvastatin Pharmathen is determined by your doctor.

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

If you take more Atorvastatin Pharmathen than you should:

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

If you forget to take Atorvastatin Pharmathen:

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 Pharmathen:
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 Atorvastatin Pharmathen may 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 1 in 1000 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 Atorvastatin Pharmathen:

Common (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, back pain
- blood test results that show your liver function can become abnormal

Uncommon (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, pancreatitis (inflammation of 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 (may affect up to 1 in 1,000 people)

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

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

- 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

The following adverse reactions have been reported with other statins:

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 HPRA 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 Atorvastatin Pharmathen

Keep out of reach and sight of children.
Store below 30°C.

Do not use Atorvastatin Pharmathen 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.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

**6. Contents of the pack and other information
What Atorvastatin Pharmathen contains**

- The active substance is atorvastatin.

- o Each Atorvastatin Pharmathen 10mg film-coated tablet contains 10 mg atorvastatin (as atorvastatin calcium).
- o Each Atorvastatin Pharmathen 20mg film-coated tablet contains 20 mg atorvastatin (as atorvastatin calcium).
- o Each Atorvastatin Pharmathen 40mg film-coated tablet contains 40 mg atorvastatin (as atorvastatin calcium).
- o Each Atorvastatin Pharmathen 80mg film-coated tablet contains 80 mg atorvastatin (as atorvastatin calcium).

- The other ingredients of Atorvastatin Pharmathen are:
o **Tablet core:** Activated attapulgit, lactose monohydrate, cellulose microcrystalline, starch maize pregelatinised, hydroxypropyl cellulose, magnesium stearate and silica colloidal anhydrous.
o **Film-coating:** Titanium dioxide (E171), lactose monohydrate, macrogol/PEG 4000, hypromellose 15 cP (E464), hypromellose 3cP (E464) and hypromellose 50cP (E464)..

What Atorvastatin Pharmathen looks like and contents of the pack

10mg film-coated tablets:
White, oval, biconvex tablets, with dimensions 10.1±0.1mm x 5.6±0.1mm and 3.7±0.2mm in thickness

20mg film-coated tablets:
White, oval biconvex tablets, with breakline in one side and dimensions 12.7±0.1mm x 6.7±0.1mm and 4.6±0.2mm in thickness

40mg film-coated tablets:
White, oblong, biconvex tablets with dimensions 19.4±0.1mm x 7.8±0.1mm and 4.7±0.2mm in thickness

80mg film-coated tablets:
White, oblong, biconvex tablets with breakline in one side and dimensions 22.8±0.1mm, 10.9±0.1mm and 5.7±0.2mm in thickness
The breakline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Atorvastatin Pharmathen is supplied in PA/ALL/PVC – Aluminium foil blister packs.

The pack sizes are the following:
10, 14, 28, 30, 50, 60, 84, 90, 96, 98, 100

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

PHARMATHEN S.A., Dervenakion 6, Pallini 15351, Attiki Greece

Manufacturer:

PHARMATHEN S.A., Dervenakion 6, Pallini 15351, Attiki Greece
Or
PHARMATHEN INTERNATIONAL S.A, Industrial Park Sapes, Rodopi Prefecture, Block No 5, Rodopi 69300, Greece
Or
Mc Dermott Laboratories t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland
Or
Generics [UK] Limited, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom
Or
SUPROBION Spółka z ograniczoną odpowiedzialnością Spółka komandytowa, ul. Kielczowska 2, Mirków, 55-095, Poland (for 10mg, 20mg, 40mg only)

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

Denmark: Atorvastatin Generics
Netherlands: Atorvastatine 10 A, filmomhulde tabletten 10 mg, Atorvastatine 20 A, filmomhulde tabletten 20 mg, Atorvastatine 40 A, filmomhulde tabletten 40 mg, Atorvastatine 80 A, filmomhulde tabletten 80 mg
Cyprus, Poland: Lambrinex
Germany: Atorvastatin Mylan 10 mg, 20 mg, 40 mg, 80mg Filmtablette
Spain: Atorvastatina Amneal 10 mg, 20 mg, 40 mg, 80 mg Comprímido recubierto con película EFG
France: Atorvastatin Mylan Pharma 10 mg, 20 mg, 40 mg, 80 mg Comprímé pelliculé
Ireland: Atorvastatin Pharmathen 10 mg, 20 mg, 40 mg, 80 mg Film-coated tablet
UK: Atorvastatin 10mg, 20mg, 40mg, 80mg film-coated tablet
Greece: Lambrinex 10 mg, 20 mg, 40 mg, 80 mg

This leaflet was last approved in