Package leaflet: Information for the user

Atorvastatine STADA 10 mg, filmomhulde tabletten
Atorvastatine STADA 20 mg, filmomhulde tabletten
Atorvastatine STADA 30 mg, filmomhulde tabletten
Atorvastatine STADA 40 mg, filmomhulde tabletten
Atorvastatine STADA 60 mg, filmomhulde tabletten
Atorvastatine STADA 80 mg, filmomhulde tabletten

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.

What is in this leaflet

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

1. What [product name] is and what it is used for

[product name] belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

[product name] 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, [product name] 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 [product name]

DO NOT take [product name]
- if you are allergic to atorvastatin or 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
- if you use the combination of glecaprevir/pibrentasvir in the treatment of hepatitis C

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking [product name].
- if you have severe respiratory failure

- 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 [product name] can lead to serious muscle problems (rhabdomyolysis)
- 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
- if you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia (see section 4).

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your [product name] 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 [product name]").

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 [product name]
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 [product name] or their effect may be changed by [product name]. 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
- letermovir, 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, the combination of tipranavir/ritonavir etc.
- some medicines used in the treatment of hepatitis C e.g. telaprevir, boceprevir and the combination of elbasvir/grazoprevir, ledipasvir/sofosbuvir
- other medicines known to interact with [product name] 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) 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 [product name].

Taking [product name] with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

[product name] with food, drink and alcohol
See section 3 for instructions on how to take [product name]. 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 [product name].

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 [product name] if you are pregnant, or if you are trying to become pregnant.
- Do not take [product name] if you are able to become pregnant unless you use reliable contraceptive measures.
- Do not take [product name] 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.

[product name] 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.

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

3. How to take [product name]

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 [product name].

Dosage
- 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 a day.

Method of administration
[product name] 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.

<u>[product name] 30 mg film-coated tablets</u>
The score line is not intended for breaking the tablet.

[product name] 60 mg film-coated tablets
The score line is not intended for breaking the tablet.

The duration of treatment with [product name] is determined by your doctor.
Please ask your doctor if you think that the effect of [product name] is too strong or too weak.

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

If you forget to take [product name]
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 [product name]
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 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, 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.

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.
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

Other possible side effects with [product name]

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 and 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 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: 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
- gynaecomastia (breast enlargement in men)

Not known: frequency cannot be estimated from the available data
- muscle weakness that is constant
- myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- ocular myasthenia (a disease causing eye muscle weakness).
- Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [product name]

Keep this medicine out of the sight and reach of children.
This medicine does not require any special storage conditions.

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.

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 [product name] contains

- The active substance is atorvastatin.

Each film-coated tablet contains 10 mg atorvastatin (as atorvastatin calcium trihydrate).
Each film-coated tablet contains 20 mg atorvastatin (as atorvastatin calcium trihydrate).
Each film-coated tablet contains 30 mg atorvastatin (as atorvastatin calcium trihydrate).
Each film-coated tablet contains 40 mg atorvastatin (as atorvastatin calcium trihydrate).
Each film-coated tablet contains 60 mg atorvastatin (as atorvastatin calcium trihydrate).
Each film-coated tablet contains 80 mg atorvastatin (as atorvastatin calcium trihydrate).

- The other ingredients of [product name] are:

lactose monohydrate, cellulose, powdered, calcium carbonate, starch, pregelatinised, hypromellose, croscarmellose sodium, magnesium stearate.

The coating of [product name] contains hypromellose, macrogol, titanium dioxide (E171), talc.

What [product name] looks like and contents of the pack

Film-coated tablet.
10 mg tablet: White to off-white, round, biconvex film-coated tablets, diameter: 6 mm.
20 mg tablet: White to off-white, round, biconvex film-coated tablets, diameter: 8 mm.
30 mg tablet: White to off-white, round, biconvex film-coated tablets, with score line on one side, diameter: 9 mm. The score line is not intended for breaking the tablet.
40 mg tablet: White to off-white, round, biconvex film-coated tablets, diameter: 10 mm.
60 mg tablet: White to off-white, round, biconvex film-coated tablets, with score line on one side, diameter: 11 mm. The score line is not intended for breaking the tablet.
80 mg tablet: White to off-white, round, biconvex film-coated tablets, diameter: 12 mm.

OPA/Al/PVC-Al blisters containing 30, 50 and 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
STADA Arzneimittel AG
Stadastrasse 2-18
61118 Bad Vilbel
Duitsland

Manufacturer:
STADA Arzneimittel AG
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This medicinal product is authorised in the Member States of the EEA under the following names:
DE: Atorvastatin AL 10 mg/ 20 mg/ 30 mg/ 40 mg/ 60 mg/ 80 mg Filmtabletten
NL: Atorvastatine STADA 10 mg/ 20 mg/ 30 mg/ 40 mg/ 60 mg/ 80 mg, filmomhulde tabletten
IT: ATORVASTATINA EG

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