Package leaflet: Information for the user

Atorva TAD 20 mg film-coated tablets

Atorvastatin

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 ATORVA TAD 20 MG FILM-COATED TABLETS ARE AND WHAT THEY ARE USED FOR

Atorva TAD film-coated tablets belong to a group of medicines known as statins and is used for the treatment of lipometabolic disorders.

Atorva TAD 20 mg film-coated tablets are used to lower lipid levels known as cholesterol and triglycerides in the blood when a low fat diet and life style changes with no other measures have failed. If you are at an increased risk of heart disease, Atorva TAD 20 mg film-coated tablets can also be used to reduce such risk even if your cholesterol levels are normal. A standard cholesterol lowering diet should be continued during treatment.

Cholesterol is a naturally occurring substance in the body necessary for normal growth. However, if there is too much cholesterol in your blood it can be deposited on the walls of

Taking other medicines

There are some medicines that may change the effect of Atorva TAD 20 mg film-coated tablets or their effect may be changed by Atorva TAD 20 mg film-coated tablets. This type of interaction could make one or both of the medicines less effective. Alternatively it could increase the risk of severity of side-effects, including the important muscle wasting condition known as rhabdomyolysis described in Section 4. Your doctor will consider this in deciding upon your dose of Atorva TAD 20 mg film-coated tablets.

There are some medicines that may interact with Atorva TAD 20 mg film-coated tablets:
- Medicines used to alter the way your immune system works, e.g. ciclosporin
- Certain antibiotics or antifungal medicines, e.g. erythromycin, clarithromycin, ketoconazole, itraconazole; rifampicin
- Other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, nicotinic acid derivatives, colestipol
- Some calcium channel blockers used for angina or high blood pressure, e.g. diltiazem; medicines to regulate your heart rhythm, e.g. digoxin, amiodarone
- Benzodiazepines used for anxiety and other conditions, e.g. nefazodone
- Protease inhibitors used in the treatment of HIV
- Other medicines known to interact with Atorva TAD 20 mg film-coated tablets include warfarin (which reduces blood clotting), oral contraceptives, phenytoin (an anti-convulsant

the blood vessels, which may eventually become blocked. This is one of the most common causes of heart diseases. It is accepted that raised cholesterol levels increase the risk of heart diseases. Other factors that will increase the risk of heart disease include high blood pressure, diabetes mellitus, increased weight, lack of exercise, smoking, or a family history of cardiovascular diseases.

2. BEFORE YOU TAKE ATORVA TAD 20 MG FILM-COATED TABLETS

Do not take Atorva TAD 20 mg film-coated tablets

- if you are allergic (hypersensitive) to atorvastatin or any of the other ingredients of Atorva TAD 20 mg film-coated tablets
- if you suffer from any current disease which affects the liver
- if you have had any unexplained abnormal liver function levels
- if you are a woman of child-bearing age and not using reliable contraception
- if you are pregnant, trying to become pregnant or breast-feeding
- if you have a functional muscle disorder called myopathy (repeated or unexplained muscle aches or pains)

Take special care with Atorva TAD 20 mg film-coated tablets

- if you suffer from a kidney disease,
- 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 functional muscle disorder during treatment with other lipid-lowering medicines (e.g. other medicines with the suffix '-statin' or '-fibrate'),
- 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 any of these issues apply to you, your doctor will need to carry out a blood test before and possibly during your Atorva TAD 20 mg film-coated tablets treatment to predict your risk of muscle related side effects. The risk of side effects in terms of functional muscle disorders e.g. rhabdomyolysis is known to increase when certain medicines are taken at the same time (see Section 2 "Taking other medicines").

Check with your doctor or pharmacist before taking Atorva TAD if you:

- Have a severe functional disorder of the respiratory organs.

for epilepsy), and antacids (indigestion products containing aluminium or magnesium)

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

Taking Atorva TAD 20 mg film-coated tablets with food and drink

See Section 3 for instructions on how to take Atorva TAD 20 mg film-coated tablets. Please note the following:

Grapefruit juice

Do not drink more than one or two small glasses of grapefruit juice per day because large quantities of grapefruit juice can affect the effects of Atorva TAD 20 mg film-coated tablets.

Alcohol

Avoid drinking too much alcohol while taking this medicine. See Section 2 "Take special care with Atorva TAD 20 mg film-coated tablets" for details.

Pregnancy and breast-feeding

Do not take Atorva TAD 20 mg film-coated tablets, if you are pregnant, if you think you may be pregnant, if you are trying to become pregnant, or if you are breast feeding. Women of child-bearing age must take appropriate contraceptive measures.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive if this medicine affects your ability to drive. Do not use any tools or machines if your ability to use and to concentrate them is affected by this medicine.

Important information about some of the ingredients of Atorva TAD 20 mg film-coated tablets

Atorva TAD 20 mg film-coated tablets contain lactose. If you know that you have an intolerance to some sugars, contact your doctor before taking Atorva TAD 20 mg film-coated tablets.

3. HOW TO TAKE ATORVA TAD 20 MG FILM-COATED TABLETS

Always take Atorva TAD 20 mg film-coated tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual starting dose of atorvastatin is 10 mg once a day. 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.
Atorva TAD 20 mg film-coated tablets 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.
Before starting treatment, your doctor will place you on a low-cholesterol diet, which you should maintain also during therapy with Atorva TAD 20 mg film-coated tablets.

If you take more Atorva TAD 20 mg film-coated tablets than you should
If you accidentally take too many Atorva TAD 20 mg film-coated tablets (more than your usual daily dose), contact your doctor or nearest hospital for advice.

If you forget to take Atorva TAD 20 mg film-coated tablets
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 Atorva TAD 20 mg film-coated tablets
If you stop taking Atorva TAD 20 mg film-coated tablets for a longer time, your blood cholesterol level may increase again which can increase the risk of heart and blood vessels diseases.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Atorva TAD 20 mg film-coated tablets can cause side effects, although not everybody gets them.

The following side effects are important and will require immediate action if you experience them:

Very rare side effects affect fewer than 1 in 10,000 patients
You should stop taking Atorva TAD 20 mg film-coated tablets and see your doctor immediately if you experience the following symptoms: angioedema (swelling of the face, tongue and windpipe which can cause great difficulty in breathing), anaphylaxis (sudden allergic reaction with shortness of breath, rash, wheezing and drop of blood pressure), toxic epidermal necrolysis (TEN; severe extensive blistering skin rash with redness and peeling of the skin), Stevens-Johnson syndrome (serious blistering condition of the skin, mouth, eyes and genitals), erythema multiforme (patchy red rash). If you experience problems with unexpected or unusual bleeding or bruising, this may be suggestive of a liver complaint.

Rare side effects affect 1 to 10 in 10,000 patients

5. HOW TO STORE ATORVA TAD 20 MG FILM-COATED TABLETS

Keep out of the reach and sight of children.

Store in the original package in order to protect from light and moisture.

Do not use Atorva TAD 20 mg film-coated tablets after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Atorva TAD 20 mg film-coated tablets contain
- The active substance is atorvastatin. Each Atorva TAD 20 mg film-coated tablet contains 20 mg of atorvastatin as atorvastatin hemicalcium.
- The other ingredients are sodium hydroxide, sodium laurilsulfate, hydroxypropylcellulose, lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, crospovidone, magnesium stearate (Ph. Eur.) [vegetable origin] in the tablet core and polyvinyl alcohol, titanium dioxide (E171), macrogol 3000 and talc in the film-coating.

What Atorva TAD 20 mg film-coated tablets look like and contents of the pack
The film-coated tablets are white, round, slightly convex and bevel-edged.
Boxes of 30 film-coated tablets in blisters are available.

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Muscle wasting or inflammations and tenderness that may progress to become a serious, potentially life-threatening condition (called 'rhabdomyolysis'). It can occur for no apparent reason (e.g. not related to muscle exercise) If you have muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature, stop taking Atorva TAD 20 mg film-coated tablets and tell your doctor immediately.

Other possible side effects with Atorva TAD 20 mg film-coated tablets:
Common side effects, affecting 1 to 10 in 100 patients
Nausea, abdominal pain, constipation, wind, diarrhoea, indigestion, headache, muscle pain, weakness, sleep disturbances, including insomnia and nightmares, dizziness, chest pain, allergic reactions, numbness or tingling in the fingers and toes, reductions in sensation to pain or touch, joint pain and back pain, (ankle swelling), rash, itching.

Uncommon conditions affecting 1 to 10 in 1,000 patients. Not all of these effects have necessarily been linked to the use of these medicines.
Anorexia (loss of appetite), muscle cramps, unexpected bleeding or bruising due to low amount of cells in the circulation that stop bleeding, ringing in the ears and/or head, weight gain, loss of memory, hives, feeling unwell, impotence, hair loss, pancreatitis (inflammation of the pancreas leading to stomach pain), increases and decreases in blood sugar levels (If you have diabetes you should continue careful monitoring of your blood sugar levels).

Rare side effects affecting 1 to 10 in 10,000 patients
Hepatitis (liver inflammation), jaundice (yellowing of the skin and whites of the eyes).

Very rare side effects affecting fewer than 1 in 10,000 patients
Change in the sense of taste, visual disturbance, liver failure, hearing loss, gynecomastia (breast enlargement in men and women) and tendon injury.

Not known: frequency cannot be estimated from the available data
Depression, breathing problems including persistent cough and/or shortness of breath or fever.

If you experience side effects, please inform your doctor. He/she will decide on the further steps needed.

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.

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