

PACKAGE LEAFLET: INFORMATION FOR THE USER

Xolister-all[®] 10 mg film-coated tablets
Xolister-all[®] 20 mg film-coated tablets
Xolister-all[®] 40 mg film-coated tablets
Atorvastatin (as atorvastatin calcium trihydrate)

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What **Xolister-all[®]** is and what it is used for
2. What you need to know before you take **Xolister-all[®]**
3. How to take **Xolister-all[®]**
4. Possible side effects
5. How to store **Xolister-all[®]**
6. Other information

1. WHAT XOLISTER-ALL[®] IS AND WHAT IT IS FOR

Xolister-all[®] belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

Xolister-all[®] 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, **Xolister-all[®]** 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.

Cholesterol is a substance that can be found in the body and is essential during growth. However, if there is too much cholesterol in the blood, it may deposit on the bold vessel walls, leading to occlusion. This is one of the most common risks for heart disease. It is accepted that high cholesterol levels increase the risk for heart disease. Other factors that increase the risk are high blood pressure, diabetes, increased body weight, lack of exercise, smoking and family history of heart disease.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE XOLISTER-ALL[®]**Do not take Xolister-all[®]**

- if you are allergic to atorvastatin or to any other medication used for lowering the levels of lipids in the blood or to any on the other ingredients of **Xolister-all[®]** - see section 6 for details.
- if you have or 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 have a muscular disorder called myopathy (continuous and not justified muscular pain).

Warnings and precautions for Xolister-all[®]

Xolister-all[®] may not be suitable for you if you have any of the below listed conditions:

- If you have problem with your kidneys.

- 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 any of these apply to you, your doctor will need to carry out a blood test before and possibly during your **Xolister-all**[®] 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 **Xolister-all**[®]")

Other medicines and Xolister-all[®]

There are some medicines that may change the effect of **Xolister-all**[®] or their effect may be changed by **Xolister-all**[®]. 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.
- Some benzodiazepines used for anxiety and other conditions e.g. nefazodone.
- Some protease inhibitors that are used in the treatment of HIV.
- Other medicines known to interact with atorvastatin include warfarin (which reduces blood clotting), oral contraceptives, phenytoin (a spasmolytic used in epilepsy), and antacids (indigestion products containing aluminum or magnesium).

You should always tell to your doctor or pharmacist if you are taking, have recently taken or might take any other medicine including those that you can buy without prescription, as these may interact.

Xolister-all[®] with food and drink

See «Section 3» for instructions on how to take **Xolister-all**[®]. 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 **Xolister-all**[®].

Alcohol

Avoid drinking too much alcohol while taking this medicine. See «Section 2- Warnings and precautions for **Xolister-all**[®]» for details.

Pregnancy and breast-feeding

Do not take **Xolister-all**[®] if you are pregnant, or if you are trying to become pregnant.

Do not take **Xolister-all**[®] if you are able to become pregnant unless you are using reliable contraceptive measures.

Do not take **Xolister-all**[®] if you are breast-feeding.

The safety of **Xolister-all**[®] 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

Do not drive if this medicine does not affect your ability to drive. Do not use any tools or machines if your ability to use them is affected by this medicine.

Important information on some ingredients of Xolister-all®

If you have been told by your doctor that you have intolerance in any of the ingredients, contact your doctor before taking this medicinal product.

3. HOW TO TAKE XOLISTER-ALL®

The usual starting dose of **Xolister-all®** is 10mg once a day in adults and children aged 10 or older. This may be increased 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 **Xolister-all®** is 80mg once a day for adults and 20mg once a day for children.

Xolister-all® 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 **Xolister-all®** exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Before you start the treatment your doctor will ask you to adapt a low fat diet, which you should maintain during the treatment with **Xolister-all®**.

The duration of treatment with **Xolister-all®** is determined by your doctor.

Please ask your doctor if you think that the effect of **Xolister-all®** is too strong or too weak.

If you take more Xolister-all® than you should

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

If you forget to take Xolister-all®

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 Xolister-all®

If you have any further questions on the use of this or wish to stop your treatment. ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **Xolister-all®** can cause side effects, although not everybody gets them.

If you think that this medicine caused to you any side effect, tell your doctor or pharmacist or any health care professional or directly to National Drug Organization (284 Mesogeion Av. 15562, Cholargos, www.eof.gr).

If you experience any of the below listed side effects, it is important to seek for emergency help:

- Angioedema (Swelling of the face, tongue and throat that can cause great difficulty in breathing). This is a rare reaction that can be serious if it happens. You should stop taking **Xolister-all®** and inform you doctor immediately.
- Rarely, some patients experience loss of muscular mass or inflammation and in few cases this may be a possibly life-threatening situation (called rhabdomyolysis). If you experience muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature, stop taking **Xolister-all®** and inform you doctor immediately.

Very rare side effects that 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 Xolister-all®:

Like all medicines, **Xolister-all®** may cause side effects to some patients.

Common: (more than 1 in 100, but less than 1 in 10 people):

- Nausea, abdominal pain, constipation, meteorism, indigestion, headache, muscular pain, weakness, diarrhea, insomnia, dizziness, pectoral pain, allergic reactions, numbness or tingling of fingers and toes, reductions of sensation to pain or touch, joint pain and back pain, swelling especially of the ankles (edema), fatigue, skin rash and itching.

Other, less common side effects, have reported during treatment with **Xolister-all®** or medicines of the same type. Not all of them have been related to the use of this type of medicines. Uncommon side effects (more than 1 in 1.000, but less than 1 in 100 people), include:

- anorexia (loss of appetite), reductions to sensation to touch and pain, vomiting, skin rash, muscular cramps, unexpected bleeding or bruising, ringing in the ears and/or head, weight gain, amnesia, skin rash, feeling unwell, sexual difficulties, 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 (more than 1 in 10.000, but less than 1 in 1.000 people), include:

- Muscular weakness, hepatitis (liver inflammation), jaundice (yellowing of the skin and of the eyes) and rhabdomyolysis (severe muscular pain and weakness, usually in the presence of high fever).

Very rare side effects (less than 1 in 10.000 people) include:

- Angioedema (Swelling of the face, tongue and throat that can cause great difficulty in breathing), Stevens-Johnson syndrome (severe blistering of the skin, mouth, eyes and genitals), polymorph erosion (skin rash with pink-red blotches), change in sense of taste, visual disturbance, liver dysfunction, loss of hearing, gynecomastia (breast enlargement in men and women) and tendon injury.

Reporting side effects

If you get any side effect, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet. You can also report side effects directly to:

National Drug Organization: 284 Mesogeion Av. GR-15562 Chologos, Athens, Greece. Tel: + 30 21 32040380/337, Fax: + 30 21 06549585 website: <http://www.eof.gr>.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE XOLISTER-ALL®

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

Do not use **Xolister-all®** after the expiry date which is stated on the container and outer packaging. The expiry date refers to the last day of the month.

Do not use **Xolister-all®** if you notice visible signs of damage.

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. OTHER INFORMATION ΠΛΗΡΟΦΟΡΙΕΣ

What Xolister-all[®] contains

The active substance of **Xolister-all[®]** is atorvastatin.

Each film-coated tablet of **Xolister-all[®]** 10mg contains 10mg atorvastatin as atorvastatin calcium trihydrate.

Each film-coated tablet of **Xolister-all[®]** 20mg contains 20mg atorvastatin as atorvastatin calcium trihydrate.

Each film-coated tablet of **Xolister-all[®]** 40mg contains 40mg atorvastatin as atorvastatin calcium trihydrate.

The other ingredients of **Xolister-all[®]** are: Mannitol, Cellulose microcrystalline, Crospovidone, Sodium carbonate anhydrous, Povidone, Methionine, Magnesium stearate, Hypromellose 6cP, Titanium dioxide (E171, CI77891), Macroglol 6000, Talc.

What Xolister-all[®] looks like and content of the pack

Xolister-all[®] 10mg, white, oval, biconvex film-coated tablets, marked with “10” on one side and “A” on the other side.

Τα **Xolister-all[®]** 20mg, white, oval, biconvex film-coated tablets, marked with “20” on one side and “A” on the other side.

Xolister-all[®] 40mg, white, oval, biconvex film-coated tablets, marked with “40” on one side and “A” on the other side.

Xolister-all[®] film-coated tablets are available in blister packs containing 28 film-coated tablets and a leaflet.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder

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