

XATHOR

Ezetimibe/Simvastatin (10 mg/40 mg)

What is in this leaflet

1. What Xathor is used for
2. How Xathor works
3. Before you use Xathor
4. How to use Xathor
5. While you are using it
6. Side effects
7. Storage and Disposal of Xathor
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial number

Please read this information carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information may have changed. You should also read any information provided with other medicines you are currently taking.

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

What Xathor is used for

Xathor (ezetimibe/simvastatin) is a tablet that is available in one strength:

- Xathor 10/40 (ezetimibe 10 mg / simvastatin 40 mg)

Xathor is a medicine used to lower levels of total cholesterol, LDL (bad) cholesterol, and fatty substances called triglycerides in the blood. In addition, Xathor raises levels of HDL (good) cholesterol. Xathor is for patients who cannot control their cholesterol levels by diet alone. You should stay on a cholesterol-lowering diet while taking this medicine.

If you have heart disease, Xathor reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalization for chest pain.

Why has my doctor prescribed Xathor?

Your doctor has prescribed Xathor to reduce the amount of cholesterol and triglycerides in your blood. Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is

made up mainly of LDL and HDL cholesterol.

LDL cholesterol is often called “bad” cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called “good” cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

How can high cholesterol be treated?

High cholesterol can be treated in two main ways:

Lifestyle Changes – including a cholesterol-lowering diet, increased physical activity, and weight management.

Medication – Cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol. Your doctor has prescribed Xathor to help lower your cholesterol.

How Xathor works

Xathor works to reduce your cholesterol in two ways. It reduces the cholesterol absorbed in your digestive tract, as well as the cholesterol your body makes by itself. Xathor does not help you lose weight.

Before you use Xathor

-When you must not use it

Do not use it if you:

- are hypersensitive (allergic) to ezetimibe, simvastatin, or any of the other ingredients of Xathor tablets
- have active liver disease
- are pregnant or breast-feeding
- are taking any of the following medicines:
 - certain antifungal medicines (such as itraconazole, ketoconazole, posaconazole, or voriconazole)

- HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and saquinavir)
- hepatitis C antiviral agents (such as boceprevir, telaprevir, elbasvir, or grazoprevir)
- certain antibiotics (such as erythromycin, clarithromycin, or telithromycin)
- the antidepressant nefazodone
- medicines containing cobicistat (used as an enhancer for antiretroviral agents)
- gemfibrozil (a fibric acid medicine for lowering cholesterol)
- cyclosporine (used as an immunosuppressant medicine to prevent organ transplant rejection)
- danazol (used in treatment of endometriosis, fibrocystic breast disease and angioedema).

Ask your doctor if you are not sure if your medicine is listed above.

-Before you start use it

Tell your doctor about:

Pregnancy: Do not use Xathor if you are pregnant, trying to become pregnant or suspect that you are pregnant. If you become pregnant while taking Xathor, stop taking it and contact your physician immediately.

Breast-feeding: Do not use Xathor if you are breast-feeding.

Medical Problems or Allergies: Talk about any medical problems (including liver disease or liver problems) or allergies you have now or have had in the past.

Tell your doctor if you consume substantial quantities of alcohol or have a past history of liver disease.

Tell your doctor if you are Asian.

- Taking other medicines

Because taking Xathor with any of the following medicines or substances can increase the risk of muscle problems (see Side Effects), it is particularly important to tell your doctor if you are taking any of the following medicines or any of the medicines listed in the section “When you must not use it”:

XATHOR

Ezetimibe/Simvastatin (10 mg/40 mg)

- amiodarone (a medicine used to treat an irregular heartbeat)
- verapamil, diltiazem, or amlodipine (medicine used to treat high blood pressure, angina, or other heart conditions)
- lomitapide (a medicine used to treat a serious and rare genetic cholesterol condition)
- daptomycin (a drug used to treat complicated skin and skin structure infections and bacteremia)
- grapefruit juice (which should be avoided while taking Xathor)

It is also important to tell your doctor if you are taking anticoagulants (medicines that prevent blood clots, such as warfarin, phenprocoumon or acenocoumarol), colchicine (a medication used for gout), niacin, or fenofibrate, another fibric acid derivative.

You should always tell your doctor about all medicines that you are taking or plan to take, including those obtained without a prescription. You should also tell any doctor who is prescribing a new medication for you that you are taking Xathor.

How to use Xathor

-How much to use

- Take one Xathor 10/40 tablet by mouth each day, in the evening. Your doctor will prescribe the suitable dose for you.
- Because of the increased risk of muscle problems, the 10/80mg dose of ezetimibe/simvastatin is only for patients at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.
- No special precautions for use in elderly.

-When to use it

- Use as directed by your doctor or pharmacist.
- If your doctor has prescribed Xathor along with cholestyramine (a bile acid sequestrant) or any other bile acid sequestrant, Xathor should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.
- Take Xathor as a single daily dose in the evening, with or without food.

-How long to use it

Continue taking Xathor for as long as your doctor recommends.

Xathor should be taken as directed by your health care provider. Continue taking your other cholesterol lowering medicines unless your doctor tells you to stop.

-If you forget to use it

Try to take Xathor as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet daily.

-If you use too much (overdose)

Take Xathor only as prescribed for you. If you take more Xathor than you were prescribed, contact your doctor or pharmacist.

While you are using it

-Things you must do

- Tell all the doctors, dentists and pharmacists treating you that you are taking Xathor.
- Tell your doctor immediately if you become pregnant while taking this medication.
- It is important to have your cholesterol measured regularly, even if you are taking medication to treat high cholesterol. You should also know your cholesterol levels and goals.

-Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Xathor to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Contact your physician promptly if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death.

- The risk of muscle breakdown is greater at higher doses of ezetimibe/simvastatin, particularly the 10/80 mg dose.

- The risk of muscle breakdown is greater for older patients (65 years of age and older), female patients, patients with kidney problems, and patients with thyroid problems.

- Tell your doctor if you have or have had myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used for breathing) or ocular myasthenia (a disease causing eye muscle weakness) as statins may lead to occurrence of myasthenia or aggravate the condition.

- There have been side effects reported with Xathor that may affect your ability to drive or operate machinery. Individual responses to Xathor may vary. (See Side effects).

- Do not drive or operate machinery until you know how Xathor affects you.

Side effects

In clinical studies, Xathor was generally well tolerated. The side effects were usually mild, temporary, and similar in type and frequency to side effects in patients who were given ezetimibe alone or simvastatin alone.

The following common side effects were reported: muscle aches; elevations in laboratory blood tests of liver (certain transaminases) and/or muscle (CK) function.

The following uncommon side effects were reported: elevations in blood tests of liver function; elevations in blood uric acid; elevations in the time it takes for blood to clot; protein in urine; weight decreased; dizziness; headache; tingling sensation; abdominal pain; indigestion; flatulence; nausea; vomiting; abdominal bloating; diarrhea; dry mouth; heartburn; rash; itching; hives; joint pain; muscle pain, tenderness, weakness or spasms; neck pain; pain in arms and legs; back pain; unusual tiredness or weakness; feeling tired; chest pain; swelling, especially in the hands and feet; sleep disorder; trouble sleeping.

Additionally, the following side effects have been reported in general use with either Xathor, ezetimibe or simvastatin

XATHOR

Ezetimibe/Simvastatin (10 mg/40 mg)

tablets (tablets that contain the active ingredients of Xathor):

- allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing (which may require treatment right away), rash, and hives; severe skin problems; muscle pain, tenderness, or weakness (that in very rare cases may not go away after stopping Xathor); alterations in some laboratory blood tests; liver problems (sometimes serious); inflammation of the pancreas; constipation; depression; gallstones; inflammation of the gallbladder; poor memory; memory loss; confusion; erectile dysfunction; breathing problems including persistent cough and/or shortness of breath or fever.
- Increase in fasting blood sugar level have been reported with statins, including simvastatin.

If you have muscle problems that do not go away even after your doctor has told you to stop taking Xathor, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

Contact 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 (symptoms of myasthenia).

Talk to your doctor anytime you have a medical problem you think may be related to Xathor.

If you are prescribed Xathor, your healthcare professional may want to conduct routine blood tests to check your liver function before and after starting treatment and if you have any symptoms of liver problems while you take Xathor. Call your doctor right away if you have the following symptoms of liver problems:

- feel tired or weak
- loss of appetite
- upper belly pain
- dark urine
- yellowing of your skin or the whites of your eyes

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npdra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Xathor

-Storage

Do not store above 30°C, usual climatic temperature excursions permitted. Keep container tightly closed.

Keep Xathor and all medications away from children.

-Disposal

Do not use this medicine after the date shown following EX (or EXP) on the container.

Product Description

-What it looks like

- Xathor 10/40 mg Tablet: White to off white, oval shaped tablet, Pharmaniaga logo on one side and plain on other side.

-Ingredients

-Active ingredient

Ezetimibe and Simvastatin.

-Inactive ingredient/Excipient

Lactose monohydrate, microcrystalline cellulose, citric acid anhydrous, hydroxypropyl methyl cellulose, isopropyl alcohol, croscarmellose sodium, magnesium stearate, purified water.

-Anti-oxidant

Propyl gallate and butylated hydroxyanisole.

-MAL number

MALxxxxxxx

Product Registration Holder & Manufacturer

Pharmaniaga Manufacturing Berhad
(198001006232)
No. 11A, Jalan P/1, Kawasan Perusahaan
Bangi, 43650 Bandar Baru Bangi,
Selangor Darul Ehsan, Malaysia

Date of revision

25/7/2024

Serial Number:

NPRA (R2) 23/092