PACKAGE LEAFLET: INFORMATION FOR THE PATIENT SZ00000LT000

Ezetimibe 10 mg tablets

ezetimibe

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

What is in this leaflet

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

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1 What Ezetimibe is and what it is used for

Ezetimibe is a medicine to lower increased levels of cholesterol.

Ezetimibe lowers levels of total cholesterol, "bad" cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, this medicine raises levels of "good" cholesterol (HDL cholesterol).

Ezetimibe, the active substance of Ezetimibe, works by reducing the cholesterol absorbed in your digestive tract.

Ezetimibe adds to the cholesterol-lowering effect of statins, a group of medicines that reduce the cholesterol your body makes by itself.

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.

This medicine is used for patients who cannot control their cholesterol levels by cholesterol-lowering diet alone. You should stay on a cholesterol-lowering diet while taking this medicine.

Ezetimibe is used in addition to your cholesterol-lowering diet if you have:

- a raised cholesterol level in your blood (primary hypercholesterolaemia [heterozygous familial and non-familial])
  - together with a statin, when your cholesterol level is not well controlled with a statin alone
  - alone, when statin treatment is inappropriate or is not tolerated.
- a hereditary illness (homozygous familial hypercholesterolaemia) that increases the cholesterol level in your blood. You will also be prescribed a statin and may also receive other treatments.

If you have heart disease, this medicine combined with cholesterol-lowering medicines called statins reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalisation for chest pain.

Ezetimibe does not help you lose weight.

2 What you need to know before you take Ezetimibe

If you use Ezetimibe together with a statin, please read the package leaflet of that particular medicine.

DO NOT take Ezetimibe:
- if you are **allergic** to ezetimibe or any of the other ingredients of this medicine (listed in section 6 and end of section 2).

DO NOT take Ezetimibe together **with a statin** if:
- you currently have **liver problems**
- you are **pregnant** or **breast-feeding**.

Warnings and precautions
Talk to your doctor or pharmacist before taking Ezetimibe
- Tell your doctor about all your medical conditions including any allergies.
- Your doctor should do a blood test before you start taking this medicine with a statin. This is to check how well your liver is working.
- Your doctor may also want you to have blood tests to check how well your liver is working after you start taking this medicine with a statin.

If you have **moderate or severe liver problems**, Ezetimibe is not recommended.

The combined use of Ezetimibe and **fibrates** (medicines for lowering cholesterol) should be avoided since the safety and effectiveness of the combined use of Ezetimibe and fibrates have not been established.

Contact your doctor immediately if you experience
- unexplained muscle pain, tenderness, or weakness.

This is because on rare occasions, muscle problems, including muscle breakdown resulting in kidney damage, **can be serious and may become a potentially life-threatening condition.**

The risk of muscle breakdown is greater in some patients taking Ezetimibe with cholesterol lowering medicines, like statins.

Children and adolescents
Do not give this medicine to children and adolescents (6 to 17 years of age) unless prescribed by a specialist because there are limited data on safety and efficacy. Do not give this medicine to children less than 6 years old because there is no information in this age group.

Other medicines and Ezetimibe
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including those obtained without a prescription. In particular, tell your doctor if you are taking any of the following:
- ciclosporin (a medicine often used in organ transplant patients)
- medicines to prevent blood clots, such as warfarin, phenprocoumon, acenocoumarol or fluindione (anticoagulants)
- colestyramine (a medicine for lowering cholesterol), because it affects the way ezetimibe works (see also section 3)
- fibrates (medicines for lowering cholesterol) (see also section 2: Warnings and precautions).

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take Ezetimibe with a statin if you are pregnant, are trying to get pregnant or think you may be pregnant. If you get pregnant while taking Ezetimibe with a statin, stop taking both medicines immediately and tell your doctor.
There is no experience from the use of Ezetimibe without a statin during pregnancy.

Breast-feeding

Do not take Ezetimibe with a statin if you are breast-feeding, because it is not known if the medicines are passed into breast milk. Ezetimibe without a statin should not be used if you are breast-feeding. Ask your doctor for advice.

Driving and using machines
Ezetimibe is not expected to interfere with your ability to drive or to use machinery. However, some people may get dizzy after taking Ezetimibe. If this happens to you, do not drive or operate machinery until you feel better.

Ezetimibe contains sodium and lactose
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.
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 Ezetimibe

Always take this medicine exactly as your doctor has told you. Continue taking your other cholesterol-lowering medicines unless your doctor tells you to stop. Check with your doctor or pharmacist if you are not sure.
- Before starting this medicine, you should be on a diet to lower your cholesterol.
- You should stay on this cholesterol-lowering diet whilst taking this medicine.

The recommended dose is one tablet by mouth once a day.

Take this medicine at any time of the day. You can take it with or without food.

If your doctor has prescribed Ezetimibe together with a statin, both medicines can be taken at the same time. In this case, please read the dosage instructions in the package leaflet of that particular medicine.

If your doctor has prescribed Ezetimibe together with colestyramine or any other bile acid sequestrant (medicines for lowering cholesterol), you should take Ezetimibe at least 2 hours before or 4 hours after taking the bile acid sequestrant.

If you take more Ezetimibe than you should
Contact your doctor or pharmacist if you take more Ezetimibe than you should.

If you forget to take Ezetimibe
Do not take a double dose to make up for a forgotten tablet. Just take your normal amount of Ezetimibe at the usual time the next day.

If you stop taking Ezetimibe
Talk to your doctor or pharmacist because your cholesterol may rise again if you stop taking this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor immediately if you experience
- unexplained muscle pain,
- muscle tenderness or weakness.

This is because on rare occasions, muscle problems, including muscle breakdown resulting in kidney damage, **can be serious and may become a potentially life-threatening condition.**

Allergic reactions, including
- swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing,
- dizziness or fainting and unusually fast or irregular heart beat which **require treatment immediately**, have been reported in general use.

Other side effects reported in clinical trials

When these tablets are **taken on their own**, the following side effects were reported:

Common side effects (may affect up to 1 in 10 people):
- abdominal pain
- diarrhoea
- flatulence (breaking wind)
- feeling tired.

Uncommon side effects (may affect up to 1 in 100 people):
- elevations in some laboratory blood tests of liver (transaminases) or muscle (CK) function
- cough
- indigestion
- heartburn
- feeling sick
- joint pain
- muscle spasms
- neck pain
- decreased appetite
- pain
- chest pain
- hot flush
- high blood pressure.

Additionally, when **these tablets are taken with a statin**, the following side effects were reported:

Common side effects (may affect up to 1 in 10 people):
- elevations in some laboratory blood tests of liver function (transaminases)
- headache
- muscle pain/tenderness.

Uncommon side effects (may affect up to 1 in 100 people):
- tingling sensation (pins and needles)
- dry mouth
- inflammation of stomach lining
- itching
- rash
- hives
- back pain
- muscle weakness
- pain in arms and legs
- unusual tiredness or weakness
- swelling, especially in the hands and feet.

When **used with fenofibrate** (for high cholesterol), the following side effect was reported:

Common side effect (may affect up to 1 in 10 people):
- abdominal pain.

Additionally, the following side effects have been reported in general use (reported once marketed):

Side effects of unknown frequency
(frequency cannot be estimated from the available data):
- dizziness
- liver problems
- allergic reactions including rash, hives, swelling of the face, tongue or throat and fainting
- raised red rash, sometimes with target - shaped lesions i.e. a pink-red ring around a pale centre
- muscle pain/tenderness
- muscle weakness: cramps, stiffness or spasm
- strong muscle pain or weakness and red-brown urine because of muscle breakdown
- gallstones or inflammation of the gallbladder (which may cause abdominal pain, nausea, vomiting)
- inflammation of the pancreas often with severe abdominal pain
- constipation
- reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopaenia)
- tingling sensation
- depression
- unusual tiredness or weakness
- shortness of breath.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store). By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Ezetimibe

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tablet blister, carton and bottle after EXP. The expiry date refers to the last day of that month.

Blisters: Store in the original package in order to protect from moisture.

Bottles: Keep the container tightly closed in order to protect from moisture.

After first opening: Store below 25°C. Use within 9 months.

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 to protect the environment.

6 Contents of the pack and other information

What Ezetimibe contains
- The active substance is ezetimibe. Each tablet contains 10 mg of ezetimibe.
- The other ingredients are lactose monohydrate (*see end of the section 2 for further information*), hypromellose, croscarmellose sodium, microcrystalline cellulose, sodium lauryl sulfate and magnesium stearate.

What Ezetimibe looks like and contents of the pack
Ezetimibe is a white to almost white, oval tablet (7.4 mm x 4.0 mm) with debossing “10” on one side and “EZT” on the other side.

Alu/Alu blister: 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 and 100 (hospital pack) tablets.
HDPE bottle with a polypropylene screw cap: 100 tablets and 250 tablets (for hospital use and dose dispensing pharmacies only).
White to off-white HDPE bottles with polypropylene closure with induction heat seal liner and addition of silica gel desiccant separately added in the bottle: 250 tablets.

Not all pack sizes may be marketed.

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