

Package leaflet: Information for the user
Ezetimibe 10 mg Tablets
ezetimibe

Your medicine is called Ezetimibe 10 mg Tablets, but it will be referred to as Ezetimibe tablets or Ezetimibe throughout this leaflet.

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 side effects not listed in this leaflet. See section 4.

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1. What Ezetimibe tablets are and what they are used for

Ezetimibe tablets are a medicine to lower increased levels of cholesterol.

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

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

Ezetimibe tablets add 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.

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

Ezetimibe tablets are 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
- a hereditary illness (homozygous sitosterolaemia, also known as phytosterolaemia) that increases the levels of plant sterols in your blood

If you have heart disease, Ezetimibe 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 tablets do not help you lose weight.

2. What you need to know before you take Ezetimibe tablets

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

Do not take Ezetimibe tablets if:

- you are **allergic (hypersensitive) to ezetimibe** or any of the other ingredients of this medicine (see Section 6: Contents of the pack and other information)

Do not take Ezetimibe tablets together with a statin if:

- you currently have a liver problem
- you are pregnant or breast-feeding

Warnings and precautions

Talk to your doctor or pharmacist before taking Ezetimibe tablets:

- Tell your doctor about all your medical conditions including allergies.
- Your doctor should do a blood test before you start taking Ezetimibe tablets 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 Ezetimibe tablets with a statin.

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

The safety and efficacy of the combined use of **Ezetimibe tablets** and certain cholesterol lowering medicines, **the fibrates** have not been established.

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 tablets:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor if you are taking medicine(s) with any of the following active ingredients:

- ciclosporin (often used in organ transplant patients)
- medicines with an active ingredient to prevent blood clots, such as warfarin, phenprocoumon, acenocoumarol or fluindione (anticoagulants)
- colestyramine (also used to lower cholesterol), because it affects the way Ezetimibe tablets work
- fibrates (also used to lower cholesterol)

Pregnancy and breast-feeding

Do not take Ezetimibe tablets 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 tablets with a statin, stop taking both medicines immediately and tell your doctor.

There is no experience of the use of Ezetimibe tablets without a statin during pregnancy. Ask your doctor for advice before using Ezetimibe tablets if you are pregnant.

Do not take Ezetimibe tablets with a statin if you are **breast-feeding**, because it is not known if the medicines are passed into breast milk.

Ezetimibe tablets without a statin should not be used if you are breast-feeding. Ask your doctor for advice.

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

Driving and using machines

Ezetimibe tablets are not expected to interfere with your ability to drive or to use machinery. However, it should be taken into account that some people may get dizzy after taking Ezetimibe tablets.

Ezetimibe tablets contain lactose

Ezetimibe tablets contain a sugar called lactose. If your doctor has told you that you have intolerance to some sugars, contact your doctor before taking Ezetimibe tablets.

Ezetimibe tablets contain sodium

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

3. How to take Ezetimibe tablets

Always take Ezetimibe tablets exactly as your doctor has told you. Continue taking your other cholesterol-lowering medicines unless your doctor tells you to stop. You should check with your doctor or pharmacist if you are not sure.

- Before starting Ezetimibe tablets, you should be on a diet to lower your cholesterol.
- You should keep on this cholesterol lowering diet whilst taking Ezetimibe tablets.

The recommended dose is one Ezetimibe 10 mg tablet by mouth once a day.

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

If your doctor has prescribed Ezetimibe tablets along 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 along with another medicine for lowering cholesterol containing the active ingredient colestyramine or any other medicine containing bile acid sequestrant, you should take Ezetimibe tablets **at least 2 hours before or 4 hours** after taking the bile acid sequestrant.

If you take more Ezetimibe tablets than you should

Please contact your doctor or pharmacist.

If you forget to take Ezetimibe tablets

Do not take a double dose to make up for a forgotten dose, just take your normal amount of Ezetimibe tablets at the usual time next day.

If you stop taking Ezetimibe tablets

Talk to your doctor or pharmacist because your cholesterol may rise again.

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

4. Possible side effects

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

The following terms are used to describe how often side effects have been reported:

- Very common (may affect more than 1 of 10 patients)
- Common (may affect up to 1 of 10 patients)

- Uncommon (may affect up to 1 of 100 patients)
- Rare (may affect up to 1 of 1,000 patients)
- Very rare (may affect up to 1 of 10,000 patients, including isolated reports).

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.

Allergic reactions, including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing (which requires treatment right away) have been reported in general use.

When Ezetimibe tablets used alone, the following side effects were reported:

Common (may affect up to 1 in 10 people):

- abdominal pain
- diarrhoea
- wind (flatulence)
- feeling tired

Uncommon (may affect up to 1 in 100 people):

- elevations in some liver (transaminases) or muscle (CK) function
- cough
- indigestion
- heartburn
- nausea
- joint pain
- muscle spasms
- neck pain
- decreased appetite
- pain
- chest pain
- hot flush
- high blood pressure

Additionally, when Ezetimibe tablets used with a statin, the following side effects were reported:

Common (may affect up to 1 in 10 people):

- elevations in some laboratory blood tests of liver function (transaminases)
- headache
- muscle pain
- tenderness
- weakness

Uncommon (may affect up to 1 in 100 people):

- tingling sensation
- dry mouth

- itching
- rash
- hives
- back pain
- muscle weakness
- pain in arms and legs
- unusual tiredness or weakness
- swelling, especially in the hands and feet

When Ezetimibe tablets used with fenofibrate, the following common side effect was reported:

- abdominal pain

The following side effects have also been reported in the general use of Ezetimibe tablets:

- dizziness
- muscle aches
- liver problems
- allergic reactions including rash and hives
- raised red rash, sometimes with target-shaped lesions (erythema multiforme)
- muscle pain, tenderness or weakness
- 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 (thrombocytopenia)
- 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:

United Kingdom: Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for the MHRA Yellow Card in the Google Play or Apple App Store.

Ireland: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store Ezetimibe tablets

- Keep Ezetimibe tablets out of the sight and reach of children.

- Do not use Ezetimibe tablets after the expiry date which is stated on the blister and carton after “EXP”. The expiry date refers to the last day of that month.
- Blister: Keep in the outer carton in order to protect from moisture.

Do not use this medicine if you notice any visible signs of deterioration.

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 tablets contain

- The active substance is ezetimibe. Each tablet contains 10 mg ezetimibe.
- The other ingredients are: lactose monohydrate, croscarmellose sodium, sodium lauryl sulphate, hypromellose, colloidal silicon dioxide, microcrystalline cellulose, hydrogenated castor oil and sodium stearyl fumarate.
- See section 2 ‘Ezetimibe tablets contain lactose’ and ‘Ezetimibe tablets contain sodium’ for further excipient information.

What Ezetimibe tablets looks like and contents of the pack

Ezetimibe tablets are white to off-white, capsule shaped, flat beveled edged, uncoated tablets debossed with ‘EZE’ on one side and plain on other side, approximately 8.2mm in length and 4.1mm in width.

Pack size:

Ezetimibe 10 mg Tablets are available in PVC/PVDC transparent film - Plain Aluminium Foil blister pack of 28 tablets (2 x 14’s Blister).

Marketing Authorisation Holders:

UK: Key Pharmaceuticals Ltd.
Galen House, 83 High Street,
Somersham, Cambridgeshire,
PE28 3JB, UK

IE: Lexon Pharmaceuticals (Ireland) Limited
Block 4, Port Tunnel Business Park,
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Ireland

Manufacturer:

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