

Package leaflet: Information for the patient

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
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1. What Ezetimibe is and what it is used for

Ezetimibe contains the active substance ezetimibe. Ezetimibe is a medicine used 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, Ezetimibe raises levels of "good" cholesterol (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.

Ezetimibe works by reducing the cholesterol absorbed in your digestive tract. Ezetimibe does not help you lose weight.

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

Ezetimibe 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 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, 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 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).

Do not take Ezetimibe together with a statin:

- if you currently have liver problems
- if 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 allergies.

Your doctor should do a blood test before you start taking Ezetimibe 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 with a statin.

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

The safety and efficacy of the combined use of ezetimibe and certain lowering medicines, the fibrates have not been established.

If you have unexplained muscular pain, tenderness or weakness while taking these tablets, particularly if this is associated with a high temperature, please tell your doctor.

Children and adolescents

Do not give this medicine to children and adolescents aged 6 to 17 years unless it is 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 medicines obtained without a prescription. In particular, tell your doctor or pharmacist 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)
- cholestyramine (a medicine for lowering cholesterol), because it affects the way Ezetimibe works
- fibrates (medicines for lowering cholesterol).

Pregnancy and breast-feeding

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.

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.

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.

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 do not drive or use machinery.

Ezetimibe contains lactose monohydrate and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

3. How to take Ezetimibe

Always take this medicine exactly as your doctor or pharmacist 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 Ezetimibe, you should be on a diet to lower your cholesterol. You should keep on this cholesterol lowering diet whilst taking Ezetimibe.

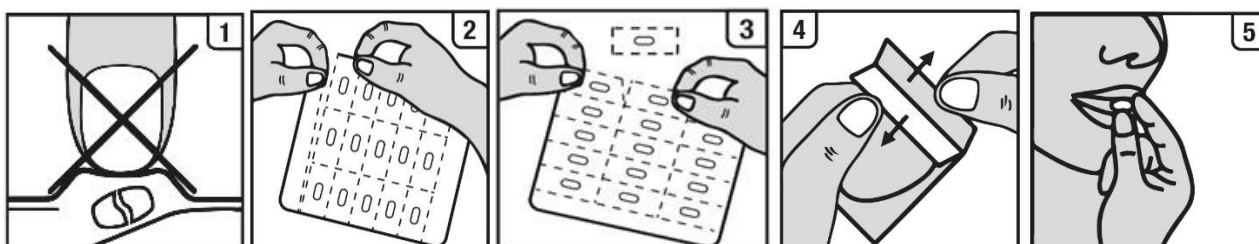
Adults and adolescents (10 to 17 years of age)

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

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

Opening instruction for the peelable blister:

1. Do not press blister pocket to open product.
2. For perforated blister; remove any one side of the perforated zone as indicated in the picture.
3. Hold the blister strips at the edges and separate one blister cell from the rest of the strip by gentle tearing along the perforation around it.
4. Carefully peel off the paper lidding material from unsealed area.
5. Take the product from the opened blister pocket.



If your doctor has prescribed Ezetimibe 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 cholestyramine 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

If you take more Ezetimibe than you have been told to, contact your doctor or pharmacist.

If you forget to take Ezetimibe

Do not take a double dose to make up for a forgotten dose, 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 before you stop taking this medicine because your cholesterol levels may increase 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.

Tell your doctor or go to your nearest hospital casualty department straight away if you have any of the following serious side effects; these effects are not known (frequency cannot be estimated from the available data) but you may need medical attention:

- 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).
- inflammation of the pancreas often with severe abdominal pain.
- gallstones or inflammation of the gallbladder (which may cause abdominal pain, feeling or being sick).
- raised red rash, sometimes with target shaped lesions.
- inflammation of the liver (which may cause tiredness, fever, feeling or being sick, feeling generally unwell, yellowing of the skin and eyes, light coloured stools and dark coloured urine).

When 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 and muscle enzymes seen on a blood test
- cough
- indigestion
- heartburn
- feeling sick
- joint pain
- muscle spasms
- neck pain
- decreased appetite
- pain
- chest pain
- hot flush
- high blood pressure.

Additionally, when used with a statin, the following side effects are possible:

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

- elevations in some liver enzymes seen on a blood test
- headache
- muscle pain.

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

- tingling sensation
- dry mouth
- stomach pain, feeling sick, vomiting blood, blood in bowel motions
- 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 or without a statin, the following side effects are possible:

Not known (frequency cannot be estimated from the available data):

- dizziness
- allergic reactions including rash and hives
- constipation
- reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopenia)
- tingling sensation
- depression
- unusual tiredness or weakness
- shortness of breath.

When used with fenofibrate, the following side effect is possible:

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

- abdominal pain.

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 HPRA Pharmacovigilance. Website: www.hpra.ie. 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 blister, carton or bottle after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Bottles: Use within 100 days of opening.

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. Contents of the pack and other information

What Ezetimibe contains

- The active substance is ezetimibe. Each tablet contains 10 mg ezetimibe.
- The other ingredients are: lactose monohydrate (see section 2 “Ezetimibe contains lactose monohydrate”); sodium laurilsulfate (E487); croscarmellose sodium; hypromellose (E464); crospovidone (Type B); cellulose, microcrystalline; magnesium stearate.

What Ezetimibe looks like and contents of the pack

Ezetimibe 10 mg Tablets are white to off white capsule shaped, bevelled edge tablets debossed with "M" on one side of the tablet and "EE1" on the other side.

Ezetimibe 10 mg Tablets are available in blister packs or peelable blister packs of 14, 28, 30, 56, 84, 90, 98 & 100 tablets; perforated unit dose blister packs of 14 x 1, 28 x 1, 30 x 1, 50 x 1, 90 x 1 & 98 x 1 tablets, calendar blisters of 28 and 30 tablets and plastic bottles of 14, 28, 50, 56, 84, 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. T/A Gerard Laboratories
35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Manufacturer

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft, H-2900 Komárom, Mylan utca 1, Hungary.

This medicinal product is authorised in the Member States of the EEA and in the United Kingdom (Northern Ireland) under the following names:

Belgium	Ezetimibe Viatris 10 mg tabletten
Cyprus	Ezetimibe/Mylan 10 mg Tablets
Czech Republic	Ezetimib Viatris 10 mg, tablety
Denmark	Ezetimibe Viatris
France	EZETIMIBE VIATRIS 10 mg, comprimé
Germany	Ezetimib Mylan 10 mg Tabletten
Greece	Ezetimibe Mylan 10mg Tablets
Ireland	Ezetimibe 10 mg Tablets
Italy	Ezetimibe Mylan
Luxembourg	Ezetimibe Viatris 10 mg comprimés
Portugal	Ezetimiba Mylan
Slovak Republic	Ezetimib Viatris 10 mg, tablety
Spain	Ezetimiba Viatris 10 mg comprimidos EFG
Sweden	Ezetimibe Viatris
The Netherlands	Ezetimibe Mylan 10 mg, tabletten
United Kingdom (Northern Ireland)	Ezetimibe 10 mg Tablets

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