Package leaflet: Information for the patient

EZETROL® 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 EZETROL is and what it is used for

EZETROL is a medicine to lower increased levels of cholesterol.

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

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

EZETROL 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.

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.

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

If you have heart disease, EZETROL 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.

EZETROL does not help you lose weight.

2. What you need to know before you take EZETROL

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

Do not take EZETROL 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 EZETROL 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 EZETROL.
- Tell your doctor about all your medical conditions including allergies.
- Your doctor should do a blood test before you start taking EZETROL 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 EZETROL with a statin.

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

The safety and efficacy of the combined use of EZETROL 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 EZETROL

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 EZETROL works
- fibrates (also used to lower cholesterol)

Pregnancy and breast-feeding

Do not take EZETROL with a statin if you are pregnant, are trying to get pregnant or think you may be pregnant. If you get pregnant while taking EZETROL with a statin, stop taking both medicines immediately and tell your doctor.

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

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

EZETROL 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

EZETROL is 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 EZETROL.

EZETROL contains lactose.

EZETROL tablets contain a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take EZETROL

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. You should check with your doctor or pharmacist if you are not sure.

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

The recommended dose is one EZETROL 10 mg Tablet by mouth once a day.

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

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

If you take more EZETROL than you should

Please contact your doctor or pharmacist.

If you forget to take EZETROL

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

If you stop taking EZETROL

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 used alone, the following side effects were reported:
Common: abdominal pain; diarrhoea; flatulence; feeling tired.
Uncommon: elevations in some laboratory blood tests of 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 used with a statin, the following side effects were reported:
Common: elevations in some laboratory blood tests of liver function (transaminases); headache; muscle pain, tenderness or weakness.
Uncommon: 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 used with fenofibrate, the following common side effect was reported:
abdominal pain.

Additionally, the following side effects have been reported in general use: 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 (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 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 EZETROL

- 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 carton or container after "EXP." The expiry date refers to the last day of that month.
- Do not store EZETROL above 30 °C.

Blisters: Store in the original package. Bottles: Keep bottles tightly closed. These measures will protect the product from moisture.

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 EZETROL contains

- The active substance is ezetimibe. Each tablet contains 10 mg ezetimibe.
- The other ingredients are: lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, sodium laurilsulfate, magnesium stearate.

What EZETROL looks like and contents of the pack

EZETROL tablets are white to off-white, capsule-shaped tablets with code “414” on one side.

Pack sizes:
7, 10, 14, 20, 28, 30, 50, 98, 100 or 300 tablets in push-through blisters or unit dose peelable blisters;
84 or 90 tablets in push-through blisters;
50, 100 or 300 tablets in unit dose push-through blisters;
100 tablets in bottles.

Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Organon Pharma (Ireland) Limited
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This medicinal product is authorised under the name EZETROL in Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden and United Kingdom.

This leaflet was last revised in November 2022