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

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, Ezetimibe raises levels of "good" cholesterol (HDL cholesterol).

Ezetimibe, the active ingredient 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.

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 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, ezetimibe combined with cholesterol-lowering medicines called statins reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalization 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 (hypersensitive) to ezetimibe or any of the other ingredients of this medicine (listed in section 6: Contents of the pack and other information).

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 EzetimibeTell your doctor about all your medical conditions including 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 safety and efficacy of the combined use of Ezetimibe and certain cholesterol lowering medicines, the fibrates have not been established.

Children and adolescents

Do not give this medicine to children and adolescents between 6 and 17 years 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. 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 works
- fibrates (also used to lower 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. Ask your doctor for advice before using Ezetimibe if you are pregnant.

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.

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

Driving and using machines
Ezetimibe 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 Ezetimibe.

Ezetimibe contains lactose
Ezetimibe 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.

Ezetimibe 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 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. You should 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 keep on this cholesterol lowering diet whilst taking this medicine.

The recommended dose is one Ezetimibe 10 mg 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 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 at least 2 hours before or 4 hours after taking the bile acid sequestrant.

If you take more Ezetimibe than you should
Please contact your doctor or pharmacist.

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 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 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.

- This medicinal product does not require any special temperature storage conditions

Blisters: Store in the original package in order to protect from moisture.
Bottles: Keep the container tightly closed in order to protect 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 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 ezetimibe.
- The other ingredients are: lactose monohydrate, croscarmellose sodium (E468), povidone k-30 (E1201), sodium laurilsulfate, magnesium stearate (E470b), Polysorbate 80 (E433).

What Ezetimibe looks like and contents of the pack
Product description: white to off white, capsule shaped, flat faced with beveled edge, uncoated tablets, debossed with "10" on one side and plain on other side.

Pack sizes:
7, 10, 14, 20, 28, 30, 50, 98, 100, or 300 tablets in aluminium-aluminium or aluminium-PVC / Aclar blister packs.

30 and 100 tablets in HDPE bottles with polypropylene cap.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturers
Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

Laboratori FUNDACIO DAU
C/ De la letra C, 12-14, Poligono Industrial de la Zona,
Franca, 08040 Barcelona, Spain

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

The medicinal product is authorized in the Member States of the EEA under the following names:

Name of Member States	Name of the medicinal product
Austria	Ezetimib Accord 10 mg Tabletten
Czech Republic	Ezetimibe Accord 10 mg
Germany	Ezetimibe Accord 10 mg Tabletten
Denmark	Ezetimibe Accord 10 mg tabletter
Estonia	Ezetimibe Accord
Finland	Ezetimibe Accord 10 mg tabletti
France	Ezetimibe Accord 10 mg comprimé
Iceland	Ezetimibe Accord 10 mg töflur
Ireland	Ezetimibe 10 mg tablets
Latvia	Ezetimibe Accord 10 mg tabletes
Netherland	Ezetimibe Accord 10 mg tabletten
Norway	Ezetimibe Accord
Poland	Exebir
Portugal	Ezetimibe Accord 10 mg Comprimidos
Slovakia	Ezetimibe Accord 10 mg tablety
Sweden	Ezetimibe Accord 10 mg tabletter
Spain	Ezetimiba Accord 10 mg comprimidos
United kingdom (Northern Ireland)	Ezetimibe 10 mg tablets

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