Package leaflet: Information for the user

Ezetimibe Krka 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 Krka is and what it is used for

Ezetimibe Krka is a medicine to lower increased levels of cholesterol.

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

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

Ezetimibe Krka 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 Krka 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 Krka 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 Krka does not help you lose weight.

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

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

Do not take Ezetimibe Krka
- if you are allergic to ezetimibe or any of the other ingredients of this medicine (listed in section 6),

Do not take Ezetimibe Krka 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 Krka.
- Tell your doctor about all your medical conditions including allergies.
- Your doctor should do a blood test before you start taking Ezetimibe Krka 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 Krka with a statin.
- If you have moderate or severe liver problems, Ezetimibe Krka is not recommended.
- The safety and efficacy of the combined use of Ezetimibe Krka and fibrates (medicines for lowering cholesterol) 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 Krka
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 (a medicine often used in organ transplant patients),
- medicines with an active ingredient to prevent blood clots, such as warfarin, phenprocoumon, acenocoumarol or fluindione (anticoagulants),
- colestyramine (a medicine for lowering cholesterol), because it affects the way Ezetimibe Krka works,
- fibrates (medicines for lowering cholesterol).

Ezetimibe Krka with food and drink

You can take Ezetimibe Krka with or without food.

Pregnancy and breast-feeding
Do not take Ezetimibe Krka 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 Krka with a statin, stop taking both medicines immediately and tell your doctor.

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

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

Ezetimibe Krka 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 Krka 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 Krka.

Ezetimibe Krka 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 Krka

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

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

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

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

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

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

If you stop taking Ezetimibe Krka

If you stop taking Ezetimibe Krka, your blood cholesterol 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.

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 (may affect up to 1 in 10 people): abdominal pain; diarrhoea; flatulence; feeling tired.

Uncommon (may affect up to 1 in 100 people): 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 (may affect up to 1 in 10 people): elevations in some laboratory blood tests of liver function (transaminases); headache; muscle pain; tenderness or 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 used with fenofibrate, the following common side effect was reported:
abdominal pain.

Additionally, the following side effects have been reported in general use *(frequency not known)*: 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 Krka

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 packaging after "EXP". The expiry date refers to the last day of that month.

Store in the original package 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 protect the environment.

6. Contents of the pack and other information

What Ezetimibe Krka contains
- The active substance is ezetimibe. Each tablet contains 10 mg ezetimibe.
- The other ingredients are: sodium laurilsulfate, povidone K30, mannitol (E421), croscarmellose sodium (E468), microcrystalline cellulose (E460), sodium stearyl fumarate. See section 2 "Ezetimibe Krka contains sodium".

What Ezetimibe Krka looks like and contents of the pack
Tablets are presented as white to off white, capsule shaped tablets with bevelled edges. Tablet dimensions: 8 x 4 mm.

Ezetimibe Krka is available in boxes containing:
- 14, 28, 30, 50, 56, 60, 90, 98 or 100 tablets in blisters (OPA/Alu/PVC//Alu),
- 14 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1, 60 x 1, 90 x 1, 98 x 1 or 100 x 1 tablet in perforated unit dose blisters (OPA/Alu/PVC//Alu).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Slovenia, Denmark, Finland, Norway, Sweden, Iceland	Ezetimib Krka
Austria	Ezetimib HCS
Belgium, France, Ireland, Italy, Netherlands	Ezetimibe Krka
United Kingdom (Northern Ireland)	Ezetimibe
Czeck Republic, Hungary, Poland, Romania, Slovakia, Malta	Ezoleta
Germany	Ezetad
Spain, Portugal	Ezetimiba Krka

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