

PACKAGE LEAFLET: INFORMATION FOR THE USER
EZETROL® 10 mg Tablets
Ezetimibe

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What EZETROL is and what it is used for
2. Before you take EZETROL
3. How to take EZETROL
4. Possible side effects
5. How to store EZETROL
6. Further information

1. WHAT EZETROL IS AND WHAT IT IS USED FOR

EZETROL is a medicine used to lower 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). It is used for patients who cannot control their cholesterol levels by diet alone. You should stay on a cholesterol-lowering diet while taking this medicine.

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

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

EZETROL is used in addition to 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.

2. 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 EZETROL Tablets (see Section 6: Further Information).

Do not take EZETROL together with a statin if:

- you currently have liver problems
- you are pregnant or breast-feeding.

Take special care with 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 fibrates (medicines for lowering cholesterol) have not been established.

Children

EZETROL is not recommended for children under age of 10.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including those obtained without a prescription. In particular, tell your doctor 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 fludione (anticoagulants)
- colestyramine (a medicine for lowering cholesterol), because it affects the way EZETROL works
- fibrates (medicines for lowering 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.

Important information about some of the ingredients of EZETROL

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.

3. HOW TO TAKE EZETROL

Always take EZETROL 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 diet whilst taking EZETROL.

Adults and adolescents (10 to 17 years of age): The 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 colestyramine or any other bile acid sequestrant (medicines for lowering cholesterol), 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 an extra dose, just take your normal amount of EZETROL at the usual time the next day.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, EZETROL 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 (occurring in 1 or more of 10 patients treated)
- Common (occurring in 1 or more of 100 and less than 1 of 10 patients treated)
- Uncommon (occurring in 1 or more of 1000 and less than 1 of 100 patients treated)
- Rare (occurring in 1 or more of 10000 and less than 1 of 1000 patients treated)
- Very rare (occurring in less than 1 of 10000 patients treated 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; 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE EZETROL

- Keep out of the reach and sight of children.
- Do not use EZETROL after the expiry date 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER 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:

Merck Sharp & Dohme Limited
Hertford Road
Hoddesdon
Hertfordshire EN11 9BU, United Kingdom

Manufacturer:
SP Labo N. V.
Industriepark 30 – Zone A
B-2220 Heist-op-den-Berg
Belgium

This medicinal product is authorized under the name EZETROL in Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden and United Kingdom.

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