PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine can be sold under doctor's prescription only

EZETROL® 10 mg
Tablets

Each tablet contains:
Ezetimibe 10 mg
For a list of inactive ingredients please refer to section 6.

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

- This leaflet contains concise information about **EZETROL**. 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 ailment seems similar to yours.
- **EZETROL** is not intended for children under age 10.

1. WHAT EZETROL IS AND WHAT IT IS USED FOR?

1.1 What is EZETROL?

Therapeutic group:
Ezetimibe, a member of a class of medicines called *CAI* (Cholesterol Absorption Inhibitors), which inhibits the intestinal absorption of cholesterol.

1.2 What is EZETROL used for?

EZETROL is intended for patients with:

Primary hypercholesterolemia heterozygous familial and non-familial (conditions in which there is a high cholesterol level in the blood) as a single treatment or in combination with a statin (HMG-CoA reductase inhibitor) as adjunctive to diet.

Homozygous familial hypercholesterolemia (HoFH) (condition in which there is a high cholesterol level in the blood) in combination with a statin and other treatments for reduction of lipid levels in the blood (e.g. LDL apheresis).

Homozygous familial sitosterolemia (disorder of lipid absorption and removal from the gastrointestinal tract)

EZETROL 10 mg tablets are used for lowering high blood lipid levels.
EZETROL is sometimes given together with medicines of the Statins family (e.g., simvastatin, atorvastatin, etc.); if that is the case, a thorough review of the patient's circular of the statin should be done before starting treatment and you should consult your physician.

2. BEFORE YOU TAKE EZETROL

2.1 Do not take EZETROL:

- if you are allergic (hypersensitive) to ezetimibe or any of the other ingredients of **EZETROL** (see also section 6);
- together with a statin, if you currently have liver problems;
- together with a statin, if you are pregnant or breast feeding.

If you use **EZETROL** together with a statin, please read the package leaflet of that particular medicine.
If you think any of these are relevant to you, do not take the tablets until you have consulted your doctor.

2.2 Special warnings concerning use of 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.

2.3 Taking other medicines

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, you should inform the attending doctor or pharmacist.

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)

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

2.4 Taking EZETROL with food and drink

You can take **EZETROL** with or without food.

2.5 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.

2.6 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**.

2.7 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.

2.8 Children and adolescents

Do not give this medicine to children and adolescents (10 to 17 years of age) unless prescribed by a specialist because there are limited data on safety and efficacy.

This medicine is not intended for children under age 10.

2.9 EZETROL contains sodium

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

3. HOW DO YOU USE 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.
Your physician will determine the dosage and duration of the treatment.
Swallow the medicine with a small amount of water.
No information is available regarding crushing/splitting/chewing of the tablets
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 usually recommended dose is:
One **EZETROL** 10 mg tablet by mouth once a day.
Do not exceed the recommended dose.
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.
EZETROL is not intended for children under age 10.

If you take more EZETROL than you should
Please contact your doctor or pharmacist.
If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

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.

How can you contribute to the success of the treatment?
Complete the full course of treatment as instructed by the doctor.
Even if there is an improvement in your health, do not discontinue use of this medicine before consulting your doctor.
Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.
If you have any further question on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **EZETROL** can cause side effects, in some of the users.
Do not be alarmed by reading the list of side effects, you may not suffer from any of 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.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Side effects can be reported to the Ministry of Health by using the link "Adverse Drug Reactions Report" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link:
https://sideeffects.health.gov.il/

5. HOW TO STORE EZETROL?

Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor!
Do not use **EZETROL** after the expiry date (exp. date) which is stated on pack. The expiry date refers to the last day of the indicated month.
Store this medicine below 30ºC.
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

6.1 What EZETROL contains?

The active substance is ezetimibe. Each tablet contains 10 mg ezetimibe.
The other ingredients are: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, povidone, sodium laurilsulfate, magnesium stearate.
EZETROL Tablets contain lactose:
Each tablet of **EZETROL** 10 mg contains 55 mg lactose monohydrate.

6.2 What EZETROL looks like and contents of the pack

EZETROL tablets are white to off-white, capsule-shaped tablets debossed with “414” on one side.
Pack sizes:
Each pack contains 10, 30 tablets in blisters.
Not all pack sizes may be marketed.

Marketing authorization holder:
Merck Sharp & Dohme (Israel-1996) Company Ltd., P.O.Box 7121, Petah-Tikva 49170.

Manufacturer:
Merck Sharp & Dohme Corp., NJ, USA.
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Drug registration no. listed in the official registry of the Ministry of Health:
128.41.30721