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Please read this information carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information may have changed. You should also read any information provided with other medicines you are currently taking.

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

What EZETROL is used for

EZETROL (*ezetimibe*) is a tablet that contains 10 mg of ezetimibe as the active ingredient.

- EZETROL is a cholesterol-lowering medicine.
- EZETROL is for patients whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.
- EZETROL reduces elevated total-cholesterol, LDL (bad) cholesterol and triglycerides and increases HDL (good) cholesterol.

- EZETROL may be taken with other cholesterol-lowering medicines known as statins or alone, in addition to diet.
- EZETROL may be taken with fenofibrate, another cholesterol-lowering medicine, in addition to diet.
- For patients with heart disease, EZETROL 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.

If you have sitosterolemia, your doctor has prescribed EZETROL to lower the level of plant sterols in your blood.

Sitosterolemia is a hereditary illness that increases the levels of plant sterols in your blood.

How EZETROL works

- EZETROL works by decreasing the absorption of cholesterol in the small intestine. Statins and fenofibrate lower cholesterol in a different way; they work in the liver.
- EZETROL adds to the cholesterol-lowering effect of statins and fenofibrate.

Why has my doctor prescribed EZETROL?

Your doctor has prescribed EZETROL to reduce the amount of cholesterol and triglycerides in your blood. 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.

How can high cholesterol be treated?

High cholesterol can be treated in two main ways:

Lifestyle Changes – including a cholesterol-lowering diet, increased physical activity, and weight management.

Medication –

Cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol. Your doctor has prescribed EZETROL to help lower your cholesterol.

Before you take EZETROL

It is important that you continue taking EZETROL daily as prescribed by your doctor.

Even if you are taking medication to treat high

cholesterol, it is important to have your cholesterol measured regularly. You should also know your cholesterol levels and goals.

Use in elderly

No special precautions.

Use in children

EZETROL is not recommended in children under age 10.

When you must not take it

Patients who are hypersensitive (allergic) to EZETROL or any of its ingredients should not take EZETROL.

Before you start to take it

Tell your doctor about:

Pregnancy: If you are pregnant or plan to become pregnant, EZETROL may not be right for you.

Breast-feeding: If you are breast-feeding, EZETROL may be passed in your milk to your baby.

Medical Problems or Allergies:

Talk about any medical problems (including liver disease or liver problems) or allergies you have now or have had in the past.

Taking other medicines

You should always tell your doctor about all drugs that you are taking or plan to take, including those obtained without a prescription.

In particular, tell your doctor if you are taking medicine(s) with any of the following active ingredients:

- cyclosporin (often used in organ transplant patients)

- medicines with an active ingredient to prevent blood clots, such as warfarin or fluindione (anticoagulants)
- cholestyramine (also used to lower cholesterol), because it affects the way EZETROL works
- fibrates (also used to lower cholesterol)

How to take EZETROL

How much to use

Take one 10 mg tablet by mouth each day, at any time of day.

When to use it

- Take EZETROL with or without food.
- Your doctor may let you take EZETROL along with other medicines, known as statins, or with another medicine known as fenofibrate, to help you better control your cholesterol.
- If you are taking a statin or fenofibrate, EZETROL can be taken at the same time as the other medicine.
- If your doctor has prescribed EZETROL along with cholestyramine (a bile acid sequestrant) or any other bile acid sequestrant, EZETROL should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.

How long to use it

Continue taking your cholesterol-lowering medicines unless your doctor tells you to stop.

If you forget to take it

Try to take EZETROL as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet daily.

If you take too much (overdose)

Take EZETROL only as prescribed for you. If you take more EZETROL than you were prescribed, contact your doctor or pharmacist.

While you are taking EZETROL

Things you must do

- EZETROL should be taken as directed by your health care provider.
- Talk about any other medicines that you are taking or plan to take. Include those you can get without a prescription.
- Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

- Do not take EZETROL if you are hypersensitive (allergic) to EZETROL or any of its ingredients.
- Do not give EZETROL to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of **Can I drive or operate machinery while using EZETROL?**

There have been side effects reported with EZETROL that may affect your ability to drive or operate machinery. Individual responses to EZETROL may vary. (See **Side effects**)

Side effects

In clinical studies, EZETROL was generally well tolerated. The side effects were usually mild and similar in type and frequency to side effects in patients who were given a placebo (a pill containing no

medication). Side effects generally did not cause patients to stop taking EZETROL.

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 side effect was reported:

Common: abdominal pain.

Additionally, the following side effects have been reported in general use: allergic reactions (which may require treatment right away) including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing, rash, and hives;

severe skin problems; muscle aches; unusual tiredness or weakness; alterations in some laboratory blood tests; liver problems; inflammation of the pancreas constipation; dizziness; tingling sensation; depression; gallstones; and inflammation of the gallbladder

Contact your doctor promptly if you experience unexplained muscle pain, tenderness, or weakness while taking EZETROL.

This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage.

Talk to your doctor anytime you have a medical problem you think may be related to EZETROL.

If you are prescribed EZETROL with a statin, your healthcare professional may want to conduct routine blood tests to check your liver function before and after starting treatment.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

How can I learn more about EZETROL and my condition?
You may obtain further information from your doctor or pharmacist.

Storage and disposal of EZETROL

Storage

Do not store EZETROL above 30°C (86°F). Store in the original package.

Keep EZETROL and all medications away from children.

Disposal

How long should I keep my medicine?

Do not use this medicine after the date shown following EX (or EXP) on the container.

Product description

What it looks like

White to off-white capsule-shaped, debossed tablet.

Ingredients

Active ingredient: Ezetimibe

Inactive ingredients:
Croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone and sodium laurilsulfate.

MAL number:

MAL20034627ACRZ

Product Manufacturer

MSD International GmbH
(Singapore Branch)
70 Tuas West Drive,
Singapore 628414,
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Product Registration Holder:

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Date of revision:

15/10/2025 (version 062023)

Serial Number

NPRA (R1/4) 23072024/137