

LETIMBLE TABLETS

Consumer Medication Information Leaflet (RiMUP)

Ezetimibe (10 mg)

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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 LETIMBLE is used for

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

- LETIMBLE is a cholesterol-lowering medicine.
- LETIMBLE is for patients whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.
- LETIMBLE reduces elevated total-cholesterol, LDL (bad) cholesterol and triglycerides and increases HDL (good) cholesterol.
- LETIMBLE may be taken with other cholesterol-lowering medicines known as statins or alone, in addition to diet.
- LETIMBLE may be taken with fenofibrate, another cholesterol-lowering medicine, in addition to diet.
- For patients with heart disease, LETIMBLE combined with cholesterol-lowering medicines called statins reduces the risk of

heart attack, stroke, surgery to increase blood flow or hospitalization for chest pain.

If you have sitosterolemia, your doctor has prescribed LETIMBLE 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 LETIMBLE works

- LETIMBLE 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.
- LETIMBLE adds to the cholesterol-lowering effect of statins and fenofibrate.

Why has my doctor prescribed LETIMBLE?

Your doctor has prescribed LETIMBLE 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 LETIMBLE to help lower your cholesterol.

Before you take LETIMBLE

It is important that you continue taking LETIMBLE 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

LETIMBLE is not recommended in children under age 10.

When you must not take it

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

Before you start to take it

Tell your doctor about:

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

Breast-feeding: If you are breast-feeding, LETIMBLE 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

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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 LETIMBLE works
- fibrates (also used to lower cholesterol)

How to take LETIMBLE

How much to use

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

When to use it

- Take LETIMBLE with or without food.
- Your doctor may let you take LETIMBLE 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, LETIMBLE can be taken at the same time as the other medicine.
- If your doctor has prescribed LETIMBLE along with cholestyramine (a bile acid sequestrant) or any other bile acid sequestrant, LETIMBLE 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 LETIMBLE as

prescribed. However, if you miss a dose, just resume the usual schedule of one tablet daily.

If you take too much (overdose)

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

While you are taking LETIMBLE ***Things you must do***

- LETIMBLE 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 LETIMBLE if you are hypersensitive (allergic) to LETIMBLE or any of its ingredients.
- Do not give LETIMBLE 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 LETIMBLE?

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

Side effects

LETIMBLE 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 LETIMBLE.

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; raised red rash, sometimes with target-shaped lesions; 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 LETIMBLE.

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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 LETIMBLE.

If you are prescribed LETIMBLE 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 LETIMBLE and my condition?
You may obtain further information from your doctor or pharmacist.

Storage and disposal of LETIMBLE

Storage

Store below 30°C. Store in the original package to protect from moisture.

Keep LETIMBLE 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 almost white, oval tablets with debossing “10” on one side and “EZT” on the other side.

Ingredients

Active ingredient: Ezetimibe

Inactive ingredients:
Lactose monohydrate,

Hypromellose,
Croscarmellose sodium,
Microcrystalline cellulose,
Sodium lauryl sulfate,
Magnesium stearate.

MAL number

MAL18106138AZ

Product Manufacturer

Sandoz Private Limited
MIDC, Plot No. 8-A/2 & 8-B, TTC
Industrial Area, Kalwe Block,
Thane – 400708, India.

Product Registration Holder

Sandoz Products Malaysia Sdn.
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