

PATIENT INFORMATION LEAFLET

INFORMATION FOR THE PATIENT ABOUT EZETROL™

- Read all of this leaflet carefully before you start taking EZETROL. Keep this leaflet. You may need to read it again. If you have further questions please ask your doctor or pharmacist.
- You should also read any information provided with other medicines you are currently taking.
- EZETROL has been prescribed for you personally and you should not share your medicine with other people. It may harm them even if their symptoms are the same as yours.

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

EZETROL™ 10 mg tablet

WHAT EZETROL CONTAINS

What is EZETROL?

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

In addition, EZETROL contains the following inactive ingredients: Lactose Monohydrate, Microcrystalline Cellulose, Povidone, Croscarmellose Sodium, Sodium Lauryl Sulfate and Magnesium Stearate.

- 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 and LDL (bad) cholesterol.

- EZETROL may be taken with other cholesterol-lowering medicines known as statins or alone, in addition to diet.

How does EZETROL work?

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

WHAT EZETROL IS USED FOR

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.

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

What should I know before and while taking 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.

Who should not take EZETROL?

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

What should I tell my doctor or other healthcare professional before taking EZETROL?

Tell your doctor or healthcare professional about:

Pregnancy: If you are pregnant or plan to become pregnant, you should not use EZETROL.

Breastfeeding: If you are breastfeeding, EZETROL may be passed in your milk to your baby. You should not breastfeed while using EZETROL.

Other Medicines: Talk about any other medicines that you are taking or plan to take. Include those you can get without a prescription.

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.

Can I take EZETROL with other medicines?

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

Can I drive or operate machinery while taking 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 What undesirable effects may EZETROL have?)

HOW TO TAKE EZETROL

How should I take EZETROL?

- Take one 10 mg tablet by mouth each day, at any time of day.
- Take EZETROL with or without food.
- Your doctor may have you take EZETROL along with other medicines, known as statins, to help you better control your cholesterol.
- If you are taking a statin, EZETROL can be taken at the same time as the statin.
- 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.
- EZETROL should be taken as directed by your health care provider. Continue taking your other cholesterol-lowering medicines unless your doctor tells you to stop.

What should I do if I take more EZETROL than I should?

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

What should I do if I miss a dose?

Try to take EZETROL as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet daily. Do not take a double dose to make up for the missed dose.

POSSIBLE SIDE EFFECTS

When used alone, the following common side effects were reported: headache, abdominal pain and diarrhoea.

When used with a statin, the following common side effects were reported: headache, fatigue, abdominal pain, constipation, diarrhoea, flatulence, nausea, muscle aches, and alterations in some laboratory blood tests.

When used with fenofibrate, the following common side effects were reported: 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; joint pain; muscle aches; alterations in some laboratory blood tests; liver problems; inflammation of the pancreas; nausea; 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.

Not all side effects reported for EZETROL are included in this leaflet. Should your general health worsen while taking EZETROL, please consult your doctor, pharmacist or other healthcare professional for advice.

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.

STORING AND DISPOSING OF EZETROL

How long should I keep EZETROL?

Do not use this medicine after the month and year following EXPIRES/VERVAL on the container.

How should I store EZETROL?

Do not store above 30°C. Store in the original package.

Keep all medicines out of reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

PRESENTATION OF EZETROL

The product will be packed in clear push through or peelable ACLAR®/PVC blisters in pack sizes of 30's.

IDENTIFICATION OF EZETROL

White to off-white capsule-shaped tablet, debossed with "414" on one side and plain on the other side.

REGISTRATION NUMBER

37/7.5/0413

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE

OF REGISTRATION

MSD (Pty) Ltd

16th Road

HALFWAY HOUSE

1685

011 655 3000

THE DATE OF PUBLICATION

25 November 2011

WPPI-EZE-T-052009