PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

EZETROL® 10 mg Tablets

ezetimibe

Contains sugar (lactose monohydrate):

Each tablet contains 55,0 mg of lactose monohydrate.

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, pharmacist, nurse or other healthcare provider.
- 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.

What is in this leaflet

1. What EZETROL is and what it is used for
2. What you need to know before you take EZETROL
3. How to take EZETROL
4. Possible side effects
5. How to store EZETROL
6. Contents of the pack and other information

1. What EZETROL is and what it is used for

EZETROL is a cholesterol-lowering medicine. It works by decreasing the absorption of

cholesterol in the small intestine.

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.

EZETROL is for patients whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.

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 hospitalisation for chest pain.

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.

2. What you need to know before you take EZETROL

Do not take EZETROL

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

Warnings and precautions

Take special care with 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.

Medical Problems or Allergies: Tell your doctor about any medical problems (including liver disease or liver problems) or allergies you have now or have had in the past.

Use in elderly

No special precautions.

Use in children

EZETROL is not recommended in children under age 6.

Other medicines and EZETROL

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Pregnancy and Breastfeeding

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.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking EZETROL.

Driving and using machines

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 section 4).

EZETROL contains lactose

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 EZETROL.

3. How to take EZETROL

Do not share medicines prescribed for you with any other person.

Always take EZETROL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults and children (6 to 17 years of age): 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. Your doctor will tell you how long your treatment with EZETROL will last. Do not stop treatment early. Continue taking your other cholesterol-lowering medicines unless your doctor tells you to stop.

If you have the impression that the effect of EZETROL is too strong or too weak, tell your doctor or pharmacist.

If you take more EZETROL than you should

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

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take EZETROL

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 forgotten individual doses.

4. Possible side effects

EZETROL can have side effects.

If any of the following happens, stop taking EZETROL and tell your doctor immediately or go to the casualty department at your nearest hospital:
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.

These are all very serious side effects. If you have them, you may have had a serious reaction to EZETROL. You may need urgent medical attention or hospitalisation.

Additionally, 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.

These are all serious side effects. You may need urgent medical attention.

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.

Tell your doctor if you notice any of the following side effects which are seen with EZETROL,

when used alone:

Frequent: abdominal pain; diarrhoea; flatulence; feeling tired.

Less frequent: 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:

Frequent: elevations in some laboratory blood tests of liver function (transaminases); headache; muscle pain; tenderness or weakness.

Less frequent: 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 effects were reported:

Frequent: abdominal pain.

Not all side effects reported for EZETROL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EZETROL, please consult your healthcare provider 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of EZETROL.

5. How to store EZETROL

How long should I keep EZETROL?

Do not use this medicine after the month and year following EXP.: on the container.

How should I store EZETROL?

Store at or below 30 °C. Store in the original package.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What EZETROL contains

What is EZETROL?

EZETROL contains 10 mg of ezetimibe per tablet as the active ingredient.

The other ingredients are: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone and sodium lauryl sulphate.

What EZETROL looks like and contents of the pack

The product is packed in clear push through or peelable ACLAR®/PVC blisters in pack sizes

of 30's.

White to off-white capsule-shaped tablets, debossed with “414” on one side and plain on the other side.

Holder of Certificate of Registration

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