

EZETROL[®]

ezetimibe

10 mg tablet

What is in this leaflet

This leaflet answers some common questions about EZETROL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking EZETROL against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

You should also read any information provided with other medicines you are currently taking.

What EZETROL is used for

- EZETROL is a cholesterol-lowering medicine.
- EZETROL is for adults and adolescents (10 to 17 years of age) whose cholesterol levels are too high and when diet alone can not 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.

Cholesterol

Some of the reasons cholesterol is needed by the body include; building cell walls, making bile acids (which help to digest food) and certain hormones. However, too much cholesterol can be a problem.

Your body makes cholesterol, but it also comes from food.

Normally the body balances the cholesterol it makes with the cholesterol it gets from food. This means if more cholesterol comes from food, less is made by the body. However, if you eat a diet high in fat, your body may not keep this balance and your cholesterol levels rise.

High cholesterol is more likely to occur with certain diseases or if you have a family history of high cholesterol.

When you have high levels of cholesterol, it may 'stick' to the inside of your blood vessels instead of being carried to the parts of the body where it is needed. Over time, this can form hard areas, called plaque, on the walls of blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to coronary heart disease (such as heart attack and angina), and stroke.

There are different types of cholesterol, called LDL and HDL cholesterol. LDL cholesterol is the 'bad' cholesterol that can block your blood vessels. HDL cholesterol is often called 'good' cholesterol because it helps to keep the bad cholesterol from building up in the arteries and protects against heart disease.

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

Triglycerides

Triglycerides are an energy source for the body. However, as with cholesterol, too much triglycerides can be a problem.

How EZETROL Works

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.

Before you take EZETROL

When you must not take it

Do not take EZETROL if:

- you have an allergy to EZETROL, or to any of the ingredients listed at the end of this leaflet
- you are under 10 years of age. EZETROL is not recommended in children under age 10
- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking EZETROL, talk to your doctor.

Before you start to take it

Tell your doctor if:

- you are pregnant or plan to become pregnant, EZETROL may not be right for you
- you are breast-feeding; EZETROL may be passed in your milk to your baby
- you have any medical problems (including liver disease or liver problems) you have now or have had in the past
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you take any EZETROL.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and EZETROL may interfere with each other.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking EZETROL.

How to take EZETROL

How much to take

- Adults and adolescents (10 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. Continue taking your other cholesterol-lowering medicines unless your doctor tells you to stop. Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When to take it

Take EZETROL once a day, at any time of day.

How long to take it

EZETROL helps lower your cholesterol. It does not cure your condition. Therefore, you must continue to take it as directed by your doctor if you expect to lower your cholesterol and keep it down. If you stop taking EZETROL, your cholesterol levels may rise again.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much EZETROL. Do this even if there are no signs of discomfort or poisoning.

While you are using EZETROL

Things you must do

If you become pregnant while taking EZETROL, talk to your doctor.

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.

Things you must not do

Do not give EZETROL to anyone else, even if they have the same condition as you.

Things to be careful of

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 Adverse Effects.)

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.

Adverse Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking EZETROL.

EZETROL helps most people with high cholesterol, but it may have unwanted adverse effects in a few people. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

In clinical studies, EZETROL was generally well tolerated. The adverse effects were usually mild and similar in type and frequency to adverse effects in patients who were given a placebo (a pill containing no medication). Adverse effects generally did not cause patients to stop taking EZETROL.

Tell your doctor if you notice any of the following and they worry you:

EZETROL used alone:

These are the more common adverse effects reported with the use of EZETROL when used alone:

- abdominal pain
- diarrhoea
- flatulence
- feeling tired

These are uncommon adverse effects that have been reported with the use of EZETROL when used alone:

- 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

EZETROL used with a statin:

These are the more common adverse effects reported with the use of EZETROL when used in combination with a statin:

- elevations in some laboratory blood tests of liver function (transaminases)
- headache
- aching muscles/muscle pain, tenderness or weakness

These are uncommon adverse effects reported with the use of EZETROL when used in combination with a statin:

- 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

Tell your doctor immediately if you notice any of the following:

EZETROL used alone or with a statin:

- 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
- aching muscles, muscle tenderness or weakness, not caused by exercise
- unusual tiredness or weakness
- yellowing of the skin/eyes which may indicate hepatitis
- dizziness
- tingling sensation
- depression
- sudden and intense abdominal pain which may be caused by an inflamed pancreas or gallbladder, or gallstones
- constipation
- bruising more easily than normal

These may be serious adverse effects of EZETROL. You may need urgent medical attention.

Serious adverse effects are rare.

Contact your doctor promptly if you experience unexplained muscle pain, tenderness, or weakness while taking EZETROL. These may be serious adverse effects. 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.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using EZETROL

Storage

Keep EZETROL in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking EZETROL or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

- EZETROL comes as a white to off white capsule-shaped tablet debossed with 414 on one side.

A box of EZETROL contains 30 tablets.

Ingredients

Active ingredient:

- EZETROL 10 mg tablets contain 10 mg ezetimibe per tablet

Inactive ingredients:

- croscarmellose sodium
- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- povidone
- sodium laurilsulfate

Supplier

EZETROL is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99 851
Newmarket
Auckland
NEW ZEALAND
Tel: 0800 500 673

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