

EZETROL®

(pronounced ez-eh-trol)

Ezetimibe

Consumer Medicine Information

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.

What EZETROL is used for

EZETROL helps to lower cholesterol levels. It is used in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.

EZETROL may be taken alone or with other cholesterol-lowering medicines known as HMG-CoA reductase inhibitors (or statins), in addition to diet.

In people who have high levels of plant sterols in their blood (which doctors call sitosterolaemia), EZETROL helps to lower these levels.

Cholesterol

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

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

How EZETROL works

EZETROL reduces elevated total-cholesterol, LDL (bad) cholesterol and triglycerides and increases HDL (good) cholesterol.

EZETROL works by decreasing the absorption of cholesterol in the small intestine. Statins lower cholesterol in a different way, by reducing the amount of cholesterol made in the liver.

EZETROL adds to the cholesterol-lowering effect of statins.

For patients with heart disease and a history of a heart attack or

hospitalisation for unstable angina (chest pain), 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 may have prescribed EZETROL for another reason. Ask your doctor if you have any questions about why EZETROL has been prescribed for you.

EZETROL is not addictive.

Use in Children and Adolescents

EZETROL is used in children and adolescents (10 to 17 years of age) to treat familial hypercholesterolaemia, a type of high cholesterol that is hereditary (i.e. passed on through families).

EZETROL is not recommended in children under 10 years of age as there have been very few studies of its effects in these children.

Your doctor will assess whether if EZETROL is suitable for your child. Depending on the pubertal development of your child, EZETROL may not be suitable for him or her.

Before you take EZETROL

When you must not take it

Do not take EZETROL if:

- **you have an allergy to EZETROL or any of the**

ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the face, lips, mouth, tongue or throat.

- **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.

Do not take EZETROL together with a statin if:

- **you have active liver disease**
- **you are pregnant or breast feeding.**

Do not take EZETROL together with fenofibrate if:

- **you have gall bladder disease.**

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:

1. **you are pregnant or intend to become pregnant**

If there is a need to consider using EZETROL during pregnancy, your doctor will discuss the risks and benefits of taking it.

2. **you are breast-feeding**

It is not known if EZETROL passes into breast milk.

3. **you have, or have had, any medical conditions, including liver disease or liver problems**

If you are prescribed EZETROL with a statin, your doctor will do a blood test to make sure you have no problems with your liver.

4. **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 should not be taken with EZETROL, including:

- Certain fibrate medicines used to lower cholesterol levels, for example, gemfibrozil. However, the fibrate medicine fenofibrate can be taken with EZETROL.

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

Some medicines and EZETROL may interfere with each other, including:

- Bile acid sequestrants, such as colestyramine, used to lower cholesterol levels.
- Ciclosporin, used to suppress the immune system.
- Warfarin or fluindione, used to prevent blood clots.

These medicines may be affected by EZETROL, may affect how well it works, or may increase the risk of side effects with EZETROL. You may need different amounts of your medicine, or you may need to take different medicines or take your medicines at different times.

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

Take EZETROL only when prescribed by your doctor.

The recommended dose is 10mg taken once a day, at any time of the day.

Swallow EZETROL with a glass of water.

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, ask your doctor or pharmacist for help.

When to take it

EZETROL may be taken at any time of the day.

It does not matter if you take EZETROL with or without food.

However, take it about the same time each day.

Taking EZETROL at the same time each day will have the best effect. It will also help you remember when to take the dose.

Your doctor may ask you to take EZETROL with other cholesterol-lowering medicines, such 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 you are taking a bile acid sequestrant, such as colestyramine, take your EZETROL either at least two hours before or four hours after taking the bile acid sequestrant.

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.

You may have to take cholesterol lowering medicine for the rest of your life. 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 Poisons Information Centre (telephone 13 11 26), 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, tell your doctor.

Have your blood fats checked when your doctor says, to make sure EZETROL is working.

Even if you are taking medicines to treat high cholesterol, it is important to have your cholesterol measured regularly. You should also know your cholesterol levels and goals.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking EZETROL.

If you are prescribed EZETROL with a statin, your doctor will do blood tests to check that there are no problems with your liver.

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

Be careful driving or operating machinery until you know how EZETROL affects you.

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

High cholesterol can be treated in two main ways:

Lifestyle Changes -

this includes a cholesterol-lowering diet, increasing physical activity, and weight management. Ask your doctor for advice before increasing physical activity.

Medicines -

cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol.

Side 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 side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing

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

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

- skin rash and hives
- raised red rash, sometimes with target-shaped lesions
- dark coloured urine
- light coloured bowel motions
- yellowing of the skin and eyes
- joint pain
- bleeding or bruising more easily than normal
- steady abdominal pain with nausea and vomiting

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor immediately if you notice the following:

- unexplained muscle aches, tenderness or weakness, not caused by exercise

This may be a serious side effect. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage. You may need urgent medical attention.

Serious side effects are rare.

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

Additionally, the following side effects have been reported with use of EZETROL:

- nausea

- diarrhoea
- wind or excessive gas in the stomach or bowel
- indigestion
- heartburn
- decreased appetite
- dry mouth
- abdominal pain
- constipation
- inflammation of the pancreas
- dizziness
- headache
- tingling or numbness of the hands or feet
- gallstones
- inflammation of the gallbladder
- elevations in some laboratory blood test of liver or muscle function
- unusual tiredness or weakness
- fatigue
- muscle spasms
- neck pain
- chest pain
- pain
- pain in arms and legs
- back pain
- hot flush
- high blood pressure
- itching
- swelling, especially in the hands and feet
- depression
- cough

In adolescent patients (10 to 17 years of age) there have been no studies longer than one year of the effect of taking EZETROL in combination with simvastatin on bone development, growth, social and emotional development, or fertility. Do not be alarmed by these lists of possible side effects. You may not experience any of them.

After using EZETROL

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

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 with "414" marked on one side.

A starter pack of EZETROL contains 5 or 10 tablets. A trade pack contains 30 tablets

Ingredients

Active ingredient:

10 mg ezetimibe per tablet

Inactive ingredients:

- lactose monohydrate
- microcrystalline cellulose
- povidone
- croscarmellose sodium
- sodium lauryl sulfate

- magnesium stearate

EZETROL does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

EZETROL is supplied in Australia by:

Organon Pharma Pty Limited
Building A 26 Talavera Road
Macquarie Park NSW 2113

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