

# EZETROL®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using EZETROL?

EZETROL contains the active ingredient ezetimibe. EZETROL is used to help lower cholesterol levels.

For more information, see Section [1. Why am I using EZETROL?](#) in the full CMI.

### 2. What should I know before I use EZETROL?

Do not use if you have ever had an allergic reaction to ezetimibe or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use EZETROL?](#) in the full CMI.

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### 3. What if I am taking other medicines?

Some medicines may interfere with EZETROL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use EZETROL?

- The recommended dose is 10 mg once a day.
- For the best effect take EZETROL at about the same time each day.

More instructions can be found in Section [4. How do I use EZETROL?](#) in the full CMI.

### 5. What should I know while using EZETROL?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking ezetimibe.</li><li>• If you become pregnant while taking EZETROL, tell your doctor.</li><li>• Have any blood tests your doctor requests to make sure EZETROL is right for you.</li></ul>
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<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not give EZETROL to anyone else, even if they have the same condition as you</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Side effects have been reported that may affect your ability to drive or operate machinery. Be careful driving or operating machinery until you know how EZETROL affects you.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep EZETROL in a cool dry place where the temperature stays below 30°C.</li> </ul>

For more information, see Section [5. What should I know while using EZETROL?](#) in the full CMI.

## 6. Are there any side effects?

When EZETROL is used as the only cholesterol lowering medicine, common side effects are abdominal pain, diarrhea, flatulence and fatigue.

Allergic reactions to ezetimibe or other ingredients of EZETROL occur very rarely. Serious side effects are rare, but may need urgent medical attention.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# **EZETROL®** (pronounced ez-eh-trol)

**Active ingredient(s):** *ezetimibe*

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## **Consumer Medicine Information (CMI)**

This leaflet provides important information about using EZETROL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EZETROL.**

**Where to find information in this leaflet:**

- [1. Why am I using EZETROL?](#)
- [2. What should I know before I use EZETROL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use EZETROL?](#)
- [5. What should I know while using EZETROL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I using EZETROL?**

**EZETROL contains the active ingredient ezetimibe. EZETROL helps to lower cholesterol levels.**

**EZETROL 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.

## **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.

### **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.

## **2. What should I know before I use EZETROL?**

### **Warnings**

#### **Do not use EZETROL if:**

- you are allergic to ezetimibe, 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. Always check the ingredients to make sure you can use this medicine.
- 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.
- you have active liver disease
- you are pregnant or breastfeeding.

#### **Do not use EZETROL together with fenofibrate if:**

- you have gall bladder disease

#### **Check with your doctor if you:**

- have, or have had, any other medical conditions, including liver disease. If you are prescribed



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

- take any medicines for any other condition
- have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if EZETROL passes into breast milk.

## **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 EZETROL is suitable for your child. Depending on the pubertal development

of your child, EZETROL may not be suitable for him or her.

### **3. What if I am taking other medicines?**

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

**Some medicines should not be taken with EZETROL including some fibrate medicines used to lower cholesterol levels**

e.g., gemfibrozil. However, the fibrate medicine fenofibrate can be taken with EZETROL.

**Some medicines may interfere with EZETROL and affect how it works.**

You may need different amounts of your medicine, or you may need to take different medicines or take your medicines at different times.

**Medicines that may increase the effect of EZETROL include:**

- Ciclosporin, used to suppress the immune system.

**Medicines that may reduce the effect of EZETROL include:**

- Bile acid sequestrants, such as colestyramine, used to lower cholesterol levels.

**EZETROL may interfere with some medicines and affect how they work:**

- Warfarin or fluindione, used to prevent blood clots.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EZETROL.**

## **4. How do I use EZETROL?**

### **How much to take**

- The recommended dose is 10mg taken once a day. Swallow EZETROL with a glass of water.
- Take EZETROL only when prescribed by your doctor.
- Follow the instructions provided and use EZETROL until your doctor tells you to stop.
- 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.

### **When to take EZETROL**

- EZETROL can be taken at any time of the day, however, take it at 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.
- It does not matter if you take EZETROL with or without food.

## **If you forget to take EZETROL**

EZETROL should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

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

**If you are not sure whether to skip the dose, talk to your doctor or pharmacist. If you have trouble remembering to take your tablets, ask your pharmacist for some hints.**

## **If you use too much EZETROL**

If you think that you have used too much EZETROL, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using EZETROL?**

### **Things you should do**

**If you become pregnant while taking EZETROL, tell your doctor.**

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

Remind any doctor, dentist or pharmacist you visit that you are taking EZETROL.

## **Things you should not do**

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

## **Driving or using machines**

**Be careful before you drive or use any machines or tools 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.

## **Looking after your medicine**

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<b>Muscle/skeleton-related:</b> <ul style="list-style-type: none"> <li>• muscle spasms</li> <li>• neck pain</li> <li>• back pain</li> <li>• pain in arms and legs</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● elevations in some laboratory tests of muscle function</li> </ul> <p><b>Gastrointestinal-related:</b></p> <ul style="list-style-type: none"> <li>● nausea</li> <li>● diarrhoea</li> <li>● wind or excessive gas in the stomach or bowel</li> <li>● indigestion</li> <li>● heartburn</li> <li>● dry mouth</li> <li>● abdominal pain</li> <li>● constipation</li> </ul> <p><b>Liver-related:</b></p> <ul style="list-style-type: none"> <li>● gallstones</li> <li>● inflammation of the gallbladder</li> <li>● elevations in some laboratory tests of liver function</li> </ul> <p><b>Heart and circulation-related:</b></p> <ul style="list-style-type: none"> <li>● hot flush</li> <li>● high blood pressure</li> <li>● swelling, especially in the hands and feet</li> </ul>	



<b>Less serious side effects</b>	<b>What to do</b>
<p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>• itching</li> </ul> <p><b>Metabolism and nutrition-related:</b></p> <ul style="list-style-type: none"> <li>• decreased appetite</li> <li>• inflammation of the pancreas</li> </ul> <p><b>Head and nervous system-related:</b></p> <ul style="list-style-type: none"> <li>• dizziness</li> <li>• headache</li> <li>• tingling or numbness of the hands or feet</li> </ul> <p><b>Mood related:</b></p> <ul style="list-style-type: none"> <li>• depression</li> </ul> <p><b>Respiratory related:</b></p> <ul style="list-style-type: none"> <li>• cough</li> </ul> <p><b>General conditions:</b></p> <ul style="list-style-type: none"> <li>• unusual tiredness or weakness</li> <li>• fatigue</li> <li>• chest pain</li> <li>• pain</li> </ul>	

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>● swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing</li></ul> <p>If you have these side effects, you may have had a serious allergic reaction to EZETROL. You may need urgent medical attention or hospitalisation.</p> <p>These side effects are very rare.</p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>
<ul style="list-style-type: none"><li>● skin rash and hives</li><li>● severe skin problems;</li><li>● dark coloured urine</li><li>● light coloured bowel motions</li><li>● yellowing of the skin and eyes</li><li>● joint pain</li><li>● bleeding or bruising more easily than normal</li></ul>	<p><b>Tell your doctor immediately if you notice any of these side effects. These may be serious side effects and you may need urgent medical attention.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● steady abdominal pain with nausea and vomiting</li> <li>● unexplained muscle aches, tenderness or weakness, not caused by exercise</li> <li>● On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage.</li> </ul> <p>Serious side effects are rare.</p>	

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

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What EZETROL contains

<b>Active ingredient (main ingredient)</b>	10 mg ezetimibe per tablet
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate microcrystalline cellulose povidone croscarmellose sodium sodium lauryl sulfate

	magnesium stearate
<b>Potential allergens</b>	EZETROL contains lactose It does not contain gluten, sucrose, tartrazine or any other azo dyes.

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What EZETROL looks like**

EZETROL is a white to off-white, capsule-shaped tablet with "414" marked on one side. (Aust R 91161).

There are 30 tablets in a pack.

### **Who distributes EZETROL**

Organon Pharma Pty Limited

Building A 26 Talavera Road

Macquarie Park NSW 2113

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