

EZALO COMPOSITE PACK®

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.

1. Why am I using EZALO COMPOSITE PACK?

EZALO COMPOSITE PACK contains the active ingredients ezetimibe and rosuvastatin. EZALO COMPOSITE PACK is used in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately

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

2. What should I know before I use EZALO COMPOSITE PACK?

Do not use if you have ever had an allergic reaction to ezetimibe, rosuvastatin 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 EZALO COMPOSITE PACK?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EZALO COMPOSITE PACK 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 EZALO COMPOSITE PACK?

- There are two different medicines in EZALO COMPOSITE PACK: Ezetrol (ezetimibe) tablets; and OGN-rosuvastatin (rosuvastatin) tablets.
- Take one Ezetrol (ezetimibe) tablet and one OGN Rosuvastatin (rosuvastatin) tablet at the same time once a day. [

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

5. What should I know while using EZALO COMPOSITE PACK?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking EZALO COMPOSITE PACK.• If you become pregnant while taking EZALO COMPOSITE PACK, tell your doctor immediately.• Have any blood tests your doctor requests to make sure EZALO COMPOSITE PACK is right for you.
Things you should not do	<ul style="list-style-type: none">• Do not give EZALO COMPOSITE PACK to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• 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 EZALO COMPOSITE PACK affects you
Drinking alcohol	<ul style="list-style-type: none">• Drinking large quantities of alcohol while taking EZALO COMPOSITE PACK may increase your chance of getting liver problems
Looking after your medicine	<ul style="list-style-type: none">• Keep EZALO COMPOSITE PACK in a cool dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Common side effects of EZALO COMPOSITE PACK are muscle aches, tiredness or weakness; constipation; nausea; stomach or belly pain; elevation in some laboratory blood tests of liver function; headache; dizziness; diabetes.

Allergic reactions to ezetimibe, rosuvastatin or other ingredients of EZALO COMPOSITE PACK 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.

EZALO COMPOSITE PACK®

Active ingredients: ezetimibe and rosuvastatin calcium

Consumer Medicine Information (CMI)

This leaflet provides important information about using EZALO COMPOSITE PACK. **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 EZALO COMPOSITE PACK.**

Where to find information in this leaflet:

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

1. Why am I using EZALO COMPOSITE PACK?

EZALO COMPOSITE PACK contains the active ingredients ezetimibe and rosuvastatin. EZALO COMPOSITE PACK helps to lower cholesterol levels.

EZALO COMPOSITE PACK is used in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.

What is high 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.

How EZALO COMPOSITE PACK works

EZALO COMPOSITE PACK is a combination pack, which contains two different medicines. One is Ezetrol (ezetimibe) and the other is rosuvastatin (rosuvastatin calcium). EZALO COMPOSITE PACK reduces elevated total-cholesterol, LDL ('bad') cholesterol and increases HDL ('good') cholesterol.

EZALO COMPOSITE PACK works by decreasing the absorption of cholesterol in the small intestine and by reducing the amount of cholesterol made in the liver.

Your doctor may have prescribed EZALO COMPOSITE PACK for another reason.

Ask your doctor if you have any questions about why EZALO COMPOSITE PACK has been prescribed for you.

EZALO COMPOSITE PACK is not addictive.

2. What should I know before I use EZALO COMPOSITE PACK?

Warnings

Do not use EZALO COMPOSITE PACK if:

- you are allergic to ezetimibe, rosuvastatin, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin
- Always check the ingredients to make sure you can use this medicine.
- you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.
- you are pregnant or intend to become pregnant or you are breastfeeding.
- you have active liver disease.
- you are taking any medicine containing fusidic acid (for bacterial infections)
- you are taking fenofibrate and you have gall bladder disease

Do not use EZALO COMPOSITE PACK 10mg+40mg if you:

- have low thyroid hormone levels (hypothyroidism)
- have a personal or family history of hereditary muscular disorders
- have a previous history of muscular problems from using other medicines used to treat high cholesterol or triglycerides
- have a history of very heavy alcohol consumption
- have severe kidney impairment
- are of Asian descent
- are taking another type of lipid-lowering medicine called a fibrate

Before you start to take EZALO COMPOSITE PACK:

- your doctor will ask you to have your liver function tested.
- talk to your doctor about situations that can increase rosuvastatin blood levels.

Check with your doctor if you have, or have had:

- any other medical conditions
- liver problems. Your doctor will do a blood test to make sure you have no problems with your liver.

- kidney problems
- a personal or family history of muscle problems
- unexplained muscle aches or pains in your muscle
- breathing problems
- low thyroid hormone levels (hypothyroidism)
- diabetes or risk factors for diabetes
- myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used for breathing) or ocular myasthenia (a disease causing eye muscle weakness) as statins may lead to occurrence of myasthenia or aggravate the condition.

Tell your doctor if:

- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- you drink alcohol regularly. Excessive alcohol consumption may not be safe in patients taking EZALO COMPOSITE PACK

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 you are a woman of child-bearing age and are taking EZALO COMPOSITE PACK, use a proven method of birth control to avoid pregnancy. The medicine may affect your developing baby if you take it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. This medicine may pass into breast milk and affect your baby.

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 EZALO COMPOSITE PACK, including::

- fusidic acid, antibiotic used to treat infection
- fenofibrate (a medicine to lower triglyceride levels) if you have gall bladder disease

Some medicines may be affected by EZALO COMPOSITE PACK, may affect how well it works, or may increase the risk of side effects with EZALO COMPOSITE PACK.

You may need different amounts of your medicines, or you may need to take different medicines or take your medicines at different times. Your doctor will advise you.

Tell your doctor if you are taking any of the following:

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

- other medicines to lower cholesterol or triglyceride levels, for example, gemfibrozil, other fibrates, Vitamin B3
- warfarin or fluindione or ticagrelor used to prevent blood clots
- HIV protease inhibitors, used to treat HIV infection
- hepatitis C antiviral agents, such as elbasvir or grazoprevir, used to treat the hepatitis C virus infection
- colchicine, used to treat gout
- ciclosporin, used to suppress the immune system
- antacids, used to treat reflux or ulcers. EZALO COMPOSITE PACK should be taken 2 hours before or 2 hours after taking antacid.
- daptomycin, a medicine used to treat complicated skin and skin structure infections and bacteraemia

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

4. How do I use EZALO COMPOSITE PACK?

How much to take

There are two different medicines in EZALO COMPOSITE PACK. Your doctor will prescribe a strength that is appropriate for you. It is very important that you take EZALO COMPOSITE PACK exactly as follows:

- Take one Ezetrol (ezetimibe) tablet and one OGN Rosuvastatin (rosuvastatin) tablet at the same time once a day.
- Take EZALO COMPOSITE PACK only when prescribed by your doctor.
- Take EZALO COMPOSITE PACK every day and continue taking it for as long as your doctor tells you. EZALO COMPOSITE PACK helps to lower your cholesterol levels but does not cure your condition. If you stop taking EZALO COMPOSITE PACK your cholesterol levels may rise again.
- If you do not understand these instructions, ask your doctor or pharmacist for help.
- If your doctor has increased the strength of EZALO COMPOSITE PACK tablets you take, do not take multiple doses of any remaining supplies of lower strength EZALO COMPOSITE PACK tablets instead of the new higher strength tablets as this will result in you taking more medicine (ezetimibe) than you need
- If you are currently taking a medicine that contains ezetimibe and/or rosuvastatin which are contained in EZALO COMPOSITE PACK stop taking your current medicine(s) that contain ezetimibe and/or rosuvastatin as this may result in you taking more medicine than you need. Take the remaining medicine(s) to your pharmacist for safe disposal

When to take EZALO COMPOSITE PACK

- EZALO COMPOSITE PACK can be taken at any time of the day. However, EZALO COMPOSITE PACK should be taken at about the same time each day. Taking it at

the same time each day will have the best effect. It will also help you remember when to take it.

- Take EZALO COMPOSITE PACK with or without food.

How to take EZALO COMPOSITE PACK

- Swallow the tablets whole with a full glass of water.
- Do not chew or crush the tablets

Taking EZALO COMPOSITE PACK with other cholesterol-lowering agents

Your doctor may ask you to take EZALO COMPOSITE PACK with other cholesterol-lowering agents such as bile acid sequestrants.

If you are taking a bile acid sequestrant, such as colestyramine, take EZALO COMPOSITE PACK either at least two hours before or four hours after taking the bile acid sequestrant.

If you forget to take EZALO COMPOSITE PACK

EZALO COMPOSITE PACK 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 tablets 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. This may increase the chance of you getting a side effect.

If you are not sure what to do, talk to your doctor or pharmacist. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much EZALO COMPOSITE PACK

If you think that you have used too much EZALO COMPOSITE PACK, 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 EZALO COMPOSITE PACK?

Call your doctor straight away and stop taking EZALO COMPOSITE PACK if you become pregnant while you are taking EZALO COMPOSITE PACK

Things you should do

- Keep all your doctor's appointments.
- 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.

- Your doctor will ask you to have your liver function tested from time to time while you are taking EZALO COMPOSITE PACK. This may help prevent unwanted side effects. Your doctor may adjust your dose depending on the result of the test.

Remind any doctor, dentist or pharmacist you visit that you are using EZALO COMPOSITE PACK. If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking EZALO COMPOSITE PACK.

Things you should not do

- Do not take EZALO COMPOSITE PACK to treat any other conditions unless your doctor tells you to..
- Do not give EZALO COMPOSITE PACK to anyone else, even if they have the same condition as you..

Things that may help your condition

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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how EZALO COMPOSITE PACK affects you.

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

Drinking alcohol

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol while taking EZALO COMPOSITE PACK may increase your chance of getting liver problems.

Looking after your medicine

- Keep your tablets in a cool dry place where the temperature stays below 25°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

Less serious side effects	What to do
<p>Muscle/skeleton-related:</p> <ul style="list-style-type: none"> muscle aches, spasms, tiredness or weakness aches and pain pain in arms and legs <p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> diarrhoea constipation nausea stomach or belly pain heartburn, indigestion or wind dry mouth decreased appetite <p>Heart and circulation-related:</p> <ul style="list-style-type: none"> hot flush swelling, especially in the hands and feet <p>Head and nervous system-related]:</p> <ul style="list-style-type: none"> dizziness headache tingling or numbness of the hands or feet memory loss <p>Mood -related]:</p> <ul style="list-style-type: none"> trouble sleeping 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<p>Respiratory-related]:</p> <ul style="list-style-type: none"> shortness of breath cough <p>Skin-related:</p> <ul style="list-style-type: none"> itchy skin <p>General conditions:</p> <ul style="list-style-type: none"> unusual tiredness or weakness generally feeling unwell 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>
<p>Muscle/skeleton related:</p> <ul style="list-style-type: none"> elevation in some laboratory blood tests of muscle function <p>Liver-related:</p> <ul style="list-style-type: none"> elevation in some laboratory blood tests of liver function <p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> inflammation of the pancreas gallstones inflammation of the gallbladder <p>Heart and circulation-related:</p> <ul style="list-style-type: none"> high blood pressure <p>Metabolism and Nutrition-related:</p> <ul style="list-style-type: none"> elevation in blood glucose levels diabetes thyroid function abnormalities <p>Mood-related:</p> <ul style="list-style-type: none"> depression 	<p>Tell your doctor if you have been diagnosed with any of these conditions.</p>
<ul style="list-style-type: none"> You notice a significant increase in your need to urinate you are significantly more hungry or thirsty than usual 	<p>Tell your doctor if you experience any of these conditions</p>

Serious side effects

Serious side effects	What to do
<p>Heart and circulation-related:</p> <ul style="list-style-type: none"> chest pain <p>Skin-related:</p> <p>severe skin problems.</p>	<p>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.</p>

Serious side effects	What to do
<p>Allergic reaction:</p> <ul style="list-style-type: none"> swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing. <p>These may be serious side effects. If you have them, you may have had a serious allergic reaction to EZALO COMPOSITE PACK. You may need urgent medical attention or hospitalisation.</p> <p>These side effects are very rare.</p> <p>Muscle-related:</p> <p>unexpected muscle pain, tenderness, or weakness not caused by exercise, particularly if you also have a fever or generally feel unwell.</p> <p>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.</p>	<p>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.</p>
<ul style="list-style-type: none"> skin rash and hives raised red rash, sometimes with circular-shaped lesions steady abdominal pain with nausea and vomiting joint pain bleeding or bruising more easily than normal yellowing of the skin and eyes dark coloured urine light coloured bowel motions problems with breathing including shortness of breath, persistent cough and fever weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath (symptoms of myasthenia). 	<p>Tell your doctor immediately if you notice any of these symptoms.</p> <p>These may be serious side effects. You may need urgent medical attention.</p>

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. 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 EZALO COMPOSITE PACK contains

EZALO COMPOSITE PACK contains EZETROL tablets and OGN-rosuvastatin tablets.

<p>Active ingredients (main ingredients)</p>	<p>EZETROL:</p> <p>Ezetimibe 10 mg per tablet</p> <p>OGN-rosuvastatin:</p> <p>Rosuvastatin (as calcium) 5, 10, 20 or 40 mg per tablet</p>
<p>Other ingredients (inactive ingredients)</p>	<p>EZETROL:</p> <p>Croscarmellose sodium</p> <p>Magnesium stearate</p> <p>Lactose monohydrate</p> <p>Microcrystalline cellulose</p> <p>Povidone</p> <p>Sodium lauryl sulfate</p> <p>OGN-rosuvastatin:</p> <p>Purified talc</p> <p>Microcrystalline cellulose</p> <p>Silicon dioxide</p> <p>Colloidal anhydrous silica</p> <p>Maize starch</p> <p>Sodium stearyl fumarate</p> <p>Hypromellose</p> <p>Mannitol</p> <p>Lactose</p> <p>Macrogol 6000</p> <p>Titanium dioxide</p> <p>Iron oxide yellow</p> <p>Iron oxide red</p>
<p>Potential allergens</p>	<p>EZETROL tablets and OGN-rosuvastatin tablets contain lactose.</p>

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

What EZALO COMPOSITE PACK looks like

EZALO COMPOSITE PACK comes in four different strengths:

EZALO COMPOSITE PACK mg + 5 mg	10	Aust R 203693
EZALO COMPOSITE PACK mg + 10 mg	10	Aust R 203689
EZALO COMPOSITE PACK mg + 20 mg	10	Aust R 203691
EZALO COMPOSITE PACK mg + 40 mg	10	Aust R 203688

Ezetrol 10 mg tablet is a white to off-white, capsule-shaped tablet with "414" marked on one side.

OGN Rosuvastatin 5 mg is a brown, round, film coated tablet.

OGN Rosuvastatin 10 mg is a brown, round, film coated tablet with "RSV 10" marked on one side.

OGN Rosuvastatin 20 mg is a brown, round, film coated tablet with "RSV 20" marked on one side.

OGN Rosuvastatin 40 mg is a brown, round, film coated tablet with "RSV 40" marked on one side.

Ezetrol 10mg and OGN Rosuvastatin (5, 10, 20, 40 mg) are supplied in 10-day calendar packs of 10 Ezetrol and 10 OGN Rosuvastatin tablets.

A trade pack contains 3 x 10-day calendar packs.

A starter pack contains 1 x 10-day calendar pack.

Who distributes EZALO COMPOSITE PACK

Organon Pharma Pty Limited
Level 5, 66 King St
Sydney NSW 2000
Australia

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