

EZECREST 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 EZECREST COMPOSITE PACK?

EZECREST COMPOSITE PACK contains the active ingredient ezetimibe and rosuvastatin calcium. EZECREST COMPOSITE 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.

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

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

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

3. What if I am taking other medicines?

Some medicines may interfere with EZECREST 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 EZECREST COMPOSITE PACK?

Take EZECREST COMPOSITE PACK only when prescribed by your doctor. Follow all directions given to you by your doctor or pharmacist carefully. If you do not understand these instructions, ask your doctor or pharmacist for help. Swallow the tablets whole with a full glass of water. Do not chew or crush the tablets.

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

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

Things you should do	<ul style="list-style-type: none">• Take EZECREST COMPOSITE PACK only when prescribed by your doctor.• Follow all directions given to you by your doctor or pharmacist carefully.• If you become pregnant while you are taking EZECREST COMPOSITE PACK, stop taking it and tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not take EZECREST COMPOSITE PACK to treat any other conditions unless your doctor tells you to.• Do not give EZECREST COMPOSITE PACK to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how EZECREST COMPOSITE PACK affects you.• There have been side effects reported with EZECREST COMPOSITE PACK that may affect your ability to drive or operate machinery. Individual responses to EZECREST COMPOSITE PACK may vary.
Drinking alcohol	<ul style="list-style-type: none">• Avoid drinking large quantities of alcohol.• Drinking large quantities of alcohol while taking EZECREST COMPOSITE PACK may increase your chance of getting liver problems.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in a cool dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

All medicines have some unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking EZECREST COMPOSITE PACK. EZECREST COMPOSITE PACK helps most people with high cholesterol levels, but it may have unwanted side effects in a few people. Tell your doctor or pharmacist if you notice any of the following and they worry you: diarrhea, muscle aches, spasms, tiredness or weakness, constipation, nausea stomach or belly pain, heartburn, indigestion or wind, aches and pain, pain in arms and legs, trouble sleeping, dizziness, headache, tingling or numbness of the hands or feet, hot flush, shortness of breath, unusual tiredness or weakness, generally feeling unwell, memory loss, itchy skin, decreased appetite, dry mouth, swelling, especially in the hands and feet, cough. Tell your doctor if you have been diagnosed with: inflammation of the pancreas, gallstones, inflammation of the gallbladder, elevation in some laboratory, blood tests of liver or muscle function, depression, elevation in blood glucose levels, diabetes, high blood pressure, thyroid function abnormalities. The above list includes the more common and uncommon side effects of your medicine. They are usually mild and short-lived. Tell your doctor if you notice a significant increase in your need to urinate or if you are significantly more hungry or thirsty than usual.

Tell your doctor immediately if you notice any of the following: 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). These may be serious side effects. You 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.

EZECREST COMPOSITE PACK

Active ingredient(s): [Ezetimibe and Rosuvastatin]

Consumer Medicine Information (CMI)

This leaflet provides important information about using EZECREST 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 EZECREST COMPOSITE PACK.

Where to find information in this leaflet:

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

1. Why am I using EZECREST COMPOSITE PACK?

EZECREST COMPOSITE PACK 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.

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.

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

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

EZECREST COMPOSITE PACK is not addictive.

EZECREST COMPOSITE PACK is available only with a doctor's prescription.

Use in children

EZECREST COMPOSITE PACK is not recommended for use in children.

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

Warnings

Do not take EZECREST COMPOSITE PACK if:

- **you have an allergy to EZECREST COMPOSITE PACK 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

- you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.
- you have active liver disease.
- you are taking any medicine containing fusidic acid (for bacterial infections)
- the expiry date on the pack has passed or if the packaging is torn or shows signs of tampering.

If you take EZECRESTCOMPOSITE PACK after the expiry date has passed, it may not work.

Do not take EZECREST COMPOSITE PACK together with fenofibrate if:

- you have gall bladder disease.

Do not use EZECRESTCOMPOSITE 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 taking EZECREST COMPOSITE PACK 10mg+40mg, talk to your doctor about situations that can increase rosuvastatin blood levels.

Also talk to your doctor if you are not sure whether you should start taking EZECREST COMPOSITE PACK.

Check with your doctor if you:

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

you have, or have had, any medical condition, including:

- liver problems

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

- kidney problems
- personal or family history of muscle problems
- muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides
- unexplained muscle aches or pains in your muscle
- breathing problems
- low thyroid hormone levels (hypothyroidism)
- diabetes or risk factors for diabetes
- you drink alcohol regularly.
Excessive alcohol consumption may not be safe in patients taking EZECREST COMPOSITE PACK.
- you have or have had 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.

If you have not told your doctor about any of the above, tell him/her before you start taking EZECREST COMPOSITE PACK.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You are pregnant or intend to become pregnant.

If you are a woman of child-bearing age and are taking EZECREST 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.

- **you are breast-feeding.**

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 that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines should not be taken with EZECREST 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 EZECREST COMPOSITE PACK, or may affect how well it works, or may increase the risk of side effects with EZECREST COMPOSITE PACK.

- **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. EZECREST 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 [Ezecrest].

4. How do I use EZECREST COMPOSITE PACK?

Take EZECREST COMPOSITE PACK only when prescribed by your doctor.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand these instructions, ask your doctor or pharmacist for help.

If you are currently taking a medicine that contains ezetimibe and/or rosuvastatin which are contained in EZECREST 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**

Check with your doctor if you are not sure about the medicines you are taking.

How much to take

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

Take one PHARMACOR EZETIMIBE (ezetimibe) tablet and one CRESTABS (rosuvastatin) tablet at the same time once a day.

If your doctor has increased the strength of EZECREST COMPOSITE PACK tablets you take, do not take multiple doses of any remaining supplies of lower strength EZECREST COMPOSITE PACK tablets instead of the new higher strength tablets as this will result in you taking more medicine (ezetimibe) than you need.

How to take it

Swallow the tablets whole with a full glass of water.

Do not chew or crush the tablets.

When to take it

EZECREST COMPOSITE PACK can be taken at any time of the day. However, EZECREST 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 EZECREST COMPOSITE PACK with or without food.

Taking EZECREST COMPOSITE PACK with other cholesterol-lowering agents.

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

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

How long to take it

Take EZECREST COMPOSITE PACK every day and continue taking it for as long as your doctor tells you.

EZECREST COMPOSITE PACK helps to lower your cholesterol levels but does not cure your condition. If you stop taking EZECREST COMPOSITE PACK 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 tablets as you would normally.

Do not take a double dose to make up for the dose that 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 (overdose)

If you think that you have used too much EZECREST 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 EZECREST COMPOSITE PACK?

Things you should do

If you become pregnant while you are taking EZECREST COMPOSITE PACK, stop taking it and tell your doctor immediately.

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 EZECRESTCOMPOSITE PACK. This may help prevent unwanted side effects.

Your doctor may adjust your dose depending on the result of the test.

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking EZECRESTCOMPOSITE PACK.

Things you must not do

Do not take EZECRESTCOMPOSITE PACK to treat any other conditions unless your doctor tells you to.

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

Drinking alcohol

Avoid drinking large quantities of alcohol.

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

Driving or using machines

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

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

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.

Looking after your medicine

- Keep your tablets in cool dry place where the temperature stays below 25C.

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

- Store it in a cool dry place 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.

Getting rid of any unwanted medicine

Return any expired or damaged EZECREST COMPOSITE PACK to your pharmacist for disposal

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>General</p> <ul style="list-style-type: none">• headache• dizziness• trouble sleeping• unusual tiredness or weakness• generally feeling unwell <p>Gastrointestinal system:</p> <ul style="list-style-type: none">• diarrhoea• constipation• nausea• stomach or belly pain• heartburn, indigestion or wind• decreased appetite• dry mouth• hot flush <p>Musculoskeletal related:</p> <ul style="list-style-type: none">• muscle aches, spasms, tiredness or weakness	<p>Tell your doctor or pharmacist if you notice any of the following and they worry you. Tell your doctor if you notice a significant increase in your need to urinate or if you are significantly more hungry or thirsty than usual.</p>

<ul style="list-style-type: none"> • aches and pain • pain in arms and legs • swelling, especially in the hands and feet • tingling or numbness of the hands or feet <p>Respiratory tract related:</p> <ul style="list-style-type: none"> • cough • shortness of breath <p>Skin related:</p> <ul style="list-style-type: none"> • itchy skin <p>Brain related:</p> <ul style="list-style-type: none"> • memory loss <p>Tell your doctor if you have been diagnosed with:</p> <ul style="list-style-type: none"> • inflammation of the pancreas • gallstones • inflammation of the gallbladder • elevation in some laboratory blood tests of liver or muscle function • depression • elevation in blood glucose levels • diabetes • high blood pressure • thyroid function abnormalities 		<p>easily than normal</p> <ul style="list-style-type: none"> • 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). • severe blisters and bleeding of the lips, eyes, mouth, nose or genitals. 	<p>these serious side effects or if you have any thoughts of harming yourself or committing suicide. You may need urgent medical attention or hospitalisation.</p>
		<ul style="list-style-type: none"> • swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing. • chest pain • unexpected muscle pain, tenderness, or weakness not caused by exercise, particularly if you also have a fever or generally feel unwell. • severe skin problems. 	<p>If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:</p>

The above list includes the more common and uncommon side effects of your medicine. They are usually mild and short-lived.

Serious side effects

Serious side effects	What to do
<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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</p>

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects as follows: Australia: 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 EZECREST COMPOSITE PACK contains

Active ingredient (main ingredient)	Ezetimibe 10mg + Rosuvastatin 10mg, Ezetimibe 10mg + Rosuvastatin 20mg, Ezetimibe 10mg + Rosuvastatin 40mg
Other ingredients (inactive ingredients)	EZECREST COMPOSITE PACK lactose monohydrate, croscarmellose sodium, crospovidone, microcrystalline cellulose, magnesium stearate, hypromellose and sodium lauryl sulfate. CRESTABS crospovidone, light magnesium oxide, microcrystalline cellulose, lactose monohydrate, magnesium stearate and Opadry II complete film coating system 32K140052 Pink (ARTG PI No. 141463).
Potential allergens	-

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

What EZECRESTCOMPOSITE PACK looks like

EZECREST EZETIMIBE is White to off white capsule shaped, flat faced, beveled edge tablets, debossed with A25 on one side and plain on other

side.

CRESTABS 10 mg are pink color, circular, biconvex, film coated tablets debossed with "R" on one side and "10" on the other side.

CRESTABS 20 mg are pink color, circular, biconvex, film coated tablets debossed with "R" on one side and "20" on the other side.

CRESTABS 40 mg are pink color, oval shape, biconvex, film coated tablets debossed with "R" on one side and "40" on the other side.

EZECRESTCOMPOSITE PACK is a combination pack containing EZECREST EZETIMIBE (ezetimibe) tablets 10 mg and CRESTABS (rosuvastatin, as calcium) tablets 10, 20, 40 mg.

EZECRESTCOMPOSITE PACK is supplied in 10- day calendar packs of 10 EZECREST EZETIMIBE (ezetimibe) tablets in PVC/PCTFE(Aclar)/Al blisters and 10 CRESTABS (rosuvastatin, as calcium) tablets in Al/Al blisters. Each carton contains one 10-day calendar pack (for starter packs) or three 10-day calendar packs (for commercial packs).

Who distributes EZECREST COMPOSITE PACK

Pharmacor Pty Ltd.

Suite 803, Level 8, Tower A,
The Zenith, 821 Pacific Highway,
Chatswood, NSW, 2067, Australia
www.pharmacor.com.au

EZECREST COMPOSITE PACK

Blister composite pack:

10 mg + 10 mg: 375662
10 mg + 20 mg: 375655
10 mg + 40 mg: 375670

This leaflet was prepared in 02/2024.