

Rosuvastatin Lupin

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 Rosuvastatin Lupin?

Rosuvastatin Lupin contains the active ingredient rosuvastatin calcium. Rosuvastatin Lupin is used to lower high cholesterol levels. Even though you may have normal cholesterol, Rosuvastatin Lupin can also be used to reduce the risk of you having a stroke or heart attack. For more information, see Section [1. Why am I using Rosuvastatin Lupin?](#) in the full CMI.

2. What should I know before I use Rosuvastatin Lupin?

Do not use if you have ever had an allergic reaction to Rosuvastatin Lupin or any of the ingredients listed at the end of the CMI, or if you become pregnant while you are taking Rosuvastatin Lupin. **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 Rosuvastatin Lupin?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Rosuvastatin Lupin 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 Rosuvastatin Lupin?

- The usual dose is 5 mg to 20 mg taken once daily, but some patients may need to increase this to 40 mg once daily. Your doctor will monitor your cholesterol and triglyceride levels during your treatment and, if needed, may increase your dose.
- Swallow each tablet whole with a drink of water. You can take your tablet at any time of the day, with or without food.

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

5. What should I know while using Rosuvastatin Lupin?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking Rosuvastatin Lupin.• Have your blood cholesterol and triglycerides checked when your doctor says so to make sure Rosuvastatin Lupin is working.• Stop taking Rosuvastatin Lupin and seek medical attention immediately if you experience any of the serious side effects listed in Section 6. Are there any side effects? in the full CMI.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not stop taking Rosuvastatin Lupin unless you have discussed it with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving a car or operating machinery as Rosuvastatin Lupin may cause dizziness in some people.
Drinking alcohol	<ul style="list-style-type: none">• Excessive alcohol consumption may not be safe in patients taking Rosuvastatin Lupin.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the blister pack until it is time to take them. Store your medicine in a cool dry place below 25°C. Keep your medicine where children cannot reach it.

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

6. Are there any side effects?

The most common side effects of Rosuvastatin Lupin are headache, constipation, dizziness, nausea, stomach pain, unusual tiredness or a general feeling of weakness, muscle pain, and stiff or painful joints. 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. Seek medical attention immediately if you experience muscle aches, tenderness or weakness not caused by exercise, particularly if you also have fever or generally feel unwell; develop difficulty in breathing, swelling of the face, eyelids or lips; experience difficulty breathing and coughing, particularly if you also feel generally unwell (eg. fatigue, weight loss, fever); or develop widespread rash, high body temperature and enlarged lymph nodes. 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.

Rosuvastatin Lupin

Active ingredient(s): *rosuvastatin calcium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Rosuvastatin Lupin. **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 Rosuvastatin Lupin.**

Where to find information in this leaflet:

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

1. Why am I using Rosuvastatin Lupin?

Rosuvastatin Lupin contains the active ingredient rosuvastatin. Rosuvastatin belongs to a group of medicines known as HMG-CoA reductase inhibitors (also known as ‘statins’).

It lowers the “bad” cholesterol (LDL), and raises the “good” cholesterol (HDL) when exercise and changes to diet are not enough on their own.

Rosuvastatin Lupin is used to lower high cholesterol levels.

Even though you may have normal cholesterol, Rosuvastatin Lupin can also be used to reduce the risk of you having a stroke or heart attack if you are a man 50 or more years old or a woman 60 or more years old and have at least 2 risk factors for having a heart attack or stroke, such as high blood pressure, low levels of “good” cholesterol, smoking or a family history of premature coronary heart disease. Your doctor may also do a blood test to measure a substance called C Reactive Protein to help decide if you should be given Rosuvastatin Lupin for this use.

Cholesterol and triglycerides

Everyone has cholesterol and triglycerides in their blood. They are fatty substances needed by the body for many things.

Triglycerides are an energy source for the body. Cholesterol is used for such things as building cells, making bile acids (which help to digest foods) and making some hormones.

There are different types of cholesterol. Too much of the “bad” cholesterol can block the blood vessels that supply your heart and brain with blood, and can cause heart attack, angina and stroke. The “good” cholesterol helps to

remove the “bad” cholesterol from the blood vessels. High levels of triglycerides can be associated with a low level of “good” cholesterol and may increase the risk of heart disease.

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

Cholesterol is present in many foods and is also made by your body. Rosuvastatin Lupin does not reduce the cholesterol that comes from fat in food. Because of this, when you are taking Rosuvastatin Lupin, you need to follow a low-fat diet, control your weight and exercise regularly.

2. What should I know before I use Rosuvastatin Lupin?

Warnings

Do not use Rosuvastatin Lupin if you:

- are allergic to rosuvastatin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- are pregnant, become pregnant while taking Rosuvastatin Lupin, are breastfeeding, or trying to become pregnant (unless you are taking adequate contraceptive precautions).
- have active liver disease or if tests show you have elevated levels of liver enzymes which may show that you have a problem with your liver.

Do not take Rosuvastatin Lupin 40 mg if you have:

- low thyroid hormone levels (hypothyroidism);
- a personal or family history of hereditary muscular disorders;
- a previous history of muscular problems from using other lipid-lowering agents;
- a history of very heavy alcohol use;
- Asian heritage;
- been prescribed another class of lipid lowering agent called a fibrate;
- been prescribed any medicine containing fusidic acid;
- severe kidney impairment;
- situations that may increase Rosuvastatin Lupin blood levels.

Pregnancy and breastfeeding

Do not use Rosuvastatin Lupin if you are pregnant or intend to become pregnant. Ask your doctor about effective methods of contraception.

If you become pregnant, stop taking Rosuvastatin Lupin as soon as you find out and see your doctor immediately.

Do not use Rosuvastatin Lupin if you are breastfeeding. It is not known if your baby can take in Rosuvastatin Lupin from breast milk if you are breastfeeding.

Check with your doctor if you:

- have allergies to any other statins such as simvastatin (eg. Zocor, Lipex), pravastatin (eg. Pravachol), atorvastatin (eg. Lipitor), fluvastatin (eg. Vastin). If you have an allergic reaction, you may get a skin rash, hay fever, difficulty in breathing or feel faint.
- have any of these medical conditions:
 - liver problems;
 - kidney problems;
 - low thyroid hormone levels (hypothyroidism);
 - a personal or family history of muscle disorders;
 - a history of muscle problems from using other lipid-lowering agents.

It may not be safe for you to take Rosuvastatin Lupin if you have any of these conditions. Your doctor may do a blood test to check if you have any problems and may adjust the dose of Rosuvastatin Lupin.

- have any unexplained aches or pains in your muscles.
- regularly drink large amounts of alcohol. Excessive alcohol consumption may not be safe in patients taking Rosuvastatin Lupin.

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?](#)

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 may interfere with Rosuvastatin Lupin and affect how it works. These include:

- ciclosporin (eg. Sandimmun and Neoral) used, for example, after organ transplant;
- antacids (medicines used to treat heartburn and indigestion). Rosuvastatin Lupin can be taken 2 hours before or 2 hours after taking an antacid;
- warfarin (eg. Coumadin and Marevan), used to stop blood clots;
- clopidogrel (eg. Plavix), a medicine used to prevent blood clots;
- gemfibrozil (eg. Lopid, Jezil, and Ausgem), used to lower blood lipids;
- fusidic acid (eg. Fucidin) used to treat some infections;
- fostamatinib, used to treat low platelet counts;
- febuxostat (eg. Adenuric), used to treat and prevent high blood levels of uric acid;
- teriflunomide, used to treat relapsing remitting multiple sclerosis;
- antiviral medications used alone or in combination to fight infections, including the HIV infection, such as lopinavir, ritonavir, sofosbuvir, velpatasvir, voxilaprevir, grazoprevir, elbasvir, ombitasvir,

paritaprevir, dasabuvir, glecaprevir, pibrentasvir (eg. Kaletra, Sovaldi, Epclusa, Vosevi, Zepatier, Maviret);

- capmatinib, regorafenib and darolutamide (eg. Stivarga, Nubeqa) used to treat cancer;
- simeprevir (eg. Olysio), a medicine used for treatment of chronic hepatitis C;
- eltrombopag (eg. Revolade), used to increase your platelet count in your blood.

Your doctor will consider if Rosuvastatin Lupin should be used together with any of these medicines, or may wish to adjust the dose of Rosuvastatin Lupin or the other medicines. These medicines may affect the way Rosuvastatin Lupin works.

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

4. How do I use Rosuvastatin Lupin?

How much to take

- Depending on your condition and ethnic background, your doctor will decide the most appropriate starting dose for you.
- **DO NOT INCREASE OR ADJUST YOUR ROSUVASTATIN LUPIN DOSE YOURSELF.**
- If you have high cholesterol, your doctor will probably start you on a 5 mg or 10 mg tablet taken once daily. Your doctor will then monitor your cholesterol and triglyceride levels during your treatment and, if needed, may increase your Rosuvastatin Lupin dose to 20 mg once daily. For most patients a maximum 20 mg Rosuvastatin Lupin daily dose is sufficient to treat high cholesterol.
- A small number of patients may need to further increase their Rosuvastatin Lupin dose to 40 mg once daily, for example patients whose high cholesterol is hereditary.
- If your cholesterol is not high but you have risks for having a heart attack or stroke, your doctor may start you on 20 mg.
- Your doctor will advise you on the dose that's right for your condition. The daily dose of Rosuvastatin Lupin must not exceed 40 mg daily.
- You must continue to take it as directed.

How to take Rosuvastatin Lupin

- Swallow each tablet whole with a drink of water.

When to take Rosuvastatin Lupin

- Take Rosuvastatin Lupin once a day, at about the same time each day. Keeping a regular time for taking Rosuvastatin Lupin will help to remind you to take it.
- Rosuvastatin Lupin can be taken at any time of the day. It does not matter whether you take Rosuvastatin Lupin with food or on an empty stomach.

If you forget to take Rosuvastatin Lupin

Rosuvastatin Lupin should be used regularly at the same time each day. If you miss your dose at the usual time,

take it as soon as you remember, as long as it is more than 6 hours before your next dose is due. Otherwise, wait until your next dose is due and take it as normal.

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 have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much Rosuvastatin Lupin

If you think that you have used too much Rosuvastatin Lupin, 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 Rosuvastatin Lupin?

Things you should do

Have your blood cholesterol and triglycerides checked when your doctor says so to make sure Rosuvastatin Lupin is working.

You must continue to take Rosuvastatin Lupin as directed. Rosuvastatin Lupin helps lower your blood cholesterol and triglycerides. It does not cure your condition. If you stop taking Rosuvastatin Lupin, your cholesterol and triglycerides levels may rise again.

You may have to take cholesterol-lowering medicines for the rest of your life.

Call your doctor straight away if you:

- become pregnant while you are taking Rosuvastatin Lupin. Remind any doctor, dentist or pharmacist you visit that you are taking Rosuvastatin Lupin.

Things you should not do

- Do not stop taking Rosuvastatin Lupin unless you have discussed it with your doctor.

Things that may help your condition

- While taking Rosuvastatin Lupin, you also need to follow a low-fat diet, control your weight and exercise regularly.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Rosuvastatin Lupin affects you.

Rosuvastatin Lupin generally does not cause any problems with your ability to drive a car or operate machinery.

However, as with many other medicines, Rosuvastatin Lupin may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Excessive alcohol consumption may not be safe in patients taking Rosuvastatin Lupin.

Looking after your medicine

- Store it in a cool dry place below 25°C.
- Keep your tablets in the blister pack until it is time to take them. If you take Rosuvastatin Lupin out of the blister pack, it will not keep well.

Follow the instructions on 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.

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
<ul style="list-style-type: none">• Headache.• Constipation.• Dizziness.• Nausea (feeling sick).• Stomach pain.• Unusual tiredness or general feeling of weakness (asthenia).• Muscle pain (myalgia).• Stiff or painful joints (arthralgia).	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Metabolism-related:	Call your doctor straight away, or go straight to the

<ul style="list-style-type: none"> • Significant increase in your need to urinate or if you are significantly more hungry or thirsty than usual. <p>Muscle-related:</p> <ul style="list-style-type: none"> • Aching muscles, muscle tenderness or weakness not caused by exercise, particularly if you also have a fever or generally feel unwell. <p>Allergic and severe skin reaction-related:</p> <ul style="list-style-type: none"> • Difficulty breathing, swelling of the face, eyelids or lips. • Develop widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome). <p>Lung-related:</p> <ul style="list-style-type: none"> • Difficulty breathing, coughing, particularly if you also feel generally unwell (eg. fatigue, weight loss, fever). 	<p>Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
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	Titanium dioxide. Iron oxide yellow (5 mg tablets) Opadry II complete film-coating system (10 mg, 20 mg and 40 mg tablets)
Potential allergens	Sugars as lactose

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

What Rosuvastatin Lupin looks like

Rosuvastatin Lupin 5 mg tablets are yellow, round, biconvex, film-coated tablets, debossed with “5” on one side and “R” on the other side (AUST R 338651).

Rosuvastatin Lupin 10 mg tablets are pink, round, biconvex, film-coated tablets, debossed with “10” on one side and “R” on the other side (AUST R 338650).

Rosuvastatin Lupin 20 mg tablets are pink, round, biconvex, film-coated tablets, debossed with “20” on one side and “R” on the other side (AUST R 338652).

Rosuvastatin Lupin 40 mg tablets are pink, oval, biconvex, film-coated tablets, debossed with “40” on one side and “R” on the other side (AUST R 338653).

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.

Who distributes Rosuvastatin Lupin

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This leaflet was prepared in January 2023.

7. Product details

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

What Rosuvastatin Lupin contains

Active ingredient (main ingredient)	Rosuvastatin calcium
Other ingredients (inactive ingredients)	Lactose monohydrate Microcrystalline cellulose Light magnesium oxide Crospovidone Magnesium stearate Triacetin Hypromellose