

PHARMACOR ROSUVASTATIN

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 taking PHARMACOR ROSUVASTATIN?

PHARMACOR ROSUVASTATIN contains the active ingredient rosuvastatin calcium. PHARMACOR ROSUVASTATIN is used to lower high cholesterol levels. For more information, see Section [1. Why am I using PHARMACOR ROSUVASTATIN?](#) in the full CMI.

2. What should I know before I take PHARMACOR ROSUVASTATIN?

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

3. What if I am taking other medicines?

Some medicines may interfere with PHARMACOR ROSUVASTATIN 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 take PHARMACOR ROSUVASTATIN?

- If you have high cholesterol, your doctor will probably start you on 5 mg or 10 mg tablet taken once daily
- The daily dose of PHARMACOR ROSUVASTATIN must not exceed 40 mg daily

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

5. What should I know while taking PHARMACOR ROSUVASTATIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using PHARMACOR ROSUVASTATIN• Have your blood cholesterol and triglycerides checked when your doctor says so to make sure PHARMACOR ROSUVASTATIN is working
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly, unless you have discussed it with your doctor• Do not use it to treat any other complaints unless your doctor tells you to
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how PHARMACOR ROSUVASTATIN affects you. PHARMACOR ROSUVASTATIN may cause dizziness in some people.
Drinking alcohol	<ul style="list-style-type: none">• Excessive alcohol consumption may not be safe in patients taking PHARMACOR ROSUVASTATIN.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the blister/bottle pack until it is time to take them• Store it in a cool dry place (below 25°C) away from moisture, heat or sunlight

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

6. Are there any side effects?

Common less serious side effects include headache, constipation, dizziness, nausea, stomach pain, unusual tiredness, itchy skin, memory loss, stiff or painful joints (arthralgia). You may need urgent medical attention if you experience any of the following: aching muscles, muscle tenderness or weakness not caused by exercise, particularly if you also have a fever or generally feel unwell; difficulty breathing, swelling of the face, eyelids or lips; difficulty breathing, coughing, particularly if you also feel generally unwell (e.g., fatigue, weight loss, fever); widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome). 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.

PHARMACOR ROSUVASTATIN

Active ingredient(s): *rosuvastatin calcium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PHARMACOR ROSUVASTATIN. **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 PHARMACOR ROSUVASTATIN.**

Where to find information in this leaflet:

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

1. Why am I taking PHARMACOR ROSUVASTATIN?

PHARMACOR ROSUVASTATIN contains the active ingredient *rosuvastatin calcium*. PHARMACOR ROSUVASTATIN belongs to a group of medicines known as HMG-CoA reductase inhibitors (also known as 'statins').

PHARMACOR ROSUVASTATIN is used to lower high cholesterol levels. It lowers the "bad" cholesterol (LDL) and raises the "good" cholesterol (HDL) when exercise and changes to diet are not enough on their own.

Even though you may have normal cholesterol, PHARMACOR ROSUVASTATIN 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 (HDL), 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 PHARMACOR ROSUVASTATIN 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 (LDL) can block the blood vessels that supply your heart and brain with blood, and can cause heart attack, angina and stroke. The "good" cholesterol (HDL) 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.

PHARMACOR ROSUVASTATIN does not reduce the cholesterol that comes from fat in food. Because of this, when you are taking PHARMACOR ROSUVASTATIN, you need to follow a low-fat diet, control your weight and exercise regularly.

2. What should I know before I take PHARMACOR ROSUVASTATIN?

Warnings

Do not take PHARMACOR ROSUVASTATIN if:

- you are allergic to *rosuvastatin calcium*, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You are pregnant, become pregnant while taking PHARMACOR ROSUVASTATIN, are breastfeeding, or trying to become pregnant unless you are taking adequate contraceptive precautions
- you 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 PHARMACOR ROSUVASTATIN 40mg 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 blood levels

Check with your doctor if you:

- have any allergies to any other statins such as simvastatin (e.g. ZOCOR, LIPEX); pravastatin (e.g. PRAVACHOL); atorvastatin (e.g. LIPITOR); fluvastatin (e.g. VASTIN). If you have an allergic reaction, you may get a skin rash, hay fever, difficulty in breathing or feel faint
- have any other medical conditions, in particular:
 - 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 PHARMACOR ROSUVASTATIN 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 PHARMACOR ROSUVASTATIN.

- 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 PHARMACOR ROSUVASTATIN.

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

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

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

Do not use PHARMACOR ROSUVASTATIN if you are breast feeding. Your baby may absorb this medicine from the breast milk and there is a possibility of harm to the 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 may interfere with PHARMACOR ROSUVASTATIN and affect how it works. These include:

- ciclosporin (e.g. SANDIMMUN and NEORAL), used, for example, after organ transplant
- antacids (medicines used to treat heartburn and indigestion). PHARMACOR ROSUVASTATIN can be

taken 2 hours before or 2 hours after taking an antacid

- warfarin (e.g. COUMADIN and MAREVAN), used to stop blood clots
- clopidogrel (e.g. PLAVIX), a medicine used to prevent blood clots
- gemfibrozil (e.g. LOPID, JEZIL, and AUSGEM), used to lower blood lipids
- fusidic acid (eg FUCIDIN) used to treat some infections
- febuxostat (e.g. 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 such as, lopinavir, ritonavir, sofosbuvir, velpatasvir, voxilaprevir, grazoprevir, elbasvir, ombitasvir, paritaprevir, dasabuvir, glecaprevir, pibrentasvir used to fight infections, including the HIV infection (e.g. KALETRA, SOVALDI, EPCLUSA, VOSEVI, ZEPATIER, MAVIRET)
- eltrombopag, used to increase your platelet count in your blood
- tafamidis, used to treat a protein disorder.
- capmatinib, regorafenib and darolutamide (e.g. STIVARGA, NUBEQA) used to treat cancer

Your doctor will consider if PHARMACOR ROSUVASTATIN should be used together with any of these medicines, or may wish to adjust the dose of PHARMACOR ROSUVASTATIN or the other medicines.

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

4. How do I take PHARMACOR ROSUVASTATIN?

How much to take / use

- Depending on your condition and ethnic background, your doctor will decide the most appropriate starting dose for you
- If you have high cholesterol, your doctor will probably start you on 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 PHARMACOR ROSUVASTATIN dose to 20 mg once daily. For most patients a maximum 20 mg PHARMACOR ROSUVASTATIN daily dose is sufficient to treat high cholesterol
- A small number of patients may need to further increase their PHARMACOR ROSUVASTATIN 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
- The daily dose of PHARMACOR ROSUVASTATIN must not exceed 40 mg daily

DO NOT INCREASE OR ADJUST YOUR PHARMACOR ROSUVASTATIN DOSE YOURSELF

When to take PHARMACOR ROSUVASTATIN

- PHARMACOR ROSUVASTATIN should be used once a day, at about the same time each day. Keeping a regular time for taking PHARMACOR ROSUVASTATIN will help to remind you to take it
- PHARMACOR ROSUVASTATIN can be taken at any time of the day.

How to take PHARMACOR ROSUVASTATIN

- Swallow each tablet whole with a drink of water
- It does not matter whether you take PHARMACOR ROSUVASTATIN with food or on an empty stomach.

If you forget to take PHARMACOR ROSUVASTATIN

- PHARMACOR ROSUVASTATIN 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.

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 take too much PHARMACOR ROSUVASTATIN

If you think that you have used too much PHARMACOR ROSUVASTATIN, 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 taking PHARMACOR ROSUVASTATIN?

Things you should do

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

Call your doctor straight away if you:

- become pregnant while you are taking PHARMACOR ROSUVASTATIN

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

Things you should not do

- Do not stop using this medicine suddenly, unless you have discussed it with your doctor
- Do not use it to treat any other complaints unless your doctor tells you to
- Do not give this medicine to anyone else

Things that may help your condition

- While taking PHARMACOR ROSUVASTATIN, 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 PHARMACOR ROSUVASTATIN affects you.

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

However, as with many other medicines, PHARMACOR ROSUVASTATIN 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 PHARMACOR ROSUVASTATIN.

Looking after your medicine

- keep your tablets in the blister/bottle pack until it is time to take them
- if you take PHARMACOR ROSUVASTATIN out of the blister/bottle pack it will not keep well

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.

Keep it where young children cannot reach it.

A locked cupboard, at least one-and-a-half metres above the ground, is a good place to store medicines.

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>Gastrointestinal and urinary:</p> <ul style="list-style-type: none"> constipation nausea (feeling sick) stomach pain <p>Head and neurology:</p> <ul style="list-style-type: none"> headache dizziness <p>General body:</p> <ul style="list-style-type: none"> unusual tiredness stiff or painful joints (arthralgia) Muscle pain (myalgia) 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Metabolism-related:</p> <ul style="list-style-type: none"> significant increase in the need to urinate 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 widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome) rash on the skin or sores in the mouth <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>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>

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 PHARMACOR ROSUVASTATIN contains

Active ingredient (main ingredient)	rosuvastatin calcium
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> lactose monohydrate microcrystalline cellulose light magnesium oxide crospovidone magnesium stearate triacetin Hypromellose titanium dioxide The 5 mg tablets also contain iron oxide yellow The 10 mg and 20 mg contain iron oxide red, quinoline yellow aluminum lake, brilliant blue FCF aluminum lake The 40 mg tablets also contain sunset yellow FCF aluminum lake, allura red AC aluminum lake and brilliant blue FCF aluminum lake
Potential allergens	Lactose monohydrate

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

What PHARMACOR ROSUVASTATIN looks like

PHARMACOR ROSUVASTATIN film-coated tablets 5 mg are yellow, round, biconvex, film-coated tablet, debossed “5” on one side and “R” on other side. (AUST R 234468 (blister); AUST R 235364 (bottle)).

PHARMACOR ROSUVASTATIN film-coated tablets 10 mg are pink, round, biconvex, film-coated tablet, debossed “10” on one side and “R” on other side. (AUST R 234479 (blister); AUST R 234520 (bottle)).

PHARMACOR ROSUVASTATIN film-coated tablets 20 mg are pink, round, biconvex, film-coated tablet, debossed “20” on one side and “R” on other side. (AUST R 234539 (blister); AUST R 234496 (bottle)).

PHARMACOR ROSUVASTATIN film-coated tablets 40 mg are pink, oval, biconvex, film-coated tablet, debossed “40” on one side and “R” on other side. (AUST R 234477 (blister); AUST R 234464 (bottle)).

PHARMACOR ROSUVASTATIN tablets are available in blisters packs of 7, 14, 15, 20, 28, 30, 42, 50, 56, 60, 84, 90, 98 and 100 tablets and bottle packs of 30, 90, 100 and 500 tablets.

Who distributes PHARMACOR ROSUVASTATIN

Pharmacor Pty Ltd

Suite 803, Level 8, Tower A, The Zenith

821 Pacific Highway

Chatswood NSW 2067

Web: www.pharmacor.com.au

Phone: 1300 138 805

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