

ROSUVASTATIN PCOR

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 PCOR?

ROSUVASTATIN PCOR contains the active ingredient Rosuvastatin calcium. ROSUVASTATIN PCOR is used to lower high cholesterol levels. Even though you may have normal cholesterol, ROSUVASTATIN PCOR 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 PCOR?](#) in the full CMI.

2. What should I know before I use ROSUVASTATIN PCOR?

Do not use if you have ever had an allergic reaction to ROSUVASTATIN PCOR or any of the ingredients listed at the end of the CMI or if you become pregnant while you are taking ROSUVASTATIN PCOR.

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 PCOR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ROSUVASTATIN PCOR 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 ROSUVASTATIN PCOR?

- 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 PCOR?](#) in the full CMI.

5. What should I know while using ROSUVASTATIN PCOR?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking ROSUVASTATIN PCOR.• Have your blood cholesterol and triglycerides checked when your doctor says so• Stop taking ROSUVASTATIN PCOR and seek medical attention immediately if you experience any of the serious side effects listed in Section 6 in the full CMI.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking ROSUVASTATIN PCOR 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 PCOR 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 PCOR.
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 ROSUVASTATIN PCOR?](#) in the full CMI.

6. Are there any side effects?

The most common side effects of ROSUVASTATIN PCOR 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 any of the following, particularly if you also generally feel unwell: muscle aches, tenderness or weakness not caused by exercise particularly if you also have fever; difficulty breathing, coughing, swelling of the face, eyelids or lips; widespread rash, high body temperature, enlarged lymph nodes; or skin rash or sores in the mouth. 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 PCOR

Active ingredient(s): [*Rosuvastatin calcium*]

Consumer Medicine Information (CMI)

This leaflet provides important information about using [ROSUVASTATIN PCOR]. **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 PCOR].**

Where to find information in this leaflet:

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

1. Why am I using ROSUVASTATIN PCOR?

ROSUVASTATIN PCOR contains the active ingredient Rosuvastatin calcium
ROSUVASTATIN PCOR 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 PCOR is used to lower high cholesterol levels.

Even though you may have normal cholesterol, ROSUVASTATIN PCOR 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 PCOR 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 essential for 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 PCOR does not reduce the cholesterol that comes from fat in food. Because of this, when you are taking ROSUVASTATIN PCOR, you need to follow a low-fat diet, control your weight and exercise regularly.

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

Warnings

Do not use ROSUVASTATIN PCOR 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 ROSUVASTATIN PCOR, 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 ROSUVASTATIN PCOR 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 PCOR blood levels.

Pregnancy and breastfeeding

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

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

Do not take ROSUVASTATIN PCOR if you are breast feeding. Your baby may absorb this medicine from breast milk and there is a possibility of harm to the baby.

Check with your doctor if you:

- have allergies to any other statins such as simvastatin pravastatin (e.g.); atorvastatin; fluvastatin. 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 PCOR 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 PCOR.

- 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 PCOR.

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 PCOR and affect how it works. These include:

- ciclosporin, used for example, after organ transplant
- antacids used to treat heartburn and indigestion). ROSUVASTATIN PCOR can be taken 2 hours before or 2 hours after taking an antacid
- warfarin, used to stop blood clots
- clopidogrel, or ticagrelor a medicine used to prevent blood clots
- gemfibrozil, fenofibrate or ezetimibe, used to lower blood lipids
- fusidic acid used to treat some infections
- febuxostat, used to treat and prevent high bloodlevels of uric acid
- teriflunomide, used to treat relapsing remittingmultiple
- antiviral medications (alone or in combination), such as atazanavir, darunavir, glecaprevir, lopinavir, pibrentasvir, ritonavir, sofosbuvir, velpatasvir, and, voxilaprevir, used to fight infections, including the HIV infection
- anti-cancer medications, such as regorafeniband darolutamide, used to treat cancer ROSUVASTATIN PCOR
- eltrombopag, used to increase your platelet count in your blood
- tafamidis, used to treat a protein disorder.

Your doctor will consider if ROSUVASTATIN PCOR should be taken together with any of these medicines, or may wish to adjust the dose of ROSUVASTATIN PCOR or the other medicines. These medicines may affect the way ROSUVASTATIN PCOR 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 PCOR.

4. How do I take ROSUVASTATIN PCOR?

How much to take

- 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 ROSUVASTATIN PCOR dose to 20 mg once daily. For most patients a maximum 20 mg ROSUVASTATIN PCOR daily dose is sufficient to treat high cholesterol.
- A small number of patients may need to further increase their ROSUVASTATIN PCOR 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 PCOR must not exceed 40 mg daily.

DO NOT INCREASE OR ADJUST YOUR ROSUVASTATIN PCOR DOSE YOURSELF.

- Swallow each tablet whole with a drink of water.
- You must continue to take it as directed.
- ROSUVASTATIN PCOR helps lower your blood cholesterol and triglycerides. It does not cure your condition. If you stop taking ROSUVASTATIN PCOR, your cholesterol and triglycerides levels may rise again.
- You may have to take cholesterol-lowering medicines for the rest of your life.

When to take ROSUVASTATIN PCOR

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

If you forget to take ROSUVASTATIN PCOR

- ROSUVASTATIN PCOR should be taken regularly at the same time each day. If you forget to take dose of ROSUVASTATIN PCOR, 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.

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hint.

If you use too much ROSUVASTATIN PCOR

If you think that you or anyone else may have taken too much ROSUVASTATIN PCOR, urgent medical attention needed.

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 PCOR?

Things you should do

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

Call your doctor straight away if you:

- become pregnant while you are taking ROSUVASTATIN PCOR.

Remind any doctor, dentist or pharmacist you visit that you are using ROSUVASTATIN PCOR.

Things you should not do

- Do not stop taking ROSUVASTATIN PCOR unless you have discussed it with your doctor.

Things that may help your condition

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

Driving or using machines

Be careful before driving a car or operating machinery until you know how ROSUVASTATIN PCOR affects you.

ROSUVASTATIN PCOR generally does not cause any problems with your ability to drive a

car or operate machinery. However, as with many other medicines, ROSUVASTATIN PCOR may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you regularly drink large amounts of alcohol.

Excessive alcohol consumption may not be safe in patients taking ROSUVASTATIN PCOR.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.

Follow the instructions in the carton on how to take care of your medicine properly. Keep your tablets in the blister pack until it is time to take them. If you take ROSUVASTATIN PCOR out of the blister pack, it will not keep well.

Store it in a cool dry place below 25°C and 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)	Speak to your doctor if you have

<ul style="list-style-type: none"> • stomach pain • unusual tiredness or a general feeling of weakness (asthenia) • muscle pain • stiff or painful joints (arthralgia) 	any of these less serious side effects and they worry you.
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Serious side effects

Serious side effects	What to do
Metabolism-related <ul style="list-style-type: none"> • significant increase in your need to urinate or if you are significantly more hungry or thirsty than usual Muscle-related: <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 Allergic and severe skin reaction related: <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 Lung-related: <ul style="list-style-type: none"> • difficulty breathing, coughing, particularly if you also feel generally unwell (e.g. fatigue, weight loss, fever) 	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.

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

ROSUVASTATIN PCOR contains

Active ingredient (main ingredient)	Rosuvastatin calcium equivalent to rosuvastatin 10 mg, 20 mg and 40 mg.
Other ingredients (inactive ingredients)	Crospovidone (XL-10) Magnesium oxide (Light) Microcrystalline cellulose (GR101) Lactose monohydrate (Supertab 30 GR) Magnesium Stearate Opadry II pink 32K140052 (ARTG 141463)

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

What ROSUVASTATIN PCOR looks like

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

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

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

The film-coated tablets are packed in

- Alu-Alu blister Pack of 10's & 30's, Tablets
- HDPE Bottle Pack of 30's & 90's Tablets.

Who distributes ROSUVASTATIN PCOR

PHARMACOR PTY LTD
Chatswood NSW 2067
Australia

ROSUVASTATIN PCOR

10mg: Blister Pack: 363424
Bottle Pack: 363428

20mg: Blister Pack: 363414
Bottle Pack: 363429

40mg: Blister Pack: 363419
Bottle Pack: 363412

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