

Rosuvastatin Sandoz®

Rosuvastatin calcium film coated tablet

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Rosuvastatin Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT ROSUVASTATIN SANDOZ IS USED FOR

This medicine is used to:

- Lower high blood cholesterol levels (hypercholesterolaemia).
- 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.

It contains the active ingredient rosuvastatin calcium.

Rosuvastatin calcium belongs to a group of medicines called HMG-CoA reductase inhibitors (also known as 'statins').

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

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.

Rosuvastatin Sandoz works by reducing the level of "bad" cholesterol, and raises the "good" cholesterol when exercise and changes to diet are not enough on their own. Cholesterol is present in many foods and is also made by your body. It does not reduce the cholesterol that comes from fat in food. Because of this, when you are taking Rosuvastatin Sandoz, you need to follow a low-fat diet, control your weight and exercise regularly.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

There is not enough information to recommend the use of this medicine for children.

BEFORE YOU TAKE ROSUVASTATIN SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- rosuvastatin calcium, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicine in the same drug class as Rosuvastatin Sandoz (statins), such as simvastatin (e.g. ZOCOR, LIPEX); pravastatin (e.g. PRAVACHOL); atorvastatin (e.g. LIPITOR); fluvastatin (e.g. VASTIN).

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you are pregnant or plan to become pregnant.

It may affect your developing baby if you take it during pregnancy. Ask your doctor about effective methods of contraception.

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

Do not breastfeed if you are taking this medicine.

It is not known whether Rosuvastatin Sandoz passes into breast milk.

Do not take this medicine if 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 Sandoz 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
- severe kidney impairment
- been prescribed any medicine called fusidic acid
- situations that may increase Rosuvastatin Sandoz blood levels.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver disease
- 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 Sandoz 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 Sandoz.

- any unexplained aches or pains in your muscles.
- you regularly drink large amounts of alcohol

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

Rosuvastatin Sandoz contains lactose.

If you have been told by your doctor that you have intolerance to some sugars, tell your doctor before taking it.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Rosuvastatin Sandoz may interfere with each other. These include:

- medicines used after organ transplant such as cyclosporin (e.g. SANDIMMUN and NEORAL)
- medicines used to treat heartburn and indigestion such as antacids. Rosuvastatin Sandoz can be taken 2 hours before or 2 hours after taking an antacid
- warfarin (e.g. COUMADIN and MAREVAN), a medicine used to prevent blood clots
- clopidogrel (e.g. PLAVIX), a medicine used to prevent blood clots
- medicines used to lower blood lipids such as gemfibrozil (e.g. LOPID, JEZIL, and AUGEM)
- medicines used to treat HIV infection such as various protease inhibitor combinations with ritonavir (e.g. KALETRA)
- fusidic acid (eg FUCIDIN), a medicine used to treat some infections
- simeprevir (OLYSIO), a medicine used for treatment of chronic hepatitis C
- eltrombopag (REVELOADE), used to increase your platelet count in your blood.

These medicines may be affected by Rosuvastatin Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor about any of these things, tell them before you take Rosuvastatin Sandoz.

Effects on driving and using machinery

Be careful driving a car or operating machinery until you know if Rosuvastatin Sandoz affects you.

Rosuvastatin Sandoz generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Rosuvastatin Sandoz may cause dizziness in some people.

HOW TO TAKE ROSUVASTATIN SANDOZ

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 the instructions, ask your doctor or pharmacist for help.

How much to take it

The standard dose for this medicine is one tablet a day.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

DO NOT INCREASE OR ADJUST YOUR ROSUVASTATIN SANDOZ DOSE YOURSELF.

Follow the instructions they give you.

If you take the wrong dose, Rosuvastatin Sandoz may not work as well and your problem may not improve.

If you have high cholesterol, your doctor will probably start you on 5 mg or 10 mg tablet taken once daily.

Your doctor will monitor your cholesterol and triglyceride levels during your treatment, and, if needed, may increase your dose to 20 mg once daily. For most patients a maximum 20 mg daily dose is sufficient to treat their condition.

A small number of patients may need to further increase their dose to 40 mg once daily, for example patients whose high cholesterol is hereditary.

Your doctor will advise you on the dose that's right for your condition. The daily dose of Rosuvastatin Sandoz must not exceed 40 mg daily.

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.

How to take it

Swallow the tablets whole with a full glass of water.

When to take Rosuvastatin Sandoz

Take your medicine 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 your medicine at any time of the day with food or on an empty stomach.

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

How long to take Rosuvastatin Sandoz

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. If you stop taking your medicine, your cholesterol and triglycerides levels may rise again.

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

If you forget to take it

If you forget to take a dose of Rosuvastatin Sandoz, 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 take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask 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)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Rosuvastatin Sandoz. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

WHILE YOU ARE TAKING ROSUVASTATIN SANDOZ

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Rosuvastatin Sandoz.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, stop taking it and tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may check your blood cholesterol and triglycerides level from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Rosuvastatin Sandoz to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Rosuvastatin Sandoz affects you.

This medicine may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Rosuvastatin Sandoz.

All medicines can have 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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- constipation
- dizziness
- nausea (feeling sick)
- stomach pain
- unusual tiredness
- itchy skin
- memory loss
- stiff or painful joints (arthralgia).

These are mild side effects of the medicine.

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.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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 and lips.
- difficulty breathing, coughing, particularly if you also feel generally unwell (eg fatigue, weight loss, fever).

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

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

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

AFTER TAKING ROSUVASTATIN SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect from light

Do not store Rosuvastatin Sandoz or any other medicine in the bathroom or near a

sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

20mg tablet: AUST R 311402 (blisters)

40mg tablet: AUST R 311403 (blisters)

PRODUCT DESCRIPTION

What it looks like

Rosuvastatin Sandoz comes in four types of tablets:

Rosuvastatin Sandoz 5mg - Brown, round, film coated tablets.

Rosuvastatin Sandoz 10mg - Brown, round, film coated tablets with "RSV 10" debossed on one side.

Rosuvastatin Sandoz 20mg - Brown, round, film coated tablets with "RSV 20" debossed on one side.

Rosuvastatin Sandoz 40mg - Brown, round, film coated tablets with "RSV 40" debossed on one side.

Available in blister packs of 30 tablets.

Ingredients

Active ingredients:

- Rosuvastatin Sandoz 5mg - 5mg rosuvastatin (as calcium)
- Rosuvastatin Sandoz 10mg - 10mg rosuvastatin (as calcium)
- Rosuvastatin Sandoz 20mg - 20mg rosuvastatin (as calcium)
- Rosuvastatin Sandoz 40mg - 40mg rosuvastatin (as calcium)

Inactive ingredients:

- lactose
- colloidal anhydrous silica
- maize starch
- purified talc
- sodium stearyl fumarate
- hypromellose
- mannitol
- macrogol 6000
- titanium dioxide
- iron oxide yellow
- iron oxide red
- microcrystalline cellulose and silicon dioxide.

Supplier

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5mg tablet: AUST R 311400 (blisters)

10mg tablet: AUST R 311401 (blisters)