

ROSUVASTATIN APOTEX

Rosuvastatin calcium

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. 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 this medicine is used for

ROSUVASTATIN APOTEX is used to lower high cholesterol levels.

Even though you may have normal cholesterol, 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 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.

How Rosuvastatin works

Rosuvastatin belongs to a group of medicines known as HMG-CoA reductase inhibitors (also known as 'statins'). It lowers the "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.

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

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

Your doctor will have explained why you are being treated with Rosuvastatin and told you what dose to take. Your doctor may need to check your cholesterol levels before prescribing Rosuvastatin or changing your dose.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Rosuvastatin is not addictive.

Rosuvastatin is not recommended for use in children as its effects in children have not been established.

Before you take this medicine

When you must not take it

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

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

Do not use Rosuvastatin if you are breast feeding.

We do not know if your baby can take in Rosuvastatin from breast milk if you are breast feeding.

Do not use Rosuvastatin 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 use Rosuvastatin 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 blood levels

Do not use after the use by (expiry) date printed on the pack.

It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not use Rosuvastatin if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaints unless your doctor tells you to. Do not give this medicine to anyone else.

Before you start to take it

You must tell your doctor if:

1. 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)
 - any ingredients listed at the end of this leaflet
 - If you have an allergic reaction, you may get a skin rash, hay fever, difficulty in breathing or feel faint.
- 2. you 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 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.

3. you have any unexplained aches or pains in your muscles

4. you regularly drink large amounts of alcohol

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

Taking other medicines

Tell your doctor if you are taking any other medicines including

- cyclosporin (e.g. SANDIMMUN and NEORAL, used, for example, after organ transplant)
- antacids (medicines used to treat heartburn and indigestion). 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 (e.g. FUCIDIN) use to treat some infections
- various protease inhibitors used in combination with ritonavir to treat HIV infection (e.g. KALETRA)
- simeprevir (OLYSIO), a medicine used for treatment of chronic hepatitis C
- eltrombopag (REVOLADE, used to increase your platelet count in your blood)
- medicines that you buy at the chemist, supermarket or health food shop, including herbal medicines.

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

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

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

Effects on driving and using machinery

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

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

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

How to take this medicine

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 on the box/bottle, ask your doctor or pharmacist for help.

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 dose to 20 mg once daily. For most patients a maximum 20 mg Rosuvastatin daily dose is sufficient to treat high cholesterol.

A small number of patients may need to further increase their 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.

Your doctor will advise you on the dose that's right for your condition.

The daily dose of Rosuvastatin must not exceed 40 mg daily.

How much to take

Do not increase or adjust your rosuvastatin dose yourself.

Take Rosuvastatin once a day, at about the same time each day.

Keeping a regular time for taking Rosuvastatin will help to remind you to take it.

How to take it

Swallow each tablet whole with a drink of water.

When to take it

Rosuvastatin can be taken at any time of the day. It does not matter whether you take Rosuvastatin with food or on an empty stomach.

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

How long to take it

You must continue to take it as directed.

Rosuvastatin helps lower your blood cholesterol and triglycerides. It does not cure your condition. If you stop taking Rosuvastatin, 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, 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 one you missed.

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

If you take too much (overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26), or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Rosuvastatin even if there are no signs of discomfort or poisoning.

While you are using this medicine

Things you must do

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

Stop taking Rosuvastatin and contact your doctor immediately if you become pregnant while you are taking Rosuvastatin.

Things you must not do

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

Side effects

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

Rosuvastatin helps most people with too much cholesterol, but it may have unwanted side effects in a few people.

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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 side effects are usually mild.

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 or go to Accident and Emergency at your nearest hospital if you notice 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).

These are all serious side effects.

You may need urgent medical attention

Serious side effects are rare.

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

Some people may get other side effects while taking Rosuvastatin

Do not be alarmed by this list of side effects.

You may not experience any of them.

Storage and Disposal

Storage

Keep your tablets in the blister / bottle until it is time to take them.

If you take the tablets out of the blister/bottle they may not keep well.

Keep it in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

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.

Do not leave it in the car on hot days.

Disposal

Ask your pharmacist what to do with any Rosuvastatin tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product description

What it looks like

ROSUVASTATIN APOTEX film-coated tablets 5 mg are yellow, round, biconvex, film-coated tablet, debossed "5" on one side and "R" on other side.

5 mg blister pack:

AUST R 234497

5 mg bottle pack:

AUST R 234489

ROSUVASTATIN APOTEX film-coated tablets 10 mg are pink, round, biconvex, film-coated tablet, debossed "10" on one side and "R" on other side.

10 mg blister pack:

AUST R 234484

10 mg bottle pack:

AUST R 234462

ROSUVASTATIN APOTEX film-coated tablets 20 mg are pink, round, biconvex, film-coated tablet, debossed "20" on one side and "R" on other side.

20 mg blister pack:

AUST R 234460

20 mg bottle pack:

AUST R 234494

ROSUVASTATIN APOTEX film-coated tablets 40 mg are pink, oval, biconvex, film-coated tablet, debossed "40" on one side and "R" on other side.

40 mg blister pack:

AUST R 234503

40 mg bottle pack:

AUST R 234481

ROSUVASTATIN APOTEX tablets are available in blisters packs of, 30 tablets and bottle packs of 30 and 90 tablets.

Ingredients

This medicine contains rosuvastatin calcium as the active ingredient, equivalent to rosuvastatin 5mg 10mg, 20mg and 40mg

This medicine also contains the following:

- Lactose
- 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 tablets also contain iron oxide red, quinoline yellow aluminium lake, brilliant blue FCF aluminium lake.
- The 40 mg tablets also contain sunset yellow FCF aluminium lake, allura red AC aluminium lake and brilliant blue FCF aluminium lake.

Name and Address of the Sponsor

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne VIC 3000
Australia

Distributor

This medicine is made/distributed/supplied in Australia by:
Apotex Pty Ltd
16 Giffnock Avenue

Macquarie Park NSW 2113

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