

ROSUVASTATIN LUPIN

(rosuvastatin calcium) film-coated tablet

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about Rosuvastatin Lupin. It does not contain all the information that is known about Rosuvastatin Lupin.

It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking Rosuvastatin Lupin 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 Lupin is used for

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 (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 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 (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 Lupin works

Rosuvastatin Lupin 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 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.

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 Lupin and told you what dose to take. Your doctor may need to check your cholesterol levels before prescribing Rosuvastatin Lupin 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 Lupin is not addictive.

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

Before you take Rosuvastatin Lupin

When you must not take it

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 breast feeding.

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

Do not use Rosuvastatin Lupin 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 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 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 Lupin 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 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.

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 Lupin.

Taking other medicines

Tell your doctor if you are taking any other medicines including:

- cyclosporin (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 (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) use to treat some infections;
- various protease inhibitors used in combination with ritonavir to treat HIV infection (eg 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 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.

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 Lupin.

Effects on driving and using machinery

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

How to take Rosuvastatin Lupin

How to take it

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 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.

DO NOT INCREASE OR ADJUST YOUR ROSUVASTATIN LUPIN DOSE YOURSELF.

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.

Swallow each tablet whole with a drink of water.

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.

While taking Rosuvastatin Lupin 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 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.

If you forget to take it

If you forget to take a dose of Rosuvastatin Lupin, 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 Lupin even if there are no signs of discomfort or poisoning.

While you are taking Rosuvastatin Lupin

Things you must do

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

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

Things you must not do

Do not stop taking Rosuvastatin Lupin 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 Rosuvastatin Lupin.

Rosuvastatin Lupin 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 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 (eg. 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 Lupin.

Do not be alarmed by this list of side effects.

You may not experience any of them.

After taking Rosuvastatin Lupin

Storage

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

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 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.

Do not leave it in the car on hot days.

Disposal

Ask your pharmacist what to do with any Rosuvastatin Lupin

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

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

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

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

Rosuvastatin Lupin tablets are available in blister packs of 30 tablets.

Ingredients

Active ingredients

Rosuvastatin Lupin contains rosuvastatin calcium as the active ingredient, equivalent to rosuvastatin 5 mg 10 mg, 20 mg and 40 mg.

Other ingredients

- Lactose,
- Lactose monohydrate,
- Microcrystalline cellulose,
- Light magnesium oxide,
- Crospovidone,
- Magnesium stearate,
- Triacetin,
- Hypromellose,
- Titanium dioxide.

The 5 mg tablets also contain iron oxide yellow whereas the 10 mg, 20 mg and 40 mg tablets contain Opadry II complete film-coating system.

Australian Registration Numbers

5 mg blister pack:
AUST R 338651

10 mg blister pack:
AUST R 338650

20 mg blister pack:
AUST R 338652

40 mg blister pack:
AUST R 338653

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