

ROSUVASTATIN-DRLA

Contains the active ingredient rosuvastatin (as calcium)

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some of the common questions about rosuvastatin. It does not contain all the information that is known about rosuvastatin.

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 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

The name of your medicine is Rosuvastatin-DRLA. It contains the active ingredient rosuvastatin.

Rosuvastatin 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 this medicine 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 this medicine, 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 this medicine 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.

Use in children

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 take this medicine if:

1. you are pregnant or intend to become pregnant.

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.

2. if you are breastfeeding

It is not known if this medicine passes into breast milk

3. you have an active liver disease or if tests show you have elevated levels of liver enzymes which may show you have a problem with your liver.

4. the package is torn or shows signs of tampering

5. the expiry date (EXP) printed on the pack has passed

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking this medicine, talk to your doctor.

Do not use Rosuvastatin-DRLA 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

Before you start to take it

Tell your doctor or pharmacist if you have 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 of the ingredients listed at the end of this leaflet
- any other medicines

- any other substances, such as foods, preservatives or dyes.

If you have an allergic reaction, you may get a skin rash, hay fever, difficulty in breathing or feel faint.

Tell your doctor if:

1. you have or have ever had any medical conditions, especially the following:
 - liver problems
 - kidney problems
 - low thyroid hormone levels (hypothyroidism)
 - a personal or family history of muscle disorders
 - a history of muscle problems using other lipid-lowering agents.

It may not be safe for you to take this medicine 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 your medicine.

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 this medicine.

If you have not told your doctor about any of the above, tell them before you use this medicine.

Taking other medicines

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

Tell your doctor if you are taking the following:

- 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)
- gemfibrozil (e.g. Lopid, Jezil, and Ausgem, used to lower blood lipids)
- fusidic acid (eg Fucidin) used 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

These medicines may be affected by rosuvastatin, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using this medicine.

How to take it

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

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.

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.

DO NOT INCREASE OR ADJUST YOUR DOSE YOURSELF.

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

How to take it

Swallow each tablet whole with a drink of water.

When to take it

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

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

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

If you are not sure when to take this medicine, ask your doctor.

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 this 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, 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)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

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

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

Tell all the doctors, dentists and pharmacists who are treating you that you are using this medicine.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using this medicine.

Things you must not do

Do not:

- Stop taking your medicine, or change the dosage, without first discussing it with your doctor.
- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Let yourself run out of medicine over the weekend or on holidays

Things to be careful of

Be careful driving a car or operating machinery until you know how this medicine 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, it may cause dizziness in some people.

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 have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

- headache
- constipation
- dizziness
- diarrhoea
- 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 serious side effects. You may need urgent medical attention.

These serious 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 occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

After taking this medicine

Storage

Keep your medicine in its original packaging until it is time to take it

The medicine will not keep as well if taken out of the packaging.

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

Do not store your medicine, 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 this medicine 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 or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What Rosuvastatin-DRLA looks like

Rosuvastatin-DRLA 5 mg are Pale yellow to yellow colored round shaped film-coated tablets having '5' on one side & "Y" (symbol like DR. REDDY'S logo) on other side of tablet.

Rosuvastatin-DRLA 10 mg are Pale pink to pink colored round shaped film-coated tablets having '10' on one side & "Y" (symbol like DR. REDDY'S logo) on other side of tablet.

Rosuvastatin-DRLA 20 mg are Pale pink to pink colored round shaped film-coated tablets having '20' on one side & "Y" (symbol like DR. REDDY'S logo) on other side of tablet.

Rosuvastatin-DRLA 40 mg are Pale pink to pink colored oval shaped film-coated tablets having '40' on one side & "Y" (symbol like DR. REDDY'S logo) on other side of tablet.

Available in blister packs of 30 tablets.

Ingredients

Each Rosuvastatin-DRLA tablet contains 5, 10, 20, or 40 mg of rosuvastatin (as calcium) as the active ingredient.

It also contains the following inactive ingredients:

- microcrystalline cellulose
- lactose
- crospovidone
- meglumine
- magnesium stearate
- Opadry II complete film coating system 32K520045 Yellow
- Opadry II complete film coating system 32K540017 Pink

This medicine is gluten-free, tartrazine-free and free of other azo dyes.

Australian RegistrationNumbers

Rosuvastatin-DRLA 5 mg:

AUST R 210836

Rosuvastatin-DRLA 10 mg:

AUST R 210832

Rosuvastatin-DRLA 20 mg:

AUST R 210837

Rosuvastatin-DRLA 40 mg:

AUST R 210829

Sponsor

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