

Rosuvastatin AMNEAL

contains the active ingredient rosuvastatin (as calcium)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ROSUVASTATIN AMNEAL.

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

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

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

Keep this leaflet with your medicine. You may need to read it again.

What ROSUVASTATIN AMNEAL is used for

ROSUVASTATIN AMNEAL is used to lower high cholesterol levels.

Even though you may have normal cholesterol, ROSUVASTATIN AMNEAL 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 AMNEAL 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. 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 low level of "good" cholesterol and may increase the risk of heart disease.

How ROSUVASTATIN AMNEAL works

ROSUVASTATIN AMNEAL belongs to a group of medicines called HMG-CoA reductase inhibitors (also known as 'statins'). These medicines work by lowering the "bad" cholesterol and raising the "good" cholesterol when exercises and changes in diet are not enough on their own.

Cholesterol is present in many foods and is also made by your body. ROSUVASTATIN AMNEAL does not reduce the cholesterol that comes from fat in food. Because of this, when you are taking ROSUVASTATIN AMNEAL, 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 AMNEAL and told you what dose to take. Your doctor may need to check your cholesterol levels before prescribing ROSUVASTATIN AMNEAL 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 have prescribed ROSUVASTATIN AMNEAL for another reason. Ask your doctor if you have any questions about why ROSUVASTATIN AMNEAL has been prescribed for you.

ROSUVASTATIN AMNEAL is not recommended for use in children, as its effects in children have not been established.

ROSUVASTATIN AMNEAL is available only with a doctor's prescription.

ROSUVASTATIN AMNEAL is not addictive.

Before you take ROSUVASTATIN AMNEAL

When you must not take it

Do not take ROSUVASTATIN AMNEAL if you are allergic to medicines containing rosuvastatin or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take ROSUVASTATIN AMNEAL if you have active liver disease or if tests show you have elevated levels of liver enzymes which may indicate that you have a problem with your liver.

Do not take ROSUVASTATIN AMNEAL 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 AMNEAL blood levels.

Do not take ROSUVASTATIN AMNEAL if you are pregnant or intend to become pregnant.

ROSUVASTATIN AMNEAL may affect your developing baby if you take it during pregnancy.

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

Do not take ROSUVASTATIN AMNEAL if you are breastfeeding.

It is not known whether ROSUVASTATIN AMNEAL passes into breast milk.

Do not take ROSUVASTATIN AMNEAL if the expiry date (Exp.) printed on the pack has passed.

Do not take ROSUVASTATIN AMNEAL if the packaging is torn or shows signs of tampering.

Do not give ROSUVASTATIN AMNEAL to children.

Before you start to take it

Tell your doctor if you have allergies to:

- any other statin medicines including simvastatin (e.g. ZOCOR, LIPEX); pravastatin (e.g. PRAVACHOL); atorvastatin (e.g. LIPTOR); fluvastatin (e.g. VASTIN)
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you plan to become pregnant or breastfeed.

Tell your doctor if you have 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 from using other lipid-lowering agents.

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you have any unexplained aches or pains in your muscles.

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

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

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you start taking ROSUVASTATIN AMNEAL.

Taking other medicines

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

Some medicines may be affected by ROSUVASTATIN AMNEAL, or may affect how well it works. These include:

- cyclosporine (e.g. SANDIMMUN and NEORAL, used for example, after organ transplant).
- antacids (medicines used to treat heartburn and indigestion). ROSUVASTATIN AMNEAL 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 (e.g. FUCIDIN) used to treat some infections.
- various protease inhibitor combinations with ritonavir used to treat HIV infection (e.g. KALETRA).
- medicines that you buy at the chemist, supermarket or health food shop, including herbal medicines.

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

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take ROSUVASTATIN AMNEAL

How much to take

The dose varies from patient to patient. 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 AMNEAL dose to 20 mg once daily. For most patients a maximum 20 mg ROSUVASTATIN AMNEAL daily dose is sufficient to treat high cholesterol.

A small number of patients may need to further increase their ROSUVASTATIN AMNEAL 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 AMNEAL must not exceed 40 mg daily.

DO NOT INCREASE OR ADJUST YOUR ROSUVASTATIN AMNEAL DOSE YOURSELF.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take ROSUVASTATIN AMNEAL

Swallow the tablets whole with a glass of water.

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

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

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

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

If you forget to take ROSUVASTATIN AMNEAL

If you forget to take a dose of ROSUVASTATIN AMNEAL, 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 you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have any questions about this, check with your doctor or pharmacist.

How long to take ROSUVASTATIN AMNEAL for

Do not stop taking ROSUVASTATIN AMNEAL unless advised by your doctor. ROSUVASTATIN AMNEAL helps lower your blood cholesterol and triglycerides. It does not cure your condition. If you stop taking ROSUVASTATIN AMNEAL, your cholesterol and triglycerides levels may rise again.

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

If you take too much ROSUVASTATIN AMNEAL (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) if you think you or anyone else may have taken too much ROSUVASTATIN AMNEAL. Do this even if there are no signs of discomfort or poisoning.

While you are taking ROSUVASTATIN AMNEAL

Things you must do

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

Before starting any new medicine, tell your doctor or pharmacist that you are taking ROSUVASTATIN AMNEAL.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ROSUVASTATIN AMNEAL.

Stop taking ROSUVASTATIN AMNEAL and contact your doctor immediately if you become pregnant while taking ROSUVASTATIN AMNEAL.

Visit your doctor regularly so they can check on your progress.

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

Things you must not do

Do not use ROSUVASTATIN AMNEAL to treat any other conditions unless your doctor tells you to.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ROSUVASTATIN AMNEAL. Like all other medicines, ROSUVASTATIN AMNEAL may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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.

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

These are rare, but serious side effects which can need urgent medical attention.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using ROSUVASTATIN AMNEAL

Storage

Keep ROSUVASTATIN AMNEAL 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.

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

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

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

Do not leave ROSUVASTATIN AMNEAL in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ROSUVASTATIN AMNEAL, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

ROSUVASTATIN AMNEAL comes in 4 strengths of tablets:

- ROSUVASTATIN AMNEAL 5 mg - round, white, biconvex tablet, debossed with 'ST1' on one side
- ROSUVASTATIN AMNEAL 10 mg - round, pink, biconvex tablet, debossed with 'ST2' on one side
- ROSUVASTATIN AMNEAL 20 mg - round, pink, biconvex tablet, debossed with 'ST3' on one side
- ROSUVASTATIN AMNEAL 40 mg - oval, pink, biconvex tablet, debossed with 'ST4' on one side.

Each pack contains 30 tablets.

Ingredients

The active ingredient in ROSUVASTATIN AMNEAL is rosuvastatin calcium.

- each ROSUVASTATIN AMNEAL 5 mg tablet contains 5 mg of rosuvastatin
- each ROSUVASTATIN AMNEAL 10 mg tablet contains 10 mg of rosuvastatin
- each ROSUVASTATIN AMNEAL 20 mg tablet contains 20 mg of rosuvastatin
- each ROSUVASTATIN AMNEAL 40 mg tablet contains 40 mg of rosuvastatin.

The tablets also contain:

- microcrystalline cellulose
- calcium hydrogen phosphate
- crospovidone
- lactose
- magnesium stearate
- Opadry II White 33G28435 (5 mg tablet only)
- Opadry II Pink 33G240007 (10 mg, 20 mg and 40 mg tablets).

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Amneal Pharma Australia Pty Ltd
12 River Street
South Yarra VIC 3141
Australia

Australian Registration Numbers:

ROSUVASTATIN AMNEAL 5 mg - AUST R 183634

ROSUVASTATIN AMNEAL 10 mg - AUST R 183639

ROSUVASTATIN AMNEAL 20 mg - AUST R 183643

ROSUVASTATIN AMNEAL 40 mg - AUST R 183647

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