

APO-Rosuvastatin

5 MG/ 10 MG/ 20 MG/ 40 MG

Contains the active ingredient rosuvastatin calcium

Consumer Medicine Information

For a copy of a large print leaflet ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about rosuvastatin. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine is used for

The name of your medicine is APO-Rosuvastatin. It contains the active ingredient rosuvastatin (as rosuvastatin calcium).

This medicine is used to lower high cholesterol levels.

Even though you may have normal cholesterol, this medicine 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. Risk factors include: 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 this medicine 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 vessel 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.

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

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

How it 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.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have active liver disease. If tests show you have elevated levels of liver enzymes, this may indicate that you have a problem with your liver.**
- **You have been prescribed any medicine containing fusidic acid.**
- **You are pregnant, you intend to become pregnant or you are not taking an effective method of contraception.**

Rosuvastatin 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.

- **You are breastfeeding.** Rosuvastatin may pass into human breast milk.
- **You are hypersensitive to, or have had an allergic reaction to, rosuvastatin or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts

of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**

The packaging is torn, shows signs of tampering or it does not look quite right. You must not use APO-Rosuvastatin 40 mg if you have:

- **low thyroid hormone levels (hypothyroidism)**
- **personal or family history of hereditary muscular disorders**
- **history of muscular problems from using other lipid-lowering agents**
- **history of heavy alcohol use**
- **Asian heritage**
- **been prescribed another class of lipid-lowering agent called a fibrate**
- **severe kidney impairment**
- **situations that may increase rosuvastatin blood levels (ask your doctor).**

Before you start to take it

Before you start taking this, tell your doctor if:

1. You have allergies to:
 - any other statins such as simvastatin, pravastatin, atorvastatin, fluvastatin
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - liver problems
 - kidney problems
 - low thyroid hormone levels (hypothyroidism)

- personal or family history of muscle disorders
 - history of muscle problems from using other lipid-lowering agents
 - unexplained aches or pains in your muscles.
3. You regularly drink large amounts of alcohol. Excessive alcohol consumption may not be safe in patients taking this medicine.
 4. You are currently pregnant, you plan to become pregnant or you are not taking an effective method of contraception. Do not take this medicine whilst pregnant.
 5. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding.
 6. You are planning to have surgery or an anaesthetic.
 7. You are currently receiving or are planning to receive dental treatment.
 8. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with rosuvastatin. These include:

- cyclosporins (may be used after organ transplant)
- antacids (medicines used to treat heartburn and indigestion). This medicine can be taken 2 hours before or 2 hours after taking an antacid
- warfarin (used to stop blood clots)
- clopidogrel (used to prevent blood clots)
- gemfibrozil (used to lower blood lipids)
- fusidic acid used to treat some infections, you must not take this medicine with fusidic acid
- various protease inhibitors used in combination with ritonavir to treat HIV infection.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with rosuvastatin.

Your doctor can tell you what to do if you are taking any of these medicines. These medicines may affect the way rosuvastatin works.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition, your ethnicity and whether you are taking any other medicines.

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 their condition.

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.

DO NOT INCREASE OR ADJUST YOUR ROSUVASTATIN DOSE YOURSELF.

How to take it

Tablets must not be broken or crushed and must be swallowed whole with a glass of water.

When to take it

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

Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

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

This medicine helps lower your blood cholesterol and triglycerides. It does not cure your condition. If you stop taking this medicine, your cholesterol and triglyceride levels may rise again.

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

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is within 6 hours your next dose is due, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

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

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

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant, are planning to become pregnant or are not taking an effective method of contraception. Stop taking this medicine immediately if you are pregnant.
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- 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 tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

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

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking rosuvastatin or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Tell your doctor if you notice any of the following:

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

Tell your doctor if you notice an increase in your need to urinate if you are 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.

These may be serious side effects and you may need medical attention:

- aching muscles, muscle tenderness or weakness not caused by exercise, particularly if you also have a fever or generally feel unwell
- severe skin reaction with painful red areas, large blisters and peeling of layers of the skin, may be accompanied by fever and chills, aching muscles and generally feeling unwell
- difficulty breathing, coughing, particularly if you also feel

generally unwell (e.g. fatigue, weight loss, fever).

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to rosuvastatin, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

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

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C and protected from light and moisture.

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, light 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 it has passed its

expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What this medicine looks like*

APO-Rosuvastatin 5mg tablets:

White, round, biconvex, film coated tablet, engraved "APO" on one side, "ROS" over "5" on the other side.

APO-Rosuvastatin 10mg tablets:

White, round, biconvex, film-coated tablet, engraved "APO" on one side, "ROS" over "10" on the other side.

APO-Rosuvastatin 20mg tablets:

White, round, biconvex, film-coated tablet, engraved "APO" on one side, "ROS" over "20" on the other side.

APO-Rosuvastatin 40mg tablets:

White, oval, biconvex, film-coated tablet, engraved "APO" on one side, "ROS40" on the other side.

Tablets are packaged in blister packs of 7 and 30.

Tablets are also packaged in bottles of 30, 100 and 500.

* Not all strengths, pack types and/or pack sizes are marketed. Alternative brands should be used if required.

Ingredients

Each tablet contains 5 mg, 10 mg, 20 mg or 40 mg of rosuvastatin calcium, as the active ingredient.

The tablets also contain the following inactive ingredients:

- lactose
- cellulose-microcrystalline
- crospovidone
- magnesium stearate
- colloidal anhydrous silica
- hypromellose
- hydroxypropylcellulose
- macrogol 8000.

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

Australian Registration Numbers

APO-Rosuvastatin 5 mg tablets
(blister pack): AUST R 183061.

APO-Rosuvastatin 10 mg tablets
(blister pack): AUST R 183073.

APO-Rosuvastatin 20 mg tablets
(blister pack): AUST R 183057.

APO-Rosuvastatin 40 mg tablets
(blister pack): AUST R 183074.

APO-Rosuvastatin 5 mg tablets
(bottle): AUST R 183075.

APO-Rosuvastatin 10 mg tablets
(bottle): AUST R 183067.

APO-Rosuvastatin 20 mg tablets
(bottle): AUST R 183060.

APO-Rosuvastatin 40 mg tablets
(bottle): AUST R 183059.

Sponsor

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