

ROSTOR™ 5, 10, 20 & 40

Rosuvastatin (as calcium) 5 mg, 10 mg, 20 mg and 40 mg film-coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about ROSTOR.

It does not contain all the available information.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ROSTOR 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 ROSTOR is used for

ROSTOR is used to lower high cholesterol levels.

Even though you may have normal cholesterol, ROSTOR 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 ROSTOR 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 ROSTOR works

ROSTOR 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. ROSTOR does not reduce the cholesterol that comes from fat in food. Because of this, when you are taking ROSTOR, 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 ROSTOR and told you what dose to take. Your doctor may need to check your cholesterol levels before prescribing ROSTOR 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.

ROSTOR is only available with a doctor's prescription

There is no evidence that ROSTOR is addictive.

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

Before you take it

When you must not take it

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

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

Do not use ROSTOR if you are breast feeding.

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

Do not use ROSTOR 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 ROSTOR if you have been prescribed any medicine containing fusidic acid.

Do not use ROSTOR 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;**
- **severe kidney impairment; or**
- **situations that may increase ROSTOR blood levels.**

Do not take ROSTOR after the use by (expiry) date printed on the pack has passed.

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

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

If you are not sure whether you should start taking this medicine, talk to your doctor.

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:

- **you have any allergies to:**
 - any other statins such as simvastatin, pravastatin, atorvastatin or fluvastatin; or
 - 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.

- **you have any of these medical conditions:**

- liver problems;
- kidney problems;
- low thyroid hormone levels (hypothyroidism);
- a personal or family history of muscle disorders; or
- a history of muscle problems from using other lipid-lowering agents.

It may not be safe for you to take ROSTOR 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 ROSTOR.

- **you have any unexplained aches or pains in your muscles.**

- **you regularly drink large amounts of alcohol.**

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

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines including

- cyclosporin used, for example, after organ transplant;
- antacids (medicines used to treat heartburn and indigestion). ROSTOR can be taken 2 hours before or 2 hours after taking an antacid;
- warfarin used to stop blood clots;
- gemfibrozil, used to lower blood lipids;
- fusidic acid, used to treat some infections;
- various protease inhibitors used in combination with ritonavir to treat HIV infection; or
- medicines that you buy at the chemist, supermarket or health

food shop, including herbal medicines.

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

Effects on driving and using machinery

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

ROSTOR generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, ROSTOR may cause dizziness in some people.

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

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

DO NOT INCREASE OR ADJUST YOUR ROSTOR DOSE YOURSELF.

How and when to take it:

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

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

Swallow each tablet whole with a drink of water.

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

While taking ROSTOR 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.

ROSTOR helps lower your blood cholesterol and triglycerides. It does not cure your condition. If you stop taking ROSTOR, 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 ROSTOR, 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):

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

While you are taking it

Things you must do:

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking ROSTOR.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking ROSTOR.

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

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

Things you must not do:

Do not stop taking ROSTOR, or lower the dose, unless you have discussed it with your doctor.

Do not let yourself run out of tablets over the weekend or on holidays.

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

Do not give ROSTOR 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 ROSTOR.

ROSTOR helps most people 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.

Do not be alarmed by the 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; or
- 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;
- bleeding or bruising more easily than normal;

- yellowing of the skin and/or eyes, also called jaundice;
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine;
- numbness or weakness of the arms and legs;
- depression, sleep disorders;
- breast enlargement in men; or
- 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 ROSTOR.

Ask your doctor or pharmacist if you do not understand anything in this list.

After taking it

Storage:

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

If you take ROSTOR out of the blister pack it will not keep well.

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

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

Do not leave ROSTOR on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep your ROSTOR tablets where children cannot reach them.

A locked cupboard, at least one-and-a-half metres above the ground, is a good place to store medicines.

Disposal:

Ask your pharmacist what to do with any ROSTOR 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 ROSTOR looks like

ROSTOR* 5, 10, 20 & 40 (5, 10, 20 & 40 mg rosuvastatin as calcium) are presented in pack size of 7, 28 or 30 tablets in blister pack.

ROSTOR 5

Pink coloured, oval shaped, biconvex film-coated tablets debossed with "J" on one side and '53' on the other.

ROSTOR 10

Pink coloured, round shaped, biconvex film-coated tablets debossed with "J" on one side and '54' on the other.

ROSTOR 20

Pink coloured, round shaped, biconvex film-coated tablets debossed with "J" on one side and '55' on the other.

ROSTOR 40

Pink coloured, oval shaped, biconvex film-coated tablets debossed with "J" on one side and '56' on the other.

*Some of these presentations and pack sizes are not marketed.

Ingredients

Active ingredient

Rosuvastatin (as calcium)

Other ingredients

- crospovidone;
- lactose;
- microcrystalline cellulose;
- calcium hydrogen phosphate anhydrous;
- magnesium stearate; and
- Opadry II complete coating system 32K84302 PINK.

Sponsor/Marketing Authorisation Holder

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