

APX-ROSUVASTATIN

Rosuvastatin calcium

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions people ask about APX-ROSUVASTATIN. It does not contain all the information that is known about APX-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 APX-ROSUVASTATIN 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 APX-ROSUVASTATIN IS FOR

APX-ROSUVASTATIN is used to lower high cholesterol levels.

Although 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 male, 50 years or over, or female, 60 years or over, and have at least 2 risk factors for having a heart attack or stroke. Examples of such risk factors would be 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 determine whether Rosuvastatin should be prescribed 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 APX-ROSUVASTATIN works

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

APX-ROSUVASTATIN is not addictive.

APX-ROSUVASTATIN is not recommended for use in children as its effects in children have not been established.

BEFORE YOU USE APX-ROSUVASTATIN

When you must not use it

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

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

Do not use APX-ROSUVASTATIN if you are breast feeding.

We do not know if your baby can take in APX-ROSUVASTATIN from breast milk if you are breast feeding.

Do not use APX-ROSUVASTATIN 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 APX-ROSUVASTATIN 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 APX-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 APX-ROSUVASTATIN 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 use 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 APX-ROSUVASTATIN 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 APX-ROSUVASTATIN.

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 APX-ROSUVASTATIN.

Taking other medicines

Tell your doctor if you are taking any other medicines including

- ciclosporin (e.g. SANDIMMUN and NEORAL, used, for example, after organ transplant)
- antacids (medicines used to treat heartburn and indigestion). APX-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)
- 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 (e.g. FUCIDIN) used to treat some infections
- various protease inhibitor combinations with ritonavir used to treat HIV infection
- 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 APX-ROSUVASTATIN should be used together with any of these medicines, or may wish to adjust the dose of APX-ROSUVASTATIN or the other medicines. These medicines may

affect the way APX-ROSUVASTATIN 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 APX-ROSUVASTATIN.

Effects on driving and using machinery

Be careful driving a car or operating machinery until you know if APX-ROSUVASTATIN affects you.

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

TAKING APX-ROSUVASTATIN

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, the usual starting dose is one 5 mg or 10 mg tablet taken once daily. Your doctor will 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 daily dose of 20 mg APX-ROSUVASTATIN is sufficient to treat high cholesterol.

A small number of patients may need to further increase their APX-ROSUVASTATIN dose to 40 mg once daily, for example patients whose high cholesterol is hereditary.

If your cholesterol is not high but you have risk factors 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 APX-ROSUVASTATIN must not exceed 40 mg daily.

DO NOT INCREASE OR ADJUST YOUR APX-ROSUVASTATIN DOSE YOURSELF.

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

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

Swallow each tablet whole with a drink of water.

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

While taking APX-ROSUVASTATIN 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. APX-ROSUVASTATIN helps lower your blood cholesterol and triglycerides. It does not cure your condition. If you stop taking APX-ROSUVASTATIN, 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 APX-ROSUVASTATIN, 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.

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 APX-ROSUVASTATIN even if there are no signs of discomfort or poisoning.

WHILE YOU ARE TAKING APX-ROSUVASTATIN

Things you must do

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

Stop taking APX-ROSUVASTATIN and contact your doctor immediately if you become pregnant while you are taking APX-ROSUVASTATIN.

Things you must not do

Do not stop taking APX-ROSUVASTATIN 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 APX-ROSUVASTATIN.

APX-ROSUVASTATIN 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 are all usually mild side effects.

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 casualty 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 APX-ROSUVASTATIN.

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

You may not experience any of them.

AFTER TAKING APX-ROSUVASTATIN

Storage

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

If you take APX-ROSUVASTATIN out of the blister pack it will not keep well.

Keep it in a cool dry place where the temperature stays below 25°C. Protect from light and moisture.

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 APX-ROSUVASTATIN 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 APX-ROSUVASTATIN looks like

APX-ROSUVASTATIN 5 are Yellow, round, biconvex, coated tablet debossed with "ROS" over "5" on one side and plain on the other side.

APX-ROSUVASTATIN 10 are Pink, round, biconvex, coated tablet debossed with "ROS" over "10" on one side and plain on the other side

APX-ROSUVASTATIN 20 are Pink, round, biconvex, coated tablet debossed with "ROS" over "20" on one side and plain on the other side.

APX-ROSUVASTATIN 40 are Pink, oval, biconvex, coated tablet debossed with "ROS" on one side and "40" on the other side.

Available in blister packs of 30 tablets.

Ingredients:

APX-ROSUVASTATIN contains rosuvastatin calcium as the active ingredient, equivalent to rosuvastatin 5mg, 10mg, 20mg and 40mg.

The tablets also contain the following inactive ingredients:

- Microcrystalline cellulose
- Colloidal anhydrous silica
- Crospovidone
- Lactose monohydrate
- Magnesium stearate
- Opadry II Yellow 33K620000 (ARTG 109007, contains hypromellose, titanium dioxide, lactose monohydrate, triacetin, quinolone yellow aluminium lake, sunset yellow FCF, indigo carmine) – 5mg
- Opadry II Pink 33K640001 (ARTG 109004, contains hypromellose, titanium dioxide, lactose monohydrate, triacetin, sunset yellow FCF, indigo carmine, allura red AC aluminium lake) – 10mg & 20mg
- Opadry II Pink 33K640000 (ARTG 109005, contains hypromellose, titanium dioxide, lactose monohydrate, triacetin, sunset yellow FCF, indigo carmine, allura red AC aluminium lake) – 40mg

This medicine contains sugars as lactose.

Supplier:

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

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