

PATIENT INFORMATION LEAFLET

Crestor® 5 mg, 10 mg and 20 mg tablet

rosuvastatin

Read all of this leaflet carefully before you start taking Crestor

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

What Crestor is used for

Crestor belongs to a group of medicines called statins.

You have been prescribed Crestor because:

- You have a high cholesterol level. This means you are at risk from a heart attack or stroke.

You have been advised to take a statin, because changing your diet and taking more exercise were not enough to correct your cholesterol levels. You should continue with your cholesterol-lowering diet and exercise while you are taking Crestor.

Or

- You have other factors that increase your risk of having a heart attack, stroke or related health problems.

Heart attack, stroke and other problems can be caused by a disease called atherosclerosis. Atherosclerosis is due to build up of fatty deposits in your arteries.

Before you take Crestor

When you must not take it

Do not take Crestor:

- If you have ever had an allergic reaction to Crestor or similar medicines,, or to any of its ingredients. Crestor contains lactose, which may cause a problem in a small number of patients who are allergic to lactose.
- If you are pregnant, trying to become pregnant or are breast-feeding. If you become pregnant while taking Crestor stop taking it immediately and tell your doctor.
- If you have liver disease.
- If you have severe kidney problems.
- If you have repeated or unexplained muscle aches or pains.
- If you take a drug called ciclosporin (used, for example, after organ transplants)

If any of the above applies to you (or you are in doubt), please go back and see your doctor.

Before you start to take it

Take special care with Crestor and tell your doctor or pharmacist:

- If you have ever been told that you have problems with your kidneys.
- If you have ever been told that you have problems with your liver.
- If you have had unexplained muscle aches or pains, a history of muscle pains, or a previous history of muscle problems when taking other cholesterol-lowering medicines.

- If you regularly drink large amounts of alcohol.
- If you take other medicines called fibrates to lower your cholesterol.
- If you take medicines used to fight the HIV infection e.g. lopinavir/ritonavir, please see Taking other medicines.
- If you have high blood sugar or raised HbA1c.

While taking it:

Tell your doctor or pharmacist:

- If you have any unexplained aches or pains in your muscles especially if you feel unwell or have a fever.

If you become seriously ill, receive treatment for another condition or you go into hospital, let the medical staff looking after you know that you are taking Crestor, as it may be better for you to stop taking it for a short time.

Taking other medicines

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines including any you bought without a prescription.

Tell your doctor if you are taking any of the following: ciclosporin (used for example, after organ transplants), warfarin (or any other drug used for thinning the blood), fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe), indigestion remedies (used to neutralise acid in your stomach), erythromycin (an antibiotic), or medications used to fight the HIV infection – please see Take special care with Crestor. The effects of these medicines could be changed by Crestor or they could change the effects of Crestor.

How to take Crestor

How much to take

Always take Crestor as your doctor has told you. You should check with your doctor or pharmacist if you are not sure what to do.

Starting dose

In adults treatment with Crestor is usually started with the 10 mg dose taken once daily, even if you have taken a higher dose of a different statin before. Some people may be asked to start treatment with one 5 mg tablet taken once a day. The choice of your start dose will depend upon:

- Your cholesterol level.
- The level of risk you have of experiencing a heart attack or stroke.
- Whether you may be more sensitive to possible side effects.

Increasing the dose and maximum daily dose

After checking the amount of lipids in your blood, your doctor may decide to increase your dose until you are taking the amount of Crestor that is right for you. There will be a gap of four weeks between every dose adjustment.

In adults the maximum daily dose of Crestor is 40 mg. It is only for patients with high cholesterol levels and at high risk of heart attacks or stroke whose cholesterol levels are not lowered enough with 20 mg. A dosage of 40 mg once daily should only be initiated under specialist supervision.

In children 10-17 years of age the maximum daily dose is 20 mg. Crestor should not be given to children younger than 10 years.

When to take it**Taking your tablets**

Swallow each tablet whole with a drink of water.

Take Crestor once daily. You can take it at any time of the day with or without food.

Try to take your tablet at the same time every day to help you to remember to take it.

Regular cholesterol checks

It is important to go back to your doctor for regular cholesterol checks, to make sure your cholesterol has reached and is staying at the correct level.

Your doctor may decide to increase your dose so that you are taking the amount of Crestor that is right for you.

How long to take it

Do not stop taking your Crestor, even if you are feeling well, unless your doctor tells you to or unless you become pregnant.

Talk to your doctor if you want to stop taking Crestor. Your cholesterol levels might increase again if you stop taking Crestor.

If you forget to take it

Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for the one you have missed.

If you take too much (overdose)

Contact your doctor or nearest hospital for advice.

Things to be careful of**Pregnancy and breast-feeding**

Do not take Crestor if you are pregnant, trying to become pregnant or are breast-feeding. If you become pregnant while taking Crestor stop taking it immediately and tell your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Crestor is not expected to affect your ability to drive a car or to operate machinery.

Side effects

Like all medicines, Crestor can cause side effects, although not everybody gets them.

It is important that you are aware of what these side effects may be. They are usually mild and disappear after a short time.

Stop taking Crestor and seek medical help immediately if you have any of the following allergic reactions:

- Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat.
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing.
- Severe itching of the skin (with raised lumps).

Also, stop taking Crestor and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than you might expect. Muscle symptoms are more common in children and adolescents than in adults. As with other statins, a very small number of people have experienced unpleasant muscle effects and rarely these have gone on to become a potentially life threatening muscle damage known as rhabdomyolysis.

Common possible side effects (these may affect between 1 in 10 and 1 in 100 patients):

- Headache
- Muscle pain
- Stomach pain
- General feeling of weakness
- Constipation
- Dizziness
- Feeling sick

Uncommon possible side effects (these may affect between 1 in 100 and 1 in 1,000 patients):

- Skin rash
- Itching
- Hives

Rare possible side effects (these may affect between 1 in 1,000 and 1 in 10,000 patients):

- Severe allergic reaction – signs include swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing, a severe itching of the skin (with raised lumps). If you think you are having an allergic reaction, stop taking Crestor and seek medical help immediately.
- Muscle damage in adults – as a precaution, stop taking Crestor and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than expected.
- A severe stomach pain (inflamed pancreas).
- Increase in liver enzymes in the blood.

Very rare possible side effects (these may affect less than 1 in 10,000 patients):

- Jaundice (yellowing of the skin and eyes).
- Hepatitis (an inflamed liver).
- Joint pain.
- Memory loss.

Side effects of unknown frequency and reported less frequently than 1% may include:

- Sleep disturbances, including insomnia (difficulty in sleeping) and nightmares.
- Depression.
- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your Crestor tablets.
- Traces of blood in your urine (generally temporary and not associated with worsening kidney function).
- Increases in HbA1c - (a measure of the average amount of sugar in your blood over time).

If any of the side effects become troublesome, or if you experience any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Storage and Disposal of Crestor

Keep out of the reach and sight of children.

Do not use Crestor after the expiry date which is stated on the box/blisters/label after EXP. The expiry date refers to the last day of the month.

Store your tablets below 25°C.

Product description

Crestor comes in blister packs containing 28 tablets.

Crestor comes in three tablet strengths:

- Crestor 5 mg film-coated tablets are yellow, round and marked with ZD4522 and 5 on one side and plain on the reverse.
- Crestor 10 mg film-coated tablets are pink, round and marked with ZD4522 and 10 on one side and plain on the reverse.
- Crestor 20 mg film-coated tablets are pink, round and marked with ZD4522 and 20 on one side and plain on the reverse.

Ingredients

The active substance in Crestor is rosuvastatin. Crestor film-coated tablets contain rosuvastatin calcium equivalent to 5 mg, 10 mg, or 20 mg of rosuvastatin.

The other ingredients are: lactose monohydrate, microcrystalline cellulose, calcium phosphate, crospovidone, magnesium stearate, hypromellose, triacetin, titanium dioxide (E171). Crestor 10 mg and 20 mg film-coated tablets also contain red iron oxide (E172). Crestor 5 mg film-coated tablets also contain yellow iron oxide (E172).

Malaysian registration numbers:

Crestor 5mg: MAL20051356AR

Crestor 10mg: MAL20041089AR

Crestor 20mg: MAL20051357AR

Manufacturer

IPR Pharmaceuticals Inc., Puerto Rico

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