

# Crestor®

## Rosuvastatin 5 mg, 10 mg, 20 mg or 40 mg tablets

### CONSUMER MEDICINE INFORMATION

#### What is in this leaflet

This leaflet answers some of the common questions people ask about **Crestor**. It does not contain all the information that is known about **Crestor**.

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

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Crestor** 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 Crestor is used for

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 food) 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.

**Crestor** 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. It also lowers the risk of heart attacks and strokes.

Cholesterol is present in many foods and is also made by your body. While you are taking **Crestor**, you should reduce saturated fats, trans fats and cholesterol in your 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 to you why you are being treated with **Crestor**, and told you what dose to take. Your doctor may need to check your cholesterol levels before prescribing **Crestor** or changing your dose. Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

**Crestor** is not addictive.

**Crestor** is only available with a doctor’s prescription.

#### Before you use Crestor

##### **When you must not use it**

Do not use **Crestor** if you are pregnant or intend to become pregnant. Ask your doctor about effective methods of contraception. If you become pregnant, stop taking **Crestor** as soon as you find out and see your doctor immediately.

**Do not use Crestor if you are breastfeeding.** We do not know if your baby can take in **Crestor** from breast milk if you are breast feeding.

**Do not use Crestor if you have active liver disease.**

**Do not use Crestor 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**
- **situations that may increase Crestor blood levels**

**Do not use Crestor 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 **Crestor** if the packaging is torn or shows signs of tampering. Do not use **Crestor** 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, pravastatin, atorvastatin, fluvastatin.
- any other 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 **Crestor** 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 **Crestor**.

**3. you have any unexplained aches or pains in your muscles or have a history of muscle pain or if you have muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.**

**4. you regularly drink large amounts of alcohol.** Excessive alcohol consumption may not be safe in patients taking **Crestor**.

**5. you have high blood sugar or raised HbA1c.**

**Taking other medicines**

**You must tell your doctor if you are taking any other medicines, including**

- ciclosporin (used for example, after organ transplant)
- warfarin (or any other medicine used to stop blood clots)
- gemfibrozil (used to lower blood lipids)

- antiviral medications such as lopinavir / ritonavir (used to fight infections including infection with HIV)
- antacids (medicines used to treat heartburn and indigestion). **Crestor** can be taken 2 hours before or 2 hours after taking an antacid.
- fusidic acid (used to treat some infections)
- medicines that you buy at the chemist, supermarket or health food shop, including herbal medicines.

Your doctor will consider if **Crestor** should be used together with any of these medicines, or may wish to adjust the dose of **Crestor** or the other medicines. These medicines may affect the way **Crestor** 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 him/her before you take any **Crestor**.

### How to use Crestor

Your doctor will have explained why you are being treated with **Crestor** and told you what dose to take. Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

#### **How much to take**

The usual starting dose is one 10 mg tablet taken once daily. Depending on your condition and ethnic background, your doctor will decide the most appropriate starting dose for you.

Your doctor will monitor your cholesterol and triglyceride levels during your treatment, and, if needed, may increase your **Crestor** dose to 20 mg once daily. For most patients a maximum 20 mg **Crestor** daily dose is sufficient to treat their condition.

A small number of patients may need to further increase their **Crestor** dose to 40 mg once daily, for example patients whose high cholesterol is hereditary. Your doctor will advise you on the dose that is right for your condition. The daily dose of **Crestor** must not exceed 40 mg daily.

**Do not increase or adjust your Crestor dose yourself.**

#### **When to take it**

Take **Crestor** once a day, at about the same time each day. Keeping a regular time for taking **Crestor** will help to remind you to take it. Swallow each tablet whole with a drink of water. **Crestor** can be taken at any time of the day. It does not matter whether you take **Crestor** with food or on an empty stomach.

#### **How long to take it**

**You must continue to take it as directed by your doctor.**

**Crestor** helps lower your blood cholesterol and triglycerides. It does not cure your condition. If you stop taking **Crestor**, 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 Crestor, 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.

### While you are using Crestor

**Things you must do**

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

You also need to follow your doctor's dietary advice, control your weight and exercise regularly.

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

If you become seriously ill or go into hospital, tell the doctor or nurse that you are taking **Crestor**.

**Things you must not do**

**Do not stop taking Crestor unless you have discussed it with your doctor.**

**Things to be careful of**

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

**Crestor** generally does not cause any problems with your ability to drive a car or operate machinery.

However, as with many other medicines, **Crestor** may cause dizziness in some people.

**In case of overdose**

**Please telephone your doctor or the National Poisons Centre Ph: 0800 POISON (0800 764 766) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Crestor, even if there are no signs of discomfort or poisoning.**

**Side Effects**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Crestor.** 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 these 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
- aches or pains in your muscles
- weakness or tiredness
- constipation
- dizziness
- nausea (feeling sick)
- stomach pain
- skin rash, itching or hives
- memory loss
- stiff or painful joints (arthralgia)

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you have the following symptoms of an allergic reaction:**

- If you develop difficulty in breathing with or without swelling of the face, eyelids, lips, tongue and/or throat;
- If you develop swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing;
- If you develop severe itching of the skin (with raised lumps).

An allergic reaction can be serious. You may need urgent medical attention.

In addition, unpleasant muscle effects have occurred in a small number of people who take **Crestor**. So, as a precaution, if you have any aches or pains in your muscles for which you do not know a reason or which go on for longer than you might expect you should talk to your doctor as soon as possible. Your doctor may perform a blood test to check the condition of your muscles.

Like other statins, increases in HbA1c, a measure of blood sugar, and onset of diabetes have been reported in patients taking **Crestor**.

**Important:** This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Crestor**.

**Tell your doctor if you notice anything else that is making you feel unwell or bothering you.**

#### After using Crestor

##### Storage

**Keep your tablets in the blister pack until it is time to take them.** If you take **Crestor** out of the blister pack it will not keep well.

**Crestor** should be kept in a cool dry place where the temperature stays below 30°C. Do not store **Crestor** or any other medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.

**Keep Crestor 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 Crestor in the car on hot days.**

##### Disposal

Ask your pharmacist what to do with **Crestor** after you have used it, or you find that the expiry date has passed.

#### What Crestor looks like

**Crestor 5 mg** are yellow, round, film-coated biconvex tablets engraved "ZD4522 5" on one side.

**Crestor 10 mg** are pink, round, film-coated biconvex tablets engraved "ZD4522 10" on one side.

**Crestor 20 mg** are pink, round, film-coated biconvex tablets engraved "ZD4522 20" on one side.

**Crestor 40 mg** are pink, oval, film-coated biconvex tablets engraved "ZD4522" on one side and "40" on the other side.

**Crestor** tablets are available in blister packs of 7 tablets (5 and 10 mg only) or 30 tablets.

##### **Ingredients:**

**Active ingredient:** rosuvastatin calcium as the active ingredient equivalent to rosuvastatin 5 mg, 10 mg, 20 mg and 40 mg.

Inactive ingredients:

- lactose
- cellulose microcrystalline (E460)
- calcium phosphate
- crospovidone
- magnesium stearate (E572)
- hypromellose
- glyceryl triacetate
- titanium dioxide (E171)
- ferric oxide, red (E172) (10, 20 and 40 mg)
- iron oxide yellow (E172) (5 mg only)

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AstraZeneca Limited  
P299 Private Bag 92175  
Auckland 1142.  
New Zealand  
Telephone: (09) 306 5650.

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