

# CRESTOR<sup>®</sup>

Rosuvastatin calcium

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## Consumer Medicine Information

Name of consumer

Address of consumer

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### What is in this leaflet

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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 and 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 for

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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.

**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.

Cholesterol is present in many foods and is also made by your body. **CRESTOR** does not reduce the cholesterol that comes from fat in food. Because of this, when you are taking **CRESTOR**, 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 **CRESTOR** and told you what dose to take. Your doctor may need to check your cholesterol levels before prescribing **CRESTOR** 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.

**CRESTOR** is not addictive.

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

### Before you use CRESTOR

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#### *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 breast feeding.**

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 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 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 **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**

#### **4. you regularly drink large amounts of alcohol**

Excessive alcohol consumption may not be safe in patients taking **CRESTOR**.

### ***Taking other medicines***

**Tell your doctor if you are taking any other medicines including**

- cyclosporin (e.g. SANDIMMUN and NEORAL, used, for example, after organ transplant)
- antacids (medicines used to treat heartburn and indigestion). **CRESTOR** can be taken 2 hours before or 2 hours after taking an antacid.
- warfarin (e.g. COUMADIN and MAREVAN, used to stop blood clots)
- gemfibrozil (e.g. LOPID, JEZIL, and AUSGEM, used to lower blood lipids).
- Lopinavir/ritonavir combination (KALETRA) used to treat HIV infection
- 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 them before you take **CRESTOR**.

### ***Effects on driving and using machinery***

**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.

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## **Using CRESTOR**

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

The usual starting dose is one 5 mg or 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's right for your condition. The daily dose of CRESTOR must not exceed 40 mg daily.

### **DO NOT INCREASE OR ADJUST YOUR CRESTOR DOSE YOURSELF.**

**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.**

**While taking CRESTOR 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.** 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.

### **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 CRESTOR even if there are no signs of discomfort or poisoning.**

## **While you are using it**

### **Things you must do**

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

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

### **Things you must not do**

**Do not stop taking CRESTOR 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 CRESTOR.**

CRESTOR 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 mild side effects of CRESTOR.

**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
- swelling of the face, eyelids and lips

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 CRESTOR.

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## After using it

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### 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.

**Keep it in a cool dry place where the temperature stays below 30°C. 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.**

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## Disposal

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**Ask your pharmacist what to do with any **CRESTOR** tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.**

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## Product description

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### What **CRESTOR** looks like

**CRESTOR 5mg** are yellow, round, film-coated, biconvex tablets engraved “ZD4522 5” on one side.

**CRESTOR 10mg** are pink, round, film-coated, biconvex tablets engraved “ZD4522 10” on one side.

**CRESTOR 20mg** are pink, round, film-coated, biconvex tablets engraved “ZD4522 20” on one side.

**CRESTOR 40mg** 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 30 tablets.

### Ingredients:

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

plus,

Lactose

Cellulose Microcrystalline (E460)

Calcium phosphate

Crospovidone

Magnesium stearate (E572)

Hypromellose

Glyceryl triacetate

The 5mg tablets are coloured with titanium dioxide and iron oxide yellow.

The 10mg, 20mg and 40mg tablets are coloured with titanium dioxide (E171) and iron oxide red (E172).

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## Manufacturer

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AstraZeneca Pty Ltd  
ABN 54 009 682 311  
Alma Road  
**NORTH RYDE NSW 2113**

This leaflet was prepared in February 2007.

Australian Registration Numbers:

5mg	119120
10mg	119128
20mg	119130
40mg	119135

**CRESTOR** is a trade mark of the AstraZeneca group of companies.