

1.5.5.4 FINAL PATIENT INFORMATION LEAFLET

Read this entire leaflet carefully before you start taking CRESTOR.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- CRESTOR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS: S 4

NAME OF MEDICINAL PRODUCT (and Dosage Form):

Crestor® 5, Crestor® 10, Crestor® 20, Crestor® 40 (Tablet)

The active substance is rosuvastatin.

1. WHAT CRESTOR CONTAINS:

The active substance is rosuvastatin. CRESTOR tablets have either 5 mg, 10 mg, 20 mg or 40 mg of rosuvastatin in them. The other ingredients are: calcium phosphate, crospovidone, glycerol triacetate, hypromellose, iron oxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose and titanium dioxide.

2. WHAT CRESTOR IS USED FOR:

CRESTOR belongs to a group of medicines called HMG-CoA reductase inhibitors (also known as “statins”). CRESTOR is used to lower high levels of blood fats which are called

lipids, usually when changes to diet and exercise have failed to do this. CRESTOR in addition to diet lowers “bad” cholesterol (LDL-C) and increases “good” cholesterol (HDL-C) in the blood.

In adult patients who have an increased risk of cardiovascular disease, CRESTOR has been shown to reduce non-fatal heart attacks, non-fatal strokes and procedures such as stents and bypass surgery for heart disease.

3. BEFORE YOU TAKE CRESTOR:

Do not take CRESTOR:

- If you are hypersensitive (allergic) to rosuvastatin, similar medicines, or to any of the other ingredients of CRESTOR.
- If you currently have liver disease.
- If you are taking a medicine called ciclosporin (used for example, after an organ transplant)
- If you have any disease of the muscles.
- If you are pregnant, trying to become pregnant or are breastfeeding.

Take special care with CRESTOR:

Before taking your tablets, tell your doctor, pharmacist or other health care professional:

- If you have ever been told that you have problems with your liver or kidneys.
- If you have any unexplained aches or pains in your muscles or have a history of muscle pain.

- If you regularly drink large amounts of alcohol.
- If you have an underactive thyroid gland.
- If you are taking protease inhibitors (used to fight the HIV infection).

Whilst taking your tablets, tell your doctor, pharmacist or other health care professional if you have any unexplained aches or pains in your muscles.

If you become seriously ill 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 CRESTOR with food and drink:

CRESTOR may be given with or without food.

Pregnancy and breastfeeding:

Do not use CRESTOR if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby while taking CRESTOR please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

CRESTOR is not expected to affect your ability to drive or to operate machinery.

Important information about some of the ingredients of CRESTOR:

Your tablet contains lactose, which may cause a problem in a small number of patients who are intolerant to lactose.

Taking other medicines with CRESTOR:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of CRESTOR with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or other health care professional for advice.

In particular you must tell your doctor if you are taking the following medicines:

Ciclosporin (used for example, after an organ transplant).

Warfarin (or any other medicine used for thinning your blood).

Gemfibrozil (medicine used to lower the fat in your blood).

Antacids (medicines used to treat heartburn)

If you are taking protease inhibitors (used to fight the HIV infection).

4. HOW TO TAKE CRESTOR:

Always take CRESTOR exactly as your doctor has instructed you. The instructions on the label should remind you of what they have said. You should check with your doctor or pharmacist if you are unsure.

The usual dose:

Treatment with CRESTOR is usually started with one 5 mg tablet taken once daily. Some people may be asked to start treatment with either a 10 mg or a 20 mg tablet taken once daily.

People of Asian origin should start treatment with one 5 mg tablet taken once a day.

After checking the amount of fats in your blood, your doctor may decide to increase your dose until you are taking the amount of CRESTOR that is right for you. In adults the maximum daily dose is 40 mg. In children 10 years of age and above, the maximum daily dose is 20 mg.

If you have the impression that the effect of CRESTOR is too strong or too weak, talk to your doctor or pharmacist. Do not stop taking your tablets even if you are feeling well, unless your doctor tells you to or unless you become pregnant.

When to take your CRESTOR:

You can take your tablet at any time of the day, with or without food. However try to take your tablet at the same time each day, this will help you to remember to take it.

Swallow each tablet whole with a drink of water.

If you take more CRESTOR than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take CRESTOR:

Skip the missed dose (tablet) and take your next dose as usual.

Do not take a double dose to make up for the one you missed.

5. POSSIBLE SIDE-EFFECTS:

CRESTOR can have side-effects.

Some people may develop a severe allergic reaction.

Stop taking CRESTOR and see your doctor, or other health care professional immediately if the following occurs:

- If you develop difficulty in breathing with or without swelling of the face, 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).

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 a doctor as soon as possible. The doctor may perform a blood test to check the condition of your muscles.

Tell your doctor if you notice any of the following:

Frequent:

Headache, dizziness, constipation, nausea (feeling like you want to vomit), stomach pain, muscle pain, lack of energy.

Less frequent:

Skin rash, itching and hives.

Muscle disease and muscle ache (rhabdomyolysis), and infection of the pancreas or a severe allergic reaction.

Jaundice (yellowing of the skin), infection of the liver, joint pain or memory loss.

Not all side-effects reported for CRESTOR are included in this leaflet. Should your general health worsen while taking CRESTOR, or you notice any unwanted effects not mentioned in this leaflet, please consult your doctor, pharmacist or other health care professional for advice.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF CRESTOR:

Store below at or 30 °C. If your tablet comes in a plastic bottle, keep the lid tightly closed in order to protect from light and moisture. If your tablet comes in blisters, keep your tablets in the carton until they are required for use.

Keep all medicines out of the reach and sight of children.

Do not take your CRESTOR after the expiry date on the label or container.

If your doctor decides to stop your treatment, return all unused tablets to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF CRESTOR:

CRESTOR 5-10-20-40 mg tablets come packed in blister packs containing multiples of 7, 10 or 14 tablets.

CRESTOR 10-20-40 mg tablets come packed either in plastic bottles containing 30, 90, or 100 tablets or in blister packs containing multiples of 7, 10 or 14 tablets.

8. IDENTIFICATION OF CRESTOR:

Four tablet strengths are available:

5 mg: Yellow, film-coated, round, biconvex, approximately 7 mm (diameter) intagliated tablet; obverse side “ZD4522 5”, reverse side none.

10 mg: Pink, film-coated, round, biconvex, approximately 7 mm (diameter) intagliated tablet; obverse side “ZD4522 10”, reverse side none.

20 mg: Pink, film-coated, round, biconvex, approximately 9,1 mm (diameter) intagliated tablet; obverse side “ZD4522 20”, reverse side none.

40 mg: Pink, film-coated, oval, biconvex, approximately 11,5 x 7,1 mm (length x width) intagliated tablet; obverse side “ZD4522”, reverse side “40”.

9. REGISTRATION NUMBERS:

CRESTOR 5: 41/7.5/0298

CRESTOR 10: 36/7.5/0349

CRESTOR 20: 36/7.5/0350

CRESTOR 40: 36/7.5/0351

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:


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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

26 October 2012

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Ref.: Crestor 5-10-20-40 mg Tablets - EPI (08-02-2012)

CPIL: March 2009