



Patient Information Sheet

Rosuvastatin calcium (marketed as Crestor)

This is a summary of the most important information about Crestor. For details, talk to your healthcare professional.

FDA ALERT: Rhabdomyolysis (serious muscle damage) has been reported in patients taking Crestor as well as other statin drugs. To date, it does not appear that the risk is greater with Crestor than with other marketed statins. However, the labeling for Crestor is being revised to highlight important information on the safe use of Crestor to reduce the risk for serious muscle damage, especially at the highest approved dose of 40 mg. In addition, a study has found that the amount of drug in the blood of a diverse group of Asian patients taking Crestor was two times higher than for Caucasians patients in the study. Therefore, the labeling for Crestor will now recommend a lower starting dose of 5 mg for Asian patients. Kidney failure of various types has also been reported in patients treated with Crestor as well as other statins. FDA has determined that there is not enough evidence to conclude that kidney damage is a direct result of Crestor therapy. If you are currently taking Crestor or any statin and develop signs and symptoms of muscle pain and weakness, fever, dark urine, nausea or vomiting, you should contact your healthcare professional right away.

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

What Is Crestor?

Crestor is a medicine that lowers "bad" cholesterol and triglycerides and raises "good" cholesterol in the blood. Crestor is part of a treatment program that should also include a low-fat diet and exercise.

Who Should Not Take Crestor?

Do not take Crestor if you:

- Have liver problems or have persistently high liver enzymes
- Are pregnant or planning to become pregnant. Crestor may harm your unborn baby. If you get pregnant, stop Crestor and call your healthcare professional right away.
- Are breast-feeding. It is not known if Crestor can pass into your milk, and if it can harm your baby. You should choose to either take Crestor or breastfeed, but not both.
- Are allergic to Crestor or any of its ingredients

Crestor has not been studied in children.

What Are The Risks?

Crestor may cause rare, but serious, side effects including: **Muscle damage.** Crestor can cause serious muscle damage that can lead to kidney damage. The risk of muscle damage may be increased by taking certain drugs. Crestor should be used with caution if you have kidney problems, advanced age, and

hypothyroidism because you are at a greater risk of muscle damage. Tell your healthcare professional if you develop unexplained muscle pain, tenderness, or weakness while on Crestor, particularly if accompanied by malaise or fever.

Liver damage. Crestor can cause liver damage like other lipid lowering medicines. This risk may be increased when Crestor is used with certain medicines. Your healthcare professional may do blood tests to check your liver before you start taking Crestor, and while you take it. Crestor should be used with caution if you have a history of liver disease or drink substantial amounts of alcohol.

Other side effects include muscle pain, constipation, weakness, abdominal pain, and nausea

What Should I Tell My Healthcare Professional?

Before starting Crestor, tell your healthcare professional about all your medical conditions, including if you:

- Are pregnant or planning to become pregnant
- Are breast-feeding
- Have liver problems
- Have kidney problems
- Drink alcohol

Are There Any Interactions With Drugs Or Foods?

Tell your healthcare professional about all the medicines you take, including prescription and over the counter drugs, and supplements. Crestor and certain medicines may interact with each other causing serious side effects. Crestor and other medicines may affect each other, causing serious side effects. Especially tell your healthcare professional if you take:

- Cyclosporine (Gengraf, Neoral, Sandimmune)
- Warfarin (Coumadin)
- Gemfibrozil (Lopid)
- Drugs that may decrease the levels or activity of your body's own steroid hormones. These drugs include ketoconazole (Nizoral), spironolactone (Aldactone), and cimetidine (Tagamet)
- Aluminum and magnesium hydroxide combination antacids (for example, Maalox)

How do I take Crestor?

- You should be placed on a standard lipid-lowering diet and an exercise routine before receiving Crestor and should continue these during treatment. Crestor can be taken as a single dose at any time of day, with or without food.
- The dose range for Crestor is 5 to 40 mg once daily. **You should start on the lowest possible dose, and never start with 40 mg.** After starting or changing your dose of Crestor, your lipid levels should be checked within 2 to 4 weeks and your dose adjusted as needed.

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Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570
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