

PATIENT INFORMATION
Rosuvastatin Calcium
(roe-soo-va-STAT-in KAL-see-um)
Tablets

Read this Patient Information carefully before you start taking rosuvastatin calcium tablets and each time you get a refill. If you have any questions about rosuvastatin calcium tablets, ask your doctor. Only your doctor can determine if rosuvastatin calcium tablets are right for you.

What is rosuvastatin calcium tablet?

Rosuvastatin calcium tablet is a prescription medicine that contains a cholesterol-lowering medicine called rosuvastatin calcium. Most of the cholesterol in your blood is made in the liver. Rosuvastatin calcium tablets works by reducing cholesterol in two ways: rosuvastatin calcium tablets blocks an enzyme in the liver causing the liver to make less cholesterol, and rosuvastatin calcium tablets increases the uptake and breakdown by the liver of cholesterol already in the blood.

- Rosuvastatin calcium tablets are used along with diet to:
 - lower the level of your “bad” cholesterol (LDL)
 - increase the level of your “good” cholesterol (HDL)
 - lower the level of fat in your blood (triglycerides)
- Rosuvastatin calcium tablets are used to treat:
 - Adults who cannot control their cholesterol levels by diet and exercise alone

It is not known if rosuvastatin calcium tablets are safe and effective in people who have Fredrickson Type I and V dyslipidemias.

Pediatric use information for patients 7 to 17 years of age is approved for AstraZeneca’s CRESTOR (rosuvastatin calcium) tablets. However, due to AstraZeneca’s marketing exclusivity rights, this drug product is not labeled with that pediatric information.

Who should not take rosuvastatin calcium tablets?

Do not take rosuvastatin calcium tablets if you:

- are allergic to rosuvastatin calcium or any of the ingredients in rosuvastatin calcium tablets. See the end of this leaflet for a complete list of ingredients in rosuvastatin calcium tablets.
- have liver problems.
- are pregnant or think you may be pregnant, or are planning to become pregnant. Rosuvastatin calcium tablets may harm your unborn baby. If you become pregnant, stop taking rosuvastatin calcium tablets and call your doctor right away. If you are not planning to become pregnant you should use effective birth control (contraception) while you are taking rosuvastatin calcium tablets.
- are breastfeeding. Medicines like rosuvastatin calcium can pass into your breast milk and may harm your baby.

What should I tell my doctor before and while taking rosuvastatin calcium tablets?

Tell your doctor if you:

- have unexplained muscle aches or weakness
- have or have had kidney problems
- have or have had liver problems
- drink more than 2 glasses of alcohol daily
- have thyroid problems
- are 65 years of age or older
- are of Asian descent
- are pregnant or think you may be pregnant, or are planning to become pregnant
- are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Talk to your doctor before you start taking any new medicines.

Taking rosuvastatin calcium tablets with certain other medicines may affect each other causing side effects. Rosuvastatin calcium tablets may affect the way other medicines work, and other medicines may affect how rosuvastatin calcium tablets works.

Especially tell your doctor if you take:

- cyclosporine (a medicine for your immune system)
- gemfibrozil (a fibric acid medicine for lowering cholesterol)
- anti-viral medicines including HIV or hepatitis C protease inhibitors (such as lopinavir, ritonavir, fosamprenavir, tipranavir, atazanavir, or simeprevir)
- certain anti-fungal medicines (such as itraconazole, ketoconazole and fluconazole)
- coumarin anticoagulants (medicines that prevent blood clots, such as warfarin)
- niacin or nicotinic acid
- fibric acid derivatives (such as fenofibrate)
- colchicine (a medicine used to treat gout)

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Know all of the medicines you take. Keep a list of them to show your doctor and pharmacist when you get new medicine.

How should I take rosuvastatin calcium tablets?

- Take rosuvastatin calcium tablets exactly as your doctor tells you to take it.
- Take rosuvastatin calcium tablets, by mouth, 1 time each day. Swallow the tablet whole.
- Rosuvastatin calcium tablets can be taken at any time of day, with or without food.
- **Do not** change your dose or stop rosuvastatin calcium tablets without talking to your doctor, even if you are feeling well.
- Your doctor may do blood tests to check your cholesterol levels before and during your treatment with rosuvastatin calcium tablets. Your doctor may change your dose of rosuvastatin calcium tablets if needed.

- Your doctor may start you on a cholesterol lowering diet before giving you rosuvastatin calcium tablets. Stay on this diet when you take rosuvastatin calcium tablets.
- Wait at least 2 hours after taking rosuvastatin calcium tablets to take an antacid that contains a combination of aluminum and magnesium hydroxide.
- If you miss a dose of rosuvastatin calcium tablets, take it as soon as you remember. However, **do not take 2 doses of rosuvastatin calcium tablets within 12 hours of each other.**
- If you take too much rosuvastatin calcium tablets or overdose, call your doctor or go to the nearest hospital emergency room right away.

What are the Possible Side Effects of rosuvastatin calcium tablets?

Rosuvastatin calcium tablets may cause serious side effects, including:

- **Muscle pain, tenderness and weakness (myopathy).** Muscle problems, including muscle breakdown, can be serious in some people and rarely cause kidney damage that can lead to death. **Tell your doctor right away if:**
 - o you have unexplained muscle pain, tenderness, or weakness, especially if you have a fever or feel more tired than usual, while you take rosuvastatin calcium tablets.
 - o you have muscle problems that do not go away even after your doctor has told you to stop taking rosuvastatin calcium tablets. Your doctor may do further tests to diagnose the cause of your muscle problems.

Your chances of getting muscle problems are higher if you:

- o are taking certain other medicines while you take rosuvastatin calcium tablets
- o are 65 years of age or older
- o have thyroid problems (hypothyroidism) that are not controlled
- o have kidney problems
- o are taking higher doses of rosuvastatin calcium tablets.
- **Liver problems.** Your doctor should do blood tests to check your liver before you start taking rosuvastatin calcium tablets and if you have symptoms of liver problems while you take rosuvastatin calcium tablets. Call your doctor right away if you have any of the following symptoms of liver problems:
 - o feel unusually tired or weak
 - o loss of appetite
 - o upper belly pain
 - o dark urine
 - o yellowing of your skin or the whites of your eyes

The most common side effects may include: headache, muscle aches and pains, abdominal pain, weakness, and nausea.

Additional side effects that have been reported with rosuvastatin calcium tablets include memory loss and confusion.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of rosuvastatin calcium tablets. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store rosuvastatin calcium tablets?

- Store rosuvastatin calcium tablet at room temperature, between 68° to 77°F (20° to 25°C) and in a dry place.
- Safely throw away medicine that is out of date or no longer needed.

Keep rosuvastatin calcium tablets and all medicines out of the reach of children.

What are the Ingredients in rosuvastatin calcium tablets?

Active Ingredient: rosuvastatin as rosuvastatin calcium

Inactive Ingredients: crospovidone, FD&C blue #2/indigo carmine aluminum lake, FD&C red #40/allura red AC aluminum lake, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium bicarbonate, talc, titanium dioxide and triacetin. Additionally 5 mg tablets contain FD&C yellow #5/tartrazine aluminum lake and 10 mg, 20 mg and 40 mg tablets contain FD&C yellow #6/sunset yellow FCF aluminum lake.

General Information about the safe and effective use of rosuvastatin calcium tablets

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use rosuvastatin calcium tablets for a condition for which it was not prescribed. Do not give rosuvastatin calcium tablets to other people, even if they have the same medical condition you have. It may harm them.

You can ask your pharmacist or doctor for information about rosuvastatin calcium tablets that is written for health professionals.



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This Patient Information has been approved by the U.S. Food and Drug Administration.

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