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PATIENT INFORMATION

Rosuvastatin (roe-SOO-va-STAT-in) Tablets, USP

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

What are rosuvastatin tablets?

Rosuvastatin tablets are a prescription medicine that contains a cholesterol-lowering medicine called rosuvastatin calcium.

- Rosuvastatin tablets are used along with diet to:
 - o lower the level of your "bad" cholesterol (LDL)
 - o increase the level of your "good" cholesterol (HDL)
 - o lower the level of fat in your blood (triglycerides)
 - o slow the buildup of fatty deposits (plaque) in the walls of blood vessels
- Rosuvastatin tablets are used to treat:
 - o adults who cannot control their cholesterol levels by diet and exercise alone
 - o children 8 to 17 years of age with heterozygous familial hypercholesterolemia (an inherited condition that causes high levels of LDL)

Rosuvastatin tablets are not approved for use in children with heterozygous familial hypercholesterolemia younger than 8 years of age.

Rosuvastatin tablets are used to reduce the risk of heart attacks and strokes in men 50 years of age and older and women 60 years of age and older who do not have known heart disease but do have certain additional risk factors.

It is not known if rosuvastatin 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 tablets?

Do not take rosuvastatin tablets if you:

- are allergic to rosuvastatin calcium or any of the ingredients in rosuvastatin tablets. See the end of this leaflet for a complete list of ingredients in rosuvastatin tablets.
- have liver problems.

- are pregnant or think you may be pregnant, or are planning to become pregnant. Rosuvastatin tablets may harm your unborn baby. If you become pregnant, stop taking rosuvastatin 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 tablets.
- are breastfeeding. Medicines like rosuvastatin tablets can pass into your breast milk and may harm your baby.

What should I tell my doctor before and while taking rosuvastatin 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 tablets with certain other medicines may affect each other causing side effects. Rosuvastatin tablets may affect the way other medicines work, and other medicines may affect how rosuvastatin tablets work.

Especially tell your doctor if you take:

- cyclosporine (a medicine for your immune system)
- gemfibrozil (a fibric acid medicine for lowering cholesterol)
- darolutamide (a medicine for the treatment of prostate cancer)
- regorafenib (a medicine used to treat cancer of the colon and rectum)
- anti-viral medicines including certain HIV or hepatitis C virus drugs such as:
 - o lopinavir, ritonavir, fosamprenavir, tipranavir, atazanavir, simeprevir
 - o combination of
 - sofosbuvir/velpatasvir/voxilaprevir
 - dasabuvir/ombitasvir/paritaprevir/ritonavir
 - elbasvir/grazoprevir
 - sofosbuvir/velpatasvir
 - glecaprevir/pibrentasvir **and**
 - o all other combinations with ledipasvir including ledipasvir/sofosbuvir
- 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 tablets?

- Take rosuvastatin tablets exactly as your doctor tells you to take it.
- Take rosuvastatin tablets, by mouth, 1 time each day. Swallow the tablet whole.
- Rosuvastatin tablets can be taken at any time of day, with or without food.
- **Do not** change your dose or stop rosuvastatin 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 tablets. Your doctor may change your dose of rosuvastatin tablets if needed.
- Your doctor may start you on a cholesterol lowering diet before giving you rosuvastatin tablets. Stay on this diet when you take rosuvastatin tablets.
- Wait at least 2 hours after taking rosuvastatin tablets to take an antacid that contains a combination of aluminum and magnesium hydroxide.
- If you miss a dose of rosuvastatin tablets, take it as soon as you remember. However, **do not take 2 doses of rosuvastatin tablets within 12 hours of each other.**
- If you take too many rosuvastatin tablets or overdose, call your doctor or go to the nearest hospital emergency room right away.

What are the Possible Side Effects of Rosuvastatin Tablets?

Rosuvastatin 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 tablets.**
 - o you have muscle problems that do not go away even after your doctor has told you to stop taking rosuvastatin 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 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 tablets
- **Liver problems.** Your doctor should do blood tests to check your liver before you start taking rosuvastatin tablets and if you have symptoms of liver problems while you take rosuvastatin 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 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 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 tablets?

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

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

What are the Ingredients in Rosuvastatin Tablets?

Active Ingredient: rosuvastatin as rosuvastatin calcium

Inactive Ingredients: colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized maize starch, talc, titanium dioxide, iron oxide yellow (5 mg), iron oxide red (10 mg, 20 mg, 40 mg), and FD& C Red # 40 aluminum lake (10 mg, 20 mg, 40 mg).

General Information about the safe and effective use of rosuvastatin tablets

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use rosuvastatin tablets for a condition for which it was not prescribed. Do not give rosuvastatin 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 tablets that is written for health professionals.

For more information, call 1-800-818-4555.

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