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PATIENT INFORMATION

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

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 healthcare provider. Only your healthcare provider 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.

- Rosuvastatin tablets are used:
 - to reduce the risk of major adverse cardiovascular (CV) events, such as death from cardiovascular disease, heart attack, stroke, or the need for procedures to improve blood flow to the heart called arterial revascularization, in adults who do not have known heart disease but do have certain additional risk factors.
 - along with diet to:
 - lower the level of low-density lipoprotein (LDL-C) cholesterol or “bad” cholesterol in adults with primary hyperlipidemia.
 - slow the buildup of fatty deposits (plaque) in the walls of blood vessels.
 - treat adults and children 8 years of age and older with high blood cholesterol due to heterozygous familial hypercholesterolemia (HeFH) (an inherited condition that causes high levels of LDL-C).
 - along with other cholesterol lowering treatments or alone if such treatments are unavailable in adults and children 7 years of age and older with homozygous familial hypercholesterolemia (HoFH) (an inherited condition that causes high levels of LDL-C).
 - along with diet for the treatment of adults with:
 - primary dysbetalipoproteinemia (an inherited condition that causes high levels of cholesterol and fat).
 - hypertriglyceridemia.

It is not known if rosuvastatin tablets are safe and effective in children younger than 8 years of age with HeFH or children younger than 7 years of age with HoFH or in children with other types of hyperlipidemias (other than HeFH or HoFH).

Do not take rosuvastatin tablets if you:

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

Before you take rosuvastatin tablets, tell your healthcare provider about all of your medical conditions, including 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 of Asian descent.

- are pregnant or think you may be pregnant, or are planning to become pregnant. If you become pregnant while taking rosuvastatin tablets, call your healthcare provider right away to discuss your rosuvastatin tablets treatment.
- are breastfeeding. Rosuvastatin can pass into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take rosuvastatin tablets. Do not breastfeed while taking rosuvastatin tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Tell your healthcare provider who prescribes rosuvastatin tablets if another healthcare provider increases the dose of another medicine you are taking. Rosuvastatin tablets may affect the way other medicines work, and other medicines may affect how rosuvastatin tablets work.

Especially tell your healthcare provider if you take:

- coumarin anticoagulants (medicines that prevent blood clots, such as warfarin)
- antacids (medicines you take for heartburn that contain aluminum and magnesium hydroxide)

Taking rosuvastatin tablets with certain medicines may increase the risk of muscle problems.

Especially tell your healthcare provider if you take:

- cyclosporine (a medicine for your immune system)
- teriflunomide (a medicine used to treat relapsing remitting multiple sclerosis)
- enasidenib (a medicine used to treat acute myeloid leukemia)
- capmatinib (a medicine for the treatment of non-small cell lung cancer)
- fostamatinib (a medicine used to treat low platelet counts)
- febuxostat (a medicine used to treat and prevent high blood levels of uric acid)
- gemfibrozil (a fibric acid medicine for lowering cholesterol)
- tafamidis [used to treat cardiomyopathy (enlarged and thickened heart muscle)]
- anti-viral medicines including certain HIV or hepatitis C virus drugs such as:
 - lopinavir, ritonavir, fosamprenavir, tipranavir, atazanavir, simeprevir
 - combination of
 - sofosbuvir/velpatasvir/voxilaprevir
 - dasabuvir/ombitasvir/paritaprevir/ritonavir
 - elbasvir/grazoprevir
 - sofosbuvir/velpatasvir
 - glecaprevir/pibrentasvir **and**
 - all other combinations with ledipasvir including ledipasvir/sofosbuvir
- darolutamide (a medicine for the treatment of prostate cancer)
- regorafenib (a medicine used to treat cancer of the colon and rectum)
- fibric acid derivatives (such as fenofibrate)
- ticagrelor (helps reduce the chance of a blood clot formation that can block a blood vessel)
- niacin or nicotinic acid
- colchicine (a medicine used to treat gout)

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get new medicine.

How should I take rosuvastatin tablets?

- Take rosuvastatin tablets exactly as your healthcare provider tells you to take it.
- Take rosuvastatin tablets, by mouth, 1 time each day, with or without food. 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 healthcare provider, even if you are feeling well.
- Your healthcare provider may do blood tests to check your cholesterol levels before and during your treatment with rosuvastatin tablets. Your healthcare provider may change your dose of rosuvastatin tablets if needed.
- While taking rosuvastatin tablets, continue to follow your cholesterol-lowering diet and to exercise as your healthcare provider told you to.
- If you take a medicine called an antacid that contains a combination of aluminum and magnesium hydroxide, take rosuvastatin tablets at least 2 hours before you take the antacid.
- If you miss a dose of rosuvastatin tablets, take your next dose at your normal scheduled time. **Do not take** an extra dose of rosuvastatin tablets.
- In case of an overdose, get medical help or contact a live Poison Center expert right away at 1-800-222-1222. Advice is also available online at poisonhelp.org.

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 healthcare provider right away if:
 - 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.
 - you have muscle problems that do not go away even after your healthcare provider has told you to stop taking rosuvastatin tablets. Your healthcare provider may do further tests to diagnose the cause of your muscle problems.

Your chances of getting muscle problems are higher if you:

- are taking certain other medicines while you take rosuvastatin tablets (see “Especially tell your healthcare provider if you take”)
- are 65 years of age or older
- are of Asian descent
- have thyroid problems (hypothyroidism) that are not controlled
- have kidney problems
- are taking higher doses of rosuvastatin tablets
- **Liver problems.** Your healthcare provider may 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 healthcare provider right away if you have any of the following symptoms of liver problems:
 - feel unusually tired or weak
 - loss of appetite
 - upper belly pain
 - dark urine
 - yellowing of your skin or the whites of your eyes

• **Protein and blood in the urine.** Rosuvastatin tablets may cause you to have protein and blood in your urine. If you develop protein or blood in your urine, your healthcare provider may decrease your dose of rosuvastatin tablets.

• **Increase in blood sugar (glucose) levels.** Rosuvastatin tablets may cause an increase in your blood sugar levels.

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

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

For more information, ask your healthcare provider 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.
- Rosuvastatin tablets come in a child-resistant package.

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

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 healthcare provider for information about rosuvastatin tablets that is written for health professionals.

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).

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

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