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Rosuvastatin

pronounced as (roe soo" va stat' in)

Notice:

[Posted 07/20/2021]

AUDIENCE: Patient, Health Professional, OBGYN, Cardiology, Endocrinology, Pharmacy

ISSUE: The FDA is requesting revisions to the information about use in pregnancy in the prescribing information of the entire class of statin medicines. These changes include removing the contraindication against using these medicines in all pregnant patients. A contraindication is FDA's strongest warning and is only added when a medicine should not be used because the risk clearly outweighs any possible benefit. Because the benefits of statins may include prevention of serious or potentially fatal events in a small group of very high-risk pregnant patients, contraindicating these drugs in all pregnant women is not appropriate.

FDA expects removing the contraindication will enable health care professionals and patients to make individual decisions about benefit and risk, especially for those at very high risk of heart attack or stroke. This includes patients with homozygous familial hypercholesterolemia and those who have previously had a heart attack or stroke.

BACKGROUND: Statins are a class of prescription medicines that have been used for decades to lower low-density lipoprotein (LDL-C or "bad") cholesterol in the blood. Medicines in the statin class include atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin, and simvastatin.

RECOMMENDATIONS:

- **Patients:** Patients taking statins should notify their health care professionals if they become pregnant or suspect they are pregnant. Your health care professional will be able to advise whether you should stop taking the medicine during pregnancy and whether you may stop your statin temporarily while breastfeeding. Patients who are at high risk of heart attack or stroke who require statins after giving birth should not breastfeed and should use alternatives such as infant formula.
- **Health Care Professionals:** Health care professionals should discontinue statin therapy in most pregnant patients, or they can consider the ongoing therapeutic needs of the individual

patient, particularly those at very high risk for cardiovascular events during pregnancy. Because of the chronic nature of cardiovascular disease, treatment of hyperlipidemia is not generally necessary during pregnancy. Discuss with patients whether they may discontinue statins temporarily while breastfeeding. Advise those who require a statin because of their cardiovascular risk that breastfeeding is not recommended because the medicine may pass into breast milk

The FDA hopes the revised language in the prescribing information will help reassure health care professionals that statins are safe to prescribe in patients who can become pregnant, and help them reassure patients with unintended statin exposure in early pregnancy or before pregnancy is recognized that the medicine is unlikely to harm the unborn baby.

For more information visit the FDA website at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation>

[<http://www.fda.gov/Safety/MedWatch/SafetyInformation>] and <http://www.fda.gov/Drugs/DrugSafety>

[<http://www.fda.gov/Drugs/DrugSafety>] .

Why is this medication prescribed?

Rosuvastatin is used together with diet, weight-loss, and exercise to reduce the risk of heart attack and stroke and to decrease the chance that heart surgery will be needed in people who have heart disease or who are at risk of developing heart disease. Rosuvastatin is also used to decrease the amount of cholesterol such as low-density lipoprotein (LDL) cholesterol ('bad cholesterol') and triglycerides in the blood and to increase the amount of high-density lipoprotein (HDL) cholesterol ('good cholesterol') in the blood. Rosuvastatin may also be used together with diet to decrease the amount of cholesterol and other fatty substances in the blood in children and teenagers 8 to 17 years of age who have familial heterozygous hypercholesterolemia (an inherited condition in which cholesterol cannot be removed from the body normally). Rosuvastatin is used together with diet, and alone or in combination with other medications, to decrease the amount of cholesterol and other fatty substances in the blood in adults and children and teenagers 7 to 17 years of age who have familial homozygous hypercholesterolemia (an inherited condition in which cholesterol cannot be removed from the body normally). Rosuvastatin is in a class of medications called HMG-CoA reductase inhibitors (statins). It works by slowing the production of cholesterol in the body to decrease the amount of cholesterol that may build up on the walls of the arteries and block blood flow to the heart, brain, and other parts of the body.

Accumulation of cholesterol and fats along the walls of your arteries (a process known as atherosclerosis) decreases blood flow and, therefore, the oxygen supply to your heart, brain, and other parts of your body. Lowering your blood level of cholesterol and fats with rosuvastatin has been shown to prevent heart disease, angina (chest pain), strokes, and heart attacks.

How should this medicine be used?

Rosuvastatin comes as a tablet (Crestor) to take by mouth. Rosuvastatin also comes as a capsule (Ezallor) to take by mouth or to open, mix with water, and give through a feeding tube. It is usually taken once a day with or without food. Take rosuvastatin at around the same time every day. Follow the

directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take rosuvastatin exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your doctor will probably start you on a low dose of rosuvastatin and gradually increase your dose, not more than once every 2 to 4 weeks.

Swallow the capsules (Ezallor) whole; do not chew or crush them. If you cannot swallow the capsule, open the capsule and carefully sprinkle the contents onto 1 teaspoonful of applesauce. Swallow the entire mixture immediately without chewing. Do not save the applesauce mixture for later use.

Continue to take rosuvastatin even if you feel well. Do not stop taking rosuvastatin without talking to your doctor.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking rosuvastatin,

- tell your doctor and pharmacist if you are allergic to rosuvastatin, any other medications, or any of the ingredients in rosuvastatin tablets or capsules. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: anticoagulants ('blood thinners') such as warfarin (Coumadin, Jantoven); colchicine (Colcrys); cimetidine (Tagamet); cyclosporine (Gengraf, Neoral, Sandimmune); darolutamide (Nubeqa); eltrombopag (Promacta); ketoconazole (Nizoral); other medications for high cholesterol such as fenofibrate (Tricor), gemfibrozil (Lopid), and niacin (Niaspan, Niacor); certain hepatitis C virus (HCV) medications including dasabuvir taken with ombitasvir, paritaprevir, and ritonavir (Viekira Pak); glecaprevir taken with pibrentasvir (Mavyret), ledipasvir taken with sofosbuvir (Harvoni), simeprevir (no longer available in US), or sofosbuvir taken with velpatasvir and/or voxilaprevir (Epclusa, Vosevi); certain HIV protease inhibitors including atazanavir (Reyataz) taken with ritonavir (Norvir), and lopinavir and ritonavir (Kaletra); regorafenib (Stivarga); and spironolactone (Aldactone). Many other medications may also interact with rosuvastatin, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- if you are taking aluminum and magnesium hydroxide antacids (Mylanta, Maalox), take them at least 2 hours after rosuvastatin.
- tell your doctor if you have liver disease. Your doctor will order laboratory tests to see how well your liver is working even if you do not think you have liver disease. Your doctor will probably tell you not to take rosuvastatin if you have liver disease or if the tests show that you may be developing liver disease.
- tell your doctor if you are Asian, if you drink more than 2 alcoholic beverages daily, if you are 65 years of age or older, if you have ever had liver disease, or if you have or have ever had seizures, muscle aches or weakness, low blood pressure, or kidney or thyroid disease.

- tell your doctor if you are pregnant or plan to become pregnant. You should not become pregnant while you are taking rosuvastatin. Talk to your doctor about birth control methods that you can use during your treatment. If you become pregnant while taking rosuvastatin, call your doctor immediately. Rosuvastatin may harm the fetus.
- do not breastfeed while taking rosuvastatin.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking rosuvastatin. If you are hospitalized due to serious injury or infection, tell the doctor who treats you that you are taking rosuvastatin.
- ask your doctor about the safe use of alcoholic beverages while you are taking rosuvastatin. Alcohol can increase the risk of serious side effects.

What special dietary instructions should I follow?

Eat a low-fat, low-cholesterol diet. Be sure to follow all exercise and dietary recommendations made by your doctor or dietitian. You can also visit the National Cholesterol Education Program (NCEP) website for additional dietary information at http://www.nhlbi.nih.gov/health/public/heart/chol/chol_tlc.pdf [http://www.nhlbi.nih.gov/health/public/heart/chol/chol_tlc.pdf].

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is less than 12 hours before your next dose is scheduled, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Rosuvastatin may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- constipation
- stomach pain
- dizziness
- difficulty falling asleep or staying asleep
- depression
- joint pain
- headache
- memory loss or forgetfulness
- confusion

Some side effects can be serious. If you experience any of the following symptoms, call your doctor immediately or get emergency medical help:

- muscle pain, tenderness, or weakness (or if these symptoms continue after stopping rosuvastatin)

- lack of energy
- fever
- chest pain
- dark, reddish urine; decreased amount of urine; weakness; and muscle aches
- yellowing of the skin or eyes
- dark colored urine
- pain in the upper right part of the abdomen
- nausea
- extreme tiredness
- weakness
- unusual bleeding or bruising
- loss of appetite
- flu-like symptoms
- rash
- hives
- itching
- difficulty breathing or swallowing
- swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- hoarseness

Rosuvastatin may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order lab tests during your treatment, especially if you develop symptoms of liver damage.

Before having any laboratory test, tell your doctor and the laboratory personnel that you are taking rosuvastatin.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Crestor[®]
- Ezallor[®]

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