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Fluvastatin

pronounced as (floo' va sta tin)

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?

Fluvastatin 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. Fluvastatin is also used to decrease the amount of fatty substances 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. Fluvastatin may also be used to decrease the amount of cholesterol and other fatty substances in the blood in children and teenagers 10 to 17 years of age who have familial heterozygous hypercholesterolemia (an inherited condition in which cholesterol cannot be removed from the body normally). Fluvastatin 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 fluvastatin has been shown to prevent heart disease, angina (chest pain), strokes, and heart attacks.

How should this medicine be used?

Fluvastatin comes as a capsule and an extended-release (long-acting) tablet to take by mouth. The capsule is usually taken with or without food once a day at bedtime or twice a day. The extended-release tablet is usually taken once a day with or without food. Take fluvastatin at around the same time(s) 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 fluvastatin exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the extended-release tablets whole; do not split, chew, or crush them.

Your doctor may start you on a low dose of fluvastatin and gradually increase your dose, not more than once every 4 weeks.

Continue to take fluvastatin even if you feel well. Do not stop taking fluvastatin 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 fluvastatin,

- tell your doctor and pharmacist if you are allergic to fluvastatin, any other medications, or any of the ingredients in fluvastatin capsules or extended release tablets. 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; cimetidine (Tagamet); colchicine (Colcrys); cyclosporine (Neoral, Sandimmune); diclofenac (Cataflam, Voltaren); digoxin (Lanoxin); erythromycin (E.E.S., E-Mycin, Erythrocin); fluconazole (Diflucan), glyburide (DiaBeta, Glynase, Micronase); ketoconazole (Nizoral); omeprazole (Prilosec); other cholesterol-lowering medications such as cholestyramine (Questran), fenofibrate (Tricor), gemfibrozil (Lopid), and niacin (nicotinic acid, Niacor, Niaspan); phenytoin (Dilantin); ranitidine (Zantac); rifampin (Rifadin, Rimactane); and spironolactone (Aldactone). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with fluvastatin, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- 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 fluvastatin if you have liver disease or if the tests show that you may be developing liver disease.
- tell your doctor if you drink more than 2 alcoholic beverages per day, if you are 65 years of age or older, and if you have ever had liver disease or have or ever had muscle aches or weakness, diabetes, low blood pressure, seizures, or thyroid or kidney disease.
- tell your doctor if you are pregnant, or plan to become pregnant. You should not become pregnant while you are taking fluvastatin. Talk to your doctor about birth control methods that you can use during your treatment. If you become pregnant while taking fluvastatin, stop taking fluvastatin and call your doctor immediately. Fluvastatin may harm the fetus.
- do not breast-feed while you are taking this medication.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking fluvastatin. If you are hospitalized due to infection or serious injury, tell the doctor who treats you that you are taking fluvastatin.

- ask your doctor about the safe use of alcoholic beverages while you are taking fluvastatin. 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 has been more than 12 hours since your last dose, 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?

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

- headache
- heartburn
- difficulty falling asleep or staying asleep
- sinus pain
- cough
- 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
- lack of energy
- fever
- yellowing of the skin or eyes
- pain in the upper right part of the stomach
- dark colored urine
- nausea
- extreme tiredness
- 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

Fluvastatin 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 laboratory 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 fluvastatin.

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

- Lescol[®]
- Lescol[®] XL

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