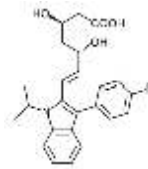


# Rx FLUVASTATIN

(Lovastatin belongs to a class of cholesterol-lowering drugs called HMG-CoA reductase inhibitors)



## GENERIC NAME: lovastatin

### DRUG CLASS AND MECHANISM

Lovastatin belongs to a class of cholesterol-lowering drugs called HMG-CoA reductase inhibitors, or, more commonly "statins." Other statins include simvastatin (Zocor), atorvastatin (Lipitor), fluvastatin (Lescol), and rosuvastatin (Crestor). Statins reduce cholesterol by inhibiting an enzyme in the liver (HMG-CoA reductase) that is necessary for the production of cholesterol. In the blood, statins lower total cholesterol, low density lipoprotein (LDL) cholesterol ("bad" cholesterol) and triglycerides. LDL cholesterol is believed to be an important cause of coronary artery disease. Lowering LDL cholesterol levels slows and may even reverse coronary artery disease. Statins also increase high density lipoprotein (HDL) cholesterol ("good" cholesterol). Raising HDL cholesterol levels, like lowering LDL cholesterol may slow coronary artery disease. The FDA approved lovastatin in August 1987.

### PRESCRIPTION: Yes

### GENERIC AVAILABLE: Yes

**PREPARATIONS: Tablets:** 10, 20, and 40 mg. Extended release tablets: 10, 20, 40, and 60 mg.

### PRESCRIBED FOR

Lovastatin is used for reducing total cholesterol and LDL cholesterol, and triglycerides, and for increasing HDL cholesterol in patients with elevated blood cholesterol levels (hypercholesterolemia). Lovastatin is used for reducing the risk of heart attacks, angina, coronary revascularization procedures in individuals without symptomatic cardiovascular disease, average to moderately elevated cholesterol levels and below average HDL cholesterol levels. It also is used for slowing the progression of coronary atherosclerosis in individuals with coronary heart disease.

### DOSING

The dose range for lovastatin is 10-80 mg daily given preferably in the evening when it may be most effective. The usual starting dose is 20 mg once daily and the maximum dose is 80 mg daily. Blood cholesterol determinations are performed at regular intervals during treatment so that adjustments in dosage can be made.

### DRUG INTERACTIONS

Decreased elimination of lovastatin could increase the levels of lovastatin in the body and increase the risk of muscle toxicity from lovastatin. Examples of drugs that decrease elimination of lovastatin include erythromycin (E-Mycin), ketoconazole (Nizoral), itraconazole (Sporanox), clarithromycin (Biaxin), telithromycin (Ketek), cyclosporine (Sandimmune), nefazodone (Serzone), and protease inhibitors such as indinavir (Crixivan) and ritonavir (Norvir). Large quantities of grape fruit juice (>1 quart daily) also will increase blood levels of lovastatin.

### SIDE EFFECTS

The most common side effects of lovastatin are headache, nausea, vomiting, diarrhea, abdominal pain, muscle pain, and abnormal liver tests. Hypersensitivity reactions have also been reported. The most serious potential side effects are liver damage and muscle inflammation or breakdown. Lovastatin is a statin. Therefore it shares side effects, such as liver and muscle damage associated with all statins. Serious liver damage caused by statins is rare. More often, statins cause abnormalities of liver tests, and, therefore, periodic measurement of liver tests in the blood is recommended during treatment with all statins. Abnormal tests usually return to normal even if a statin is continued, but if the abnormal test value is greater than three times the upper limit of normal, the statin usually is stopped. Liver tests should be measured before lovastatin is started, at 6 and 12 weeks after initiation of therapy, with an increase in dose, and periodically thereafter or if there is a medical concern about liver damage.

Inflammation of the muscles caused by statins can lead to a serious breakdown of muscle cells called rhabdomyolysis. Rhabdomyolysis causes the release of muscle protein (myoglobin) into the blood. Myoglobin can cause kidney failure and even death. When used alone, statins cause rhabdomyolysis in less than one percent of patients. To prevent the development of rhabdomyolysis, patients taking lovastatin should contact their healthcare provider immediately if they develop unexplained muscle pain, weakness, or muscle tenderness.

## USES

Lovastatin is an enzyme blocker (HMG-CoA reductase inhibitor), also known as a "statin". It is used along with a proper diet to help lower cholesterol and fats (triglycerides) in the blood. In general, this drug is prescribed after non-drug treatment options have not been fully successful at lowering cholesterol (e.g., diet change, increase in exercise, weight loss if overweight). Reducing cholesterol and triglycerides help prevent strokes and heart attacks. Lovastatin is used in adults and children (10 years of age and older). Young girls must have had their menstrual periods for at least one year before starting this medication.

## HOW TO USE

Take this medication by mouth usually once daily with your evening meal, or as directed by your doctor. Some patients may require twice daily dosing. Dosage is based on your medical condition, response to therapy, and use of certain interacting medicines. Many of the drugs listed in the Drug Interactions section may increase the chances of muscle injury when used with lovastatin. Consult your doctor or pharmacist for more details. Limit the amount of grapefruit or grapefruit juice you may eat or drink (less than 1 quart a day) while being treated with this medication, unless specifically directed otherwise. Grapefruit juice may increase the amount of certain medications in your bloodstream. Consult your doctor or pharmacist for more details. If you also take certain other drugs to lower your cholesterol (bile acid-binding resins such as cholestyramine or colestipol), take lovastatin at least 1 hour before or at least 2 hours after these medications. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time each day. It may take up to 4 weeks before the full benefit of this drug takes effect. It is important to continue taking this medication even if you feel well. Most people with high cholesterol or triglycerides do not feel sick.

## SIDE EFFECTS

Constipation or stomach pain may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. This drug may infrequently cause muscle damage (which can rarely lead to a very serious, possibly fatal, condition called rhabdomyolysis). Seek immediate medical attention if you develop: muscle pain/tenderness/weakness (especially with fever or unusual tiredness). Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: yellowing eyes and skin, dark urine, severe fatigue, severe stomach/abdominal pain, persistent nausea, change in the amount of urine. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

## PRECAUTIONS

Before taking lovastatin, tell your doctor or pharmacist if you are allergic to it; or to other "statins"; or if you have any other allergies. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: active liver disease. Before using this medication, tell your doctor or pharmacist your medical history, especially of: heart disease, history of liver disease, kidney disease, underactive thyroid (hypothyroidism), diabetes (poorly controlled), alcohol use. The rare development of severe muscle damage (see Side Effects) can infrequently lead to serious kidney problems. This medication is usually temporarily stopped if you have any condition which can increase your risk of developing kidney problems. Before stopping your medication, notify your doctor immediately if you have any of the following conditions: major surgery, trauma, serious illness (e.g., sepsis, severe metabolic/endocrine/electrolyte disorders), very low blood pressure, uncontrolled seizures. Limit alcoholic beverages. Daily use of alcohol may increase your chance for serious side effects. Caution is advised when using this drug in the elderly because they may be more sensitive to the side effects of the drug, especially muscle damage. This medication must not be used during pregnancy. If you become pregnant or think you may be pregnant, inform your doctor immediately. It is recommended that young girls and women of child-bearing age use effective birth control measures to prevent pregnancy while taking this drug since lovastatin may cause fetal harm. Based on information from related drugs, this medication may pass into breast milk and have undesirable effects on a nursing infant. Breast-feeding is not recommended while using this drug. Consult your doctor before breast-feeding.

## OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

**MISSED DOSE**

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

**STORAGE**

Store between 41 and 86 degrees F (5 to 30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

**Note :** This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



**Taj Group of Companies**<sup>INDIA</sup>

**Taj Pharmaceuticals Ltd.**

Phone : *General EPA BX* : 91 - (0)22 - 26374592/92 91,  
(0)22 - 26374592/93 91 - (0)22 - 30601000,  
Fax : 91-(0)22-26341274

Revised November 2010