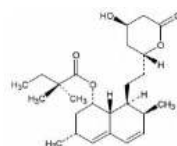


Rx SIMVASTATIN

(Simvastatin is a cholesterol-lowering drug)



DRUG CLASS AND MECHANISM: Simvastatin is a cholesterol-lowering drug. It belongs to a class of drugs called HMG-CoA reductase inhibitors, commonly called "statins." Other statins include lovastatin (Mevacor), 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 and LDL ("bad") cholesterol as well as 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 HDL ("good") cholesterol. Raising HDL cholesterol levels, like lowering LDL cholesterol may slow coronary artery disease. The FDA approved simvastatin in December 1991.

PRESCRIPTION: Yes

GENERIC AVAILABLE: Yes

PREPARATIONS:

* Tablets: 5, 10, 20, 40, and 80 mg.

* Oral disintegrating tablets: 10, 20, 40, and 80 mg.

STORAGE:

* Tablets should be stored between 5-30 C (41-86 F).

* Oral disintegrating tablets should be stored between 20-25 C (68-77 F).

PRESCRIBED FOR: Simvastatin is used for reducing total cholesterol, LDL cholesterol, and triglycerides, and for increasing HDL cholesterol. In patients with coronary heart disease, diabetes, peripheral vessel disease, or history of stroke or other cerebrovascular disease, simvastatin is prescribed for reducing the risk of mortality by reducing death from coronary heart disease, reducing nonfatal myocardial infarction (heart attack) and stroke, and reducing the need for coronary and noncoronary revascularization procedures.

DOSING: The dose range for is 5-80 mg/day given preferably in the evening. The usual starting dose is 20-40 mg once daily. Dose adjustments are made at weekly intervals.

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

Amiodarone (Cordarone), verapamil (Calan Verelan, Isoptin), danazol (Danocrine), cyclosporine, niacin (Niacor, Niaspan, Slo-Niacin), gemfibrozil (Lopid) and fenofibrate (Tricor) also may increase the risk of muscle toxicity when combined with simvastatin. Patients taking amiodarone or verapamil should not take more than 20 mg of simvastatin. Patients taking danazol or cyclosporine should not take more than 10 mg of simvastatin.

Simvastatin increases the effect of warfarin (Coumadin) and the blood concentration of digoxin (Lanoxin). Patients taking simvastatin and warfarin or digoxin should be monitored carefully for toxic effects of warfarin and digoxin.

Cholestyramine (Questran, Questran Light) decreases the absorption of simvastatin. Therefore, simvastatin should only be taken 2 hours before or at least 4 hours after cholestyramine administration.

The dose of simvastatin should be reduced to 40 mg daily when combined with diltiazem (Cardizem, Dilacor, Tiazac) because the combination may increase the risk of rhabdomyolysis (severe muscle injury).

PREGNANCY: Pregnant women should not use simvastatin because the developing fetus requires cholesterol for development, and simvastatin reduces the production of cholesterol. Simvastatin should only be

administered to women of child bearing age if they are not likely to become pregnant.

NURSING MOTHERS: Because of the risk of adverse effects to the developing infant, simvastatin should not be administered to nursing mothers.

SIDE EFFECTS: The most common side effects of simvastatin 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.

Simvastatin 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 for 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 simvastatin is started and periodically thereafter or if there is a medical concern about liver damage. Liver tests should be performed before the 80 mg dose of simvastatin is initiated, three months after initiation and then periodically thereafter.

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 simvastatin should contact their health care practitioner immediately if they develop unexplained muscle pain, weakness, or muscle tenderness.

USES: Simvastatin 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. Simvastatin 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 in the evening, with or without food. Certain medical conditions (e.g., familial hypercholesterolemia) may require more frequent dosage instructions as directed by your doctor. 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 simvastatin. Consult your doctor or pharmacist for more details. Avoid eating grapefruit or drinking grapefruit juice while being treated with this medication unless your doctor instructs you otherwise. Grapefruit juice can 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 simvastatin 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

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