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simvastatin, Zocor

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GENERIC NAME: simvastatin

BRAND NAME: Zocor

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 low density lipoprotein (LDL) or "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 high density lipoprotein (HDL) or "good" cholesterol. Raising HDL cholesterol levels, like lowering LDL cholesterol may slow coronary artery disease. The FDA approved simvastatin in Decembe, 1991.

PRESCRIPTION: Yes

GENERIC AVAILABLE: Yes

PREPARATIONS:

- Tablets: 5, 10, 20, 40, and 80 mg.
- Orally disintegrating tablets: 10, 20, 40, and 80 mg.

STORAGE:

- Tablets should be stored between 5-30 C (41-86 F).
- Orally 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 vascular 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 recommended dose range of simvastatin is 10 mg to 40 mg, and it is administered once daily in the evening with or without food. Therapy usually is initiated with 10 or 20 mg daily, but individuals who have a high risk of heart disease can be started on 40 mg daily.

Simvastatin 80 mg is restricted to patients who have been taking simvastatin 80 mg chronically (for example, for 12 months or more) without evidence of muscle toxicity because the 80 mg dose is associated with increased risk of muscle toxicity, including rhabdomyolysis. Patients who are currently tolerating the 80 mg dose of simvastatin who need to start an interacting drug that should not be taken with simvastatin or is associated with a dose cap for simvastatin should be switched to an alternative statin or statin-based regimen with less potential for the drug-drug interaction.

Patients that require more than the 40 mg dose should be switched to an alternative drug.

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), boceprevir (Victrelis), telaprevir (incivek), voriconazole (Vfend), posaconazole (Noxafil), and HIV protease inhibitors such as indinavir (Crixivan) and ritonavir (Norvir). They should not be combined with simvastatin.

Large quantities of grape fruit juice (>1 quart daily) also will increase blood levels of simvastatin and should be avoided.

Amiodarone (Cordarone), verapamil (Calan Verelan, Isoptin), diltiazem, amlodipine (Norvasc), danazol (Danocrine), ranolazine (Ranexa), 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, amlodipine, or ranolazine should not exceed 20 mg, and patients taking verapamil or diltiazem should not exceed 10 mg of of simvastatin daily. Patients taking gemfibrozil or danazol should not take 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.

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

Chinese patients taking ≥1 g/day of niacin in combination with simvastatin 40 mg have an increased risk of muscle-related side effects. Therefore, these patients should not receive simvastatin 80 mg combined with niacin in doses ≥1 g/day. Simvastatin doses greater than 20 mg daily should be administered cautiously when combined with niacin ≥1 g/day.

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 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. 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 if there is a medical concern about liver damage 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 professional immediately if they develop unexplained muscle pain, weakness, or muscle tenderness.

Statins have been associated with increases in HbA1c and fasting serum glucose levels as are seen in diabetes.

There are also post-marketing reports of memory loss, forgetfulness, amnesia, confusion, and memory impairment. Symptoms may start one day to years after starting treatment and resolve within a median of three weeks after stopping the statin.

Reference: FDA Prescribing Information

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