

FDA Drug Safety Communication: Ongoing safety review of high-dose Zocor* (simvastatin) and increased risk of muscle injury

The U.S. Food and Drug Administration (FDA) is informing the public about an increased risk of muscle injury in patients taking the highest approved dose of the cholesterol-lowering medication, Zocor (simvastatin) 80 mg, compared to patients taking lower doses of simvastatin and possibly other drugs in the "statin" class.

The muscle injury, also called myopathy, is a known side effect with all statin medications. Patients with myopathy generally have muscle pain, tenderness or weakness, and an elevation of a muscle enzyme in the blood (creatinine kinase). The higher the dose of statin used, the greater the risk of developing myopathy. The risk of myopathy is also increased when simvastatin, especially at the higher doses, is used with certain drug. The most serious form of myopathy is called rhabdomyolysis. It occurs when a protein (myoglobin) is released as muscle fibers break down. Myoglobin can damage the kidneys.

Patients with rhabdomyolysis may have dark or red urine and fatigue, in addition to their muscle symptoms. Damage to the kidneys from rhabdomyolysis can be so severe that patients may develop kidney failure, which can be fatal. Known risk factors for developing rhabdomyolysis include age (> 65 years), low thyroid hormone levels (hypothyroidism), and poor kidney function. Myopathy and rhabdomyolysis are listed as possible side effects in the simvastatin and other statin drug labels.

For more information, visit the FDA Web site at:

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204882.htm>