

March 30, 2010

FDA Safety Announcement: High-Dose Zocor 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 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.

Healthcare professionals should:

- Understand that rhabdomyolysis is a rare adverse event reported with all statins.
- Be aware of the potential increased risk of muscle injury with the 80 mg dose of simvastatin compared to lower doses of simvastatin and possibly other statin drugs.
- Follow the recommendations in the simvastatin label regarding drugs that may increase the risk for muscle injury when used with simvastatin.
- Understand that rhabdomyolysis is a rare adverse event reported with all statins.
- Be aware of the potential increased risk of muscle injury with the 80 mg dose of simvastatin compared to lower doses of simvastatin and possibly other statin drugs.
- Review patients' medical history and medications to determine if simvastatin is clinically appropriate.
- Discuss with patients the benefits and risks, including the risk of myopathy and rhabdomyolysis, of simvastatin therapy.
- Be aware of potential drug-drug interactions with simvastatin.
- Report any adverse events associated with the use of simvastatin to FDA's MedWatch program.

Patients should:

- Not stop taking simvastatin unless told to by their healthcare professional.
- Talk to their healthcare professional about any questions they have about the use of simvastatin.
- Call their healthcare professional if they experience any of the following: muscle pain, tenderness or weakness, urine that is dark or red-colored, or unexplained tiredness.
- Know that rhabdomyolysis is a rare side effect reported with all statin medications.
- Not stop taking simvastatin unless told to by their healthcare professional.
- Review their medical history and current medications with their healthcare professional to determine if they should continue using simvastatin.
- Talk to their healthcare professional about any questions or concerns they have about simvastatin.
- Call their healthcare professional if they have muscle pain, tenderness or weakness, dark or red colored urine, or unexplained tiredness.
- Report any side effects with simvastatin to FDA's MedWatch program..

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm199082.htm>

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www.kcercoalition.com/alerts.htm