MedicalXpress

FDA announces new limits on high-dose simvastatin (Zocor)

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The United States Food and Drug Administration (FDA) today announced new limitations to the use of high-dose simvastatin, due to the increased risk of muscle pain and weakness (myopathy) and in rare cases, kidney damage and failure.

The American Heart Association recommends that all physicians and patients follow the FDA's recommendations regarding high-dose simvastatin.

Simvastatin is prescribed, along with a healthy diet and exercise to lower the low-density lipoprotein (LDL) cholesterol ("bad cholesterol") in the blood, and to decrease the risk of heart attack, stroke, and cardiovascular death. It is used in doses ranging from 10 mg to 80 mg. per day.

The changes are based on the FDA's recent review of the SEARCH trial, a seven-year, randomized double-blind clinical trial comparing patients with a previous heart attack taking 80 mg of simvastatin daily vs. 20 mg. daily. The trial found that the incidence of major vascular events was 25.7 percent for those taking 20 mg vs. 24.5 percent taking 80 mg. Approximately 52 patients in the study taking the 80 mg. dose experienced myopathy. About 60 percent of those experiencing myopathy had a genetic difference making it more likely.

A rare but serious form of myopathy, called rhabdomyolysis, can damage the kidneys and lead to potentially fatal kidney failure.

The American Heart Association supports the FDA recommendations for:

· Patients who have taken the 80 mg. dose of simvastatin for a year or more without myopathy to remain on their current dose, unless recommended otherwise by their healthcare provider.
· Patients with any symptoms of muscle pain or weakness, dark or red urine, or unexplained tiredness to contact their healthcare provider immediately.
· Patients taking 80 mg. of simvastatin for less than a year to talk to their provider about changing their dose, and not to discontinue their dose on their own.
· Healthcare providers not to write new prescriptions for 80 mg. simvastatin or increase patients' dosage to 80 mg.
· Providers to reduce the dosage or try an alternative drug to lower LDL cholesterol for patients taking 80 mg. simvastatin daily for less than a year.

According to the FDA, in 2010, 2.1 million Americans were taking the 80 mg. dose of simvastatin.

Provided by American Heart Association