FDA announces new safety recommendations for high-dose simvastatin

Increased risk of muscle injury cited

The U.S. Food and Drug Administration today is announcing safety label changes for the cholesterol-lowering medication simvastatin because the highest approved dose--80 milligram (mg)--has been associated with an elevated risk of muscle injury or myopathy, particularly during the first 12 months of use.

The agency is recommending that simvastatin 80 mg be used only in patients who have been taking this dose for 12 months or more and have not experienced any muscle toxicity. It should not be prescribed to new patients. There are also new contraindications and dose limitations for when simvastatin is taken with certain other medications.

Simvastatin is used together with diet and exercise to reduce the amount of "bad cholesterol" (low-density lipoprotein cholesterol or LDL-C) in the blood. High levels of LDL-C are linked to a higher risk of heart attack, stroke and cardiovascular death. In 2010, about 2.1 million patients in the United States were prescribed a product containing simvastatin 80 mg.

"The FDA has completed its review of the safety of high-dose simvastatin and is making label changes to reduce the risk of statin-associated muscle injury," said Eric Colman, M.D., deputy director of the Division of Metabolism and Endocrinology Products in the FDA's Center for Drug Evaluation and Research. "We want to ensure that patients and health care professionals are aware of the new labeling changes to simvastatin, including the increased risk of myopathy when using the 80 mg dose of simvastatin."

The changes to the label for simvastatin-containing medications are based on the FDA's review of the results of the seven-year Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine clinical trial, other clinical trial data, and analyses of adverse events submitted to the FDA's Adverse Event Reporting System. All showed that patients taking simvastatin 80 mg daily had an increased risk of muscle injury compared to patients taking lower doses of simvastatin or other statin drugs. The risk of muscle injury is highest during the first year of treatment with the 80 mg dose of simvastatin, is often the result of interactions with certain other medicines, and is frequently associated with a genetic predisposition for simvastatin-related muscle injury.

Simvastatin is sold under the brand-name Zocor and as a single-ingredient generic product. It is also sold in combination with ezetimibe as Vytorin and in combination with niacin as Simcor.

The FDA has revised the drug labels for simvastatin and Vytorin to include the new 80 mg dosing restrictions. The agency also revised the labels for simvastatin, Vytorin and Simcor to include new dosing recommendations when these drugs are used with certain medications that interact to increase the level of simvastatin in the body, which can increase the risk for myopathy. Patients who are unable to adequately lower their level of LDL-C on simvastatin 40 mg should not be given the higher 80 mg dose of simvastatin; instead, they should be placed on an alternative LDL-C-lowering treatment(s).

For more information:

- FDA Drug Safety Communication: New restrictions, contraindications, and dose limitations for Zocor (simvastatin) to reduce the risk of muscle injury [1]
- FDA Consumer Update: Limit use of 80 mg simvastatin [2]
- Previous FDA Drug Safety Communication: Ongoing safety review of high-dose Zocor (simvastatin) and increased risk of muscle injury [3]
- FDA Warns about Increased Risk of Muscle Injury with Zocor [4]

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