

Feds Slap New Warnings on Cholesterol-Lowering Statins, Including Diabetes Risk

U.S. health officials will be adding new safety warnings of memory loss, confusion, high blood sugar, and type II diabetes as possible side effects to popular cholesterol-lowering drugs called statins, the U.S. Food and Drug Administration announced on Tuesday.

BY CHRISTINE HSU | FEBRUARY 28, 2012

U.S. health officials will be adding new safety warnings of memory loss, confusion, high blood sugar, and type II diabetes as possible side effects to popular cholesterol-lowering drugs called statins, the U.S. Food and Drug Administration announced on Tuesday.

The FDA on Tuesday also removed the requirement that health care providers must monitor patients' livers because serious liver injury is "rare" with statins, the agency said in a statement.

The new safety labels of statins like Pfizer's Lipitor, AstraZeneca's Crestor and Merck & Co. Inc.'s Zocor, must now contain information that warns patients of the risk of cognitive impairment, mental confusion, risk of high blood sugar and risk of being diagnosed with type II diabetes.

The health agency also singled out lovastatin, sold under the brand name Mevacor, with an additional warning for risk of muscle damage. All statin medications have a small risk for muscle injury, but the FDA said that this risk is especially high for patients taking lovastatin along with certain other drugs for HIV and some antibiotics.

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"We want health care professionals and patients to have the most current information on the risks of statins, but also to assure them that these medications continue to provide an important health benefit of lowering cholesterol," Mary Parks, MD, director of the FDA's Division of Metabolism and Endocrinology Products, said in a news release.

The products subject to FDA's new labeling requirements include: Lipitor (atorvastatin), Lescol (fluvastatin), Mevacor (lovastatin), Altoprev (lovastatin extended-release), Livalo (pitavastatin), Pravachol (pravastatin), Crestor (rosuvastatin), and Zocor (simvastatin). Combination products include: Advicor (lovastatin/niacin extended-release), Simcor (simvastatin/niacin extended-release), and Vytorin (simvastatin/ezetimibe).

However, the FDA stresses that the new information should not "scare people off" statins.

Statins have been shown to significantly reduce the risk of heart attack and heart disease, said the deputy director for safety in FDA's Division of Metabolism and Endocrinology Products, Amy Egan, and

that “their benefit is indisputable” but patients need to know about the drugs side effects and that statins “need to be taken with care”.

This article has been revised to reflect the following correction:

Correction: March 7, 2012

The article from Feb 28, 2012 misstated 'high blood pressure' as one of the possible side effects of statins in the third paragraph. The new safety labels of statins must now contain information that warns patients of the risk of high blood sugar, not high blood pressure.

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