Statin Drugs - Drug Safety Communication: Class Labeling Change

U.S. Food & Drug Administration

ISSUE: FDA has approved important safety label changes for the class of cholesterol-lowering drugs known as statins. The changes include removal of routine monitoring of liver enzymes from drug labels. Information about the potential for generally non-serious and reversible cognitive side effects and reports of increased blood sugar and glycosylated hemoglobin (HbA1c) levels has been added to the statin labels.

The lovastatin label has been extensively updated with new contraindications and dose limitations when it is taken with certain medicines that can increase the risk for muscle injury.

Read the FDA Drug Safety Communication for more information.

BACKGROUND: Statins are a class of prescription drugs used together with diet and exercise to reduce blood levels of low-density lipoprotein (LDL) cholesterol (“bad cholesterol”). Marketed as single-ingredient products, including Lipitor (atorvastatin), Lescol (fluvastatin), Mevacor (lovastatin), Altoprev (lovastatin extended-release), Livalo (pitavastatin), Pravachol (pravastatin), Crestor (rosuvastatin), and Zocor (simvastatin). Also marketed as combination products, including Advicor (lovastatin/niacin extended-release), Simcor (simvastatin/niacin extended-release),and Vytorin (simvastatin/ezetimibe).

RECOMMENDATION: Healthcare professionals should perform liver enzyme tests before initiating statin therapy in patients and as clinically indicated thereafter. If serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs during treatment, therapy should be interrupted. If an alternate etiology is not found, the statin should not be restarted.

Healthcare professionals should follow the recommendations in the lovastatin label regarding drugs that may increase the risk of myopathy/rhabdomyolysis when used with lovastatin.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[02/28/2012 - Drug Safety Communication [2] - FDA]

SOURCE [3]

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