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FDA Adds Warnings to Statin Label

Reed Miller | Feb 28, 2012

February 28, 2012 (Silver Spring, Maryland) — Taking a statin can raise blood sugar and glycosylated hemoglobin HbA1c levels, according to a new labeling change approved by the Food and Drug Administration (FDA) today for the entire drug class [1].

As reported by **heart*wire*** , recent studies of popular statins showed a significant increase in the risk of diabetes mellitus associated with high-dose statin therapy. The **Justification for the Use of Statins in Primary Prevention: An Intervention Trial Evaluating Rosuvastatin** (JUPITER) trial showed a 27% increase in diabetes mellitus in patients taking **rosuvastatin** compared to placebo. Also, the **Pravastatin or Atorvastatin Evaluation and Infection Therapy: Thrombolysis In Myocardial Infarction 22** (PROVE-IT TIMI 22) substudy showed that high-dose atorvastatin can worsen glycemic control.

The labeling changes approved by the FDA also include new information on the potential for usually minor and reversible cognitive side effects. Also, the label for **lovastatin** has been significantly updated to provide information on contraindications and dose limitations for the drug in patients taking other medicines that may increase the risk for muscle injury.

The FDA says it is also eliminating the recommendation that patients on statins undergo routine periodic monitoring of liver enzymes, because this approach is ineffective in detecting and preventing the "rare and unpredictable" serious liver injuries related to statins. Statin therapy should be interrupted if the patient shows signs of serious liver injury, hyperbilirubinemia, or jaundice. The statin therapy should not be restarted if the drugs cannot be ruled out as a cause of the problems, the labeling will now state.

References

1. Food and Drug Administration. FDA Drug Safety Communication: Important safety label changes to cholesterol-lowering statin drugs. February 28, 2012. Available here

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