FDA Update Statin Labels Updated

HCV Protease Inhibitor Contraindication Highlighted

by George Ochoa

The product labels on statins are changing to reflect new information deemed important by the FDA. The FDA announced the changes in late February as part of an overhaul of statin prescribing information.

One of the changes regards interactions between certain statins and hepatitis C virus (HCV) and HIV protease inhibitors. Taken together, statins and protease inhibitors may raise the blood levels of statins and increase the risk for muscle injury. One statin in particular, lovastatin, has been updated with new contraindications and dose limitations when it is taken with certain other drugs that can increase the risk for myopathy and rhabdomyolysis, including the HCV protease inhibitors boceprevir and telaprevir.

The FDA also approved labeling changes regarding the potential for statins to increase levels of blood sugar and glycosylated hemoglobin, signs of incipient type 2 diabetes. This decision was based on accumulating studies linking statins with the development of type 2 diabetes, the agency said. These included the Justification for the Use of Statins in Primary Prevention: an Intervention Trial Evaluating Rosuvastatin trial, which reported a 27% increase in investigator-reported diabetes in patients who received rosuvastatin compared with those who took a placebo (Ridker PM et al. N Engl J Med 2008;359:2195-2207); the Pravastatin or Atorvastatin Evaluation and Infection Therapy—Thrombolysis In Myocardial Infarction 22 substudy, which found an association between high-dose atorvastatin and worsening glycemic control (Sabatine MS et al. Circulation 2004;110:S834); and meta-analyses such as one by Sattar et al (Lancet 2010;375:735-742), which found that statin therapy was associated with a 9% increased risk for incident diabetes.

The potential for cognitive side effects, such as memory loss and confusion, in patients taking statins also was noted by the FDA. These side effects are generally reversible and not serious. The FDA stressed that “the cardiovascular benefits of statins outweigh these small increased risks.”

Additionally, statin labels have been revised to eliminate the need for routine periodic monitoring of liver enzymes in patients taking these drugs. Instead, statin labels now recommend the use of liver enzyme tests before starting the drugs and as clinically indicated afterward. Serious liver injury with statins is rare and unpredictable, according to the FDA, and routine periodic monitoring does not seem effective in detecting or preventing the problem.