New warning for statin drug

FDA Consumer, May-June, 2005

The FDA has issued a public health advisory on the cholesterol-lowering drug Crestor (rosuvastatin calcium) to inform people about a possible risk of serious muscle damage from a condition called rhabdomyolysis that could occur with use of the drug. This advisory is part of an ongoing agency effort to provide people with earlier access to emerging safety information about their medicines so they can make more informed choices about their health care. Extensive review of the available data indicates that patients taking recommended doses of Crestor have a similar risk of rhabdomyolysis as patients on other statin cholesterol treatments. Rhabdomyolysis is a rare but well-known side effect of all statins. Various types of kidney failure also have been reported in patients treated with Crestor, as well as other statins.

At the same time that the FDA issued the advisory, Crestor's manufacturer, AstraZeneca Pharmaceuticals of Wilmington, Del., revised the package insert for the drug, based on discussions with the agency. These changes re-emphasize recommendations made in the original label about the need for physicians to consider using lower starting doses of the drug in some individuals as a means of reducing the risk of rhabdomyolysis.

Overall, the FDA believes that the potential benefits of statin drugs when used as labeled and indicated for the treatment of elevated cholesterol outweigh their potential risks and provide an important treatment option for millions of Americans at risk for heart disease. The agency will continue to evaluate the scientific data on Crestor and other statin drugs and, when appropriate, will modify the particular drug's labeling.

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