

FDA Issues Health Warning About Zocor

By J.D. Heyes, NaturalNews

Federal drug safety regulators are calling for limits on the maximum dose of the cholesterol-lowering medication simvastatin, more commonly known as Zocor, because they say the 80 mg version may harbor an increased risk of muscle injury.

One report noted the Food and Drug Administration completed a safety review of Zocor last month, recommending that no new patients be given the max dose of 80 mg, because of an increased risk of developing myopathy and rhabdomyolysis, both rare forms of muscle injury.

The agency also recommended that Zocor not be used in combination with a number of other drugs, including the cholesterol drugs Vytorin and Simcor.

FDA drug safety officials began examining the max-dose side effects of Zocor in March 2010, when the agency warned the drug may carry an increased risk of muscle injury. The agency found that about 4.9 people out of 100,000 who are on the 80 mg dose could be hospitalized for rhabdomyolysis within the first year, when the risk is at its highest level.

Because of those findings, the FDA says doctors should only prescribe the maximum 80 mg dose to patients who have already been taking the drug for more than a year without exhibiting problematic signs and symptoms.

In addition, FDA regulators are urging doctors not to start patients on doses any higher than 40 mg, and, if they don't respond favorably at that level, then to try another treatment rather than prescribe the higher 80 mg dose.

According to data, damage from Zocor occurs when muscle fibers start to break down, releasing the protein myoglobin, which can cause kidney damage as those organs work to filter the protein out of the bloodstream.

Patients suffering from rhabdomyolysis exhibit symptoms of muscle cramping, tenderness, stiffness and pain sometimes accompanied with muscle spasms. The disease is most often reported in patients older than 65 years old or in patients with renal deficiency or uncontrollable hypothyroidism.

Zocor is a statin, and all statins have been found to carry a risk of causing muscle damage, rhabdomyolysis being the most severe (and rarest) form. The disease, if severe enough, can cause renal damage, kidney failure and even death.

And yet, statins are among the best-selling medications in the nation, resulting in about \$14.5 billion in sales annually. Some of the most popular statins include Crestor, Lipitor, Mevacor, Lescol and Pravachol. They work through the liver to block the creation of cholesterol, which is a major cause of coronary artery (heart) disease.