

**Zocor (simvastatin): increased risk of muscle injury with high doses**

Simvastatin is sold as a single-ingredient generic medication and as the brand-name, Zocor. It is also sold in combination with ezetimibe as Vytorin; and niacin as Simcor.

**Audience:** Primary care providers, patients

[Posted 03/19/2010] FDA notified healthcare professionals and patients that, based on review of data from a large clinical trial and other sources, there is an increased risk of muscle injury in patients taking the highest approved dose of the cholesterol-lowering medication, Zocor (simvastatin) 80 mg, compared to patients taking lower doses of simvastatin and possibly other drugs in the "statin" class. FDA is also reviewing data from other clinical trials, observational studies, adverse event reports, and data on prescription use of simvastatin to better understand the relationship between high-dose simvastatin use and muscle injury.

Recommendations for healthcare professionals, recommendations for patients and a data summary of information used in this ongoing review are provided in the Drug Safety Communication.