

FDA Announces Safety Recommendations for High-Dose Simvastatin

Merck has announced changes to prescribing information in the US for the highest dose of the cholesterol-lowering drug simvastatin (marketed as *Zocor*), 80 mg, and the use of simvastatin with certain other medicines. The revised prescribing information also applies to Merck's *Vytorin* (ezetimibe/simvastatin), another cholesterol-lowering drug. The changes follow an FDA review, announced by the agency in March 2010, of the risk of myopathy, including its most serious form, rhabdomyolysis, with the highest dose of simvastatin. Merck has updated US prescribing information to limit the use of the 80 mg dose of simvastatin to patients who have been taking that amount for 12 months or more without evidence of muscle toxicity; to contraindicate and/or limit the dose of simvastatin when used in combination with certain drugs that may increase the risk of myopathy and rhabdomyolysis. Simvastatin is contraindicated with certain azole antifungals and antibiotics, with HIV protease inhibitors, and with nefazodone, gemfibrozil, cyclosporine, and danazol. The maximum recommended doses of simvastatin have been revised when used with amiodarone, ranolazine, and the calcium channel blockers verapamil, diltiazem, and amlodipine. See Simvastatin info [online](#) for patient information.