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Generic Name:

Simvastatin

Trade Name:

Zocor

Company:

Merck

Notes:

The dose limitation for simvastatin has been increased from 10 mg to 20 mg when coadministered with amiodarone, according to an [FDA safety communication](#). The agency noted that a June 2011 reduction in simvastatin dose for this combination was made when FDA restricted use of simvastatin 80 mg and lowered recommended doses for the drug.

FDA stated that unlike other interacting drugs, there were no pharmacokinetic or clinical trial data to support the simvastatin dose reduction approved with amiodarone. Based on this assessment, the agency determined that the simvastatin dose limitation, when taken with amiodarone, should be restored to 20 mg.

The label for simvastatin has been modified to reflect this change.

Medication Monitor Categories:

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