Zocor (simvastatin): Label Change - New Restrictions, Contraindications, and Dose Limitations(2)

AUDIENCE : Family Practice, Cardiology, Pharmacy

ISSUE : FDA notified healthcare professionals that it is recommending limiting the use of the highest approved dose of the cholesterol-lowering medication simvastatin (80 mg) because of increased risk of muscle damage. Patients taking simvastatin 80 mg daily have an increased risk of myopathy compared to patients taking lower doses of this drug or other drugs in the same class. This risk appears to be higher during the first year of treatment, is often the result of interactions with certain medicines, and is frequently associated with a genetic predisposition toward simvastatin-related myopathy. The most serious form of myopathy, called rhabdomyolysis, can damage the kidneys and lead to kidney failure which can be fatal. FDA is requiring changes to the simvastatin label to add new contraindications (should not be used with certain medications) and dose limitations for using simvastatin with certain medicines.

BACKGROUND : The new changes to the drug labels for simvastatin-containing medicines are based on FDA's review of the Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine (SEARCH) trial and other data described in the Agency's March 2010 Ongoing safety review of high-dose Zocor (simvastatin) and increased risk of muscle injury. Simvastatin 80 mg should be used only in patients who have been taking this dose for 12 months or more without evidence of muscle injury (myopathy).

RECOMMENDATION : Simvastatin 80 mg should not be started in new patients, including patients already taking lower doses of the drug.

Healthcare professionals and patients are encouraged to report adverse events, side effects, or product quality problems related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[06/08/2011 - Drug Safety Communication [3] - FDA]
[06/08/2011 - News Release [4] - FDA]
[06/08/2011 - Consumer Update [5] - FDA

SOURCE [6]

Source URL (retrieved on *04/24/2014 - 3:52am*):
http://www.mdtmag.com/news/2011/06/zocor-simvastatin-label-change-new-restrictions-contraindications-and-dose-limitations2

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm
[4] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm258338.htm
[5] http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm257884.htm
[6] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm258384.htm