MedWatch The FDA Safety Information and Adverse Event Reporting Program

Zocor (simvastatin): Label Change - New Restrictions, Contraindications, and Dose Limitations (包含 simvastatin 單方 Zocor、複方 Vytorin)

[Updated 06/08/2011]

FDA 建議限制使用 simvastatin 最高劑量（80 mg），因為會增加肌肉損傷的風險。病患使用 simvastatin 80 mg，與使用同類藥品的病患及使用低劑量 simvastatin 的病患相比，肌肉損傷的風險較高。這種風險在第一年治療時較高，這種結果通常是因藥品交互作用和遺傳因素所導致。FDA 要求仿單內增加新的禁忌症（不可與特定藥品併用），與特定藥品並用時要限制劑量。

Simvastatin 80 mg 只可用於已經使用此劑量超過 12 個月以上，且沒有肌肉損傷證據之病人。剛開始治療或使用較低劑量治療的病人，不可用 Simvastatin 80 mg。

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AUDIENCE: Family Practice, Cardiology, Pharmacy

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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.

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).

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