MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

Simvastatin (Zocor)

[03/19/2010]

美國FDA 近期回顧降膽固醇用藥Zocor（藥品成分：Simvastatin）之臨床試驗（臨床試驗名稱SEARCH，the **S**tudy of the **E**ffectiveness of **A**dditional **R**eductions in **C**holesterol and **H**omocysteine trial）及其他藥品安全資訊，初步發現每日服用該藥品核准之最高劑量80 毫克，與服用該成分藥品較低劑量或其他statin 類藥品相比較，會增加肌肉損傷（例如：肌肉疼痛、橫紋肌溶解等）之風險。美國 FDA 正彙整該成分藥品之其他臨床試驗資料、觀察性研究、和藥品不良反應通報資料，以進一步了解高劑量使用simvastatin 成分藥品和肌肉損傷之間的關係。同時提醒醫療人員，服用simvastatin 與statin 類藥品一樣，都會引起肌病的不良反應，包括罕見的橫紋肌溶解，尤其每日服用高劑量simvastatin 成分藥品，又併用某些特定藥品，會增加其風險。FDA 也提醒目前正在服用降低膽固醇藥品之病患，倘若病患對於服用藥品有任何疑慮，應洽詢開立處方之醫師，不應擅自停藥。

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Audience: Primary care providers, patients

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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.