MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

Statin Drugs - Drug Safety Communication: Class Labeling Change

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最近美國食品藥物管理局於回顧statin 類藥品之上市後安全資訊及多個臨床試驗結果報告，作出以下建議(1)肝功能監測：病人於開始使用statin 前，需監測肝功能指數，服藥期間若出現疑似肝功能異常之臨床症狀時，需再次檢測肝功能指數；(2)於仿單中新增不良事件訊息：部分報告顯示，該類藥品可能導致非嚴重且停藥後可恢復之可逆性認知障礙（例如失憶、混亂），及些微增加血糖及糖化血色素(HbA1c)上升之風險；惟美國食品藥物管理局認為該類藥品對心血管之臨床效益仍高於些微血糖上升之風險 (3) lovastatin 藥物交互作用：lovastatin 併用CYP3A4 抑制劑藥品時會產生交互作用，而提高橫紋肌溶解症之不良反應風險。

前述藥品安全資訊，除認知障礙及血糖升高風險外，均已刊載於衛生署核准之statin 類藥品仿單中，為保障民眾用藥安全，食品藥物管理局將儘速蒐集國、內外相關安全資訊，評估是否修訂國內該類成分藥品之仿單。

經查，衛生署核准含statin類藥品製劑許可證共有103張，包括含simvastatin 36張、atorvastatin 28張、fluvastatin 4張、lovastatin 9張、pitavastatin 1張、rosuvastatin 3張、pravastatin 22張，核准用於治療高膽固醇血症、高三酸甘油脂血症，降低冠心病高危險群或冠心病患者的心血管事件發生率及冠心病致死率，患有異核質家族性高膽固醇血症的兒童病患等疾病。

衛生署食品藥物管理局提醒醫師，處方含statin 類藥品前，宜醫師謹慎評估其臨床效益及風險，尤其是併用藥品為病人治療時，注意監測病人服藥後之不良反應發生情形。食品藥物管理局提醒正在服用該成分藥品之患者，不可擅自停藥，如發生不尋常之疲倦、虛弱、食慾不振、上腹疼痛等不適症狀，應儘速回診開立處方之醫師。(行政院衛生署藥品不良反應通報系統公告)

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AUDIENCE: Cardiology, Family Practice, Patients

ISSUE: FDA has approved important safety label changes for the class of cholesterol-lowering drugs known as statins. The changes include removal of routine monitoring of liver enzymes from drug labels. Information about the potential for generally non-serious and reversible cognitive side effects and reports of increased blood sugar and glycosylated hemoglobin (HbA1c) levels has been added to the statin labels.

The lovastatin label has been extensively updated with new contraindications and dose limitations when it is taken with certain medicines that can increase the risk for muscle injury.

Read the FDA Drug Safety Communication for more information.

BACKGROUND: Statins are a class of prescription drugs used together with diet and exercise to reduce blood levels of low-density lipoprotein (LDL) cholesterol ("bad cholesterol"). Marketed as single-ingredient products, including Lipitor (atorvastatin), Lescol (fluvastatin), Mevacor (lovastatin), Altoprev (lovastatin extended-release), Livalo (pitavastatin), Pravachol (pravastatin), Crestor (rosuvastatin), and Zocor (simvastatin). Also marketed as combination products, including Advicor (lovastatin/niacin extended-release), Simcor (simvastatin/niacin extended-release),and Vytorin (simvastatin/ezetimibe).

RECOMMENDATION: Healthcare professionals should perform liver enzyme tests before initiating statin therapy in patients and as clinically indicated thereafter. If serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs during treatment, therapy should be interrupted. If an alternate etiology is not found, the statin should not be restarted.
Healthcare professionals should follow the recommendations in the lovastatin label regarding drugs that may increase the risk of myopathy/rhabdomyolysis when used with lovastatin.