Statins and HIV or Hepatitis C Drugs: Drug Safety Communication - Interaction Increases Risk of Muscle Injury

U.S. Food & Drug Administration

AUDIENCE: Infectious Disease, Family Practice, Patients

ISSUE: FDA notified healthcare professionals of updates to the prescribing information concerning interactions between protease inhibitors and certain statin drugs. Protease inhibitors and statins taken together may raise the blood levels of statins and increase the risk for muscle injury (myopathy). The most serious form of myopathy, called rhabdomyolysis, can damage the kidneys and lead to kidney failure, which can be fatal.

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"). HIV protease inhibitors are a class of prescription anti-viral drugs used to treat HIV. HCV protease inhibitors are a class of prescription anti-viral drugs used to treat hepatitis C infection.

RECOMMENDATION: Healthcare professionals should follow the recommendations in the prescribing information (drug labels) when prescribing HIV or HCV protease inhibitors with statins. See the FDA Drug Safety Communication for additional information, including a data summary.

Healthcare professionals and patients are encouraged to report adverse events or side effects 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

SOURCE [3]

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http://www.mdtmag.com/news/2012/03/statins-and-hiv-or-hepatitis-c-drugs-drug-safety-communication-interaction-increases-risk-muscle-injury?qt-recent_content=0

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/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm294294.htm