FDA: Samsca may cause irreversible liver damage

January 26 2013

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(HealthDay)—Patients who take Samsca (tolvaptan) may be at elevated risk for significant liver injury, according to a Jan. 25 safety alert issued by the U.S. Food and Drug Administration.

The FDA and Otsuka notified health care providers of this potential risk after three patients with Autosomal Dominant Polycystic Kidney Disease (ADPKD) participating in a drug trial developed significant increases in serum alanine aminotransferase, along with significant increases in serum total bilirubin. The patients were taking a higher dose (90 mg in the morning and 30 mg in the afternoon) than the 60-mg dose approved for hyponatremia. Samsca is not approved for treating of ADPKD.

An external panel of liver experts determined that tolvaptan was most likely the culprit in these three cases; all of the patients improved once

they stopped taking the drug.

"Health care providers should perform liver tests promptly in patients who report symptoms that may indicate liver injury," the authors write. "If hepatic injury is suspected, Samsca should be promptly discontinued, appropriate treatment should be instituted, and investigations should be performed to determine probable cause. Samsca should not be re-initiated in patients unless the cause for the observed liver injury is definitively established to be unrelated to treatment with Samsca."

More information: More Information