

FDA reports Samsca may cause liver damage

May 2 2013



After reviewing data from recent large clinical trials, the U.S. Food and Drug Administration has determined that Samsca (tolvaptan) should not be used for longer than 30 days and should not be used at all by patients with underlying liver disease.

(HealthDay)—After reviewing data from recent large clinical trials, the U.S. Food and Drug Administration has determined that Samsca (tolvaptan) should not be used for longer than 30 days and should not be used at all by patients with underlying liver disease.

Samsca, a selective vasopression V2-receptor antagonist indicated for the treatment of patients with hypervolemic and euvolemic hyponatremia, was shown to increase the risk of [liver injury](#) in trials evaluating the drug in patients with autosomal dominant [polycystic kidney disease](#).

Samsca's recognized limitations will be reflected in its drug label, created in tandem by the FDA and Otsuka, the drug's manufacturer.

According to the FDA, "Samsca treatment should be stopped if the

patient develops signs of liver disease. Treatment duration should be limited to 30 days or less, and use should be avoided in patients with underlying liver disease, including cirrhosis. Patients should be aware that Samsca may cause liver problems, including life-threatening [liver failure](#), and should contact their health care professional to discuss any questions or concerns about Samsca."

More information: [More Information](#)

[Health News](#) Copyright © 2013 [HealthDay](#). All rights reserved.

Citation: FDA reports Samsca may cause liver damage (2013, May 2) retrieved 26 April 2024 from <https://medicalxpress.com/news/2013-05-fda-samsca-liver.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.