

## FDA warns of liver problems for some taking hep C drugs

August 29 2019



(HealthDay)—Taking the hepatitis C drugs Mavyret, Zepatier or Vosevi



can trigger rare cases of severe liver problems or liver failure in patients who already have moderate-to-severe liver impairment, the U.S. Food and Drug Administration warned Wednesday.

The agency has identified 63 cases of worsening liver function, some resulting in <u>liver failure</u> or death, among patients taking the drugs.

While the medicines are safe and effective in patients with no or mild liver impairment, the same cannot be said for those with moderate-tosevere liver impairment, the FDA said.

"Hepatitis C virus remains a significant public health issue, but effective therapeutic options have helped patients to receive important curative treatments," said Dr. Debra Birnkrant, director of the FDA's Division of Antiviral Products at the Center for Drug Evaluation and Research.

"Chronic hepatitis C, or HCV, is a viral disease that causes inflammation of the liver that can lead to serious liver problems if left untreated. Hepatitis C medicines reduce the amount of HCV in the body by preventing it from multiplying and eventually curing a patient of HCV," Birnkrant explained in an agency news release.

Health care providers should continue to prescribe Mavyret, Zepatier or Vosevi as indicated, but should not give these medicines to patients with signs and symptoms of worsening liver function, the agency advised.

Dr. David Bernstein, chief of hepatology at Northwell Health in Manhasset, N.Y., noted that these medications "are safe and effective when properly prescribed."

Bernstein said that "most hepatitis C patients do not have impaired liver function, so these therapies should be safe."



And he added that other hepatitis drugs such as Harvoni and Epclusa are safe for patients with impaired liver function because they do not contain the agent that can threaten <u>liver function</u>.

Patients should not stop taking these medicines without first talking to a health care professional, and those with liver disease should talk with a health care professional about the benefits and risks of the medicines, the FDA said.

In many of the 63 cases, liver failure occurred in patients who should not have been prescribed these medicines, according to the FDA news release.

In some cases, patients had no cirrhosis (liver scarring) or cirrhosis with mild liver impairment, but did have indications of advanced liver disease or risk factors for <u>liver</u> impairment. In most of the patients, symptoms improved after they stopped taking the potent medicines.

**More information:** The U.S. Centers for Disease Control and Prevention has more on <u>hepatitis C</u>.

Copyright © 2019 HealthDay. All rights reserved.

Citation: FDA warns of liver problems for some taking hep C drugs (2019, August 29) retrieved 4 May 2024 from <a href="https://medicalxpress.com/news/2019-08-fda-liver-problems-hep-drugs.html">https://medicalxpress.com/news/2019-08-fda-liver-problems-hep-drugs.html</a>

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.