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Serious Liver Injury with Hepatitis C Medications: Mavyret™, Zepatier, ™ and Vosevi™

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on August 28, 2019 the US Food and Drug Administration (FDA) published a safety communication notifying that 63 cases of hepatitis C patients who were on the following direct-acting antivirals (DAAs): Mavyret™ (N=46), Zepatier™ (N=14), or Vosevi™ (N=3) resulted in rare cases of life-threatening decompensation of liver function or liver failure and death. The adverse events occurred within 4 weeks of starting treatment (median time to onset of liver-related adverse event was 22 days [2 days up to 16 weeks]). Isolated hyperbilirubinemia and jaundice were reported in 10 patient's w/o increased transaminase levels or any other liver related adverse event and death in 8 cases. Most patients have a resolution of symptoms or liver function improvement after discontinuation of the medication.

It is important to pointed out that reported drugs: (Mavyret™, Zepatier™, and Vosevi™) were approved by FDA to treat chronic hepatitis C in patients without liver impairment or with mild liver impairment (Child-Pugh A). These events occurred in patients with moderate to severe liver impairment (Child Pugh B or C) or had pre-existing risk factors i.e. liver cancer or alcohol abuse.

The FDA statement included some important suggestions for health care professionals and patients regarding the use of these medications:

Pharmacists	Patients
• **Monitor patient for signs and symptoms of liver function worsening** • **Follow recommendations in the prescribing information** • **Report** side effects involving **Mavyret™, Zepatier™, and Vosevi™,** or other medicines to the FDA MedWatch program	• DO NOT STOP taking these medications w/o talking first to your prescriber • Report any symptom while on these medications like fatigue, weakness, loss of appetite or light-colored stools, nausea, vomiting, and yellow eyes or skin • Read patient information leaflet every time you picked-up the medication in the case of new information

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For additional information visit: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-rare-occurrence-serious-liver-injury-use-hepatitis-c-medicines-mavyret-zepatier-and

To report any adverse event go to:
https://www.accessdata.fda.gov/scripts/medwatch/index.cfm

Regards,

Clinical Department

Reference:

1. Center for Drug Evaluation and Research, FDA. (2019, August 28). Risk of liver injury with certain HCV drugs in advanced liver disease. Retrieved from https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-rare-occurrence-serious-liver-injury-use-hepatitis-c-medicines-mavyret-zepatier-and

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