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FDA Warns about rare occurrence of serious liver disease with use of hepatitis C medicines Mavyret, Zepatier, and Vosevi in some patients with advanced liver disease

Mavyret (Glecaprevir and Pibrentasvir)
Zepatier (Elbasvir and Grazoprevir)
Vosevi (Sofosbuvir, Velpatasvir, and Voxila)

The FDA observed 63 reported cases of worsening liver function, (liver decompensation), in the FAERS adverse event reporting database. A majority of these cases were reported among patients who already had moderate or severe liver impairment prior to starting HCV antiviral therapy. In addition, some cases had other significant pre-existing risk factors such as hepatocellular carcinoma, alcohol abuse, or serious medical illnesses associated with serious liver problems.

Mevyret, Zepatier, and Vosevi are indicated for the treatment of HCV in patients with no or mild liver impairment (defined by Child-Pugh score of A). Patients with moderate or severe liver impairment (Child-Pugh score of B or C) should not be treated with these three medications.

Recommendations for healthcare providers:

- Perform hepatic laboratory testing as clinically indicated.
- Monitor for clinical signs and symptoms of hepatic decompensation such as the presence of jaundice, ascites, hepatic encephalopathy, and variceal hemorrhage.
- Discontinue Mavyret, Zepatier, and Vosevi in patients who develop evidence of hepatic decompensation or as clinically indicated. In most patients, symptoms resolved or new onset worsening of liver function improved after stopping the medicine.

The Safety Announcement can be found in its entirety by visiting the [FDA's website](#).