Generic Name:
Glecaprevir/pibrentasvir, elbasvir/grazoprevir, sofosbuvir/velpatasvir/voxilaprevir
Trade Name:
Mavyret, Zepatier, Vosevi
Company:
Multiple manufacturers
Notes:

FDA warns that use of glecaprevir/pibrentasvir (Mavyret), elbasvir/grazoprevir (Zepatier), or sofosbuvir/velpatasvir/voxilaprevir (Vosevi) to treat chronic hepatitis C in patients with moderate to severe liver impairment has resulted in rare cases of worsening liver function or liver failure. The medications contain a hepatitis C virus (HCV) protease inhibitor and are not indicated for use in patients with moderate to severe liver impairment. In most patients, symptoms resolved or new-onset worsening of liver function improved after stopping the medication.

These medications have been widely used and are safe and effective in patients with no or mild liver impairment.

In many of the reported cases, liver failure occurred in patients who had signs and symptoms of moderate to severe liver impairment (Child-Pugh B or C) or other serious liver problems and should not have been treated with these medications. In some cases, patients were reported to have no cirrhosis or compensated cirrhosis with mild liver impairment (Child-Pugh A), despite having evidence of decreased platelets at baseline or an increase in the pressure within the portal vein that carries blood from the digestive organs to the liver.

In addition, some patients had other significant preexisting risk factors, such as liver cancer, alcohol abuse, or serious medical illnesses associated with serious liver problems. These factors may have contributed to clinical worsening of liver function or liver failure during treatment. In most cases, liver failure or decompensation typically occurred within the first 4 weeks of starting treatment.

Health professionals should continue to prescribe Mavyret, Zepatier, or Vosevi as indicated in the prescribing information for patients without liver impairment or with mild liver impairment (Child-Pugh A). They should assess severity of liver disease at baseline and closely monitor for signs and symptoms of worsening liver function, such as increases in liver enzymes, jaundice, ascites, encephalopathy, and variceal hemorrhage. Assessment of baseline liver disease and close monitoring are especially important in those with preexisting significant liver problems or risk factors, such as hepatocellular carcinoma or alcohol abuse, which can also contribute to clinical worsening of liver function or liver failure during treatment. These medications should be discontinued in patients who develop signs and symptoms of liver decompensation or as clinically indicated.

Mavyret and Zepatier should not be prescribed in patients with any history of prior hepatic decompensation. Vosevi is indicated for patients who have previously failed certain other HCV treatments and is not recommended in patients with any history of hepatic decompensation unless the benefits outweigh the risk of liver injury, liver failure, or death.

FDA said it will continue to monitor this safety concern and will communicate any new information to the public if it becomes available.

Medication Monitor Categories:
Alerts and Recalls