FDA Warns of Rare Serious Liver Injury From Certain Hep C Meds

Alert comes after 63 reports of such outcomes, largely in people who should not have received Mavyret, Zepatier or Vosevi.

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The Food and Drug Administration (FDA) has issued a warning of rare liver injury, including liver failure and even death in some cases, that may occur among people taking the direct-acting antiviral (DAA) regimens Mavyret (glecaprevir/pibrentasvir), Zepatier (grazoprevir/elbasvir) and Vosevi (sofosbuvir/velpatasvir/voxilaprevir) to treat hepatitis C virus (HCV).

The advisory is based on 63 such reports, which largely involve individuals whose moderate to severe liver impairment meant that they should not have been prescribed these particular medications in the first place. Because Mavyret, Zepatier and Vosevi all contain drugs from the protease inhibitor class of DAAs, they are not indicated for use by people who have what is known as Child-Pugh B or C liver impairment.

However, some cases of severe liver injury reported to the FDA occurred among individuals who had Child-Pugh A, or mild liver impairment, including people who did not have cirrhosis of the liver or had compensated cirrhosis. (Compensated cirrhosis is the milder form of the severe liver disease, while decompensated cirrhosis is the more advanced form.)

In these rare cases, the worsening liver function or liver failure typically occurred during the first four weeks on Mavyret, Zepatier or Vosevi. In most cases, people's symptoms resolved or the sudden worsening of their liver function improved after the regimens were discontinued.

It is important to stress that these regimens have been widely used—an estimated 72,000 people took them in 2018—and are considered safe and effective among those with no or mild liver impairment.

The FDA has pledged to continue monitoring the use of these regimens for safety concerns and to communicate their findings to the public. The agency asks for help in this endeavor, calling for reports of safety issues involving Mavyret, Zepatier and Vosevi or other DAAs to the FDA's MedWatch program.

Because such reports are voluntary, it is possible that more than 63 cases of serious liver injury

among people receiving these regimens have occurred.

The agency advises health care professionals to continue prescribing Mavyret, Zepatier and Vosevi according to their drug labels. The labels indicate the regimens should be used only by those without liver impairment or with mild liver impairment, specifically Child-Pugh A liver disease. Providers should assess the severity of liver disease among patients with hep C before starting them on such treatment and closely monitor them for indications that their liver disease is worsening. These include increases in liver enzymes, jaundice (yellow eyes or skin), ascites (fluid accumulation in the abdomen), encephalopathy and variceal hemorrhage (bleeding veins in the esophagus or stomach).

Such liver disease severity assessment and monitoring is particularly important among those with significant liver problems or who have major risk factors for worsening liver disease. These include hepatocellular carcinoma (HCC, the most common form of liver cancer) and heavy alcohol use.

DAA treatment should be discontinued in those patients who develop signs of decompensated cirrhosis, or as clinically indicated.

While receiving treatment with Mavyret, Zepatier or Vosevi, individuals should contact their health care provider promptly if they develop fatigue, weakness, loss of appetite, nausea and vomiting, jaundice or light-colored stools. It is important for people with HCV to discuss with the clinician prescribing these regimens any existing liver impairment or risk factors for the progression of liver disease, such as heavy alcohol use.

However, individuals taking these regimens should not stop treatment without discussing doing so with a health care provider.

To read the FDA advisory, click here.

To contact the FDA MedWatch program, click here.

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