

Black-Box Warning For Harvoni, Sovaldi, Viekira Pak: Hepatitis B Risk

(Posted by Tom Lamb at www.DrugInjuryWatch.com on October 4, 2016)

Direct-acting antivirals (DAAs) are a class of prescription medicines that are FDA-approved to treat adults with hepatitis C virus (HCV) infection. These medicines are available as single-ingredient products and also in combination with other HCV medicines.

Here is a list of direct-acting antivirals currently available in the US:

Daklinza (daclatasvir) — Bristol-Myers Squibb
Epclusa (sofosbuvir and velpatasvir) — Gilead Sciences
Harvoni (ledipasvir and sofosbuvir) — Gilead Sciences
Olysio (simeprevir) — Janssen
Sovaldi (sofosbuvir) — Gilead Sciences
Technivie (ombitasvir and paritaprevir and ritonavir) — Abbvie
Viekira Pak (dasabuvir and ombitasvir and paritaprevir and ritonavir) — Abbvie
Viekira Pak XR (dasabuvir and ombitasvir and paritaprevir and ritonavir) — Abbvie
Zepatier (elbasvir and grazoprevir) — Merck Sharp Dohme

In October 2016 the FDA indicated their concern about these relatively new drugs — such as Harvoni, Sovaldi, and Viekira Pak — which are increasingly popular for treating chronic hepatitis C by issuing a Drug Safety Communication which started with this statement:

The FDA is warning about the risk of hepatitis B virus (HBV) becoming an active infection again in any patient who has a current or previous infection with HBV and is treated with certain direct-acting antiviral (DAA) medicines for hepatitis C virus. In a few cases, HBV reactivation in patients treated with DAA medicines resulted in serious liver problems or death. HBV reactivation usually occurred within 4-8 weeks.

As a result, FDA is requiring a Boxed Warning, our most prominent warning, about the risk of HBV reactivation to be added to the drug labels of these DAAs directing health care professionals to screen and monitor for HBV in all patients receiving DAA treatment. This warning will also be included in the patient information leaflet or Medication Guides for these medicines.

The FDA has advised patients using any of these DAA medicines for treat chronic hepatitis C virus (HCV) infection, to contact their health care professional immediately if they develop fatigue, weakness, loss of appetite, nausea and vomiting, yellow eyes or skin, or light-colored stools, as these may be signs of serious liver problems.

Of course, we will continue to monitor the safety profiles of Harvoni, Sovaldi, and Viekira Pak, as well as the several other direct-acting antiviral (DAA) medicines, and report further significant developments.

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Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
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