

# The Medical Letter<sup>®</sup>

## on Drugs and Therapeutics

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Objective Drug Reviews Since 1959

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## on Drugs and Therapeutics

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Volume 57 (Issue 1481)

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### IN BRIEF

## Hepatic Injury with Hepatitis C Drugs

The FDA recently announced labeling changes for the combination antiviral products *Viekira Pak* (ombitasvir/paritaprevir/ritonavir with dasabuvir)<sup>1</sup> and *Technivie* (ombitasvir/paritaprevir/ritonavir)<sup>2</sup> warning of a risk of serious, potentially fatal liver injury.<sup>3</sup> *Viekira Pak*, approved in December 2014 for treatment of hepatitis C virus (HCV) genotype 1 infection, including patients with compensated cirrhosis, and *Technivie*, approved in July 2015 for treatment of HCV genotype 4 infection without cirrhosis, have been identified as "possible" or "probable" causes in 26 postmarketing cases of hepatic decompensation, including 10 cases (mostly in patients with preexisting advanced cirrhosis) that resulted in death or liver transplant. Hepatic injury generally occurred within 1-4 weeks of treatment initiation.

All therapies for chronic HCV infection have been associated with cases of hepatic decompensation in patients with advanced fibrosis or cirrhosis, but

cause and effect are difficult to determine. *Viekira Pak* and *Technivie* are now contraindicated in patients with moderate to severe (Child-Pugh B/C) hepatic impairment. Ledipasvir/sofosbuvir (*Harvoni*), another recently approved treatment for HCV genotype 1 infection,<sup>4</sup> is still indicated for treatment of patients with any degree of compensated hepatic impairment (Child-Pugh A/B/C). The efficacy and safety of all three combinations in patients with decompensated cirrhosis have not been established. ■

1. A 4-drug combination (*Viekira Pak*) for hepatitis C. *Med Lett Drugs Ther* 2015; 57:15.
2. In brief: *Technivie* for HCV genotype 4 infection. *Med Lett Drugs Ther* 2015; in press.
3. FDA Drug Safety Communication: FDA warns of serious liver injury risk with hepatitis C treatments *Viekira Pak* and *Technivie*. Available at: [www.fda.gov/Drugs/DrugSafety/ucm468634.htm](http://www.fda.gov/Drugs/DrugSafety/ucm468634.htm). Accessed October 29, 2015.
4. A combination of ledipasvir and sofosbuvir (*Harvoni*) for hepatitis C. *Med Lett Drugs Ther* 2014; 56:111.

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