FDA Issues Warnings on Two Hepatitis C Treatment Regimens

October 26, 2015 By Lucinda K. Porter RN

On October 22, the FDA issued a warning for the hepatitis C treatment regimens, Viekira Pak and Technivie. These drugs were linked to serious liver damage in patients with advanced liver disease. Worldwide, there were 26 cases; 10 patients either died or needed a transplant due to liver failure; 16 patients had some form of liver injury. The liver damage usually occurred within one to four weeks after starting treatment.

If you are already taking Viekira Pak or Technivie, do not discontinue treatment unless directed to by your doctor. Stopping early may cause the virus to become resistant to other treatments and make it difficult to cure hep C in the future.

If you develop symptoms of fatigue, weakness, loss of appetite, nausea and vomiting, yellow eyes or skin, or light-colored stools while taking Viekira Pak or Technivie, contact your doctor immediately.

The original Viekira Pak and Technivie label information stated that the treatments were “not recommended” for those with Child-Pugh B liver disease and “contraindicated” for those with Child-Pugh C liver disease. The new labels now state that these medications are “contraindicated in patients with moderate to severe hepatic impairment (Child-Pugh B and C).”

Labeling changes were also made to the “contraindications” section. The anti-gout medication colchicine was added. The list of drugs that should not be taken with Viekira Pak and Technivie is quite long, and the warnings were strengthened.

Viekira Pak was approved ten months ago in the U.S.; Technivie has been available since July. More than 2,300 patients have taken Viekira Pak in Phase III trials. From December 2014 through August 2015, it’s estimated that Viekira Pak has been prescribed to more than 10,000 patients in the United States. I am unable to tell from the FDA data how many of the 26 reports occurred in the U.S. versus other countries. It isn’t clear if the injuries were limited to patients who had moderate to severe cirrhosis (Child-Pugh B and C), and/or those taking any of the contraindicated medications.

Should you worry if you are taking Viekira Pak or Technivie? If you don’t have moderate to severe cirrhosis and you are not taking any of the contraindicated drugs, then you may have little to be concerned about. However, it’s hard not to worry. Would I worry? Probably a little bit until I was done. Who doesn’t get a bit fatigued, nauseous or have loss of appetite occasionally during treatment? It would be hard not to worry.

Empower yourself by knowing what the warning signs of liver failure are, and if you have symptoms, call your doctor immediately. You, your doctor or nurse should report medication side effects to the FDA’s MedWatch Safety Information and Adverse Event Reporting Program or call 1-800-332-1088 to request a reporting form.

If you need further reassurance, talk to your doctor. Try not to fret away the rest of your hep C treatment; intense worry will just make everything worse.