FDA Approves New Hepatitis C Treatment Vosevi for All Genotypes

July 26, 2017 By Connie M. Welch

On July 18, 2017 the U.S. Food and Drug Administration approved the new Hepatitis C treatment Vosevi to treat adults for all genotypes 1-6. Vosevi is for patients without cirrhosis or with mild cirrhosis. Vosevi is a fixed-dose, combination tablet containing two previously approved drugs, sofosbuvir and velpatasvir, and a new drug, voxilaprevir.

Vosevi is made by Gilead Sciences who also makes Harvoni, and Epclusa. The FDA reports, "Vosevi is the first Hepatitis treatment approved for patients who have been previously treated with the direct-acting antiviral drug sofosbuvir, or other drugs for HCV (hepatitis C virus) that inhibit a protein called NS5A. Direct-acting viral drugs prevent the virus from multiplying and often cure hepatitis C."

Edward Cox, M.D., director of the Office of Antimicrobial Products in the FDA's Center for Drug Evaluation and Research states, "Vosevi provides a treatment option for some patients who were not successfully treated with other HCV drugs in the past."

There are at least six Hepatitis C virus genotypes or strains, which are genetically distinct groups of the virus. Knowing the genotype of each patient will help physicians know which treatment is best suited to work for each patient. In the U.S. approximately 75 percent of American's with Hepatitis C have genotype 1; 20 to 25 percent have genotypes 2 or 3; and a small number of patients are infected with genotypes 4, 5, or 6.

Certain genotypes can be more prevalent in different countries. Guidelines for knowing which treatment will work best for each patient include genotype, patient treatment history, complete medical history and blood work, knowing all medications, vitamins and supplements taken, liver condition, if they have cirrhosis or not, and physical exams including tests to help the physician prescribe and monitor the patients care.

Cure rate:

Vosevi was reported in clinical trials to have an SVR 12 in 96 to 97 percent of patients (no virus was detected in the blood 12 weeks after treatment) suggesting the patient is cured from Hepatitis C.

Length of treatment:

FDA states, treatment recommendations for Vosevi are different depending on viral genotype and prior treatment history. Standard length of treatment is 12 weeks.

How & When to take Vosevi:

Vosevi is a once a day, fixed dose combination pill to be taken at a scheduled time each day. Vosevi is recommended to take with food.

If you need to take an antacid medicine that contains aluminum or magnesium, take it either four hours before or four hours after you take your dose of Vosevi.

It is important that you do not miss or skip doses during treatment. If this happens, report immediately to your physician for their recommendations. Do not alter or stop taking Vosevi unless your physician has advised you to do so.

Vosevi is to be used for adults only.

Side Effects of Vosevi:

The most common side effects reported in the clinical trial were;

*headache

*fatigue

*diarrhea

*nausea

Caution: Vosevi may cause serious side effects, including:

*Hepatitis B virus (HBV) reactivation. Before starting treatment, your physician will do blood tests to check for hepatitis B virus infection. If you have ever had hepatitis B virus infection, the hepatitis B virus could become active again during or after treatment of hepatitis C virus with Vosevi.
Hepatitis B virus becoming active again (called reactivation) may cause serious liver problems including liver failure and death. Your physician will monitor you if you are at risk for hepatitis B virus reactivation during treatment and after you stop taking Vosevi.

*Slow heart rate (bradycardia). Vosevi treatment may result in slowing of the heart rate along with other symptoms when taken with amiodarone (Cordarone, Nexterone, Pacerone), a medicine used to treat certain heart problems. In some cases bradycardia has led to death or the need for a heart pacemaker when amiodarone is taken with medicines similar to Vosevi that contain sofosbuvir. Get medical help right away if you take amiodarone with Vosevi and have any of the following symptoms: fainting or near fainting, dizziness or light headedness, not feeling well, weakness, extreme fatigue, shortness of breath, chest pains, confusion or memory problems.

*Do not take Vosevi if you also take any medicines that contain rifampin (Rifater, Rifamate, Rimactane, Rifadin).

These are not all the possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Gilead's U.S. Support Path for Vosevi Patient Assistance:

To support patients and their families, Gilead's U.S. Support Path® program provides information regarding access and reimbursement coverage options to patients in the United States who need assistance with coverage for their Gilead HCV medications, including Vosevi. Support Path conducts benefits investigations and provides patients with information regarding their insurance options.

Further, the Vosevi Co-pay Coupon Program offers co-pay assistance for eligible patients with private insurance who need assistance paying for out-of-pocket medication costs.

To learn more about Support Path for Vosevi, please visit www.MySupportPath.com or call 1-855-7-MYPATH (1-855-769-7284) between 9:00 a.m. and 8:00 p.m. (Eastern), Monday through Friday.

See additional information about Vosevi provided by Gilead.

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http://beta.docker.hepmag.com/blog/fda-approves-new-hepatitis-c-treatment-vosevi-genotypes