FDA Approves New Hepatitis C Treatment Mavyret for All Genotypes

August 23, 2017 By Connie M. Welch

The U.S. FDA approved hepatitis C treatment Mavyret, for all genotypes, for patients without cirrhosis and those with compensated cirrhosis as well as patients with genotype 1 who have been previously treated with an HCV NS5A inhibitor or NS3/4A protease inhibitor but not both and for patients with severe kidney disease, including those on dialysis.

Mavyret is a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor. Mavyret is taken without ribavirin. Mavyret is made by AbbVie and U.S. FDA approved on August 3, 2017.

Prior to Treatment:
All patients should be tested for evidence of current or prior Hepatitis B (HBV) core antibody (anti-HBc) before treatment with Mavyret.

Dosage and Duration:
Mavyret is a fixed-dose combination tablet containing glecaprevir 100 mg and pibrentasvir 40 mg. No ribavirin required. The recommended oral dosage of Mavyret is three tablets taken once daily with food.

For all genotypes: 1, 2, 3, 4, 5, 6 patients without any treatment experience and no cirrhosis, treatment is for 8 weeks. Patients without any treatment experience with compensated cirrhosis, treatment is for 12 weeks.

For genotype 1 patients who have been previously treated with an NS5A inhibitor without prior treatment with an NS3/4A protease inhibitor, and no cirrhosis, recommended treatment is for 16 weeks.

For genotype 1 patients who have been previously treated with an NS3/4A PI 2 and with an NS5A inhibitor, with no cirrhosis and patients with compensated cirrhosis, treatment is for 12 weeks.

For all genotypes 1, 2, 4, 5, or 6 patients who have been previously treated with an PRS 3 with no cirrhosis, treatment is for 8 weeks and for patients with compensated cirrhosis, treatment is for 12 weeks. For patients with genotype 3 with no cirrhosis, treatment is for 16 weeks and patients with compensated cirrhosis, treatment is for 16 weeks.

For all genotype patients with chronic kidney disease recommended treatment is for 12 weeks.

Side Effects:
The most common side effects reported in clinical trials were headache, fatigue, nausea and some with diarrhea.

Cure Rate:
Clinical trials report cure rates from 92% to 100% with the average cure of 98%.

Drug Interactions:
It is very important to tell your physician and pharmacist any medical conditions you have and all medications, vitamins and supplements or herbs you take prior to taking Mavyret.

Mavyret should not be taken with atazanavir, or rifampin. Mavyret also interferes with other drugs, especially carbamazepine, efavirenz, and St. John's wort.

It is important to note that additional drug to drug interactions may occur. To get a complete listing of drug interactions, see prescribing information list provided by Mavyret.

Warning:
Mavyret is not recommended for children and is not recommended for patients with decompensated cirrhosis (severe hepatic impairment Child-Pugh C).

It has been reported that patients who are co-infected with Hepatitis B and C or patients who have had Hepatitis B in the past, could be at risk for hepatitis B reactivation. Hep B has been reported in HCV/HBV coinfected patients who were taking or had taken treatment with the Hep C direct acting antiviral and not receiving treatment for Hep B.

Prior to taking Mavyret, make sure your physician tests you for Hepatitis B antibodies and report any prior history of Hepatitis B or treatment for Hep B. Some cases have resulted in serious hepatitis reactivation, liver failure, and death.

Be sure to report pregnancy or breast feeding to your physician prior to taking Mavyret.

For full product information see Mavyret.com. For co-pay assistance or patient assistance program for Mavyret call: 1-877-628-9738 to learn more.

This entry was originally published on Life Beyond Hepatitis C, and is reprinted with permission.
