FDA Approves Changes to Hep C Treatment Harvoni to Expand Treatment Options

March 2, 2016 By Connie M. Welch

The FDA approved changes February 12, 2016 to Hep C treatment Harvoni (ledipasvir and sofosbuvir), a fixed dose treatment primary to treat chronic hepatitis C genotype 1, to now include liver transplant patients, genotype 4 liver transplant patients without cirrhosis or with compensated cirrhosis, and genotype 1 patients with decompensated cirrhosis.

All major changes also include genotype 1, 4, 5, or 6 Hep C patients. Harvoni can be used with or without ribavirin depending on liver condition.

Recommended Treatment Regimen and Length of Treatment for Harvoni, includes patients Hepatitis C Genotype 1, 4, 5, or 6.

Genotype 1
*Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)
*Harvoni 12 weeks

Genotype 1
*Treatment experienced without cirrhosis
*Harvoni 12 weeks

Genotype 1
*Treatment experienced with compensated cirrhosis (Child-Pugh A)
*Harvoni 24 weeks

Genotype 1
*Treatment naïve and treatment experienced with decompensated cirrhosis (Child-Pugh B or C)
*Harvoni + Ribavirin 12 weeks

Genotype 1 or 4
*Treatment naïve and treatment experienced liver transplant patient
without cirrhosis, or with compensated cirrhosis (Child-Pugh A)
*Harvoni +Ribavirin 12 weeks

Genotype 4, 5, or 6
*Treatment naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)
*Harvoni 12 weeks

More Hepatitis C Treatment Options:

*Harvoni for 8 weeks can be considered in Genotype 1 treatment naïve patients without cirrhosis who have RNA (viral load) less than 6 million IU/ml
** Treatment-experienced patients include those who have failed a peginterferon alfa + ribavirin based regimen with or without an HCV protease inhibitor.
HARVONI+ribavirin for 12 weeks can be considered in treatment-experienced genotype 1 patients with cirrhosis who are eligible for ribavirin [see Clinical Studies (14.2)]. See footnote for ribavirin dosage recommendations.

In patients with decompensated cirrhosis, the starting dosage of ribavirin is 600 mg and can be titrated up to 1000 mg for patients <75 kg and 1200 mg for those ≥75 kg in two divided doses with food. If the starting dosage of ribavirin is not well tolerated, the dosage should be reduced as clinically indicated based on hemoglobin levels.

The daily dosage of ribavirin is weight-based (1000 mg for patients <75 kg and 1200 mg for those ≥75 kg) administered orally in two divided doses with food.
For more details on clinical trial reports along with adverse reactions, etc… see US FDA Update changes for Harvoni for Feb 12, 2016.

Another win in the battle against the Hepatitis C virus with expanded treatment options with Harvoni and Daklinza for a variety of Hep C patients. Recent FDA approvals for Zepatier by Merck for genotype 1 and 4, adds even more Hep C treatment options for patients with a lower price tag.

Additional FDA approvals expected this summer with Gilead's Hep C treatment for all genotypes.

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