FDA approves New Hep C Treatment Zepatier by Merck for Genotypes 1 and 4

February 4, 2016 By Connie M. Welch

Jan 28, 2016 the U.S. FDA approved the newest treatment for chronic Hepatitis C, Zepatir, a fixed-dose combination (elbasvir and grazoprevir) which can be used with or without ribavirin. Zepatir produced by Merck provides another oral treatment option without interferon for patients with genotype 1 and 4.

Cure Rate

In six clinical trial studies, Zepatier helped eliminate the Hepatitis C virus (HCV) in 94 to 97% of patients with the most common HCV genotype 1 (GT1), and 97 to 100% of patients with the least common genotype 4 (GT4).

Treatment Time

Standard treatment time for most Hep C patients is 12 weeks on Zepatier but Zepatier offers treatment to patients in two small subpopulations as well. Hep C patients with genotype 1 (GT1) whose HCV has mutations with resistance to treatment and Hep C patients with genotype 4 (GT4) who have failed prior Hep C treatment with peg-interferon alfa and ribavirin, 16 weeks of treatment with Zepatier is recommended.

Dosage

The recommended dosage of Zepatier is one tablet taken orally once daily with or without food at the same time each day.

Common Treatment Side Effects when used without Ribavirin include:

Feeling tired, trouble sleeping, headache, diarrhea, nausea

Common Treatment Side Effects when used with Ribavirin include:

Low red blood cell counts (anemia), feeling irritable, headache, stomach pain, feeling tired, depression, shortness of breath, joint pain, rash or itching

NS5A Resistance Testing Recommended for Genotype 1a patients

Testing patients with Hep C genotype 1a for the presence of the virus with NS5A resistance-associated polymorphisms is recommended prior to treatment with Zepatier to determine dosage

regimen and duration. In clinical trial patients receiving Zepatier for 12 weeks, their SVR rates were lower.

For more detailed information see FDA and Merck's press release.

Warning and Precautions:

- Zepatier may cause increases in your liver-related blood tests (liver enzymes, etc..). It is recommended your physician should monitor your liver panel with blood tests before and during your treatment with Zepatier.
- Tell your healthcare provider right away if you get any of the following symptoms or if they get worse during treatment: loss of appetite, yellowing of your skin or eyes, nausea and vomiting, color changes in your stool, feeling tired or weak
- Zepatier is not recommended in patients with moderate or severe hepatic impairment. See more information from Merck's press release.

Drugs that are NOT recommended to be used with Zepatier:

- Anticonvulsants: Phenytoin, Carbamazepine
- Antimycobacterials: Rifampin
- Herbal Products: St. Johns Wart (Hypericum perforatrum)
- HIV Medications: Efavirenz
- HIV Medications: Atazanavir, Darunavir, Lopinavir, Sasquinavir, Tipranavir
- Immunosuppressants: Cyclosporine

Eirum Chaudhri, a hepatologist and executive director of scientific affairs at Merck Research Labs, states, Zepatier offers a new ribavirin-free treatment option for some genotype 4 (GT4) patients. Zepatier can also be dosed safely for patients with advanced renal dysfunction, including patients on hemodialysis, because it is excreted primarily through the liver instead of through a renal excretion pathway like sofosbuvir-containing regimens (i.e. Harvoni and Sovaldi.

Zepatir, which won two FDA breakthrough designations, previously was approved in Canada.

For more detailed information see: Merck's press release for Zepatier or FDA's press releases for Zepatier, or Zepatier.com

Merck announced its price tag for Zepatir, will be $54,600 for a 12 week regimen, which is considerably lower than its competitors.

What will this mean for Hep C patients and the Hep C treatment market? With more Hep C treatment options available now than ever, competition among the drug companies could drive prices lower. More treatment options will also be available to insurance companies with hopes to bring higher approval rates.

More Hep C treatments continue in clinical trial studies. Another blockbuster treatment for all Hep C genotypes is under review by the FDA with hopes for approval sometime this summer.

Do you have a question or comment about Merck's new Hep C treatment Zepatier?

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