Zepatier

Generic Name: grazoprevir/elbasvir

Pronunciation: ZEP-ah-teer

Drug Class: Multi-Class Combination Drugs

Company: Merck

Approval Status: Approved

Generic Version Available: No

Experimental Code: MK-8742 + MK-5172

Drug Indication

- This drug was approved by the FDA to treat genotypes 1 and 4 in adults with chronic hepatitis C, including those with cirrhosis.
- Zepatier should not be given to patients with moderate or severe liver impairment (Child-Pugh B or C).

General Info

- This drug contains an NS5A replication complex inhibitor (elbasvir) and an NS3/4A protease inhibitor (grazoprevir), combined into a single tablet.
- In clinical studies, approximately 94-97 percent of genotype 1 participants were cured with 12 to 16 weeks of therapy; 97-100 percent of genotype 4 participants were cured.
- Zepatier was approved by the U.S. Food and Drug Administration for use by people living with hepatitis C on January 28, 2016.

Dosage

Adult Dose: Zepatier combines two drugs into a single tablet taken orally once daily with or without food. If ribavirin is prescribed, follow additional dosing instructions for that drug.

Pediatric Dose: N/A

Dosing Info:

Treatment varies from 12 to 16 weeks. Duration of treatment and whether Zepatier is prescribed with ribavirin are determined by genotype and prior treatment experience. People with genotype 1a may need screening for certain viral genetic variations (NS5A polymorphisms) prior to starting treatment with Zepatier to determine dosage duration.

Side Effects

- Side effects associated with Zepatier are considered mild. The most common are fatigue, headache, and nausea. Less frequently reported side effects included diarrhea and insomnia.
- Taking Zepatier with ribavirin increases the type, frequency and intensity of side effects. The most common side effects of Zepatier with ribavirin were anemia and headache.
- Approximately 1 percent of clinical trial subjects had increases in liver enzymes (ALT) to more than 5 times the upper limit of normal.

Drug Interactions

- For a review of drug interactions, including prescription and over-the-counter medications and supplements that should not be taken with Zepatier or may require dose adjustments, consult the Zepatier package insert.

Other Info

- Warning: Patients who are coinfected with hepatitis B and C who take this medication may be at risk of hepatitis B virus (HBV) reactivation. Before taking this medication, be sure your doctor has tested you for evidence of current or prior hepatitis B virus infection. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in serious hepatitis flares, liver failure, and death.
- Pregnant women or those who are trying to become pregnant should not take Zepatier if it is prescribed with ribavirin. Women of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months after treatment if ribavirin is prescribed.
- There are no adequate, well-controlled studies in pregnant women who have taken Zepatier without ribavirin. Zepatier should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.
- The safety of breast feeding while taking Zepatier has not been established.

For More Info: https://www.zepatier.com

Co-Pay Program Info:

http://www.hepmag.com/basics/hepatitis-c-basics/paying-hepatitis-c-treatment

Patient Assistance Program Info:
http://www.hepmag.com/basics/hepatitis-c-basics/paying-hepatitis-c-treatment

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