Sovaldi

Generic Name: sofosbuvir

Pronunciation: soh-VAHL-dee

Other Market Name: Generic version marketed in India as Hepcinat, Hepcvir, Resof, Sovihep

Drug Class: Nucleotide NS5B Polymerase Inhibitors

Company: Gilead Sciences

Approval Status: Approved

Generic Version Available: No

Experimental Code: GS-7977

Drug Indication

Sovaldi is approved for the treatment of all chronic hepatitis C genotypes, but is mostly used for genotypes 2 and 3; Sovaldi is always prescribed with another medication, such as ribavirin, peginterferon plus ribavirin, or Olysio (simeprevir) with or without ribavirin.

General Info

- Sovaldi was approved by the U.S. Food and Drug Administration for use by adults living with hepatitis C on December 6, 2013.
- In clinical trials, an average of 90 percent of participants were cured with 12 weeks of therapy. Genotype 3 participants had the lowest cure rates, which were significantly improved with 24 weeks of treatment (84 percent cure rates).
- On April 7, 2017, Sovaldi was approved by the U.S. Food and Drug Administration for use by hepatitis C-positive adolescents 12 years and older, weighing at least 35 kg.

Dosage

Adult Dose: One 400 mg tablet taken orally once daily with or without food. Since Sovaldi is always prescribed with another medication, such as ribavirin, peginterferon plus ribavirin, or

Olysio with or without ribavirin, follow additional dosing instructions for those drugs.

Pediatric Dose: One 400 mg tablet taken orally once daily with or without food. People taking Sovaldi must also take ribavirin, which has additional dosing instructions based on weight.

Dosing Info: Treatment is typically 12 weeks for genotype 2; 24 weeks for genotype 3. Duration of treatment and the choice of additional drugs that are prescribed are determined by genotype, prior treatment experience and the presence of cirrhosis. For specific treatment recommendations, see Hepatitis C Treatment-Naive Recommendations or Hepatitis C Re-treatment Recommendations.

Side Effects

- Side effects associated with Sovaldi are considered mild. The most common are fatigue, headache, nausea and diarrhea.
- Less frequently reported side effects include insomnia, rash and itching.
- Taking ribavirin, peginterferon or Olysio increases the type, frequency and intensity of side effects.

Drug Interactions

- For a review of drug interactions, including prescription and over-the-counter medications and supplements that should not be taken with Sovaldi or may require dose adjustments, consult the Sovaldi 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.
- When Sovaldi is prescribed with ribavirin (a drug that may harm fetuses), it should not be taken by pregnant women or those who are trying to become pregnant. 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.
- Breast-feeding while taking a Sovaldi-based treatment with ribavirin is not recommended. When not taken with ribavirin, the effects of Sovaldi on the developing fetus during pregnancy or on babies during breast-feeding are not well-studied.

For More Info: http://www.sovaldi.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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