Harvoni

Generic Name: sofosbuvir/ledipasvir

Pronunciation: har-VOE-nee

Drug Class: Multi-Class Combination Drugs

Company: Gilead Sciences

Approval Status: Approved

Generic Version Available: Yes

Experimental Code: GS-7977 + GS-5885

Drug Indication

FDA-approved for the treatment of chronic hepatitis C infection:

- Adults with genotypes 1, 4, 5 and 6 without cirrhosis or with compensated cirrhosis.
- Adults with genotype 1 infection with decompensated cirrhosis, in combination with ribavirin.
- Adults with genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin.
- Pediatric patients 12 years of age and older or weighing at least 35 kg with genotype 1, 4, 5, or 6 without cirrhosis or with compensated cirrhosis.

General Info

- Ledipasvir is an HCV NS5A inhibitor. Sofosbuvir is an HCV nucleotide analog NS5B polymerase inhibitor.
- Harvoni was approved by the U.S. Food and Drug Administration for use by people living with hepatitis C on October 12, 2014.
- In clinical studies, 96 to 99 percent of participants who had no prior treatment were cured with 12 weeks of therapy.
- On April 7, 2017, Harvoni was approved by the U.S. Food and Drug Administration for use by hepatitis C-positive adolescents 12 years and older.
- April 27, 2017 the HCV Guidelines recommended 8 weeks of Harvoni for non-black, HIV-uninfected, and whose viral load is less than 6 million.
- In 2019, Gilead authorized it’s subsidiary, Asegua Therapeutics to sell a generic version of Harvoni

(ledipasvir/sofosbuvir).

Dosage

Adult Dose: Harvoni combines 90 mg of ledipasvir and 400 mg of sofosbuvir into a single tablet. Take orally once daily with or without food. If ribavirin is prescribed, follow additional dosing instructions for that drug.

Pediatric Dose: Harvoni combines 90 mg of ledipasvir and 400 mg of sofosbuvir into a single tablet. Take orally once daily with or without food.

Dosing Info: Treatment varies from 8 to 24 weeks. Duration of treatment and whether Harvoni is prescribed with ribavirin are determined by viral load, 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 Harvoni are considered mild. The most common are fatigue, headache, nausea and diarrhea.
- Less frequently reported side effects include insomnia, rash and itching.
- Taking Harvoni with ribavirin 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 Harvoni or may require dose adjustments, consult the Harvoni 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 Harvoni 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 Harvoni without ribavirin. Harvoni should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.
- The safety of breast feeding while taking Harvoni has not been established.

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

Last Reviewed: December 22, 2021

© 2026 Smart + Strong All Rights Reserved.