

Ledipasvir-Sofosbuvir (*Harvoni*)

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Drug Summary

The fixed-dose combination of ledipasvir-sofosbuvir provides an effective and well-tolerated one-pill once-a-day option for treatment of genotypes 1, 4, 5, and 6 chronic hepatitis C (HCV) infection. This direct-acting antiviral regimen was the first FDA-approved interferon- and ribavirin-free regimen to treat hepatitis C. Ledipasvir-sofosbuvir can be used without ribavirin in most patients with genotype 1A, except those who are cirrhotic and treatment-experienced. In addition, patients who are treatment-naïve, not black, and without cirrhosis may be eligible for an 8-week duration which has been found in clinical trials and observational studies to be as effective as 12 weeks. Like sofosbuvir-velpatasvir, the other NS5B-NS5A inhibitor combination, it has been shown to be safe and efficacious in patients with decompensated cirrhosis.

Class and Mechanism

Ledipasvir is a potent inhibitor of HCV NS5A, a viral phosphoprotein that plays an important role in viral replication, assembly, and secretion. Sofosbuvir is a nucleotide analog inhibitor of hepatitis C virus NS5B polymerase—the key enzyme mediating HCV RNA replication. The triphosphate form of sofosbuvir (GS-461203) mimics the natural cellular uridine nucleotide and is incorporated by the HCV RNA polymerase into the elongating RNA primer strand, resulting in viral chain termination.

Manufacturer for United States

The fixed-dose combination of ledipasvir and sofosbuvir (*Harvoni*) ([Figure 1](#)) is manufactured by Gilead Sciences.

Cost and Medication Access

The wholesale acquisition cost (WAC) for ledipasvir-sofosbuvir is \$1125 per pill.

- Cost of 8-week course of therapy = \$63,000
- Cost of 12-week course of therapy = \$94,500
- Cost of 24-week course of therapy = \$189,000

Gilead Sciences has an active ledipasvir-sofosbuvir patient assistance program for eligible patients with hepatitis C who do not have insurance and do not have coverage through Medicaid or Medicare. Information regarding the Gilead Sciences ledipasvir-sofosbuvir (*Harvoni*) patient assistance program can be obtained at the [Support Path for Solvaldi and Harvoni](#) web site and by contacting them directly by phone at 1-855-769-7284 (hours of operation Monday through Friday between 9:00 am and 8:00 pm Eastern Time).

Adverse Effects

Available data from clinical trials has demonstrated the combination of ledipasvir-sofosbuvir has been very well tolerated. The most common reported adverse effects are fatigue and headache.

Key Drug Interactions

Ledipasvir-sofosbuvir has significant drug-drug interactions with P-gp inducers (e.g., St. John's wort and rifampin). The concomitant use of ledipasvir-sofosbuvir with P-gp inducers is not recommended. Additional drug-drug interactions may occur with ledipasvir-sofosbuvir and other medications and these are detailed in the [Ledipasvir-sofosbuvir \(*Harvoni*\) Full Prescribing Information](#). For complete information on ledipasvir-sofosbuvir-related drug interactions, see the [Drug Interactions section in the Ledipasvir-Sofosbuvir \(*Harvoni*\) Prescribing Information](#).

Figures

Figure 1 Bottle - Ledipasvir-sofosbuvir (*Harvoni*)

Photo: Andrew Karpenko, University of Washington



Figure 2 Tablets - Ledipasvir-sofosbuvir (*Harvoni*)

Photo: Andrew Karpenko, University of Washington



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