

Sofosbuvir-Velpatasvir (*Epclusa*)

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Drug Summary

Sofosbuvir-velpatasvir ([Figure 1](#)) and ([Figure 2](#)) is a pangenotypic NS5A-NS5B inhibitor single-pill combination regimen that has potent activity against hepatitis C virus (HCV) genotypes 1, 2, 3, 4, 5, and 6. It provides a much-needed option for patients with HCV genotype 3 infection, including those with compensated cirrhosis who lack the Y93H resistance associated variant. Sofosbuvir-velpatasvir can, in contrast to HCV protease-inhibitor-containing regimens, be used safely in persons with decompensated cirrhosis. Levels of sofosbuvir-velpatasvir can be significantly reduced with concurrent use of acid-reducing agents, particularly proton-pump inhibitors.

Adverse Effects

The most common adverse effects, observed in at least 10% of phase 3 trial participants, were headache and fatigue.

Class and Mechanism

Sofosbuvir-velpatasvir is an oral fixed-dose combination of sofosbuvir, a nucleotide analog NS5B polymerase inhibitor and velpatasvir, an NS5A replication complex inhibitor. Sofosbuvir is currently approved in the United States for the treatment of HCV genotypes 1-6 HCV. Velpatasvir (formerly GS-5816) is a novel NS5A inhibitor that has potent in vitro anti-HCV activity across all genotypes at the picomolar level. The combination of sofosbuvir-velpatasvir is the first once-daily single-tablet regimen with pangenotypic activity.

Indications

The fixed-dose combination sofosbuvir-velpatasvir (400 mg/100 mg) is FDA-approved for the treatment of chronic hepatitis C genotypes 1 to 6 for the following patient populations:

- Patients without cirrhosis and patients with compensated cirrhosis (Child-Pugh A): sofosbuvir-velpatasvir for 12 weeks
 - Patients with decompensated cirrhosis (Child-Pugh B and C): sofosbuvir-velpatasvir plus ribavirin for 12 weeks
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Dosing

Sofosbuvir-velpatasvir is available as a coformulated, once-daily single-pill combination of sofosbuvir 400 mg and velpatasvir 100 mg. The recommended dose is one tablet once daily, taken with or without food.

- Renal Impairment: No dosage adjustment is recommended in patients with any degree of renal impairment including patients with end-stage renal disease on dialysis. The updated recommendation for dosing in persons with renal impairment was based on safety and pharmacokinetic data from mostly observational studies.
 - Hepatic Impairment: For patients with mild, moderate, or severe hepatic impairment (Child-Pugh Class A, B, or C), no dosage adjustment for sofosbuvir-velpatasvir is recommended. For patients with decompensated cirrhosis who are receiving sofosbuvir-velpatasvir and ribavirin, clinical and laboratory monitoring is recommended.
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Cost and Medication Access

Gilead Sciences has an active sofosbuvir-velpatasvir patient assistance program for eligible patients with hepatitis C who do not have insurance and are not covered by Medicaid or Medicare. Information regarding the Gilead Sciences sofosbuvir-velpatasvir patient assistance program can be obtained at the [Support Path](#) website or by calling 1-855-769-7284.

Key Drug Interactions

For complete information on sofosbuvir-velpatasvir-related drug interactions, see the [Drug Interactions section in the Sofosbuvir-Velpatasvir \(Epclusa\) Prescribing Information](#).

Full Prescribing Information

Sofosbuvir-velpatasvir (*Epclusa*) [Full Prescribing Information](#).

Figures

[Figure 1. Sofosbuvir-Velpatasvir \(*Epclusa*\) Bottle](#)

Photo: Andrew Karpenko, University of Washington

[Figure 2. Sofosbuvir-Velpatasvir \(*Epclusa*\) Tablets](#)

Photo: Andrew Karpenko, University of Washington