



Epclusa[®] (velpatasvir/sofosbuvir) and Harvoni[®] (ledipasvir/sofosbuvir) – First-time generics

- In January 2019, Asegua Therapeutics, a subsidiary of Gilead Sciences, launched authorized generic versions of Gilead's [Epclusa \(velpatasvir/sofosbuvir\)](#) and [Harvoni \(ledipasvir/sofosbuvir\)](#) tablets. Generic Epclusa was launched January 7, 2019 and generic Harvoni will launch late January.
 - On September 24, 2018, [Gilead Sciences announced](#) information about the authorized generics for Epclusa and Harvoni.
- Epclusa is approved for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis, and with decompensated cirrhosis for use in combination with [ribavirin](#).
- Harvoni is approved for the treatment of adult patients with chronic HCV:
 - genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
 - genotype 1 infection with decompensated cirrhosis, for use in combination with ribavirin
 - genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, for use in combination with ribavirin
 - and for pediatric patients 12 years of age and older or weighing at least 35 kg with HCV genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
- Epclusa and Harvoni carry a boxed warning for risk of hepatitis B virus (HBV) reactivation in patients co-infected with HCV and HBV.
- The authorized generics for Epclusa and Harvoni are available at a list price of \$24,000 for the most common course of therapy (eg, 12 weeks).



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