Epclusa® (sofosbuvir/velpatasvir) – Expanded indication, New strength

- On March 19, 2020, the FDA announced the approval of Gilead's Epclusa (sofosbuvir/velpatasvir), for the treatment of adults and pediatric patients 6 years of age and older or weighing at least 17 kg with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection:
  - Without cirrhosis or with compensated cirrhosis
  - With decompensated cirrhosis for use in combination with ribavirin.
- Epclusa was previously approved for this indication in adults only.
- In addition to the expanded indication, the FDA also approved a 200 mg/50 mg tablet strength of Epclusa. It was previously only available as a 400 mg/100 mg tablet.
- The approval of Epclusa for the expanded indication was based on an open-label study in 173 genotype 1, 2, 3, 4, or 6 HCV treatment-naïve or treatment-experienced pediatric patients 6 years of age and older without cirrhosis or with compensated cirrhosis. The primary endpoint was the cure rate, as measured by the sustained virologic response (SVR) 12 weeks after the cessation of treatment.
  - In patients 12 years to < 18 years of age, the SVR rate was 93% (71/76) in patients with genotype 1 HCV infection and 100% in patients with genotype 2 (6/6), genotype 3 (12/12), genotype 4 (2/2), and genotype 6 (6/6) HCV infection.
  - In patients 6 years to < 12 years of age, the SVR rate was 93% (50/54) in patients with genotype 1 HCV infection, 91% (10/11) in patients with genotype 3 HCV infection, and 100% in patients with genotype 2 (2/2), and genotype 4 (4/4) HCV infection.
- Epclusa carries a boxed warning for risk of hepatitis B virus (HBV) reactivation in patients coinfected with HCV and HBV.
- The recommended dose of Epclusa for the treatment of HCV in pediatric patients 6 years of age and older or weighing at least 17 kg is based on weight and liver function.

Body weight (kg)	Dosing of Epclusa	Epclusa daily dose
≥ 30	one 400 mg/100 mg tablet once daily or two 200 mg/50 mg tablets once daily	400 mg/100 mg per day
17 to < 30	one 200 mg/50 mg tablet once daily	200 mg/50 mg per day

  - In treatment-naïve and treatment-experienced patients, without cirrhosis and with compensated cirrhosis (Child-Pugh A), the treatment regimen is Epclusa for 12 weeks.
  - In treatment-naïve and treatment-experienced patients, with decompensated cirrhosis (Child-Pugh B or C), the treatment regimen is Epclusa plus ribavirin for 12 weeks.
  - Refer to the Epclusa drug label for complete dosing recommendations, including dosing of ribavirin and dosing in adults.
- Gilead's launch plans for the 200 mg/50 mg tablet strength are pending.