Epclusa® (sofosbuvir/velpatasvir) – Expanded indication, new formulation approval

- On June 10, 2021, Gilead announced the FDA approval of Epclusa (sofosbuvir/velpatasvir), for the treatment of adults and pediatric patients 3 years of age and older 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.
    - Epclusa was previously approved for this indication in adults and pediatric patients 6 years of age and older or weighing at least 17 kg.
- Along with the expanded indication, the FDA also approved a new oral pellet formulation of Epclusa (200 mg/50 mg and 150 mg/37.5 mg strengths).
    - Previously, Epclusa was only available as a 400 mg/100 mg and 200 mg/50 mg tablet.
- The approval of Epclusa for the expanded indication was based on an open-label study in 41 treatment-naïve patients 3 years to < 6 years of age with genotype 1, 2, 3, or 4 HCV infection.
    - At 12 weeks after treatment completion, Epclusa achieved a sustained virologic response (SVR12) or cure rate of 83% (34/41) among all patients, 88% (28/32) in children with HCV genotype 1, 50% (3/6) in children with HCV genotype 2, and 100% in children with HCV genotype 3 (2/2) and HCV genotype 4 (1/1).
    - Of the seven patients who did not achieve cure, all discontinued treatment within one to 20 days of starting treatment.
- Epclusa carries a boxed warning for risk of hepatitis B virus reactivation in patients coinfected with HCV and hepatitis B virus.
- When used in combination with ribavirin, all contraindications to ribavirin also apply to Epclusa combination therapy.
- Additional warnings and precautions for Epclusa include serious symptomatic bradycardia when coadministered with amiodarone; risk of reduced therapeutic effect due to concomitant use of Epclusa with inducers of P-gp and/or moderate to strong inducers of CYP; and risks associated with ribavirin and Epclusa combination treatment.
- The recommended treatment regimen, duration, and dosage for Epclusa combination therapy in pediatric patients 3 years of age and older are provided in the tables below.
    - Refer to the Epclusa label for additional dosing and administration recommendations, including dosing in adult patients.

Recommended treatment regimen and duration in patients 3 years of age and older with genotype 1, 2, 3, 4, 5, or 6 HCV

Patient population	Treatment regimen and duration
Treatment-naïve and treatment-experienced, without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Epclusa 12 weeks
Treatment-naïve and treatment-experienced, with decompensated cirrhosis (Child-Pugh B or C)	Epclusa + ribavirin 12 weeks

Dosing for pediatric patients 3 years and older with genotype 1, 2, 3, 4, 5, or 6 HCV

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Body weight	Epclusa daily dose	Dosing of Epclusa oral pellets	Dosing of Epclusa tablets
< 17 kg	150 mg/37.5 mg per day	one 150 mg/37.5 mg packet of pellets once daily	N/A
17 to < 30 kg	200 mg/50 mg per day	one 200 mg/50 mg packet of pellets once daily	one 200 mg/50 mg tablet once daily
≥ 30 kg	400 mg/100 mg per day	two 200 mg/50 mg packets of pellets once daily	one 400 mg/100 mg tablet once daily

- Gilead's launch plans for Epclusa oral pellets are pending.