

EPCLUSA: updates to labeling (liver transplant)

Hepatitis Updates



FDA approved changes to the Epclusa (sofosbuvir and velpatasvir) product labeling to provide for use of Epclusa for the treatment of chronic HCV infection in treatment-naïve and treatment-experienced liver transplant recipients without cirrhosis or with compensated cirrhosis (Child-Pugh A). A summary of the revisions are as follows:

Section 2: DOSAGE AND ADMINISTRATION, subsection 2.2: Recommended Treatment Regimen and Duration in Patients 6 Years of Age and Older or Weighing at Least 17 kg

For treatment-naïve and treatment-experienced liver transplant recipients without cirrhosis or with compensated cirrhosis (Child-Pugh A), the recommended regimen is EPCLUSA once daily for 12 weeks.

Section 6 ADVERSE REACTIONS, subsection 6.1 Clinical Trials Experience

Adverse Reactions in Adult Liver Transplant Recipients

The safety assessment of EPCLUSA in liver transplant recipients was based on an open-label clinical trial (Trial 2104) in 79 adults without cirrhosis or with compensated cirrhosis who received EPCLUSA for 12 weeks [see Clinical Studies (14.5)]. One subject discontinued treatment due to an adverse event on Day 7. The adverse reactions observed were consistent with the known safety profile of EPCLUSA. Adverse reactions occurring in at least 5% of subjects were headache (18%), fatigue (15%), nausea (8%), diarrhea (6%), and asthenia (5%).

Section 12 CLINICAL PHARMACOLOGY, subsection 12.4 Microbiology Addition of the trial 2104 (liver transplant recipients) subsection, as follows:

In Trial 2104 (liver transplant recipients), there were 2 virologic failures (1 subject with genotype 1a and 1 subject with genotype 3b). The genotype 1a virologic failure subject had virus with an NS5A K24R polymorphism at baseline and relapse, and treatment-emergent NS5A L31V. The genotype 3b virologic failure subject had virus at baseline and relapse with NS5A polymorphisms A30K +L31M, which are predominant in this subtype; treatment-emergent NS5B S282T was detected at relapse.

Section 14 CLINICAL STUDIES

Addition of subsection 14.5 Clinical Trial in Liver Transplant Recipients without Cirrhosis and with Compensated Cirrhosis as follows:

Trial 2104 was an open-label clinical trial that evaluated 12 weeks of treatment with EPCLUSA in 79 HCV-infected treatment-naïve and previously treated adult subjects who had undergone liver transplantation. The proportions of subjects with genotype 1, 2, 3, or 4 HCV infection were 47%, 4%, 44%, and 5%, respectively. The median age was 62 years (range: 45 to 81); 81% were male; 82% were White; 3% were Black; and 15% were Asian; 28% had a baseline body mass index at least 30 kg/m². At baseline, 18% had compensated cirrhosis, and 60% were treatment experienced (subjects with prior exposure to any HCV NS5A inhibitor were excluded). Immunosuppressants allowed for coadministration were tacrolimus, mycophenolate mofetil, cyclosporine, and azathioprine. The overall SVR₁₂ rate was 96% (76/79). Of the subjects completing 12 weeks of EPCLUSA, 2 subjects experienced virologic relapse.

The label will soon be available at Drugs@FDA or [DailyMed](https://www.fda.gov/daily-med).

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