

FDA Approves Epclusa

June 28, 2016

The U.S. Food and Drug Administration (FDA) approved Epclusa to treat adult patients with chronic hepatitis C virus (HCV) both with and without cirrhosis (advanced liver disease). For patients with moderate to severe cirrhosis (decompensated cirrhosis), Epclusa is approved for use in combination with the drug ribavirin. Epclusa is a fixed-dose combination tablet containing sofosbuvir, a drug approved in 2013, and velpatasvir, a new drug, and is the first to treat all six major forms of HCV.

Epclusa carries a warning for patients and health care providers that serious slowing of the heart rate (symptomatic bradycardia) and cases requiring pacemaker intervention have been reported when amiodarone is used with sofosbuvir in combination with another HCV direct-acting antiviral. Co-administration of amiodarone with Epclusa is not recommended. Epclusa also carries a warning not to use with certain drugs that may reduce the amount of Epclusa in the blood which could lead to reduced efficacy of Epclusa.

Epclusa is manufactured and marketed by Gilead Sciences, Inc., of Foster City, California.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- ✓ Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- ✓ Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).

[Call 1-800-332-1088 to request a reporting form or download a form at
<http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>.]

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