TREAT CHRONIC HEPATITIS C IN PEOPLE WHO INJECT DRUGS

YOU ARE INVITED TO ATTEND A SPEAKER PROGRAM



Tuesday, September 17, 2024 6:00 PM

> Boure's Restaurant 110 Courthouse Square Oxford, Mississippi (662) 234-1968

PLEASE RSVP TO

Marlon Heidelberg at (601) 906-4242 or via e-mail at marlon.heidelberg@gilead.com by 9/14/2024



INDICATION

EPCLUSA (sofosbuvir 400 mg/velpatasvir 100 mg) is indicated for the treatment of adults with chronic hepatitis C virus (HCV) genotype 1-6 infection without cirrhosis or with compensated cirrhosis.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV: Hepatitis B virus (HBV) reactivation has been reported, in some cases resulting in fulminant hepatitis, hepatic failure, and death.

Please see additional Important Safety Information for EPCLUSA, including **BOXED WARNING ON HEPATITIS B REACTIVATION**, on the next page.

Please click the link to view the full Prescribing Information for <u>EPCLUSA</u>, including **BOXED WARNING**.

Please be aware that if you are a licensed US healthcare professional, any meal or other transfers of value associated with this program may be reportable under the federal Open Payments/Sunshine Act and/or state law. Gilead does not provide or pay for alcohol at Speaker Programs. Gilead policy and the PhRMA Code on Interactions with Health Care Professionals limit attendance at this promotional educational program to healthcare professionals. Accordingly, attendance by guests who are non-healthcare professionals is not appropriate and cannot be accommodated.

IMPORTANT SAFETY INFORMATION (cont'd)

BOXED WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN HCV/HBV COINFECTED PATIENTS

Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with EPCLUSA. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals (DAAs) and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Cases have been reported in patients who are HBsAg positive, in patients with serologic evidence of resolved HBV, and also in patients receiving certain immunosuppressant or chemotherapeutic agents; the risk of HBV reactivation associated with treatment with HCV DAAs may be increased in patients taking these other agents. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.

WARNINGS AND PRECAUTIONS

- Serious Symptomatic Bradycardia When Coadministered with Amiodarone: Amiodarone is not
 recommended for use with EPCLUSA due to the risk of symptomatic bradycardia, particularly in patients also
 taking beta blockers or with underlying cardiac comorbidities and/or with advanced liver disease. A fatal
 cardiac arrest was reported in a patient taking amiodarone who was coadministered a sofosbuvir-containing
 regimen. In patients without alternative viable treatment options, cardiac monitoring is recommended. Patients
 should seek immediate medical evaluation if they develop signs or symptoms of bradycardia.
- Risk of Reduced Therapeutic Effect Due to Concomitant Use of EPCLUSA with P-gp Inducers and/or Moderate to Strong Inducers of CYP2B6, CYP2C8 or CYP3A4: Rifampin, St. John's wort, and carbamazepine are not recommended for use with EPCLUSA as they may significantly decrease sofosbuvir and/or velpatasvir plasma concentrations.

ADVERSE REACTIONS

The most common adverse reactions (≥10%, all grades) with EPCLUSA were headache and fatigue.

DRUG INTERACTIONS

- Coadministration of EPCLUSA is not recommended with topotecan due to increased concentrations of topotecan.
- Coadministration of EPCLUSA is not recommended with proton-pump inhibitors, phenobarbital, phenytoin, rifabutin, rifapentine, efavirenz, and tipranavir/ritonavir due to decreased concentrations of sofosbuvir and/or velpatasvir.

Consult the full Prescribing Information for EPCLUSA for more information on potentially significant drug interactions, including clinical comments.

Please click the link to view the full Prescribing Information for **EPCLUSA**, including **BOXED WARNING**.

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