



(ep-KLOO-suh)

MOST IMPORTANT INFORMATION ABOUT EPCLUSA

EPCLUSA can cause serious side effects, including:

Hepatitis B virus reactivation: Before starting treatment with EPCLUSA, your healthcare provider will do blood tests to check for hepatitis B infection. If you have ever had hepatitis B, the hepatitis B virus could become active again during or after treatment with EPCLUSA. This may cause serious liver problems including liver failure and death. Your healthcare provider will monitor you if you are at risk for hepatitis B reactivation during and after you stop taking EPCLUSA.

POSSIBLE SIDE EFFECTS OF EPCLUSA

EPCLUSA can cause serious side effects, including:

- **Those in the “Most Important Information about EPCLUSA” section.**
- **Slow heart rate (bradycardia):** EPCLUSA, when taken with amiodarone (Cordarone®, Nexterone®, Pacerone®), a medicine used to treat certain heart problems, may cause slow heart rate, which in some cases has led to death or the need for a pacemaker when amiodarone is taken with medicines containing sofosbuvir. Get medical help right away if you take amiodarone with EPCLUSA and get any of the following symptoms:
 - fainting or near-fainting
 - extreme tiredness
 - dizziness or lightheadedness
 - shortness of breath
 - not feeling well
 - chest pains
 - weakness
 - confusion
 - memory problems

The most common side effects of EPCLUSA include headache and tiredness in adults and children 6 years of age and older. The most common side effects of EPCLUSA when used with ribavirin in adults with decompensated cirrhosis are tiredness, low red blood cells, nausea, headache, trouble sleeping, and diarrhea. The most common side effects of EPCLUSA in children younger than 6 years are vomiting and problems with spitting up the medicine.

These are not all the possible side effects of EPCLUSA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

IMPORTANT FACTS

This is only a brief summary of important information about EPCLUSA and does not replace talking to your healthcare provider about your condition and your treatment.

ABOUT EPCLUSA

EPCLUSA is a prescription medicine used to treat adults and children 3 years of age and older with chronic (lasting a long time) hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection with or without cirrhosis (compensated). In those with advanced cirrhosis (decompensated), EPCLUSA is used with ribavirin. EPCLUSA contains the two medicines: sofosbuvir and velpatasvir. It is not known if EPCLUSA is safe and effective in children under 3 years of age.

BEFORE TAKING EPCLUSA

Tell your healthcare provider about all of your medical conditions, including if you:

- have ever had hepatitis B virus infection
- have liver problems other than hepatitis C infection
- have had a liver transplant
- have kidney problems or you are on dialysis
- have HIV-1 infection
- are pregnant or breastfeeding, or plan to become pregnant or breastfeed
 - If you take EPCLUSA with ribavirin, you should also read the ribavirin Medication Guide for important pregnancy-related information.

Tell your healthcare provider about all the medicines you take:

- Keep a list that includes all prescription and over-the-counter medicines, vitamins, and herbal supplements, and show it to your healthcare provider.
- EPCLUSA and certain medicines may affect each other, or cause side effects.

GET MORE INFORMATION

- This is only a brief summary of important information about EPCLUSA. Talk to your healthcare provider or pharmacist to learn more.
- Go to EPCLUSA.com or call 1-844-4-EPCLUSA.
- To learn about potential savings, call 1-855-7-MYPATH or go to EPCLUSA.com.

