

Patient Information
EPCLUSA® (ep-KLOO-suh)
(sofosbuvir and velpatasvir)
tablets

Read this Patient Information before you start taking EPCLUSA and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment. **If you take EPCLUSA with ribavirin, you should also read the Medication Guide for ribavirin.**

What is EPCLUSA?

- EPCLUSA is a prescription medicine used to treat adults with chronic (lasting a long time) hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection:
 - without cirrhosis or with compensated cirrhosis
 - with advanced cirrhosis (decompensated) in combination with ribavirin
 - EPCLUSA contains the two medicines: sofosbuvir and velpatasvir.
- It is not known if EPCLUSA is safe and effective in children under 18 years of age.

What is the most important information I should know 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 virus infection. If you have ever had hepatitis B virus infection, the hepatitis B virus could become active again during or after treatment of hepatitis C virus with EPCLUSA. Hepatitis B virus becoming active again (called reactivation) may cause serious liver problems including liver failure and death. Your healthcare provider will monitor you if you are at risk for hepatitis B virus reactivation during treatment and after you stop taking EPCLUSA.

For more information about side effects, see the section “What are the possible side effects of EPCLUSA?”

What should I tell my healthcare provider before taking EPCLUSA?

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 severe kidney problems or you are on dialysis
- have any other medical condition
- are pregnant or plan to become pregnant. It is not known if EPCLUSA will harm your unborn baby.
 - Females who take EPCLUSA in combination with ribavirin should avoid becoming pregnant during treatment and for 6 months after stopping treatment. Call your healthcare provider right away if you think you may be pregnant or become pregnant during treatment with EPCLUSA in combination with ribavirin.
 - **Males and females who take EPCLUSA in combination with ribavirin should also read the ribavirin Medication Guide for important pregnancy, contraception, and infertility information.**
- are breastfeeding or plan to breastfeed. It is not known if EPCLUSA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take EPCLUSA.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. EPCLUSA and other medicines may affect each other. This can cause you to have too much or not enough EPCLUSA or other medicines in your body. This may affect the way EPCLUSA or your other medicines work, or may cause side effects.

Keep a list of your medicines to show your healthcare provider and pharmacist.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with EPCLUSA.
- **Tell your healthcare provider if you take any medicines containing tenofovir disoproxil**

fumarate (ATRIPLA[®], COMPLERA[®], STRIBILD[®], TRUVADA[®], VIREAD[®]).

Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take EPCLUSA with other medicines.

How should I take EPCLUSA?

- Take EPCLUSA exactly as your healthcare provider tells you to take it. Do not change your dose unless your healthcare provider tells you to.
- Do not stop taking EPCLUSA without first talking with your healthcare provider.
- Take 1 EPCLUSA tablet each day.
- Take EPCLUSA with or without food.
- It is important that you do not miss or skip doses of EPCLUSA during treatment.
- If you take too much EPCLUSA, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of EPCLUSA?

EPCLUSA can cause serious side effects, including:

- **Hepatitis B virus reactivation.** See “What is the most important information I should know about EPCLUSA?”
- **Slow heart rate (bradycardia).** EPCLUSA treatment may result in slowing of the heart rate along with other symptoms when taken with amiodarone (Cordarone[®], Nexterone[®], Pacerone[®]), a medicine used to treat certain heart problems. In some cases bradycardia has led to death or the need for a heart pacemaker when amiodarone is taken with medicines similar to EPCLUSA that are a combination of sofosbuvir and another antiviral medicine. Get medical help right away if you take amiodarone with EPCLUSA and get any of the following symptoms:
 - fainting or near-fainting
 - dizziness or lightheadedness
 - not feeling well
 - weakness
 - extreme tiredness
 - shortness of breath
 - chest pains
 - confusion
 - memory problems
- The most common side effects of EPCLUSA include headache and tiredness.
- Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
- These are not all the possible side effects of EPCLUSA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store EPCLUSA?

- Store EPCLUSA at room temperature below 86 °F (30 °C).
- Keep EPCLUSA in its original container.
- Do not use EPCLUSA if the seal over the bottle opening is broken or missing.

Keep EPCLUSA and all medicines out of the reach of children.

General information about the safe and effective use of EPCLUSA

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use EPCLUSA for a condition for which it was not prescribed. Do not give EPCLUSA to other people, even if they have the same symptoms you have. It may harm them.

If you would like more information about EPCLUSA, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about EPCLUSA that is written for health professionals.

For more information, call 1-800-445-3235 or go to www.epclusainfo.com.

What are the ingredients in EPCLUSA?

Active ingredients: sofosbuvir and velpatasvir

Inactive ingredients: copovidone, croscarmellose sodium, magnesium stearate, and microcrystalline cellulose.

The tablet film-coat contains: iron oxide red, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Manufactured and distributed by:

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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