



# EPCLUSA<sup>®</sup> (sofosbuvir and velpatasvir)

## What are the possible side effects of EPCLUSA?

This information is provided in response to your question. It is not treatment advice on how to use EPCLUSA. Please discuss this question and others you have about your medical condition or treatment with your healthcare provider.

Download the [EPCLUSA Patient Information](http://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi) for more details, including approved use[s] and important warnings: [www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa\\_pi](http://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi)

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### The short answer<sup>1</sup>

The **most common side effects** of EPCLUSA during clinical trials were **headache** and **feeling tired**.

The most common side effects of EPCLUSA when it was taken together with ribavirin by adults with liver failure were feeling tired, low levels of red blood cells, nausea, headache, trouble sleeping, and diarrhea.

These side effects each happened in at least 10% of people who took EPCLUSA, or EPCLUSA and ribavirin, for 12 weeks in clinical studies. This means that each of these side effects happened in at least 10 in 100 people.

EPCLUSA may cause **serious side effects** such as:



**Reactivation of hepatitis B virus**, also called HBV. This can only happen if you have HCV and HBV.



**A slow heart rate** if you take a medication called amiodarone with EPCLUSA.

These are not all the possible side effects of EPCLUSA. Please tell your healthcare provider if you have any side effects.

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## What is the most important information I should know about EPCLUSA?<sup>1</sup>

Some medications have important warnings that are designed to alert you of serious or life-threatening risks that come with taking the medication.

**EPCLUSA has an important warning for: 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 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.

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## Who is EPCLUSA for?<sup>1</sup>

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:

- without cirrhosis or with compensated cirrhosis.
- with advanced cirrhosis (decompensated) in combination with ribavirin.

It is not known if EPCLUSA is safe and effective in children under 3 years of age.

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## What are the common side effects?<sup>1</sup>

- The most **common side effects** of EPCLUSA in adults and children 6 years of age or older were **headache** and **feeling tired**. These side effects each happened in at least 10% of people who were taking EPCLUSA during a 12-week clinical study. This means that at least 10 in 100 people had these side effects.
- Less common side effects that happened in at least 5% or 5 out of 100 people who took EPCLUSA for 12 weeks were:

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- Nausea
- Weakness
- Trouble sleeping
- Feeling irritable

- People with HCV who also had HIV-1 had similar side effects to those described above.



- In people with HCV who received a **liver transplant**, the most common side effects were headache, feeling tired, nausea, diarrhea, and weakness. These side effects each happened in at least 5% of people who took EPCLUSA during a 12-week clinical study. This means that at least 5 in 100 people had these side effects.



- In people with HCV who had **end-stage renal** disease or severe renal impairment and required dialysis, the most common side effect was nausea. This side effect happened in 7% of the people who took EPCLUSA during a 12-week clinical study. This means that 7 in 100 people had this side effect.

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## What are the rare side effects of EPCLUSA?<sup>1</sup>

In a clinical study, 1 % of the adult participants had a depressed mood. This means that 1 in 100 people had this side effect. A rash affected 2 % of the adult participants who had no liver damage or some liver damage but no liver failure, and 5 % of the adult participants who had liver failure. This means that 2 in 100 people who had no liver damage or some liver damage but no liver failure, and 5 in 100 people with liver failure had a rash in this clinical study.

If you experience a rash or a depressed mood, tell your doctor right away.

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## What are the side effects of EPCLUSA in children 3 years of age or older?<sup>1</sup>



- In children aged 6 years or older, the side effects were similar to those that happened in adults and included headache and feeling tired.
- The most common side effects of EPCLUSA in children younger than 6 years of age were vomiting and problems with spitting up the medication. This happened in 15% and 10% of patients, that means 15 out of every 100 patients experienced vomiting and 10 out of every 100 patients spit up the medication.

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## What are the common side effects when EPCLUSA and ribavirin are used together?<sup>1</sup>

- The most common side effects of EPCLUSA when taken with ribavirin in adults with decompensated cirrhosis were feeling tired, low numbers of red blood cells, nausea, headache, trouble sleeping, and diarrhea. These side effects each happened in at least 10% of people who took EPCLUSA with ribavirin for 12 weeks. This means that at least 10 in 100 people had these side effects.

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## What are the serious side effects?<sup>1</sup>

EPCLUSA may cause **serious side effects** such as:



- **Reactivation of hepatitis B virus**, if you have HBV, it may become active again, which is called reactivation. This can only happen if you have HCV and HBV. Before starting treatment with EPCLUSA, your doctor will do blood tests to check for HBV. If you have ever had HBV, it could become active again during your treatment of HCV with EPCLUSA. HBV activation may cause serious liver problems, including liver failure and death. Your doctor will monitor you if you are at risk of HBV reactivation during treatment and after you stop taking EPCLUSA.



- **A slow heart rate** is also called bradycardia. EPCLUSA may cause a slow heart rate and other symptoms when taken together with amiodarone (Cordarone<sup>®</sup>, Nexterone<sup>®</sup>, Pacerone<sup>®</sup>), a medication that is used to treat certain heart problems.
- In people who have taken amiodarone with medications that are similar to EPCLUSA and that also contain sofosbuvir it has caused a slower heart rate and has led to death or led to the need for a pacemaker.
- 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, feeling extremely tired, shortness of breath, chest pains, confusion, and memory problems.

These are not all of the possible side effects of EPCLUSA.

**Contact your healthcare provider right away if you are concerned about any symptoms you are experiencing or if you think that you might have any of these side effects.**

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## **What should I tell my healthcare provider before taking EPCLUSA?<sup>1</sup>**

Before taking EPCLUSA, tell your healthcare provider about all your medical conditions, including if you<sup>1</sup>:

- have ever had HBV infection.
- have liver problems other than HCV infection.
- have had a liver transplant.
- have kidney problems or you are on dialysis.
- have HIV-1 infection.

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## What should I tell my healthcare provider if I am pregnant?<sup>1</sup>

- Talk to your healthcare provider if you 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.**
- Talk to your healthcare provider if you are breastfeeding or plan to breastfeed. It is not known if EPCLUSA passes into your breastmilk.
  - Talk to your healthcare provider about the best way to feed your baby during treatment with EPCLUSA.

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## What should I tell my healthcare provider about the medicines I take before taking EPCLUSA?<sup>1</sup>

Tell your healthcare provider about all the medication 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 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.
- **Do not start taking any new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take EPCLUSA with other medicines.

Please read the Medication Guide for ribavirin for additional information.

- Copegus®: [https://www.gilead.com/download/pdf/copegus\\_medguide.pdf](https://www.gilead.com/download/pdf/copegus_medguide.pdf)

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## Glossary

**Bradycardia:** slower heartbeat

**Chronic:** long-term; continuing for a long time, ongoing.

**Cirrhosis:** scarring of the liver; Cirrhosis is a late stage of scarring (fibrosis) of the liver caused by many forms of liver diseases and conditions, such as hepatitis and chronic alcoholism.

**Clinical trial:** a study in people. It may help to find how well a medicine works and how safe it is.

**Compensated cirrhosis:** When some liver damage has occurred, but the non-damaged part of the liver is still healthy enough to work.

**Decompensated cirrhosis or liver failure:** When the liver is so damaged that it can no longer work.

**End-stage kidney disease:** A condition where the kidney does not function properly. This is also called kidney failure.

**FDA (Food and Drug Administration):** is a government agency responsible for ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

**Genotype:** the genetic constitution of a person

**Hepatitis B Virus (HBV):** a type of virus (HBV) that can cause serious liver infection.

**Hepatitis C Virus (HCV):** a type of virus (HCV) that can cause serious liver infection

**HCV genotypes:** Hepatitis C has 6 common strains, which are called genotypes.

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**Human Immunodeficiency Virus (HIV):** HIV is a virus that attacks the body's immune system. If HIV is not treated, it can lead to AIDS.

**Nausea:** feeling sick to the stomach; stomach discomfort and the sensation of wanting to vomit.

**Pacemaker:** A device that is placed in the chest to control an abnormal heartbeat.

**Supplements:** products people take to add extra nutrients to their diet, like vitamins, minerals, or other helpful substances.

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## Reference

1. Enclosed. Gilead Sciences Inc, EPCLUSA® (sofosbuvir and velpatasvir) tablets, for oral use. US Prescribing Information. Foster City, CA.

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## More information about EPCLUSA

If you would like more detailed information about EPCLUSA, please visit:

[https://www.gilead.com/-/media/files/pdfs/medicines/liver\\_disease/epclusa/epclusa\\_patient\\_pi.pdf](https://www.gilead.com/-/media/files/pdfs/medicines/liver_disease/epclusa/epclusa_patient_pi.pdf)

This is the US FDA-approved Prescribing Information, including the Patient Labeling, for EPCLUSA. It will tell you about the uses, warnings, and other important safety information about EPCLUSA.

## Important note

Gilead Sciences, Inc. is providing this letter in response to your unsolicited request for medical information. Some of the information included in this letter may not be covered in the US FDA-approved Prescribing Information for EPCLUSA. Gilead Sciences, Inc. does not intend this letter to be used as medical advice and does not promote use of EPCLUSA in a way that has not been approved by the FDA. Please discuss this question and others you may have about your medical condition or treatment with your healthcare provider.

## Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎ 1-866-MEDI-GSI (1-866-633-4474) or 🌐 <https://www.patient.askgileadmedical.com/>

## Reporting side effects

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or

🌐 [www.gilead.com/utility/contact/report-an-adverse-event](http://www.gilead.com/utility/contact/report-an-adverse-event)

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🌐 [www.accessdata.fda.gov/scripts/medwatch](http://www.accessdata.fda.gov/scripts/medwatch)

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