



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

## Will missing one or more doses of Epclusa affect treatment response?

**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** 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

**Take EPCLUSA exactly as your healthcare provider tells you to take it.**

In clinical studies, people that took their medicine correctly were more likely to rid the hepatitis C virus from their bodies. The hepatitis C virus was not detectable 12 weeks after the end of the treatment, known as a cure.<sup>1</sup>

**If you miss doses of EPCLUSA, the medicine may not work as well.** Missing a dose lowers the amount of medicine in your body, which can make it less effective; however, you may still be able to cure the hepatitis C virus. Talk with your healthcare provider if you miss a dose of EPCLUSA.<sup>2-5</sup>



Take **EPCLUSA exactly as your healthcare provider tells you to take it.**



**Do not miss a dose of EPCLUSA. Missing a dose lowers the amount of medicine in your body,** which may make it less effective. Refill your EPCLUSA prescription before you run out of medicine.



Take **EPCLUSA** once a day by mouth. You can take it with or without food.



**Children ages 3 to 6 years old**, should take EPCLUSA oral pellets with food.

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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.

Males and females who take EPCLUSA in combination with ribavirin should also read the ribavirin Medication Guide for important pregnancy, contraception, and infertility information.

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## How should I give EPCLUSA oral pellets to my child?<sup>1</sup>



Give EPCLUSA oral pellets exactly as your healthcare provider tells you.



The pellets can be taken with food or directly in the mouth.



Children ages 3 to 6 years old should take the pellets with food.



**Do not** chew the pellets, as they may taste bitter.



Do not open the EPCLUSA oral pellets packet until ready to use.

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## Glossary

**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.

**Decompensated:** reduced functioning/deterioration in the function of an organ.

**Genotype:** A way to categorize the strain of the hepatitis C virus that a patient has.

**Hepatitis B virus (HBV) infection:** HBV infection is an illness caused by the hepatitis B virus. It affects the liver and can make it swollen and damaged. People can get it through contact with infected blood, unprotected sex, or from an infected mother to her baby at birth. Some people recover from it on their own, while others can have long-term liver problems if not treated.

## References

1. Enclosed. Gilead Sciences Inc, EPCLUSA® (sofosbuvir and velpatasvir) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. Flamm SL, Foster GR, Bourliere M, et al. Curing HCV with Direct-Acting Antiviral (DAA) Treatment: Adherence and Rapid Onset of HCV-RNA Undetectability after 4 Weeks of Treatment with Sofosbuvir/Velpatasvir [Poster #1245]. Paper presented at: AASLD: The Liver Meeting; 4-8 November, 2022; Washington DC.
3. Kattakuzhy S, Wang V, Gannon C, et al. Association of sustained virologic response with measures of directacting antiviral adherence in patients with Hepatitis C: Data from the ASCEND and ANCHOR investigations [Poster #2143]. Paper presented at: EASL The International Liver Congress; 22-26 June, 2022; London, UK.
4. Heo M, Norton BL, Pericot-Valverde I, et al. Optimal hepatitis C treatment adherence patterns and sustained virologic response among people who inject drugs: The HERO study [Preprinted]. *J Hepatol.* 2024.
5. Lopes SS, Pericot-Valverde I, Arnsten J, et al. Self-reported and measured adherence to hepatitis C direct-acting antiviral therapy and sustained virologic response among people who inject drugs: The HERO study. *Int J Drug Policy.* 2024;123:104288.

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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\\_pi.pdf](https://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_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 doctor.

## 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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