



EPCLUSA[®] (sofosbuvir and velpatasvir)

How should I store 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](#) for more details, including approved use[s] and important warnings: www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi

The short answer¹

Storage for Tablets and Pellets

- Store EPCLUSA tablets or oral pellets below 86°F (30°C).
- Keep EPCLUSA tablets in the **original container**.
- Do not use if carton tamper-evident seal or packet has been opened or damaged.



Storing EPCLUSA in conditions different from those described in the [EPCLUSA Patient Information](#) may affect how well EPCLUSA works. If you have additional questions regarding EPCLUSA storage information, please contact your healthcare provider or pharmacist.

What is the most important information I should know about EPCLUSA?¹

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.

Who is EPCLUSA for?¹

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 (scarring of the liver) 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.

How is EPCLUSA supplied?¹



Oral Tablets Each bottle contains 28 tablets, polyester coil, and is closed with a child-resistant closure.

Oral Pellets are white to off-white pellets supplied as single-use packets in cartons. Each carton contains 28 packets.

How should I store EPCLUSA?¹

Store EPCLUSA tablets or oral pellets **below 86°F (30°C)**.

Keep EPCLUSA tablets **in the original container**.

Do not use EPCLUSA oral pellets if the carton tamper-evident seal or the packet has been **opened or damaged**.

Do not use EPCLUSA oral pellets if the carton tamper-evident

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.

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.

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

Prescription medicine: a drug that is available only with a written instruction from a healthcare professional.

Tamper-evident seal: A closure used to indicate if a bottle has been opened or tampered with.

References

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

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

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

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

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