

PATIENT INFORMATION

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

EPCLUSA® (ep-KLOO-suh)
(sofosbuvir and velpatasvir)
oral pellets

Important: If you take EPCLUSA with ribavirin, you should also read the Medication Guide for ribavirin.

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 is 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:

- 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 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 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 during treatment with 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.
- **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 EPCLUSA oral pellets or tablets by mouth, with or without food.
- For adults the usual dose of EPCLUSA is one 400/100 mg tablet each day.
- For children 3 years of age and older your healthcare provider will prescribe the right dose of EPCLUSA oral pellets or tablets based on your child's body weight.
 - Tell your healthcare provider if your child has problems with swallowing tablets.
 - If your healthcare provider prescribes EPCLUSA oral pellets for your child, see “How should I give EPCLUSA oral pellets to my child?”

- Do not miss a dose of EPCLUSA. Missing a dose lowers the amount of medicine in your blood. Refill your EPCLUSA prescription before you run out of medicine.
- If you take too much EPCLUSA, call your healthcare provider or go to the nearest hospital emergency room right away.

How should I give EPCLUSA oral pellets to my child?

See the detailed Instructions for Use for information about how to give or take a dose of EPCLUSA oral pellets.

- Administer EPCLUSA oral pellets exactly as instructed by your healthcare provider.
- EPCLUSA oral pellets can be taken with food or directly in the mouth.
- For children younger than 6 years, take EPCLUSA oral pellets with food.
- EPCLUSA oral pellets should be swallowed whole. Do not chew EPCLUSA oral pellets to avoid a bitter after taste.
- Do not open the EPCLUSA oral pellets packet until ready to use.

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 contain sofosbuvir. 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 in adults and children 6 years of age and older include headache and tiredness.
- 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 of age 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.

How should I store EPCLUSA?

- 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.

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.

You can ask your healthcare provider or pharmacist for information about EPCLUSA that is written for health professionals.

What are the ingredients in EPCLUSA?

Active ingredients: sofosbuvir and velpatasvir

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

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

Inactive ingredients, Oral Pellets: colloidal silicon dioxide, copovidone, croscarmellose sodium, lactose monohydrate, magnesium stearate, and microcrystalline cellulose.

The oral pellets film-coat contains: amino methacrylate copolymer, colloidal silicon dioxide, hypromellose, *L*-tartaric acid, polyethylene glycol, stearic acid, talc, and titanium dioxide.

Manufactured and distributed by:

Gilead Sciences, Inc., Foster City, CA 94404

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

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INSTRUCTIONS FOR USE
EPCLUSA® (ep-KLOO-suh)
(sofosbuvir and velpatasvir)
pellets, for oral use

Read the Patient Information that comes with EPCLUSA oral pellets for important information about EPCLUSA.

This Instructions for Use contains information on how to take EPCLUSA oral pellets. Be sure you understand and follow the instructions. If you have any questions, ask your healthcare provider or pharmacist.

Important Information You Need to Know Before Taking EPCLUSA oral pellets

- **For oral use only** (take by mouth with or without food).
- Pellets should be swallowed whole. **Do not** chew pellets.
- **Do not** open the EPCLUSA oral pellet packet(s) until ready to use.
- For children younger than 6 years, take EPCLUSA oral pellets with food.
- EPCLUSA oral pellets are white to off-white pellets supplied as single-use packets in cartons. Each carton contains 28 packets.
- **Do not** use EPCLUSA oral pellets if the carton tamper-evident seal or the packet has been opened or damaged.

Gather Supplies:

Before you prepare a dose of EPCLUSA oral pellets, gather the following supplies:

- Daily EPCLUSA oral pellet packet(s), as prescribed by your healthcare provider
- Scissors (optional)

If taking EPCLUSA oral pellets with food, gather the following additional supplies:

- One or more spoonfuls of non-acidic soft food such as pudding, chocolate syrup, or ice cream
- Bowl
- Spoon

Prepare and Administer a Dose:

Step 1: If taking EPCLUSA oral pellets with food, add one or more spoonfuls of non-acidic soft food to the bowl first.

Step 2: Hold the EPCLUSA oral pellets packet with the cut line on top (see **Figure A**).

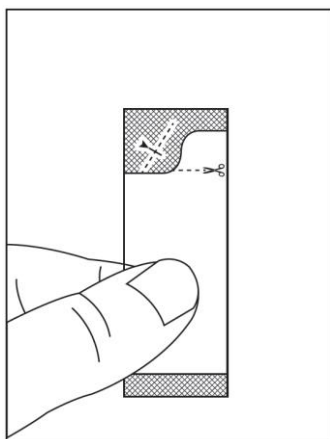


Figure A

Step 3: Shake the packet gently to settle the pellets to the bottom of the packet (see **Figure B**).

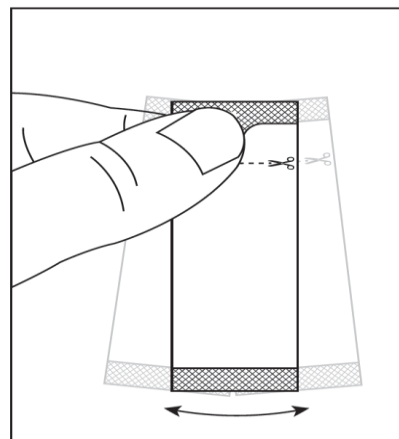


Figure B

Step 4: Cut the packet along the cut line with scissors (see **Figure C**), or fold the packet back at the tear line (see **Figure D**) and tear open (see **Figure E**).

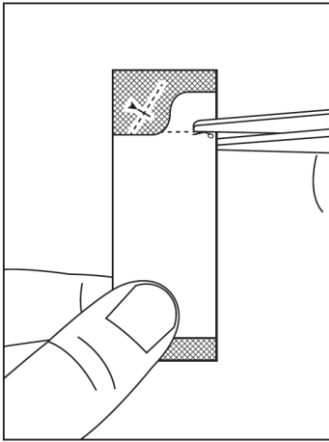


Figure C

OR

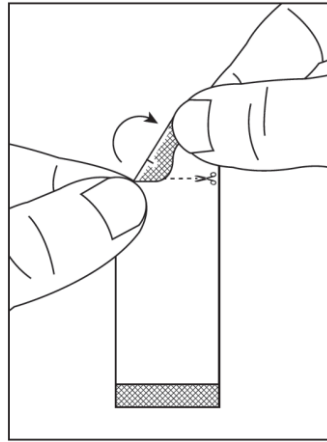


Figure D

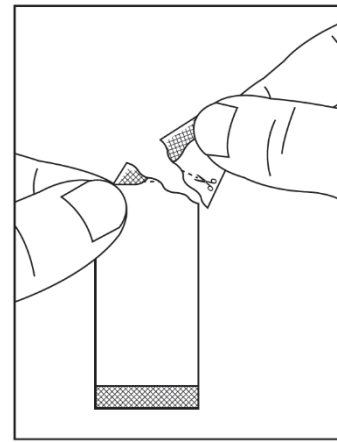


Figure E

Step 5:

- **If taking EPCLUSA oral pellets with food**, carefully pour the **entire contents** of the prescribed number of EPCLUSA oral pellet packet(s) onto the food in the bowl and gently mix with a spoon (see **Figure F**). Take the EPCLUSA oral pellets and food mixture **within 15 minutes** without chewing to avoid a bitter taste.
- **If taking EPCLUSA oral pellets by mouth**, pour the **entire contents** of the prescribed number of EPCLUSA oral pellet packet(s) directly in the mouth and swallow without chewing to avoid a bitter taste (see **Figure G**). Water may be taken after swallowing the pellets, if needed.

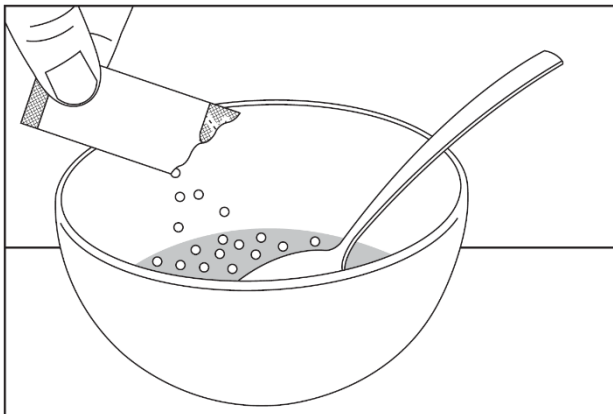


Figure F

OR

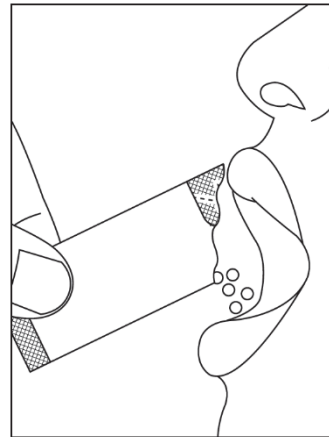


Figure G

Step 6: Make sure all of the EPCLUSA oral pellets are taken. Make sure that no EPCLUSA oral pellets remain in the packet(s) or in the food.

Storing EPCLUSA oral pellets

- Store EPCLUSA pellets below 86°F (30°C).
- **Keep EPCLUSA oral pellets and all medicines out of the reach of children.**

Disposing of EPCLUSA oral pellets

- Throw away (dispose of) any unused portion. Do not store and reuse any leftover EPCLUSA oral pellets or EPCLUSA mixture (oral pellets mixed with food).

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

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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