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2. Sofosbuvir/velpatasvir

Sofosbuvir-velpatasvir

Pronunciation: *so-fos-boo-vear/vell-pat-is-vear*

Generic name: sofosbuvir and velpatasvir

Brand name: [Epclusa](#)

Dosage form: oral tablet, oral pellets

Drug class: [Antiviral combinations](#)

Medically reviewed by [Carmen Pope, BPharm](#). Last updated on Oct 15, 2024.

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What is sofosbuvir-velpatasvir?

Sofosbuvir-velpatasvir (brand name [Epclusa](#)) is used to treat **chronic hepatitis C (HCV)** genotypes 1, 2, 3, 4, 5, or 6 infections in adults and children aged 3 years and older. It is effective against all major HCV genotypes and may be used in:

- **Adults and children aged 3 years and older** without cirrhosis or with compensated cirrhosis
- **Patients with advanced cirrhosis** (decompensated), in combination with ribavirin.

How does sofosbuvir and velpatasvir work?

Sofosbuvir-velpatasvir is a combination antiviral treatment that contains 2 active ingredients with different **mechanisms of action**:

- **Sofosbuvir** blocks an enzyme called **NS5B RNA polymerase** which prevents the hepatitis C virus from multiplying
- **Velpatasvir** blocks the effects of an HCV protein called **NS5A**, which is also required for the virus to replicate.

This combination attacks the virus at different stages of its life cycle, resulting in a [98% cure rate](#).

FDA approval and availability

Sofosbuvir-velpatasvir was approved by the FDA on **June 28, 2016**, under the brand name **Epclusa**. [Generic versions](#) of sofosbuvir-velpatasvir are available.

Cost and insurance coverage

Sofosbuvir-velpatasvir is covered by most health insurance plans, including **Medicare and Medicaid** with 99% of Medicaid patients paying \$15 or less for the full course of treatment.

The [Epclusa Copay Coupon](#) may also help reduce the cost of treatment. For more information see [Epclusa Prices, Coupons, Copay Cards & Patient Assistance](#).

Sofosbuvir-velpatasvir side effects

The **most common sofosbuvir-velpatasvir side effects** are:

- headache
- fatigue or tiredness.

Sofosbuvir-velpatasvir may also cause vomiting and spitting up of the drug in **children aged 3 to 6 years**.

When used together with ribavirin in adults with **decompensated cirrhosis**, the most common sofosbuvir-velpatasvir side effects are:

- fatigue/tiredness
- low red blood cell counts (anemia)
- nausea
- headache
- sleeplessness
- diarrhea.

Sofosbuvir-velpatasvir serious side effects and warnings

Sofosbuvir-velpatasvir carries a **Boxed Warning** for hepatitis B (HBV) reactivation in people coinfecting with HCV and HBV.

Hepatitis B virus reactivation. Before starting treatment with sofosbuvir and velpatasvir, your healthcare provider will do blood tests to check for hepatitis B virus infection. If you have ever had a hepatitis B virus infection, the hepatitis B virus could become active again during or after treatment of the hepatitis C virus with sofosbuvir velpatasvir. 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 sofosbuvir and velpatasvir. Call your healthcare provider right away if you develop:

- right-sided upper abdominal pain
- vomiting
- loss of appetite
- yellowing of your skin or eyes.

Slow heart rate (bradycardia). Sofosbuvir and velpatasvir treatment may result in slowing of the heart rate along with other symptoms when taken with amiodarone (brand names Cordarone, Nexterone, or 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 that contain sofosbuvir. Get medical help right away if you take amiodarone with sofosbuvir/velpatasvir and get any of the following symptoms:

- fainting or near-fainting

- shortness of breath
- dizziness or lightheadedness
- chest pains
- not feeling well
- confusion
- weakness
- memory problems
- extreme tiredness.

Sofosbuvir-velpatasvir is used **in combination with ribavirin** in people with advanced cirrhosis (decompensated). Ribavirin can cause birth defects or death in an unborn baby. Do not use ribavirin if you are pregnant, or if you are a man and your sexual partner is pregnant. Use effective birth control to prevent pregnancy while using these medicines together and for at least 6 months after treatment ends.

Sofosbuvir-velpatasvir may cause **allergic reactions**. Do not take if you are allergic to sofosbuvir, velpatasvir, Epclusa, or any of the inactive ingredients in the tablet. Get emergency medical help if you have symptoms of an allergic reaction to sofosbuvir/velpatasvir such as hives, difficulty breathing, or swelling of your face, lips, tongue, or throat.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

 [Sofosbuvir / velpatasvir side effects](#) (more detail)

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Before taking

Before taking sofosbuvir-velpatasvir tell your healthcare provider if you:

- have ever had a 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
- are breastfeeding or plan to breastfeed.

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

Pregnancy

It is not known if sofosbuvir and velpatasvir (Epclusa) will harm your unborn baby. Females who take sofosbuvir/velpatasvir 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 or within 6 months of the last dose of sofosbuvir velpatasvir in combination with ribavirin.

Males and females who take sofosbuvir and velpatasvir in combination with ribavirin should also read the ribavirin Medication Guide for important pregnancy, contraception, and infertility information. Ribavirin can harm an unborn baby if the father is using ribavirin. Men using ribavirin should use birth control to prevent pregnancy while taking ribavirin and until at least 6 months after their last dose of ribavirin.

Breastfeeding

It is not known if sofosbuvir and velpatasvir pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment.

 [Sofosbuvir / velpatasvir pregnancy and breastfeeding warnings](#) (more detail)

How is sofosbuvir velpatasvir administered?

Take sofosbuvir-velpatasvir exactly as your healthcare provider tells you to take it. Do not change your dose unless your healthcare provider tells you to.

- Sofosbuvir and velpatasvir tablets or pellets are taken **1 time a day**.
- May be taken **with or without food**.

Sofosbuvir-velpatasvir dosing information

Usual sofosbuvir-velpatasvir dose for adults with HCV: sofosbuvir 400 mg velpatasvir 100 mg 1 time each day.

Usual sofosbuvir-velpatasvir dose for children with HCV: the sofosbuvir-velpatasvir dosage is based on your child's body weight.

- The dose may change if the child gains or loses weight.

Tell your healthcare provider if your child has problems with swallowing tablets.

How do I give sofosbuvir velpatasvir oral pellets to my child?

Administer sofosbuvir and velpatasvir oral pellets exactly as instructed by your healthcare provider.

- The sofosbuvir velpatasvir oral pellets **can be mixed with food or placed directly in the mouth**.
- Always give the oral pellets with food if your child is younger than 6 years.
- Your child should swallow the pellets whole. Instruct your child not to chew them because they have a bitter aftertaste.
- Do not open the packet of oral pellets until ready to use.

Read and follow the Sofosbuvir Velpatasvir (Epclusa) Oral Pellets Dosage and Administration guide. Ask your doctor or pharmacist if you need help.

 [Detailed Sofosbuvir / velpatasvir dosage information](#)

What happens if I miss a dose?

Do not miss a dose of sofosbuvir-velpatasvir. Missing a dose lowers the amount of medicine in your blood. Refill your prescription before you run out of medicine.

If you do happen to forget a dose, take the dose as soon as you remember. But if it is almost time for your next dose, skip that dose. Do not take 2 doses at once.

What happens if I overdose?

If you take too much sofosbuvir and velpatasvir, call your healthcare provider, go to the nearest hospital emergency room right away, or call the Poison Help line at 1-800-222-1222.

What should I avoid while taking sofosbuvir velpatasvir?

Using sofosbuvir-velpatasvir will not prevent your disease from spreading. Do not have unprotected sex or share razors or toothbrushes. Talk with your doctor about safe ways to prevent HCV transmission during sex. Sharing drugs or medicine needles is never safe, even for a healthy person.

What other drugs will affect sofosbuvir and velpatasvir?

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take:

- omeprazole (Prilosec) or an antacid. Do not take them for at least 4 hours after you have taken your dose of sofosbuvir and velpatasvir
- amiodarone. Get medical help right away if you take this medicine and you have very slow heartbeats, chest pain, shortness of breath, confusion, memory problems, weakness, extreme tiredness, or a light-headed feeling (like you might pass out).
- P-gp inducers and/or moderate to strong CYP inducers (such as rifampin, St. John's wort, and carbamazepine). May decrease concentrations of sofosbuvir velpatasvir. Use together is not recommended

Clearance of HCV infection with direct-acting antivirals may lead to changes in liver function, which may impact the safe and effective use of other medications. Frequent laboratory monitoring and dose adjustments may be necessary.

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

 [Sofosbuvir / velpatasvir drug interactions](#) (more detail)

Does sofosbuvir/velpatasvir interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

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Add

Sofosbuvir-velpatasvir storage

Sofosbuvir and velpatasvir (Epclusa) tablets or oral pellets should be kept at room temperature, below 86°F (30°C) in the

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

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

Keep out of the reach of children.

Ingredients

The inactive ingredients in generic sofosbuvir velpatasvir vary depending on the manufacturer.

Sofosbuvir and velpatasvir are available in combination as Epclusa or as a generic.

Epclusa (sofosbuvir and velpatasvir) tablets

Active ingredients: sofosbuvir 400 mg or 200 mg; velpatasvir 100 mg or 50 mg.

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

Film coating: iron oxide red, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Epclusa tablets are a fixed-dose oral tablet in two strengths: sofosbuvir 400 mg/velpatasvir 100 mg and sofosbuvir 200 mg/velpatasvir 50 mg

Epclusa (sofosbuvir and velpatasvir) oral pellets

Active ingredients: sofosbuvir 200 mg or 150 mg; velpatasvir 50 mg or 37.5 mg

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

Film-coating: amino methacrylate copolymer, colloidal silicon dioxide, hypromellose, L-tartaric acid, polyethylene glycol, stearic acid, talc, and titanium dioxide.

Epclusa oral pellets are available in two strengths sofosbuvir 200 mg/velpatasvir 50 mg and sofosbuvir 150 mg/velpatasvir 37.5 mg.

Who makes sofosbuvir and velpatasvir?

Gilead Sciences, Inc. makes sofosbuvir velpatasvir under the brand name Epclusa.

Asequa Therapeutics LLC makes a generic sofosbuvir 400 mg velpatasvir 100 mg oral tablet.

Popular FAQ

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Does Epclusa cure Hep C, what is the success rate?



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- [How does Epclusa work in the body?](#)
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References

1. [Sofosbuvir velpatasvir \(Epclusa\) Package Insert](#)
2. [Sofosbuvir velpatasvir \(Epclusa\) Prescribing Information](#)

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Professional resources

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- [Velpatasvir and Sofosbuvir Tablets \(FDA\)](#)

Other brands

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Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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DRUG STATUS

Availability

Rx Prescription only

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 Risk data available

CSA Schedule*

N/A Not a controlled drug



Approval History

 Drug history at FDA



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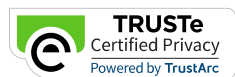
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