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Epclusa

Epclusa 🖘

Pronunciation: ep-KLOO-suh

Generic name: sofosbuvir/velpatasvir

Dosage form: oral pellet (150 mg-37.5 mg; 200 mg-50 mg), oral tablet (200 mg-50 mg; 400 mg-100 mg)

Drug class: Antiviral combinations

Medically reviewed by Melisa Puckey, BPharm. Last updated on Apr 12, 2024.

Uses Side effects Warnings Before taking Dosage Interactions FAQ

What is Epclusa?

Epclusa is an antiviral treatment for chronic hepatitis C in adults and children 3 years of age and older. Epclusa is a once-a-day medicine containing two antiviral medicines, sofosbuvir and velpatasvir. Epclusa helps stop the hepatitis C virus (HCV) from multiplying in the body by blocking a protein in the virus called HCV NS5.

Hepatitis C is a viral disease that causes inflammation of the liver that can lead to a decrease in liver function or liver failure. HCV infection can become chronic (long-lasting) and, over many years, may cause complications, such as bleeding, jaundice (yellowish eyes or skin), fluid accumulation in the abdomen, infections, liver cancer, and death. When Eplusa was taken in chronic HCV patients with mild or no cirrhosis, results of studies showed that 95–99 percent of patients had no virus detected in the blood 12 weeks after finishing treatment.

Epclusa received FDA approval on June 28, 2016, and is now approved to treat chronic hepatitis C genotypes (1 to 6) in adults and children 3 years of age and older without cirrhosis or with compensated cirrhosis. Epclusa is sometimes given in combination with another antiviral medicine called ribavirin in people who also have decompensated cirrhosis with chronic hepatitis C.

Epclusa side effects

Common Epclusa side effects may include:

- headache,
- tiredness,
- nausea,
- · vomiting,
- sleep problems (insomnia),
- · diarrhea.
- low red blood cells (anemia) in people with cirrhosis,

- · pale skin,
- · tiredness,
- feeling light-headed or short of breath,
- · cold hands and feet.

Serious Epclusa side effects

Get emergency medical help if you have signs of an allergic reaction to Epclusa with symptoms of hives, difficulty breathing, and swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have new or worsening symptoms such as:

- · right-sided upper stomach pain;
- · vomiting, loss of appetite, not feeling well; or
- jaundice (yellowing of the skin or eyes).

If you also take a heart rhythm medicine called amiodarone: Taking amiodarone with Epclusa can cause dangerous side effects on your heart. Get medical help right away if you take this medicine and you have:

- · very slow heartbeats, chest pain, shortness of breath;
- · confusion, memory problems; or
- weakness, extreme tiredness, and light-headed feeling (like you might pass out).

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.)

<u>Epclusa side effects</u> (more detail)

Related/similar drugs

Harvoni

Harvoni is used to treat hepatitis C virus (HCV) infections in adults and children aged 3 years and ...

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8.4 / 10

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Glecaprevir/pibrentasvir (Mavyret) is an oral combination medicine containing fixed doses of 2 ...

Reviews & ratings

8.3 / 10

428 Reviews

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Warnings

If you've had hepatitis B, Epclusa can cause this condition to come back or get worse. Call your doctor if you don't feel well and you have right-sided upper stomach pain, vomiting, loss of appetite, or yellowing of your skin or eyes.

Read the medication guide or patient instructions provided with each medication in your combination therapy. Do not change your doses or medication schedule without your doctor's advice.

Epclusa is sometimes used in combination with ribavirin. 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.

Before taking this medicine

Epclusa is sometimes used in combination with other antiviral medications. Before starting this combination therapy, read the medication guide or patient instructions provided with each medication.

When taking Epclusa with other medicine: Tell your doctor about all your medical conditions, and if you are pregnant or breastfeeding.

To make sure Epclusa is safe for you, tell your doctor if you have:

- hepatitis B;
- liver problems other than hepatitis C;
- kidney disease (or if you are on dialysis);
- · diabetes;
- HIV (human immunodeficiency virus); or
- if you use a blood thinner (warfarin, Coumadin, Jantoven) and you have routine "INR" or prothrombin time tests.

Pregnancy

Tell your doctor if you are pregnant or plan to become pregnant

It is not known if sofosbuvir/velpatasvir will harm your unborn baby.

Epclusa is sometimes used in combination with ribavirin. **Ribavirin** can harm an unborn baby if the mother or father is using ribavirin.

- Men and women using ribavirin should use birth control to prevent pregnancy while taking ribavirin and until at least 6 months after your last dose of ribavirin.
- If you become pregnant while taking ribavirin and in the 6 months after your last dose, you should tell your doctor right away.

Breastfeeding

Tell your doctor if you are breastfeeding or plan to breastfeed. 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 with this medicine.

1 Epclusa pregnancy and breastfeeding warnings (more detail)

How should I take Epclusa?

Take Epclusa exactly as prescribed by your doctor. Follow all directions on your prescription label and read all medication guides or instruction sheets.

Epclusa tablet instructions

Take Epclusa tablets orally with or without food.

Epclusa oral pellets instructions

For oral use only (take by mouth with or without food).

If taking oral pellets by mouth, pour the entire contents of the prescribed number of oral pellet packet(s) directly in the mouth and swallow **without chewing** to avoid a bitter taste. Water may be taken after swallowing the pellets, if needed.

If taking oral pellets with food, carefully pour the entire contents of the prescribed number of oral pellet packet(s) onto the food in the bowl and gently mix with a spoon. Take the oral pellets and food mixture within 15 minutes without chewing to avoid a bitter taste.

General administration information

- Pellets should be swallowed whole. Do not chew pellets.
- Do not open the oral pellet packet(s) until ready to use.
- For children younger than 6 years, take oral pellets with food.
- Epclusa oral pellets are white to off-white pellets supplied as single-use packets in cartons.
- Doses are based on weight in children and teenagers. The dose may change if the child gains or loses weight.
- If you've had hepatitis B, it may come back or get worse. You may need liver function tests while using this medicine and for several months after you stop.
- You should not stop using Epclusa suddenly, or your hepatitis C could become harder to treat with antiviral medicine.

- Use all medications as directed. Do not change your dose or stop using a medicine without your doctor's advice.
 Remain under the care of a doctor.
- Epclusa patient tips (more detail)

Epclusa Dosing information

Adult Epclusa Dose for Chronic Hepatitis C

Dose: The usual adult Epclusa dose is sofosbuvir 400 mg-velpatasvir 100 mg orally once a day.

Recommended Regimen and Duration of Therapy:

Therapy-naive and therapy-experienced, without cirrhosis and with compensated cirrhosis (Child-Pugh A): Sofosbuvir-velpatasvir for 12 weeks

Therapy-naive and therapy-experienced, with decompensated cirrhosis (Child-Pugh B or C): Sofosbuvir/velpatasvir plus ribavirin for 12 weeks

Comments:

- -Dose recommendations also apply to HCV/HIV-1-coinfected patients.
- -In clinical trials, therapy-experienced patients received a peginterferon alfa/ribavirin-based regimen with or without an HCV nonstructural protein 3/4A (NS3/4A) protease inhibitor (boceprevir, simeprevir, or telaprevir).
- -If applicable, the manufacturer product information should be consulted for ribavirin dose recommendations; the manufacturer product information for ribavirin should be consulted for further information regarding dosing and dose adjustments.

Usual Pediatric Dose for Chronic Hepatitis C:

6 years or older:

Weight 17 to less than 30 kg: Sofosbuvir 200 mg-velpatasvir 50 mg orally once a day Weight at least 30 kg: Sofosbuvir 400 mg-velpatasvir 100 mg orally once a day

Recommended Regimen and Duration of Therapy:

Therapy-naive and therapy-experienced, without cirrhosis and with compensated cirrhosis (Child-Pugh A): sofosbuvir/velpatasvir for 12 weeks

Therapy-naive and therapy-experienced, with decompensated cirrhosis (Child-Pugh B or C): sofosbuvir/velpatasvir plus ribavirin for 12 weeks

Comments:

- -Dose recommendations also apply to HCV/HIV-1-coinfected patients.
- -In clinical trials, therapy-experienced adults received a peginterferon alfa/ribavirin-based regimen with or without an HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir).
- -If applicable, the manufacturer product information should be consulted for ribavirin dose recommendations; the manufacturer product information for ribavirin should be consulted for further information regarding dosing and dose adjustments.

Epicusa is available as:

• Tablets: (400 mg sofosbuvir and 100 mg velpatasvir); (200 mg sofosbuvir and 50 mg velpatasvir).

- Oral Pellets: (200 mg sofosbuvir and 50 mg velpatasvir); (150 mg sofosbuvir and 37.5 mg velpatasvir).
- Detailed Epclusa dosage information

What happens if I miss a dose?

Take the medicine as soon as you remember, and then go back to your regular schedule. Do not use two doses at one time.

Get your prescription refilled before you run out of medicine completely.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while taking Epclusa?

Using this medicine 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 drug or medicine needles is never safe, even for a healthy person.

What other drugs will affect Epclusa?

When you start or stop taking Epclusa, your doctor may need to adjust the doses of any other medicines you take on a regular basis.

Sometimes it is not safe to use certain medications at the same time. Some drugs can affect your blood levels of other drugs you take, which may increase side effects or make the medications less effective.

If you also take omeprazole (Prilosec) or an antacid, do not take it for at least 4 hours after you have taken your dose of Epclusa (with food).

Many drugs can interact with sofosbuvir/velpatasvir. This includes prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible interactions are listed here. Tell your doctor about all other medicines you use.

<u>Epclusa drug interactions</u> (more detail)

Does Epclusa interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

Epclusa	
+	
Enter a drug name	Add

Epclusa Package Insert

Review the Epclusa Package Insert for more detailed information about this medicine. Discuss any medical questions you have with your doctor or other health care provider. This is not all the information you need to know about this medicine for safe and effective use, and it does not take the place of talking to your doctor about your treatment.

Storage

Tablets. Store below 30 °C (86 °F). Dispense only in original container.

Oral pellets. Store below 30 °C (86 °F).

Ingredients

Active ingredients: sofosbuvir and velpatasvir

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

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

Oral Pellets Inactive ingredients: 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.

Company

Gilead Sciences, Inc., Foster City, CA 94404

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References

1. Epclusa Full Prescribing Information FDA

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- Epclusa prescribing information
- Sofosbuvir and Velpatasvir (AHFS Monograph)

Related treatment guides

Hepatitis C

Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Epclusa only for the indication prescribed.

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

Medical Disclaimer

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DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

ം Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

8 years FDA approved 2016

User Reviews & Ratings

7.5 / 10

397 Reviews

Images

Epclusa sofosbuvir 400 mg / velpatasvir 100 mg (GSI 7916)





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