

Epclusa (velpatasvir + sofosbuvir)

Summary

Epclusa is a direct-acting antiviral medication used to treat hepatitis C. It is a combination of two medications, sofosbuvir and velpatasvir. These two medications are co-formulated into one tablet. Epclusa is approved in Canada for the treatment of chronic hepatitis C in people who are over the age of 18 years and have any genotype of the hepatitis C virus. It is taken once a day, with or without food, for 12 weeks. Epclusa has few side effects. Side effects are generally mild and temporary; they include tiredness and headache. Direct-acting antivirals are highly effective and cure over 95% of people with hepatitis C.

What is Epclusa?

Epclusa is a direct-acting antiviral medication that is used to treat hepatitis C. It is a combination of two direct-acting antivirals: sofosbuvir, which is an NS5B (hepatitis C virus non-structural protein 5B) nucleotide polymerase inhibitor, and velpatasvir, which is an NS5A (hepatitis C virus non-structural protein 5A) inhibitor.

Epclusa is approved in Canada for the treatment of chronic hepatitis C in people who are over the age of 18 years and have any genotype of the hepatitis C virus.

How does Epclusa work?

Epclusa directly blocks the ability of the hepatitis C virus to make copies of itself in the liver. Sofosbuvir interferes with the reproduction of the genetic material of the hepatitis C virus and velpatasvir works by interfering with a protein needed by the virus. Together, they greatly reduce and then stop the production of new copies of the hepatitis C virus. Over time, these actions eliminate the hepatitis C virus from the body.

FACT SHEET

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Does Epclusa cure people of hepatitis C?

Direct-acting antivirals are highly effective and cure more than 95% of people with hepatitis C. Epclusa is one of these highly effective direct-acting antiviral medications.

A cure for hepatitis C is also known as a sustained virological response (SVR). A person is cured if the hepatitis C virus is no longer detected in the blood 12 weeks after the end of treatment.

If a person is cured of hepatitis C, they can be re-infected if they are exposed to the hepatitis C virus again.

How do people with hepatitis C use Epclusa?

Epclusa is taken as one tablet, once a day, for 12 weeks. Each tablet is available as a fixed-combination tablet containing 400 mg of sofosbuvir and 100 mg of velpatasvir. It can be taken with or without food.

People with severe liver injury, called decompensated cirrhosis, may need to take Epclusa with ribavirin. Ribavirin is another type of antiviral medication; it is not a direct-acting antiviral. Information about ribavirin is included in a separate fact sheet.

How important is it to stick to treatment?

All medications work best when they are taken exactly as prescribed and directed. People taking Epclusa should take their pills every day, as prescribed by their healthcare provider. It is very important to finish the entire course of treatment. This gives the treatment the best chance of working to cure hepatitis C.

What can be done about missed doses?

When a person taking Epclusa misses a dose and it is within 18 hours of when it should have been taken, it is important to take the missed dose immediately or as soon as possible. If it has been more than 18 hours since a dose was supposed to have been taken, that dose should be skipped and

the next dose should be taken at the appropriate time. A double dose should not be taken. A person should continue their treatment until all doses have been taken.

If a person finds it difficult to stick to treatment, it is important to discuss this with their nurse or doctor. Tips for sticking to treatment can be found in CATIE's *Hepatitis C: An In-depth Guide*.

Warnings

1. Risk of hepatitis B virus reactivation in patients co-infected with hepatitis C and hepatitis B viruses

The U.S. Food and Drug Administration (FDA) recommends that all people starting hepatitis C treatment with direct-acting antiviral medications should be tested for hepatitis B before starting treatment.

There have been a small number of reports of reactivation of hepatitis B virus infection when direct-acting antivirals like Epclusa are used to treat hepatitis C infection in people who are co-infected with hepatitis B virus. Reactivation of hepatitis B virus can, in some cases, cause serious complications. People considering the use of Epclusa should speak with their doctor or nurse about their hepatitis B virus infection status.

2. Cardiovascular effects

The manufacturer of Epclusa, Gilead Sciences, states that there have been cases of problems in some people who have taken the heart drug amiodarone and medicines containing sofosbuvir. Epclusa contains sofosbuvir. Therefore, Gilead recommends that Epclusa not be used by people who take amiodarone.

3. Breastfeeding/chestfeeding

People with infants and who are taking Epclusa should not breastfeed or chestfeed their children. It is not known whether the medication is present in human milk.

4. People under the age of 18 years

The safety and effectiveness of treatment with Epclusa for people under the age of 18 years has not been determined.

5. Special populations

People with any of the following conditions should speak with their doctor or nurse about the most appropriate hepatitis C treatment options for them:

- liver problems other than hepatitis C
- previous treatment with an NS5A inhibitor (such as velpatasvir, elbasvir, ledipasvir, daclatasvir, ombitasvir and pibrentasvir)
- severe liver injury, such as Child–Pugh C cirrhosis
- pregnancy or planning to have a baby while on treatment for hepatitis C
- recent liver transplant
- severe kidney injury or on dialysis
- co-infection with hepatitis B
- co-infection with HIV

Epclusa is generally safe and highly effective. Anyone who is considering treatment with Epclusa should discuss all of their medical conditions with their doctor or nurse.

Side effects

The most common side effects of Epclusa are:

- fatigue (extreme tiredness)
- headache

In most cases these side effects are mild or moderate and gradually resolve. Headache and fatigue occurred with similar frequency among people taking Epclusa and among people taking placebo in double-blinded clinical trials.

Drug interactions

Some prescription drugs, over-the-counter drugs, herbs, supplements and street drugs can interfere

with the absorption and/or the effectiveness of Epclusa. This is called a drug interaction.

Some drugs taken for other conditions can interact with Epclusa by increasing or decreasing the level of one or both drugs in the body. Increased levels can lead to new or more severe side effects. Decreased levels may mean that the drug won't be as effective.

It is important that people discuss all the medications, supplements, herbs and street drugs they are taking with their doctor, nurse or pharmacist. If a person has more than one doctor or pharmacist, it is possible for drug interactions to get missed. Using the same pharmacy for all prescriptions can be helpful.

This fact sheet is not comprehensive and lists only some of the potential and actual drug interactions with Epclusa. Speak with a pharmacist to find out more about drug interactions with Epclusa.

The manufacturer of Epclusa does not recommend taking Epclusa with the following medications and medicinal supplements:

- medications to treat irregular heartbeat, such as amiodarone
- anti-seizure medications, such as carbamazepine (Tegretol), phenobarbital, oxcarbazepine (Trileptal) and phenytoin (Dilantin)
- tuberculosis medications, such as rifampin and rifabutin (Mycobutin)
- HIV medications that contain efavirenz (Sustiva, and in Atripla)
- any medicinal herbs, especially St. John's wort (*Hypericum perforatum*), which is an herb used to treat depression, or hyperforin or hypericin, which are active ingredients in St. John's wort

When Epclusa is taken with the following medications it could potentially cause significant drug interactions:

- antacids or buffered medications, such as Tums, milk of magnesia and calcium supplements

- medications to treat indigestion, heartburn or ulcers, such as nizatidine (Axid), famotidine (Pepcid AC, Peptic Guard), ranitidine (Zantac), esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Losec), pantoprazole (Pantoloc), rabeprazole (Aciphex) and cimetidine (Tagamet)
- the heart drug digoxin (Lanoxin, Toloxin)
- HIV treatments that contain tenofovir DF (Viread, and in Truvada, Atripla, Complera, Stribild)
- cholesterol-lowering medications, such as rosuvastatin (Crestor) and atorvastatin (Lipitor)

Availability

Epclusa, manufactured by Gilead Sciences, has been approved by Health Canada and is available in Canada. Pharmacists are a good source of information about public and private health insurance coverage for Epclusa.

The “Treatment coverage in your region” section of CATIE’s *Hepatitis C: An In-depth Guide* contains information about provincial and territorial drug coverage.

Acknowledgement

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Reference

Gilead Sciences. Epclusa (Velpatasvir/Sofosbuvir). *Product monograph*. September 11, 2019.

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Disclaimer

Decisions about particular medical treatments should always be made in consultation with a qualified medical practitioner knowledgeable about HIV- and hepatitis C-related illness and the treatments in question.

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