

Epclusa (velpatasvir + sofosbuvir)

Summary

Epclusa is a medication used to treat hepatitis C. It is approved in Canada for people with *all* genotypes of the hepatitis C virus. Epclusa is a combination of velpatasvir and sofosbuvir. These two drugs are co-formulated into one tablet. It is taken once a day with or without food. Epclusa has few side effects. They are generally mild and commonly include tiredness and headache. Hepatitis C treatment can cure a person from hepatitis C. However, a person could become infected again.

What is Epclusa?

Epclusa is a medication used to treat hepatitis C.

How does Epclusa work?

Hepatitis C is a disease of the liver that is caused by a virus. A virus is a very tiny germ that makes copies of itself to survive by a process called replication. The hepatitis C virus has at least six different strains, which are also known as genotypes.

Epclusa is a direct-acting antiviral (DAA) medication. DAAs are a group of medications that directly block the ability of the hepatitis C virus to make copies of itself.

Epclusa is a combination of two DAAs. These drugs work by weakening the activity of proteins needed by hepatitis C. One of the two drugs in Epclusa is sofosbuvir, which is a nucleotide polymerase inhibitor, and the other is velpatasvir, which is an NS5A (hepatitis C virus non-structural protein 5A) inhibitor. Sofosbuvir interferes with the reproduction of the genetic material of the hepatitis C virus. Velpatasvir works by interfering with a protein needed by the virus. Together these two drugs greatly reduce and then stop the production of new copies of hepatitis C viruses. Hepatitis C treatment can cure a person from hepatitis C. However, a person could get infected again.

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How do people use Epclusa?

Epclusa is taken as one tablet once a day. It can be taken with or without food.

People with Child-Pugh B cirrhosis, which is a high level of liver injury, take Epclusa with ribavirin.

Epclusa is approved in Canada for people over the age of 18 with chronic hepatitis C.

How long is treatment?

Treatment lasts for 12 weeks.

Sticking to treatment

All medications work best when they are taken exactly as prescribed and directed. This means taking the medications in the right amount and at the right time for the entire length of time that your treatment lasts. Skipping doses or stopping treatment altogether means that the treatment may not work and the chance of being cured is lower.

With some hepatitis C medications, there is also a chance that the virus can become resistant to the medication if it is not taken as directed. In this case, the medication will not be effective against the virus and cannot be used to treat the infection. (See the Resistance section to learn about the potential for resistance to Epclusa.)

What can you do if you forget to take your medication?

If you miss taking a dose of Epclusa and it is within 18 hours of when you were supposed to take it, take it as soon as possible. If it is after 18 hours from when you were supposed to take it, wait and take the next tablet at your regular time. Do not take a double dose.

If you find that you are not able to take your medication as prescribed and directed, talk to your nurse or doctor right away. You can also check out the section “Tips for staying on track with treatment” in CATIE’s *Hepatitis C: An in-depth guide* at www.catie.ca.

How likely is a cure from treatment that includes Epclusa?

Hepatitis C treatment can cure a person from hepatitis C.

In late-stage clinical trials of Epclusa, the cure rates for genotypes 1, 2, 4, 5 and 6 were about 98%. For genotype 3 cure rates were 95%.

The likelihood of a cure can be affected by the level of liver injury and other factors. Talk to your doctor about the likelihood of a cure for you.

Sometimes in real life the cure rates can be lower than they are in clinical trials.

A cure for hepatitis C is also known as a sustained virological response (SVR). This is when the hepatitis C virus is no longer detected in the blood at least 12 weeks after treatment ends.

Warnings

1. Breastfeeding/nursing

People with infants and who are taking Epclusa should not breastfeed or nurse their children.

2. Potential for serious heart problems when Epclusa is taken with amiodarone

A serious slowing of the heart rate (symptomatic bradycardia) may occur when the drug amiodarone, which is used to treat an irregular heartbeat, is taken with Epclusa. It is not recommended to take amiodarone and Epclusa at the same time.

3. Hepatitis B

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

This is because if someone has hepatitis C and hepatitis B and is not receiving treatment for hepatitis B, treatment with DAAs could reactivate hepatitis B during or after treatment. For more information about being tested for hepatitis B, speak to your doctor or nurse.

4. People under the age of 18

Epclusa has not been tested in people under the age of 18. If you are under 18, speak to your doctor about the most appropriate treatment option for you.

5. Special populations

Speak to your doctor about the most appropriate treatment options if you have one or more of the following issues:

- you were previously treated with an NS5A inhibitor and not cured from treatment
- You have Child-Pugh C cirrhosis, which is a high level of liver injury
- you are pregnant or plan to become pregnant
- you have liver problems other than hepatitis C
- you have had a recent liver transplant
- you have severe kidney impairment or are on dialysis
- you are co-infected with hepatitis B
- you are co-infected with HIV

Epclusa is a new drug and not everything is known about its effect on people. Make sure your doctor knows about all of your medical conditions when you are discussing Epclusa as a treatment option.

Side effects

The most common side effects of Epclusa are:

- fatigue
- headache

In most cases these side effects are mild or moderate.

Drug interactions

Always consult your doctor and pharmacist about all the other prescription and non-prescription drugs you are taking, including methadone or other opiate substitution therapies, herbs, supplements and street drugs.

Drug interactions occur when one medication affects how another is absorbed, used or flushed out of the body. Some drugs can interact with Epclusa, 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.

When Epclusa is taken with the following medications it could potentially cause significant drug interactions. This is not a complete list of possible drug interactions with Epclusa:

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

Talk to your nurse, doctor and pharmacist if you are taking any of these medicines. If you have more than one doctor or pharmacist, it is possible for drug interactions to get missed. If more than one doctor is writing prescriptions for you, let each one know about everything you are taking. If possible, use the same pharmacy for all your prescriptions.

Drug resistance

Drug resistance develops when a virus mutates, or changes, during the replication process. Some mutations of the virus may be able to resist hepatitis C medications. When this happens, the medication becomes less effective or stops working. Resistance may develop when a person does not take their medication as prescribed and directed.

In clinical trials, it was rare for the hepatitis C virus to develop resistance to Epclusa. However, it is still important for people taking Epclusa to take it exactly as prescribed. If you skip or miss doses, Epclusa could potentially fall to low levels in your body. This can allow the hepatitis C virus to mutate and become able to resist the effect of treatment.

Availability

Epclusa, manufactured by Gilead Sciences, has been approved by Health Canada and is available in Canada. Your nurse, doctor or pharmacist can tell you more about availability and coverage of Epclusa in your region.

CATIE's online Treatment coverage in your region section of *Hepatitis C: An in-depth guide* on www.catie.ca contains information about provincial and territorial drug coverage.

Acknowledgement

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References

Gilead Sciences. Epclusa (Velpatasvir/Sofosbuvir). *Product monograph*. 2016.

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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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