

Vosevi (sofosbuvir + velpatasvir + voxilaprevir)

FACT SHEET

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Summary

Vosevi is a direct-acting antiviral medication used to treat hepatitis C. It is a combination of three medications, sofosbuvir, velpatasvir and voxilaprevir. These three medications are co-formulated into one tablet. Vosevi is approved in Canada for people over the age of 18 years, who either do not have cirrhosis or have compensated cirrhosis, and who have previously taken oral direct-acting antiviral hepatitis C medication but were not cured of hepatitis C. It is taken once a day with food for 12 weeks. Vosevi has few side effects. Side effects are generally mild and temporary; they include headache, tiredness, diarrhea, nausea, sleeping problems and lack of energy and strength. Direct-acting antivirals are highly effective and cure over 95% of people with hepatitis C.

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What is Vosevi?

Vosevi is a direct-acting antiviral medication used to treat hepatitis C. It is a combination of three medications: sofosbuvir, which is an NS5B (hepatitis C virus non-structural protein 5B) nucleotide polymerase inhibitor, velpatasvir, which is an NS5A (hepatitis C virus non-structural protein 5A) inhibitor, and voxilaprevir, which is a protease inhibitor. Vosevi is approved in Canada for people over the age of 18 years with chronic hepatitis C who either do not have cirrhosis or have compensated cirrhosis in the following situations:

- people with any genotype of hepatitis C virus who have taken direct-acting antivirals *with* an NS5A inhibitor (such as daclatasvir, ledipasvir, elbasvir, ombitasvir, velpatasvir and pibrentasvir) and who were not cured
- people with genotype 1, 2, 3 or 4 of the hepatitis C virus who have taken a direct-acting antiviral *containing* sofosbuvir but *without* an NS5A inhibitor and were not cured

How does Vosevi work?

Vosevi 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. Velpatasvir works by interfering with a protein needed by the virus. Voxilaprevir interferes with the production of the pieces needed to build new virus particles. Together, these three medications 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.

Does Vosevi cure people of hepatitis C?

Direct-acting antivirals are highly effective and cure more than 95% of people with hepatitis C. Vosevi 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 not detected in the blood 12 weeks after the end of treatment.

If a person is cured of hepatitis C, they can get hepatitis C again if they are exposed to the hepatitis C virus.

How do people with hepatitis C use Vosevi?

Vosevi is taken as one tablet, once a day, for 12 weeks. Each tablet is available as a fixed-dose combination tablet containing 400 mg of sofosbuvir, 100 mg of velpatasvir and 100 mg of voxilaprevir. Vosevi should be taken with food, but it does not matter what kind of food.

How important is it to stick to treatment?

All medications work best when they are taken exactly as prescribed and directed. People taking Vosevi 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 Vosevi 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 Vosevi 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 Vosevi should speak with their doctor or nurse about their hepatitis B virus infection status.

2. Cardiovascular effects

The manufacturer of Vosevi, Gilead Sciences, states that there have been cases of problems in some people who have taken the heart drug amiodarone and medicines containing sofosbuvir.

Vosevi contains sofosbuvir. Therefore, Gilead recommends that Vosevi not be used by people who take amiodarone.

3. Breastfeeding/Chestfeeding

People with infants who are taking Vosevi 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 Vosevi 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:

- severe liver injury like Child–Pugh B or C cirrhosis
- pregnancy or planning a pregnancy while on hepatitis C treatment
- liver problems other than hepatitis C
- awaiting a liver transplant or a liver transplant recipient
- severe kidney injury or on dialysis
- co-infection with hepatitis B
- co-infection with HIV
- rare hereditary condition of galactose (milk sugar) intolerance

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

Side effects

The most common side effects of Vosevi are:

- headache

- fatigue (extreme tiredness)
- lack of energy and strength
- diarrhea
- nausea
- sleeping problems

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

Drug interactions

Some prescription drugs, over-the-counter drugs, herbs, supplements and other drugs (both legal and illegal) can interfere with the absorption and/or the effectiveness of Vosevi. This is called a drug interaction.

Some drugs taken for other conditions can interact with Vosevi 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 medications, supplements, herbs and other drugs (both legal and illegal) 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 Vosevi. Speak with a pharmacist to find out more about drug interactions with Vosevi.

The following medications are contraindicated (should not be used) with Vosevi:

- the blood thinner dabigatran etexilate (Pradaxa)
- the anti-seizure medications phenobarbital and phenytoin (Dilantin)
- the tuberculosis medication rifampin (Rifadin, Rofact)

- 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
- the cholesterol-lowering medication rosuvastatin (Crestor)

The manufacturer does not recommend taking Vosevi with the following medications:

- amiodarone, a medication to treat irregular heartbeat
- some anti-seizure medications, such as carbamazepine (Tegretol) and oxcarbazepine (Trileptal)
- the tuberculosis medications rifabutin (Mycobutin) and rifapentine
- HIV medications that contain efavirenz (Sustiva, and in Atripla), atazanavir (Reyataz) and lopinavir (in Kaletra)
- the immune-suppressant medication cyclosporine (Neoral, Sandimmune IV)

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

- antacids or buffered medications, such as Tums or milk of magnesia and calcium and magnesium 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 regimens that contain tenofovir DF (Viread, and in Truvada, Atripla, Complera, Stribild, Delstrigo)
- the cholesterol-lowering medications atorvastatin (Lipitor), fluvastatin, lovastatin, simvastatin (Zocor) and pravastatin
- oral contraceptives (birth control pills) that contain ethinyl estradiol drugs

Availability

Vosevi, 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 Vosevi.

CATIE's online module "Federal, Provincial and Territorial Drug Access Programs" also contains information about Canadian drug coverage.

Acknowledgement

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Reference

Gilead Sciences. Vosevi (Sofosbuvir/Velpatasvir/Voxilaprevir). *Product monograph*. May 19, 2021.

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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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