

Vosevi (sofosbuvir + velpatasvir + voxilaprevir)

Summary

Vosevi is a medication used to treat hepatitis C. It is approved in Canada for people who have taken all-oral direct-acting antiviral hepatitis C medication but who were not cured of the virus. Vosevi is a combination of sofosbuvir, velpatasvir and voxilaprevir. These three drugs are co-formulated into one tablet. It is taken once a day with food. Vosevi appears to have few side effects. Common side effects are generally mild and temporary; they include headache, fatigue, diarrhea and nausea. Hepatitis C treatment can cure a person from hepatitis C. If a person is cured of hepatitis C, they can be re-infected with hepatitis C if they are exposed to the virus again.

What is Vosevi?

Vosevi is a medication used to treat hepatitis C.

How does Vosevi 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 (HCV) has at least six different strains, which are also known as genotypes.

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

Vosevi is a combination of the following three DAAs:

- sofosbuvir – a nucleotide polymerase inhibitor that interferes with the reproduction of the genetic material of the hepatitis C virus.
- velpatasvir – an NS5A (hepatitis C virus non-structural protein 5A) inhibitor that works by interfering with a protein needed by the virus.

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- voxilaprevir – a protease inhibitor that interferes with the production of the pieces needed to build new virus particles.

Together, these three drugs greatly reduce and then stop the production of new copies of HCV.

Hepatitis C treatment can cure a person from hepatitis C. If a person is cured of hepatitis C, they can be re-infected with hepatitis C if they are exposed to the virus again. The Prevention and Harm Reduction section of CATIE's *Hepatitis C: An in-depth guide* contains information on preventing reinfection.

How do people use Vosevi?

Vosevi is taken as one tablet once a day. Vosevi should be taken with food, but it does not matter what kind of food.

Vosevi is approved in Canada for the following:

- people with any genotype of HCV who have taken DAA medication with a type of medicine called an NS5A inhibitor and who were not cured of the virus
- people with HCV genotypes 1, 2, 3 or 4 who have taken DAA medication with sofosbuvir but without an NS5A inhibitor and who were not cured of the virus

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

How long is treatment?

Treatment with Vosevi 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.

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

If you miss taking a dose of Vosevi and it is within 18 hours of when you were supposed to take it, take the dose 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 Tips for staying on track with treatment in CATIE's *Hepatitis C: An in-depth guide*.

How likely is a cure from treatment that includes Vosevi?

Hepatitis C treatment can cure a person from hepatitis C. 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 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

Breastfeeding/nursing

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

Potential for serious heart problems when Vosevi 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 Vosevi. It is not recommended to take amiodarone and Vosevi at the same time.

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.

Issues to discuss

Speak to your doctor about the most appropriate treatment options if:

- you have Child-Pugh B or C cirrhosis, which is a moderate to high level of liver injury
- you are pregnant or plan to have a baby
- you have liver problems other than hepatitis C
- you are waiting for a liver transplant or you have had a recent liver transplant
- you have severe kidney injury or are on dialysis
- you are co-infected with hepatitis B
- you are co-infected with HIV
- you were born with the rare problem of not being able to tolerate galactose (milk sugar)

Vosevi 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 Vosevi as a treatment option.

Side effects

The most common side effects of Vosevi are:

- headache
- tiredness or lack of energy
- diarrhea
- nausea
- sleeping problems

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 Vosevi, 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.

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

- medication to treat irregular heartbeat, such as amiodarone
- anti-seizure medication, such as carbamazepine (Tegretol), phenobarbital, oxcarbazepine (Trileptal) and phenytoin (Dilantin)
- tuberculosis medication, such as rifampin and rifabutin (Mycobutin)
- HIV medications that contain efavirenz (Sustiva, and in Atripla), atazanavir (Reyataz) or lopinavir (in Kaletra)
- the cholesterol-lowering medication rosuvastatin (Crestor)
- the transplant medicine cyclosporine
- the blood thinner dabigatram (Pradaxa)
- 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

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

- antacids or buffered medications such as Tums or Milk of Magnesia

- calcium and magnesium supplements
- medication to treat indigestion, heartburn or ulcers, such as nizatidine (Axid), famotidine (Pepcid AC, Peptic Guard), ranitidine (Zantac), esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Losec) and pantoprazole (Pantoloc)
- the heart drug digoxin (Lanoxin, Toloxin)
- HIV regimens that contain tenofovir DF (Viread, and in Truvada, Atripla, Complera, Stribild)
- the cholesterol lowering medications atorvastatin, fluvastatin, lovastatin, simvastatin and pravastatin
- vitamin K antagonist medication that reduces clotting, such as warfarin (Coumadin)
- oral contraceptives (birth control pills) that contain ethinyl estradiol drugs

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 can 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 Vosevi. However, it is still important for people taking Vosevi to take it exactly as prescribed. If you skip or miss doses, Vosevi could potentially fall to low levels in your body. This can allow the hepatitis C virus to mutate and resist the effect of treatment.

Availability

Vosevi, 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 Vosevi in your region.

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. Vosevi (Sofosbuvir/Velpatasvir/Voxilaprevir). *Product monograph*. 2017.

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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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