

# Sofosbuvir (Sovaldi)

## Summary

Sofosbuvir is a medication used to treat Hep C. It is used in combination with other medications to cure people of the Hep C virus. Sofosbuvir is taken at a dose of 400 mg once per day. It does not need to be taken with food. So far, sofosbuvir appears to have few side effects. Common side effects of treatment are associated with the other medications sofosbuvir is taken with. Hep C treatment can cure a person from Hep C. However, a person could become infected again.

## What is sofosbuvir?

Sofosbuvir is a medication used to treat hepatitis C (Hep C). It is sold under the brand name Sovaldi. It is used in combination with other medications to cure people of the hepatitis C virus.

## How does sofosbuvir work?

Hep 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 Hep C virus has at least six different strains, which are also known as genotypes.

Sofosbuvir is a direct-acting antiviral (DAA) medication. DAAs are a group of medications that directly attack the ability of a virus, such as hepatitis C, to make copies of itself.

Sofosbuvir is a type of DAA called a nucleotide polymerase inhibitor. It interferes with the reproduction of the virus' genetic material, stopping the production of new Hep C virus.

Hep C treatment can cure a person from Hep C. However, a person could get infected again.

## How do people use sofosbuvir?

Sofosbuvir is taken as a 400-mg pill once per day. Sofosbuvir must be used in combination with ribavirin.

Sofosbuvir and ribavirin is approved in Canada for people over the age of 18 with genotype 2 or 3 hepatitis C virus.

# FACT SHEET

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## How long is treatment?

Hep C virus genotype	Treatment combination	Treatment length
genotype 2	sofosbuvir + ribavirin	12 weeks
genotype 3	sofosbuvir + ribavirin	16 weeks or up to 24 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 time that your treatment lasts. Skipping doses or stopping treatment altogether means that the treatment may not work as well and the chance of being cured is lower.

With some Hep C medications, there is also a chance that the virus can become resistant to the medication if it is not taken as prescribed and 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 sofosbuvir.)

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

If you miss taking a dose of sofosbuvir, take it as soon as possible. If it is close to the next time when you would take sofosbuvir, 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. You can also check out the section "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 sofosbuvir?

Hep C treatment can cure a person from Hep C.

In late-stage clinical trials of sofosbuvir and peg-interferon and/or ribavirin, participants had approximately the following cure rates:

People with virus genotype	Cure rate
genotype 2	86%-94%
genotype 3	30%-63%

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

A cure for Hep C is also known as a sustained virological response (SVR). This is when the Hep C virus is no longer detected in the blood 12 or 24 weeks after treatment ends.

## Warnings

### Combination therapy

Sofosbuvir must be taken in combination with ribavirin, so all of the warnings that apply to ribavirin also apply to people considering sofosbuvir. For more information on ribavirin, see the ribavirin factsheet.

### Breastfeeding/nursing

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

### Potential for serious heart problems when sofosbuvir and another DAA are taken with amiodarone

A serious slowing of the heart rate (symptomatic bradycardia) can occur when the drug amiodarone which is used to treat an irregular heartbeat is taken with sofosbuvir and another DAA, such as simeprevir.

It is not recommended to take amiodarone and sofosbuvir and another DAA 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.

## Special populations

### People who are co-infected with HIV

In late-stage trials of sofosbuvir and ribavirin for people co-infected with hepatitis C and HIV, cure rates ranged from 67% to 94%. Participants had hepatitis C virus genotypes 1, 2, 3 or 4 and received either 12 or 24 weeks of treatment depending on their genotype and if they had previously been treated.

### Other populations

Sofosbuvir has not been tested in the following populations:

- people who are pregnant
- people under the age of 18
- people over the age of 65
- people with liver failure (decompensated cirrhosis)
- people with severe kidney impairment or disease
- people who are co-infected with hepatitis B

If you are in one of these groups or are co-infected with HIV, speak to your doctor about the most appropriate treatment options.

Some testing of sofosbuvir has been completed in the following populations:

- people with genotypes 5 and 6 hepatitis C virus
- people waiting for a liver transplant
- people who have had a liver transplant

In general, the results of testing sofosbuvir in these groups have been positive. However, the testing has been completed with small groups of people,

so further research is needed to draw conclusions about the effectiveness of sofosbuvir for these groups. If you are in one of these groups, speak to your doctor about whether sofosbuvir is right for you.

## Side effects

When sofosbuvir is taken with ribavirin, the most common side effects are:

- difficulty sleeping
- fatigue
- headache
- low blood platelets (thrombocytopenia)
- low red blood cells and iron in blood (anemia)
- low white blood cells (neutropenia)
- nausea

Most of these side effects can be caused by ribavirin.

## Drug interactions

Always consult your doctor and pharmacist about taking other prescription and non-prescription drugs, including methadone or 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 sofosbuvir, 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.

This is not a complete list of possible drug interactions with sofosbuvir.

It is not recommended to take sofosbuvir in combination with another DAA with the following medication:

- medication to treat irregular heartbeat, such as amiodarone

When sofosbuvir is taken with the following medications it could potentially cause significant drug interactions.

- anti-seizure medication – carbamazepine (Tegretol)
- anti-seizure medication – oxcarbazepine (Trileptal)
- anti-seizure medication – phenytoin (Dilantin)
- sleep modification medication – modafinil (Alertec)
- insomnia medication – phenobarbital
- tuberculosis medication – rifabutin (Mycobutin) and rifampin (Rifadin, Rifater, Rofact)
- any medicinal herbs, especially an herb used to treat depression – St. John's wort (*Hypericum perforatum*), or hyperforin or hypericin, active ingredients in St. John's wort

Talk to your nurse, doctor and pharmacist if you are taking any of these medicines. One way to manage drug interactions is to make sure that your doctor and pharmacist know about *everything* you are taking, including prescription drugs, over-the-counter drugs, street drugs, herbal medications, supplements or anything else. 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.

## Resistance

Drug resistance develops when a virus mutates, or changes, during the replication process. Some mutations of the virus may be able to resist Hep 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.

It is rare for the Hep C virus to develop resistance to sofosbuvir.

## Availability

Sofosbuvir, 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 sofosbuvir in your region.

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

## Acknowledgement

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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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