



# Sofosbuvir (Sovaldi)

## WHAT IS SOFOSBUVIR?

Sofosbuvir is a drug used as part of antiviral therapy against chronic hepatitis C virus (HCV). The trade name is Sovaldi. It is manufactured by Gilead Sciences.

Sofosbuvir is an HCV polymerase inhibitor. These drugs prevent the polymerase enzyme from working. This makes it harder for the virus to multiply. See Step 7 of the HCV life cycle shown in Fact Sheet 670.

Sofosbuvir is the first drug that inhibits HCV polymerase. It is the fourth drug that directly interferes with the virus.

Earlier drugs used to treat HCV were immune boosters, interferon and ribavirin (IFN and RBV, see Fact Sheet 680) and HCV protease inhibitors (see Fact Sheets 682 and 683). Sofosbuvir must be used in combination with other HCV medications.

The combination of medications depends on the strain (or genotype, see Fact Sheet 674) of HCV. Sofosbuvir should not be used by itself.

## WHO SHOULD TAKE IT?

Sofosbuvir was approved in 2013 as a direct antiviral drug for people infected with any HCV genotype with HCV/HIV co-infection or people with liver cancer who are awaiting a transplant.

Sofosbuvir has not been studied in children under the age of 18.

## HOW IS IT TAKEN?

Sofosbuvir is taken by mouth as one 400 milligram (mg) tablet once day, with or without food. Sofosbuvir is taken with other medications depending on the HCV genotype:

**Patients with HCV genotype 1 or 4** take Sofosbuvir with RBV and pegIFN for 12 weeks.

**Patients with HCV genotype 2** take Sofosbuvir with RBV for 12 weeks (no interferon)

**Patients with HCV genotype 3** take Sofosbuvir with RBV for 24 weeks

Interferon is injected under the skin, and ribavirin is taken by mouth. Fact sheet 680 has more information on these medications.

Sofosbuvir can be taken with or without food. Sofosbuvir should be stored at room temperature (below 86°F or 30°C).

## WHAT ARE THE SIDE EFFECTS?

The most common side effects of sofosbuvir when taken with RBV are tiredness (fatigue) and headache.

When taken with RBV and peg-IFN, the most common side effects are tiredness, headache, nausea, difficulty sleeping and low red blood cell counts (anemia, see Fact Sheet 552).

These are not the only possible side effects of HCV treatment. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Because sofosbuvir is always taken in combination with ribavirin, which can cause serious birth defects, do not take sofosbuvir if you or your sexual partner is pregnant or want to become pregnant. Do not become pregnant for 6 months after you or your partner stop taking sofosbuvir.

See Fact Sheet 680 for more information on the side effects of pegIFN and RBV. Be sure to tell your health care provider about any side effects that you are having.

## WHAT ABOUT DRUG RESISTANCE?

Some new copies of HCV carry mutations, meaning they are slightly different from the original virus. Some mutated virus can keep multiplying even when you are taking anti-HCV medications. When this happens, the drug will stop working. This is called "developing resistance" to the drug.

**Resistance can develop quickly. It is very important to take antiviral medications according to instructions, on schedule, and not to skip or reduce doses.**

Resistance to other HCV drugs does not mean that the virus is resistant to sofosbuvir.

## HOW DOES IT REACT WITH OTHER DRUGS?

Sofosbuvir can interact with other drugs or supplements that you are taking. **These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose.**

If sofosbuvir is taken with the boosted protease inhibitor tipranavir (Aptivus) to treat HIV, levels of sofosbuvir are reduced. Sofosbuvir is not recommended with the HIV medication tipranavir.

Other drugs to watch out for include some drugs to treat seizures (carbamazepine, oxcarbazepine and phenytoin), and medications use to treat tuberculosis (rifabutin, rifampin and rifapentine).

The herb **St. John's Wort** (See Fact Sheet 729) lowers the blood levels of some HCV medications. Do not take it while taking sofosbuvir.

**New drug interactions are being identified all the time. Make sure that your health care provider knows about ALL drugs and supplements you are taking.**

## THE BOTTOM LINE

Sofosbuvir is the first HCV polymerase inhibitor, a new class of direct acting HCV medications. It stops HCV from multiplying. Treatment with sofosbuvir includes other HCV drugs for either 12 or 24 weeks.

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