



Ledipasvir/Sofosbuvir (Harvoni)

WHAT IS LEDIPASVIR/SOFOSBUVIR?

Ledipasvir/Sofosbuvir is a combination of two drugs that treat chronic hepatitis C virus (HCV). Sold under the name Harvoni, ledipasvir/sofosbuvir is manufactured by Gilead Sciences.

Ledipasvir (formerly GS-5885) inhibits the HCV protein NS5A. The exact way the drug works is unknown.

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.

In clinical trials, more than 94% of people taking ledipasvir/sofosbuvir had HCV sustained viral response (SVR), meaning that their HCV infection was cured.

WHO SHOULD TAKE IT?

Ledipasvir/sofosbuvir was approved in October 2014 as a treatment for adults infected with HCV genotype 1.

People who have never taken HCV treatment or those who are treatment-experienced without cirrhosis should take it for 12 weeks. People who are treatment experienced with cirrhosis should take ledipasvir/sofosbuvir for 24 weeks.

It is not known if ledipasvir/sofosbuvir is safe or effective in children under the age of 18.

HOW IS IT TAKEN?

Ledipasvir/sofosbuvir is taken by mouth as one 90/400 milligram (mg) tablet once day, with or without food.

Patients with HCV genotype 1 who are taking HCV treatment for the first time take ledipasvir/sofosbuvir for 8 weeks. People who are HCV treatment experienced will take the pill for 12 weeks.

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?

Ledipasvir/sofosbuvir was very well tolerated in clinical studies. The most commonly reported side effects in clinical studies were fatigue and headache.

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.

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 necessarily mean that the virus is resistant to ledipasvir or sofosbuvir.

HOW DOES IT REACT WITH OTHER DRUGS?

Ledipasvir and 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 you take an antacid that contains aluminum or magnesium, you should

take the antacid 4 hours before or 4 hours after you take ledipasvir/sofosbuvir.

Be sure to tell your provider if you take any of the following HIV medications: Atripla, Stribild, tipranavir, or if you take tenofovir with Kaletra, atazanavir/ritonavir or darunavir/ritonavir.

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.

Other drugs to watch out for include some drugs to treat **high cholesterol (rosuvastatin)**, **medications to lower stomach acid levels (famotidine, omeprazole)**, treat seizures (carbamazepine, oxcarbazepine and phenytoin), and medications use to treat tuberculosis (rifabutin, rifampin and rifapentine).

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

THE BOTTOM LINE

Ledipasvir/sofosbuvir is the first combination for treating HCV. It is also the first approved regimen that does not require interferon or ribavirin. Treatment with ledipasvir/sofosbuvir for either 12 or 24 weeks is usually very well tolerated. It cures the majority of people with HCV genotype 1 who took the medication in clinical trials.

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