

The goal of hepatitis C virus (HCV) treatment is a cure (when there is no hepatitis C virus in a person’s bloodstream at least 12 weeks after treatment is finished).

What is Harvoni? Harvoni is two HCV-fighting drugs (sofosbuvir and ledipasvir) in one pill. In the United States, Harvoni is approved for HIV-negative and HIV-positive people with hepatitis C genotypes 1, 4, 5, and 6 who are over 18 years old. Harvoni is also approved for people with HCV genotype 1 who have advanced (called *decompensated*) cirrhosis, and for liver transplant recipients who have HCV genotype 1 or 4.

How is Harvoni used? Harvoni is taken once daily, with or without food, for 8 to 24 weeks. Treatment length depends on HCV treatment history, whether a person has cirrhosis, and the amount of hepatitis C virus in a person’s bloodstream (called *HCV RNA* or *viral load*). Some people will need to add another drug, called **ribavirin (RBV)**, twice daily with Harvoni.

FDA Recommended Treatment Length and Cure Rates in Clinical Trials*

Genotype 1, never treated for HCV, no cirrhosis	+ Cirrhosis
12 weeks (recommended): 96% to 99% (if HCV RNA is less than 6 million copies IU/mL, consider 8 weeks) 8 weeks: 94% (if HCV RNA is less than 6 million copies IU/mL: 97%)	12 weeks: 94%
Genotype 1, treatment-experienced, no cirrhosis	+ Cirrhosis
12 weeks + RBV: 95%	If past treatment with an HCV protease inhibitor: 12 weeks + RBV If past treatment with Sovaldi: 24 weeks + RBV Treatment-experienced (PEG-IFN + RBV): 100%
Genotype 1, never treated or treatment-experienced + decompensated cirrhosis (Child-Pugh Class B or Class C)	
12 weeks + RBV. Class B: 87% (45/52); Class C: 88% (35/40)	
Genotype 1, posttransplant, for all stages of cirrhosis	
12 weeks + RBV. No cirrhosis: 95% (94/99); + Child-Pugh Class A cirrhosis: 98% (55/56); + Child-Pugh Class B cirrhosis: 89% (41/46); + Child-Pugh Class C cirrhosis: 57% (4/7)	
Genotype 4, 5, and 6, never treated or treatment-experienced, with or without cirrhosis	
12 weeks. Genotype 4: 93%; Genotype 5: 93%; Genotype 6: 96%	
Genotype 4, posttransplant, with or without compensated cirrhosis	
12 weeks + RBV. Cure rates are similar to those in genotype 1	

*Cure rates in clinical trials are higher than in real life since the people in them are usually healthier and get extra monitoring and support.

The most important thing a person can do to be cured is not to miss taking doses of HCV treatment—this is called **adherence**. Adherence lowers the risk for drug resistance.

What is drug resistance? Each day, HCV makes billions of copies of itself. Some of these copies are not exactly the same as the original virus. They may have changes (called **mutations**) that can stop hepatitis C drugs from working. If people miss doses of their treatment, HCV gets a chance to reproduce—and some of the copies it makes may not respond to HCV treatment.

Some people have drug resistance even though they have never been on hepatitis C treatment—but many can be cured anyway.

Most people who are not cured have resistance to one or more of the HCV drugs they’ve taken. Resistance to certain hepatitis C drugs can disappear within months. But resistance to certain drugs, including Harvoni, can last for years and may limit re-treatment options.

Harvoni and age, gender, and race/ethnicity: In clinical trials, cure rates did not differ by age (over 65 vs. under 65). Cure rates have been the same for women and men. There is not much information about how well Harvoni works by race or ethnicity because most of the people in the trials were white. With HCV alone, black (99%, or 89/90) versus nonblack (96%, or 431/448) people were just as likely to be cured by 12 weeks of Harvoni. In ION-4, a trial in HIV/HCV coinfection, the overall cure rate was higher (96%, or 321/335) than among black participants (90%, or 105/115).

Side effects from Harvoni: Talk with your health care provider about possible side effects and how they will be managed. In clinical trials of Harvoni, the most common side effects were fatigue, headache, nausea, diarrhea, and insomnia; usually, these were mild. Some people have reported skin swelling, rash, or blisters.

Does Harvoni work for HIV-positive people? Yes. In clinical trial of 335 HIV/HCV-coinfected people, 321 (96%) were cured after 12 weeks of Harvoni. Harvoni cannot be used with certain HIV drugs (see [Harvoni and other medications](#), below).

Harvoni and other medications: Harvoni should not be used with certain drugs. Combining medications can increase or lower drug levels (called *drug-drug interactions*). Increasing drug levels can make side effects from each drug worse. If drug levels get too low, a drug can stop working, putting people at risk for drug resistance or not being cured.

Harvoni should not be used with a medication called amiodarone because sofosbuvir can cause life-threatening heart problems. For people who must take amiodarone, intensive heart monitoring in a hospital is recommended for 48 hours after starting Harvoni and daily monitoring for at least two weeks afterward.

Talk with your health care provider before starting or stopping any medications, supplements, or herbal remedies.

Some drugs should be switched, stopped or avoided while using Harvoni. More information is available in Harvoni’s prescribing information (www.accessdata.fda.gov/drugsatfda_docs/label/2015/205834s006lbl.pdf) and online at: www.hep-druginteractions.org.

Harvoni and HIV Antiretrovirals

HIV Integrase Inhibitors	
Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir DF)	Stribild is not recommended during treatment with Harvoni
HIV Non-Nucleoside Reverse Transcriptase Inhibitors	
Atripla (efavirenz/emtricitabine/tenofovir DF)	Harvoni can increase tenofovir concentration; renal monitoring for tenofovir-associated adverse events is recommended; efavirenz may lower the level of ledipasvir, one of the drugs in Harvoni
HIV Protease Inhibitors	
Boosted Aptivus (ritonavir/tipranavir)	Do not use boosted Aptivus with Harvoni
Kaletra (ritonavir/lopinavir), boosted Prezista (ritonavir/darunavir), boosted Reyataz (ritonavir/atazanavir), with Viread (tenofovir DF) or Truvada (emtricitabine/tenofovir DF)	Consider a different HCV or HIV regimen to avoid increased tenofovir concentration; renal monitoring for tenofovir-associated adverse events is recommended

Storing Harvoni: Keep Harvoni at room temperature (below 86°F).

Harvoni in people with kidney disease: Harvoni can be used in people with mild or moderate kidney disease. It is not recommended for people with severe kidney disease (eGFR < 30 mL/min/1.73 m²) or people on dialysis.

Harvoni in people with cirrhosis: HCV treatment guidelines recommend that people with serious liver damage (Child-Pugh Class B or C) be treated by a specialist. In clinical trials, people with Child-Pugh Class B or C cirrhosis have been treated with Harvoni and ribavirin.

Harvoni during pregnancy, nursing, and in children: It is not known whether Harvoni causes harm to unborn babies. If you are pregnant or planning pregnancy, talk with your health care provider about the risks and benefits of HCV treatment. It is not known whether Harvoni passes into breast milk. Harvoni is under study in children (ages 3 to 18).

Ribavirin causes birth defects, and it can be fatal to unborn babies. Ribavirin should not be used by pregnant women or by male partners of pregnant women. Ribavirin stays in a person’s body for months. Women and their male partners should avoid pregnancy for six months after they have stopped taking ribavirin. Using two forms of birth control to prevent pregnancy while taking ribavirin—and for six months afterward—is recommended. Nursing during treatment with ribavirin is not recommended (see TAG’s [ribavirin](#) fact sheet for more information).

There is a ribavirin pregnancy registry at: <http://www.ribavirinpregnancyregistry.com>.

Access to Harvoni may be restricted by public and private payers. The criteria differ depending on the type of coverage and the state it is issued in. Support Path is Gilead’s patient assistance program for Harvoni. People with private insurance may be eligible for assistance with copayments. Uninsured people may be eligible for medication at no charge. Information about Support Path is available online at: <http://www.gilead.com/responsibility/us-patient-access/support-path-for-sovaldi-and-harvoni>. Information about Support Path is also available by phone at 1.855.769.7284, Monday through Friday between 9:00 a.m. and 8:00 p.m. (Eastern Time), or online at: <https://www.harvoni.com/support>.

This fact sheet is current as of April 2016. Always check for updated information.