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

What is sofosbuvir/daclatasvir? Sofosbuvir/daclatasvir is a fixed-dose combination of two HCV-fighting drugs (sofosbuvir and daclatasvir). The brand name for sofosbuvir is Sovaldi; the brand name for daclatasvir is Daklinza. The combination of the two drugs may also be sold under the names Darvoni or Sovodak. The World Health Organization approved this regimen for people with hepatitis C genotypes 1–6 who are 18 years of age and older.

How are sofosbuvir and daclatasvir used? Sofosbuvir and daclatasvir are taken once daily, with or without food, for 12 weeks. Ribavirin-free treatment regimens are recommended for treatment-naïve patients. People who have compensated cirrhosis, or cirrhosis without liver-related symptoms, may need to take the regimen for a longer period of time or with another drug, ribavarin, if they are not treatment naïve. However, the optimal duration of sofosbuvir and daclatasvir for patients with cirrhosis has not been established. The effectiveness of the treatment depends on whether a person has cirrhosis, their virus genotype, and their previous HCV treatment history.

World Health Organization–Recommended Treatment Length and Cure Rates in Clinical Trials[1,2,*,]**

Genotypes 1 and 2, no cirrhosis	+ compensated cirrhosis
12 weeks: 92%	**12 weeks**:** 93%
Genotype 3, no cirrhosis	+ compensated cirrhosis
12 weeks: 92%	**12 weeks**:** 79-82% **24 weeks:** 90%
Genotype 4, no cirrhosis	+ compensated cirrhosis
12 weeks: 92%	**12 weeks:** 98%
Genotype 5, no cirrhosis	+ compensated cirrhosis[2]
12 weeks: 100%	**12 weeks:** 100%
Genotype 6, no cirrhosis[2]	+ compensated cirrhosis[2]
12 weeks: 98%	**12 weeks**:** 90%

1. See also Treatment Action Group. Ribavarin Fact Sheet. 2015 December. Available from: http://www.treatmentactiongroup.org/hcv/factsheets/ribavirin (Accessed 2019 February 1).
2. Iwamoto M, Sonderup MW, Sann K et al. Real-world effectiveness and safety of Daclatasvir/Sofosbuvir with or without Ribavirin among genotype 5 and 6 Hepatitis C Virus patients. Poster session presented at: the 68th Annual Meeting of American Association for the Study of Liver Diseases; 2017 October 20-24; Washington, D.C.

*Cure rates in clinical trials are higher than in the general population because the people in trials are usually healthier and receive extra monitoring and support.

**Recommended only in countries where genotype distribution is known and genotype 3 prevalence is <5%.

The most important thing a person can do to be cured is to take all your HCV medication—this is called adherence. This lowers the risk that the virus will develop resistance to treatment.

What is drug resistance? Each day, HCV makes billions of copies of itself. Some copies are not 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 may be resistant 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 have taken. Resistance to some hepatitis C drugs can disappear within months, but it can also last for years and may limit re-treatment options.

Sofosbuvir/daclatasvir and age, gender, and race/ethnicity: In clinical trials, cure rates did not differ by age (over 65 versus under 65 years), gender, or race.

Side effects from sofosbuvir/daclatasvir: Talk with your health care provider about possible side effects and how they can be managed. In clinical trials of sofosbuvir/daclatasvir, the most common side effects were headache, fatigue, and nausea, usually mild.

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Does sofosbuvir/daclatasvir work with HIV drugs? Sofosbuvir/daclatasvir can be used with some HIV medicines, but doses may need to be adjusted from the standard 60 mg/day adult dose. Check with your doctor prior to taking sofosbuvir/daclatasvir regarding possible drug interactions.

Sofosbuvir/daclatasvir and other medications: Sofosbuvir/daclatasvir can be coadministered with opiate substitution medicines (e.g., buprenorphine or methadone) with no dose adjustments needed. Combining medications can increase or decrease drug levels (called **drug-drug interactions**). An increase can make side effects worse. A decrease can prevent a drug from working, putting people at risk for resistance or not being cured.

Sofosbuvir/daclatasvir should not be used in people taking the heart rhythm medication amiodarone because sofosbuvir in combination with amiodarone can cause life-threatening heart problems. Do not take St. John's wort herbal supplements with sofosbuvir/daclatasvir, and tell your doctor if you are taking statins or medications for cancer, seizures, bacterial infections or heartburn/acid reflux.

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

Sofosbuvir/Daclatasvir and HIV Treatments (Antiretrovirals)

HIV protease inhibitors	
Atazanavir/ritonavir or atazanavir/cobicistat (Reyataz)	Reduce daclatasvir to 30 mg.
HIV integrase inhibitors	
Fixed-dose combination of elvitegravir, cobicistat, emtricitabine, and tenofovir DF (Stribild)	Reduce daclatasvir to 30 mg.
HIV non-nucleoside reverse transcriptase inhibitors	
Efavirenz (Sustiva, Atripla)	Increase daclatasvir to 90 mg.
Etravirine or nevirapine (Intelence, Viramune)	Not recommended for use with sofosbuvir/daclatasvir.
Tenofovir DF (Viread, Truvada, Atripla, Complera, Stribild)	No dose adjustment required. No known issue with TDF and daclatasvir.

Storing sofosbuvir/daclatasvir: Keep sofosbuvir and daclatasvir at room temperature (below 30°C [86°F]).

Sofosbuvir/daclatasvir in people with kidney disease: Sofosbuvir/daclatasvir is not recommended for use in persons with severe renal impairment (chronic kidney failure grades 4 and 5).

Sofosbuvir/daclatasvir 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. Use of sofosbuvir/daclatasvir has been demonstrated to be generally safe and effective in people with cirrhosis (compensated and decompensated), but treatment duration may need to be adjusted based on the hepatitis C genotype. In addition, ribavirin may be added to the treatment regimen.

Sofosbuvir/daclatasvir during pregnancy or nursing and in children: It is not known whether sofosbuvir/daclatasvir causes harm to unborn babies or passes into breast milk. If you are pregnant or breast feeding, or planning for either, talk with your health care provider about the risks and benefits of HCV treatment. In animal studies of pregnant rats and rabbits, very high doses of sofosbuvir/daclatasvir caused birth defects, miscarriage, and maternal death. No harm was seen at lower doses.

Sofosbuvir/daclatasvir is currently being tested in children younger than 18 years old, but is not yet recommended for use in this age group.

Access to sofosbuvir/daclatasvir may be restricted by public and private payers. The criteria differ depending on the type of coverage and the state in which the coverage is issued. Support Path is Gilead's patient assistance program for Sovaldi. 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 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.gilead.com/purpose/medication-access/us-patient-access.

This fact sheet is current as of May 2019. Always check for updated information.