

Daclatasvir (Daklinza)

Summary

Daclatasvir (Daklinza) is a medication used to treat hepatitis C. It is taken with sofosbuvir (Sovaldi) and sometimes ribavirin. This combination is approved in Canada for people with genotypes 1 and 2 hepatitis C virus. It has received conditional approval for people with genotype 3 virus. Daclatasvir is taken once a day along with sofosbuvir once a day. Both medicines are taken orally. Daclatasvir appears to have few side effects. Common side effects are generally mild and include tiredness, headache and nausea. Hepatitis C treatment can cure a person from hepatitis C. However, a person could become infected again.

What is daclatasvir?

Daclatasvir is a medication used to treat hepatitis C (Hep C).

How does daclatasvir 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.

Daclatasvir is a direct-acting antiviral (DAA) medication. DAAs are a group of oral medications that directly block the ability of the Hep C virus to make copies of itself.

Daclatasvir is an NS5A inhibitor. It works by interfering with a protein needed to complete the Hep C virus life cycle in the liver cell.

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

How do people use daclatasvir?

Most people take daclatasvir as one tablet once a day. It is taken in combination with sofosbuvir. For more information on sofosbuvir, see the

FACT SHEET

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sofosbuvir fact sheet. This combination may also be prescribed with ribavirin.

Daclatasvir is approved in combination with sofosbuvir in Canada for people over the age of 18 with genotypes 1 and 2 hepatitis C virus. It is conditionally approved for people with genotype 3 virus, pending the outcome of a late-stage clinical trial.

How long is treatment?

The duration of treatment is based on which genotype a person has, past treatment experience and the absence or presence of severe liver damage.

Genotype 1

Treatment experience	Severe liver damage (cirrhosis)	Treatment length
Never been treated (treatment naïve) or treatment experienced	No	12 weeks
Never been treated (treatment naïve) or treatment experienced	Yes	24 weeks

Genotype 2

Treatment experience	Severe liver damage (cirrhosis)	Treatment length
Never been treated (treatment naïve)	Yes or No	24 weeks
Treatment experienced	No	24 weeks

Genotype 3

Treatment experience	Severe liver damage (cirrhosis)	Treatment length
Never been treated (treatment naïve) or treatment experienced	No	12 weeks
Never been treated (treatment naïve) or treatment experienced	Yes	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 length of time that your treatment lasts. Skipping doses or stopping treatment altogether means that the treatment may not work 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 directed. In this case, the medication will not be effective against the virus and cannot be used to treat the infection. (See the “Drug resistance” section to learn about the potential for resistance to daclatasvir.)

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

If you miss a dose of daclatasvir and it is within 20 hours of when you were supposed to take it, take it as soon as possible. If it is after 20 hours from when you were supposed to take it, 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 right away. You can also check out the section “Tips for staying on track with treatment” in CATIE’s *Hepatitis C: An in-depth guide* at www.catie.ca.

How likely is a cure from treatment that includes daclatasvir and sofosbuvir?

How likely is a cure from treatment that includes daclatasvir and sofosbuvir?

Hep C treatment can cure a person from Hep C.

In late-stage clinical trials of daclatasvir taken with sofosbuvir, participants had the following cure rates:

People with virus genotype	Cure rate
genotype 1	99%
genotype 2	96%
genotype 3	89%

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 weeks (written as SVR12) or 24 weeks (written as SVR24) after treatment ends.

Warnings

Breastfeeding/nursing

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

People who are pregnant or who can become pregnant

People who are pregnant should not take daclatasvir. People who could become pregnant should use effective birth control while taking daclatasvir and for five weeks after the end of treatment. If ribavirin is also being taken, two effective forms of birth control should be used during treatment and for six months after the end of treatment.

Potential for serious heart problems when daclatasvir and sofosbuvir 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 daclatasvir and sofosbuvir. Therefore, it is not recommended to take amiodarone and daclatasvir and sofosbuvir 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

Speak to your doctor about the most appropriate treatment options if you have one or more of the following issues:

- previous Hep C treatment with a combination that includes ledipasvir or dasabuvir (NS5A inhibitors)
- liver failure (decompensated liver disease)
- liver transplant
- liver problems other than hepatitis C
- severe kidney impairment or are on dialysis
- HIV
- hepatitis B
- galactose intolerance

Daclatasvir is a new drug and not everything is known about its effect on people. Make sure your doctor is aware of all of your medical conditions when you are discussing daclatasvir as a treatment option. Daclatasvir has not been tested in people

under the age of 18. If you are under 18, speak to your doctor about the most appropriate treatment option for you.

Side effects

The most common side effects of daclatasvir are:

- fatigue
- headache
- nausea

In most cases these side effects are mild or moderate.

Drug interactions

Always consult your doctor *and* pharmacist about all the other prescription and non-prescription drugs you are taking, including methadone or other 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 daclatasvir, 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.

Daclatasvir should not be taken with the following medications:

- anti-seizure medicine, such as carbamazepine (Tegretol), oxcarbazepine (Trileptal) and phenytoin (Dilantin)
- steroids, such as dexamethasone (when taken by injection or mouth)
- tuberculosis medication, such as rifampin and rifabutin
- the medicinal herb used to help manage anxiety and mild depression – St. John's wort (*Hypericum perforatum*), or hyperforin or hypericin, active ingredients in St. John's wort

When daclatasvir is taken with the following medications it could potentially cause significant

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

- Hep C medicines, such as boceprevir (Victrelis), telaprevir (Incivek)
- HIV medicine, such as atazanavir (Reyataz) + ritonavir (Norvir), efavirenz (Sustiva, Atripla), etravirine (Intelence), nevirapine (Viramune)
- medicine to treat irregular heartbeat, such as amiodarone, digoxin (Toloxin)
- medicine to treat bacterial infection, such as erythromycin, clarithromycin (Biaxin)
- medicine to treat fungal infection when taken by mouth, such as itraconazole, ketoconazole, voriconazole
- medicine to treat sleep problems, such as modafinil (Alertec)
- medicine to lower blood pressure, such as verapamil
- medicine to treat heart problems and high blood pressure, such as diltiazem
- medicine for the lung problem pulmonary hypertension, such as bosentan (Tracleer)
- medicine to prevent blood clots, such as dabigatran etexilate mesylate (Pradaxa)
- cholesterol-lowering medicine, such as pravastatin, rosuvastatin (Crestor), simvastatin, fluvastatin

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.

Drug 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 altogether.

In clinical trials, it was rare for the Hep C virus to develop resistance to daclatasvir. However, it is still important for people taking daclatasvir to take it exactly as prescribed. If you skip or miss doses, daclatasvir could potentially fall to low levels in your body. This can allow the Hep C virus to mutate and become able to resist the effect of treatment.

Availability

Daclatasvir, manufactured by Bristol-Myers Squibb, 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 daclatasvir in your region.

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

References

Bristol-Myers Squibb Canada. Daclatasvir. *Product monograph*. 2015.

Sulkowski MS, Gardiner DF, Rodriguez-Torres M et al. Daclatasvir plus sofosbuvir for previously treated or untreated chronic HCV. *New England Journal of Medicine*. 2014;270: 211-21.

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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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