

Asunaprevir (Sunvepra)

Summary

Asunaprevir (Sunvepra) is a medication used to treat people with hepatitis C virus. It is taken with daclatasvir (Daklinza). This combination is approved in Canada for people with genotype 1b hepatitis C virus. Asunaprevir is taken twice a day along with daclatasvir once per day. Asunaprevir appears to have few side effects. Common side effects are generally mild and include tiredness and headache. Treatment can cure a person from hepatitis C. However, a person could become infected again. For more information about hepatitis C prevention, testing and treatment visit [Hepatitis C: An In-Depth Guide on www.catie.ca](http://www.catie.ca).

What is asunaprevir?

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

How does asunaprevir work?

Hepatitis 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 by a process called replication. The hepatitis C virus has at least six different strains, which are also known as genotypes.

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

Asunaprevir is a protease inhibitor. It works by interfering with the production of the pieces needed to build new virus particles, stopping the production of new hepatitis C virus.

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

How do people use asunaprevir?

Most people take asunaprevir as one tablet twice a day. It is taken in combination with daclatasvir (Daklinza). For more information on daclatasvir, see the daclatasvir factsheet.

Asunaprevir is approved in combination with daclatasvir in Canada for people over the age of 18 with genotype 1b hepatitis C virus.

How long is treatment?

The duration of treatment is 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 hepatitis 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. (See the Resistance section to learn about the potential for resistance to asunaprevir.)

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

If you miss taking a dose of asunaprevir and it is within eight hours of when you were supposed to take it, take it as soon as possible. If it is after eight 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 asunaprevir and daclatasvir?

Hepatitis C treatment can cure a person from hepatitis C.

In one late-stage clinical trial of asunaprevir taken with daclatasvir, participants had an 85% cure rate.

Sometimes in real life the cure rates can be lower than in clinical trials.

A cure for hepatitis C is also known as a sustained virological response (SVR). This is when the hepatitis C virus is no longer detected in the blood 12 or 24 weeks after treatment ends.

Warnings

Breastfeeding/nursing

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

People who are pregnant or who can become pregnant

People who are pregnant should not take asunaprevir. People who could become pregnant should use effective birth control while taking asunaprevir. If you want to use oral birth control, speak to your doctor or nurse about the most effective medication to use.

The potential for liver injury

In clinical trials of asunaprevir-containing treatments, a small proportion of people developed liver injury (hepatotoxicity) potentially caused by the drugs used in the trials. In these cases, participants developed elevated levels on certain tests (ALT, AST and bilirubin) that show how well the liver is working.

If you are taking asunaprevir your doctor may do blood tests to check how your liver is working every two weeks for the first 12 weeks of treatment and then every four weeks till the end of treatment. If levels are high on certain tests your doctor may stop treatment with asunaprevir.

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 medication for hepatitis B, treatment with DAAs could reactivate hepatitis B during or after treatment. This risk is extremely low.

For more information about being tested for hepatitis B, speak to your doctor or nurse.

Special populations

Asunaprevir should not be used in the following groups:

- People with severe liver injury (Child-Pugh B or C)
- People whose liver is not able to work properly (decompensated liver disease)

Asunaprevir has not been tested in the following groups:

- people with genotype 2, 3, 5 or 6 virus
- people who are pregnant
- people 18 years of age or younger
- people who have had a liver transplant
- people coinfecting with HIV
- people coinfecting with hepatitis B
- people who were not cured by a previous treatment with asunaprevir or another hepatitis C protease inhibitor

Speak to your doctor about the most appropriate treatment options if you are in any of these groups.

Asunaprevir is a new drug and some things are unknown about its effect on people. Make sure your doctor knows about all of your medical conditions when you are discussing asunaprevir as a treatment option.

Side effects

The most common side effects of asunaprevir are:

- fatigue
- headache

In most cases, these side effects are mild or moderate.

Drug interactions

Always consult your doctor and pharmacist about all 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 asunaprevir, 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.

Asunaprevir should not be taken with the following medications:

- anti-seizure medicines, carbamazepine (Tegretol), oxcarbazepine (Trileptal), phenytoin (Dilantin), phenobarbital
- some medicines to treat bacterial infections, specifically clarithromycin (Biaxin), erythromycin
- the medicine for the lung problem pulmonary hypertension, bosentan (Tracleer)
- HIV medicines, atazanavir (Reyataz) / ritonavir (Norvir), efavirenz (Sustiva, Atripla), etravirine (Intelence), nevirapine (Viramune), darunavir (Preszista) / ritonavir (Norvir), indinavir (Crixivan), Kaletra (lopinavir + ritonavir), nelfinavir (Viracept), ritonavir (Norvir), saquinavir (Invirase), fosamprenavir (Telzir), Stribild (elvitegravir + cobicistat + tenofovir disoproxil fumarate + emtricitabine), Genvoya (elvitegravir + cobicistat + tenofovir alfanamide + emtricitabine), Prezcoibix (darunavir + cobicistat),
- medicines to treat fungal infection when taken by mouth, specifically itraconazole, ketoconazole, voriconazole (Vfend), fluconazole, posaconazole (Posanol)

- a medicine used to prevent the body from rejecting an organ transplant, cyclosporine (Neoral, Sandimmune)
- medicines to treat pain in the heart caused by decreased blood flow (angina), diltiazem and verapamil
- a medicine to lower cholesterol, gemfibrozil
- a medicine to promote wakefulness, modafinil (Alertec)
- medicines to treat irregular heartbeat, specifically flecainide or propafenone
- a steroid, dexamethasone (when taken by injection or mouth)
- tuberculosis medications, specifically rifampin and rifabutin
- the medicinal herb used for depression – St. John’s wort (*Hypericum perforatum*), or hyperforin or hypericin, active ingredients in St. John’s wort
- a medication to relieve symptoms of psychosis, thioridazine

When asunaprevir is taken with the following medications, it could potentially cause drug interactions. This is not a complete list of possible drug interactions with asunaprevir:

- hormonal contraceptive pills
- medicine to treat depression, specifically amitriptyline, imipramine, nortriptyline
- medicine to suppress coughing, specifically dextromethorphan (an ingredient in over-the-counter cold medications like Dimetapp, Robitussin and Theraflu)
- a medicine for sleep problems and/or anxiety, midazolam
- cholesterol-lowering medicines, atorvastatin, pravastatin (Pravachol), rosuvastatin (Crestor), simvastatin, fluvastatin (Lescol)
- medicine to treat irregular heartbeat, specifically digoxin (Toloxin)

- a medicine to prevent blood clots, dabigatran etexilate mesylate (Pradaxa)

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 hepatitis C medications. When this happens, the medication becomes less effective or stops working.

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

Availability

Asunaprevir, 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 asunaprevir 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.

Acknowledgement

We thank Curtis Cooper, MD, FRCP(C) for expert review.

References

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Published: 2017



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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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Funding has been provided by the Public Health Agency of Canada.

CATIE Ordering Centre No: ATI-50275
(aussi disponible en français, ATI-50276)

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