

Maviret (glecaprevir + pibrentasvir)

Summary

Maviret is a direct-acting antiviral medication used to treat hepatitis C. It is a combination of glecaprevir and pibrentasvir. These two drugs are co-formulated into three tablets or granules in sachets that are taken once a day. Maviret is approved in Canada for the treatment of chronic hepatitis C in adults and children who are 3 years or older, weigh 12 kg or more and have any genotype of the hepatitis C virus. Among this population, Maviret is also approved in Canada for those who have previously taken some types of direct-acting antivirals but were not cured of hepatitis C. Maviret is taken with food for eight, 12 or 16 weeks. Maviret has few side effects. Side effects are generally mild and temporary; they include headache and tiredness. Direct-acting antivirals are highly effective and cure over 95% of people with hepatitis C.

What is Maviret?

Maviret is a direct-acting antiviral medication that is used to treat hepatitis C. It is a combination of two direct-acting antivirals: glecaprevir, which is a protease inhibitor, and pibrentasvir, which is an NS5A (hepatitis C virus non-structural protein 5A) inhibitor.

Maviret is approved in Canada for the treatment of chronic hepatitis C in adults and children who are 3 years or older, weigh 12 kg or more and have any genotype of the hepatitis C virus. Among this population, Maviret is also approved in Canada for those who have previously taken some types of direct-acting antivirals but were not cured of hepatitis C. This includes the following situations:

- those with any genotype of the virus who have taken treatment containing (peg)interferon, ribavirin and/or a direct-acting antiviral medication called sofosbuvir, *without* a type of medication called an NS3/4A protease inhibitor or an NS5A inhibitor, and who were not cured of hepatitis C

FACT SHEET

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CONTACT US

by e-mail

info@catie.ca

by mail

555 Richmond Street West
Suite 505, Box 1104
Toronto ON M5V 3B1

- those with genotype 1 of the virus who have taken direct-acting antivirals *with* a type of medicine called an NS5A inhibitor or an NS3/4A protease inhibitor (but not both), and who were not cured of hepatitis C

Examples of an NS3/4A inhibitor include asunaprevir, grazoprevir, paritaprevir, simeprevir, glecaprevir and voxilaprevir. Examples of an NS5A inhibitor include daclatasvir, ledipasvir, elbasvir, ombitasvir, velpatasvir and pibrentasvir.

How does Maviret work?

Maviret directly blocks the ability of the hepatitis C virus to make copies of itself in the liver. Glecaprevir interferes with the production of the pieces needed to build new virus particles and pibrentasvir works by interfering with a protein needed by the virus. Together, they greatly reduce and then stop the production of new copies of the hepatitis C virus. Over time, these actions eliminate the hepatitis C virus from the body.

Does Maviret cure people of hepatitis C?

Direct-acting antivirals are highly effective and cure more than 95% of people with hepatitis C. Maviret is one of these highly effective direct-acting antiviral medications.

A cure for hepatitis C is also known as a sustained virological response (SVR). A person is cured if the hepatitis C virus is not detected in the blood 12 weeks after the end of treatment.

If a person is cured of hepatitis C, they can get hepatitis C again if they are exposed to the hepatitis C virus.

How do people with hepatitis C use Maviret?

Maviret is taken for eight, 12 or 16 weeks. Generally, a person who has never been treated before will take Maviret for eight weeks. If a person has experience with previous treatment for hepatitis C and is eligible for Maviret, the length of treatment depends on the absence or presence

of severe liver injury, the genotype of the virus and past treatment experience.

Maviret is taken as three tablets once a day for adults and children who are 12 years or older or weigh 45 kg or more. Each tablet has a fixed-combination dose of 100 mg of glecaprevir and 40 mg of pibrentasvir (total dose: 300 mg of glecaprevir and 120 mg of pibrentasvir). The three tablets should be taken with food, but it does not matter what kind of food.

Maviret is taken as granules in sachets once a day for children who are 3 years or older and weigh at least 12 kg but less than 45 kg. Each sachet has a fixed-combination dose of 50 mg of glecaprevir and 20 mg of pibrentasvir. The number of sachets and dosage received is based on body weight.

The sachets should be taken with food. The dose of granules should be sprinkled on soft food with a low water content that will stick to a spoon and that can be swallowed without chewing (e.g., peanut butter, thick jam or Greek yogurt). The mixture of food and granules should be taken within 15 minutes of preparation. Once opened, the sachets with granules should be used immediately and not be stored.

How important is it to stick to treatment?

All medications work best when they are taken exactly as prescribed and directed. People taking Maviret should take their medication every day, as prescribed by their healthcare provider. It is very important to finish the entire course of treatment. This gives the treatment the best chance of working to cure hepatitis C.

What can be done about missed doses?

When a person taking Maviret misses a dose and it is within 18 hours of when it should have been taken, it is important to take the missed dose immediately or as soon as possible. If it has been more than 18 hours since a dose was supposed to have been taken, that dose should be skipped and the next dose should be taken at the appropriate time. A double dose should not be taken. A person

should continue their treatment until all doses have been taken.

If a person finds it difficult to stick to treatment, it is important to discuss this with their nurse or doctor. Tips for sticking to treatment can be found in CATIE's *Hepatitis C: An In-Depth Guide*.

Warnings

1. Risk of hepatitis B virus reactivation in patients co-infected with hepatitis C and hepatitis B viruses

The U.S. Food and Drug Administration (FDA) recommends that all people starting hepatitis C treatment with direct-acting antiviral medications should be tested for hepatitis B before starting treatment.

There have been a small number of reports of reactivation of hepatitis B virus infection when direct-acting antivirals like Maviret are used to treat hepatitis C infection in people who are co-infected with hepatitis B virus. Reactivation of hepatitis B virus can, in some cases, cause serious complications. People considering the use of Maviret should speak with their doctor or nurse about their hepatitis B virus infection status.

2. Breastfeeding/chestfeeding

People with infants who are taking Maviret should not breastfeed or chestfeed their children. It is not known whether the medication is present in human milk.

3. People under the age of 18 years

The safety and effectiveness of treatment with Maviret for children under the age of 3 years has not been determined.

The safety and effectiveness of treatment with Maviret for people under the age of 18 years with any of the following conditions has not been studied:

- infection with genotype 5 or 6 of the hepatitis C virus
- compensated cirrhosis

- previous treatment containing a type of direct-acting antiviral medication called an NS5B inhibitor (such as sofosbuvir or dasabuvir)

4. Special populations

People with any of the following conditions should speak with their doctor or nurse about the most appropriate hepatitis C treatment options for them:

- severe liver injury like Child–Pugh B or C cirrhosis
- pregnancy or planning a pregnancy while on treatment for hepatitis C
- liver problems other than hepatitis C
- previous liver or kidney transplant
- co-infection with hepatitis B
- co-infection with HIV
- rare hereditary condition of galactose (milk sugar) intolerance
- diabetes

Maviret is generally safe and highly effective. Anyone who is considering treatment with Maviret should discuss all of their medical conditions with their doctor or nurse.

Side effects

The most common side effects of Maviret are:

- headache
- fatigue (extreme tiredness)
- diarrhea
- nausea
- rash or itchy skin (pruritus)

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

Drug interactions

Some prescription drugs, over-the-counter drugs, herbs, supplements and other drugs (both legal and illegal) can interfere with the absorption

and/or the effectiveness of Maviret. This is called a drug interaction.

Some drugs taken for other conditions can interact with Maviret, 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.

It is important that people discuss all medications, supplements, herbs and other drugs (both legal and illegal) they are taking with their doctor, nurse or pharmacist. If a person has more than one doctor or pharmacist, it is possible for drug interactions to get missed. Using the same pharmacy for all prescriptions can be helpful.

This fact sheet is not comprehensive and lists only some of the potential and actual drug interactions with Maviret. Speak with a pharmacist to find out more about drug interactions with Maviret.

The following medications are contraindicated (should not be used) with Maviret:

- the blood thinner dabigatran etexilate (Pradaxa)
- the tuberculosis medication rifampin (Rifadin, Rofact)
- HIV medications that contain atazanavir (Reyataz)
- oral contraceptives (birth control pills) that contain ethinyl estradiol drugs
- the cholesterol-lowering medications atorvastatin (Lipitor) and simvastatin (Zocor)

The manufacturer does not recommend taking Maviret with the following medications:

- some anti-seizure medications, such as carbamazepine (Tegretol), phenobarbital and phenytoin (Dilantin)
- any medicinal herbs, especially St. John's wort (*Hypericum perforatum*), which is an herb used to treat depression, or hyperforin or hypericin, which are active ingredients in St. John's wort

- HIV medications that contain efavirenz (Sustiva, and in Atripla) or lopinavir/ritonavir (Kaletra) or ritonavir (Norvir) + darunavir (Prezista)
- the cholesterol-lowering medication lovastatin
- the immune-suppressant medication cyclosporine above 100 mg per day

When Maviret is taken with the following medications it could potentially cause significant drug interactions:

- the heart drug digoxin (Lanoxin, Toloxin)
- the cholesterol-lowering medications pravastatin (Pravachol) and rosuvastatin (Crestor)
- the immune-suppressant medication tacrolimus (Prograf, Advagraf, Protopic)
- HIV medications that contain rilpivirine (Edurant, and in Juluca, Complera and Odefsey)
- vitamin K antagonist medications that reduce clotting, such as warfarin (Coumadin)

Availability

Maviret, manufactured by AbbVie, has been approved by Health Canada and is available in Canada. Pharmacists are a good source of information about public and private health insurance coverage for Maviret.

CATIE's online module "Federal, Provincial and Territorial Drug Access Programs" also contains information about Canadian drug coverage.

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Reference

Abbvie. Maviret (Glecaprevir/Pibrentasvir). *Product monograph*. Nov 25, 2021.

Author: Kushner R

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.

CATIE provides information resources to help people living with HIV and/or hepatitis C who wish to manage their own health care in partnership with their care providers. Information accessed through or published or provided by CATIE, however, is not to be considered medical advice. We do not recommend or advocate particular treatments and we urge users to consult as broad a range of sources as possible. We strongly urge users to consult with a qualified medical practitioner prior to undertaking any decision, use or action of a medical nature.

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CONTACT US

by e-mail

info@catie.ca

by mail

555 Richmond Street West
Suite 505, Box 1104
Toronto ON M5V 3B1

