

Maviret (glecaprevir + pibrentasvir)

Summary

Maviret is a medication used to treat hepatitis C. It is approved in Canada for people with hepatitis C in the following situations:

- those with any genotype of the virus who have never taken direct-acting antiviral (DAA) medication
- those with any genotype of the virus who have taken DAA medication with a type of medicine called an NS5A inhibitor or an NS3/4A protease inhibitor (but not both types of medication) and who were not cured of the virus

Maviret is safe for people who have any stage of chronic kidney disease. Maviret is a combination of glecaprevir and pibrentasvir. These two drugs are co-formulated into three tablets. It is taken once a day with food. Maviret appears to have few side effects. Common side effects are generally mild and temporary; they include headache and tiredness. Hepatitis C treatment can cure a person from hepatitis C. If a person is cured of hepatitis C, they can be re-infected with hepatitis C if they are exposed to the virus again.

What is Maviret?

Maviret is a medication used to treat hepatitis C.

How does Maviret 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 to survive by a process called replication. The hepatitis C virus (HCV) has at least six different strains, which are also known as genotypes.

Maviret 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.

FACT SHEET

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Maviret is a combination of the following two DAAs:

- glecaprevir – a protease inhibitor that works by interfering with a protein needed by the virus
- pibrentasvir – an NS5A (hepatitis C virus non-structural protein 5A) inhibitor that interferes with the production of the pieces needed to build new virus particles

Together, these two drugs greatly reduce and then stop the production of new copies of HCV.

Hepatitis C treatment can cure a person from hepatitis C. If a person is cured of hepatitis C, they can be re-infected with hepatitis C if they are exposed to the virus again. The Prevention and Harm Reduction section of CATIE's *Hepatitis C: An in-depth guide* contains information on preventing reinfection.

How do people use Maviret?

Maviret is taken as three tablets once a day. Maviret should be taken with food, but it does not matter what kind of food.

Maviret is approved in Canada for the following:

- people with any genotype of HCV who have never taken DAA medication
- people with any genotype of HCV who have taken DAA medication with a type of medicine called an NS5A inhibitor or an NS3/4A protease inhibitor (but not both types of medication) and who were not cured of the virus.

Maviret is approved in Canada for people over the age of 18 with chronic hepatitis C.

How long is treatment?

The duration of treatment is based on the absence or presence of severe liver injury, the viral genotype and past treatment experience. Treatment with Maviret generally lasts for eight or 12 weeks, and sometimes 16 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 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 Resistance section to learn about the potential for resistance to Maviret.)

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

If you miss taking a dose of Maviret and it is within 18 hours of when you were supposed to take it, take the dose as soon as possible. If it is after 18 hours from when you were supposed to take it, wait and take the next dose 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 Tips for staying on track with treatment in CATIE's *Hepatitis C: An in-depth guide*.

How likely is a cure from treatment that includes Maviret?

Hepatitis C treatment can cure a person from hepatitis C. The likelihood of a cure can be affected by the level of liver injury and other factors. Talk to your doctor about the likelihood of a cure for you.

Sometimes in real life cure rates can be lower than they are 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 at least 12 weeks after treatment ends.

Warnings

Breastfeeding/nursing

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

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.

Issues to discuss

Speak to your doctor about the most appropriate treatment options if:

- you have Child-Pugh B or C cirrhosis, which is a moderate to high level of liver injury
- you are pregnant or plan to have a baby
- you have liver problems other than hepatitis C
- you have had a liver transplant
- you are co-infected with hepatitis B
- you are co-infected with HIV
- you were born with the rare problem of not being able to tolerate galactose (milk sugar)

Maviret is a new drug and not everything is known about its effect on people. Make sure your doctor knows about all of your medical conditions when you are discussing Maviret as a treatment option.

Side effects

The most common side effects of Maviret are:

- headache
- tiredness or lack of energy

- diarrhea
- nausea
- rash or itchy skin (pruritus)

For people with severe kidney disease, including people on dialysis, side effects also included sleeping problems and dizziness.

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

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 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.

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

- anti-seizure medication, such as carbamazepine (Tegretol), phenobarbital, oxcarbazepine (Trileptal) and phenytoin (Dilantin)
- the tuberculosis medication rifampin
- HIV medications that contain efavirenz (Sustiva, and in Atripla), atazanavir (Reyataz) or lopinavir/ritonavir (Kaletra) and ritonavir + darunavir
- the cholesterol-lowering medications atorvastatin, simvastatin and lovastatin
- the transplant medicine cyclosporine
- the blood thinner dabigatram (Pradaxa)
- any medicinal herbs, especially an herb used to treat depression – St. John's wort (*Hypericum perforatum*), or hyperforin or hypericin, which are active ingredients in St. John's wort

- oral contraceptives (birth control pills) that contain ethinyl estradiol drugs

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

- medication to treat indigestion, heartburn or ulcers, such as nizatidine (Axid), famotidine (Pepcid AC, Peptic Guard), ranitidine (Zantac), esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Losec) and pantoprazole (Pantoloc)
- the heart drug digoxin (Lanoxin, Toloxin)
- HIV or hepatitis B regimens that contain tenofovir DF (Viread, and in Truvada, Atripla, Complera, Stribild), as well as those that contain tenofovir alafenamide (Vemlidy, and in Genvoya, Odefsey, Descovy) or rilpivirine (Endurant, and in Complera and Odefsey)
- the cholesterol lowering medications pravastatin (Pravachol, Selektine) and rosuvastatin (Crestor)
- vitamin K antagonist medication that reduces clotting, such as warfarin (Coumadin)
- the transplant medicine tacrolimus (Prograf, Advagraf, Protopic)

Talk to your nurse, doctor and pharmacist if you are taking any of these medicines. 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. Resistance can develop when a person does not take their medication as prescribed and directed.

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

Availability

Maviret, manufactured by Abbvie, 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 Maviret in your region.

The Treatment coverage in your region section of CATIE's *Hepatitis C: An in-depth guide* contains information about provincial and territorial drug coverage.

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Reference

Abbvie. Maviret (Glecaprevir/Pibrentasvir). *Product monograph*. 2017.

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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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