

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

MAVIRET®

glecaprevir/pibrentasvir tablets

Read this carefully before you start taking MAVIRET and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about MAVIRET.

Serious Warnings and Precautions

Hepatitis B activity (e.g., inflamed liver) may increase when taking antiviral drugs like MAVIRET, sometimes leading to liver failure and death. (See the Hepatitis B Reactivation subsection.)

What is MAVIRET used for?

- MAVIRET treats adults and adolescents 12 years and older with chronic (long-lasting) hepatitis C. Hepatitis C is caused by an infection with the hepatitis C virus (HCV).
- It is not known if taking MAVIRET is safe and effective in children under 12 years of age.

How does MAVIRET work?

There are 2 medicines in each MAVIRET pill: glecaprevir and pibrentasvir. These medicines work together to stop hepatitis C virus from multiplying and to remove the virus from your blood over time. MAVIRET can cure HCV infection in most patients. Cure means HCV remains cleared from your blood 3 months after finishing the medicine.

Talk with your doctor about ways to avoid getting infected again with HCV.

What are the ingredients in MAVIRET?

Each tablet contains the following medicinal ingredients: glecaprevir, pibrentasvir.

Each tablet has the following ingredients that are not medicines: copovidone (type K 28), vitamin E polyethylene glycol succinate, colloidal silicon dioxide, propylene glycol monocaprylate (type II), croscarmellose sodium, sodium stearyl fumarate, hypromellose 2910, lactose monohydrate, titanium dioxide, polyethylene glycol 3350 and iron oxide red.

What does MAVIRET look like?

MAVIRET tablets are pink, oblong, film-coated tablets that are curved on both sides, and debossed on one side with 'NXT'.

MAVIRET comes in the following dosage forms:

Each tablet has 100 milligrams of glecaprevir and 40 milligrams of pibrentasvir.

Do not use MAVIRET if:

- you are allergic to any of the ingredients in MAVIRET. (See the section "**What are the ingredients in MAVIRET?**" to see all the ingredients.)
- your doctor has told you that you have severe liver problems.
- you are taking any of the following medicines:
 - atazanavir (Evotaz[®], Reyataz[®])
 - atorvastatin (Lipitor[®])
 - dabigatran etexilate (Pradaxa[®])
 - ethinyl estradiol-containing medicines such as tablets or vaginal rings used to prevent pregnancy
 - rifampin (Rifadin[®], Rofact[®])
 - simvastatin (Zocor[®])

To help avoid side effects and make sure you are using your medicines correctly, talk to your doctor before you take MAVIRET. Talk about any health problems you may have, including if you:

- have liver problems other than hepatitis C infection.
- are taking other drugs for viral infections.
- have had a liver or a kidney transplant.
- have diabetes.
- are pregnant or plan to become pregnant. The effects of MAVIRET during pregnancy are not known. Avoid pregnancy while taking MAVIRET. Tell your doctor if you become pregnant while taking MAVIRET.
- are breastfeeding or plan to breastfeed. It is not known if MAVIRET passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take MAVIRET.
- have galactose intolerance (e.g., lactase deficiency or glucose-galactose malabsorption) as this product contains lactose.

Hepatitis B Reactivation

Taking antiviral drugs such as MAVIRET may increase hepatitis B activity. This can lead to liver problems such as liver failure and death. Talk to your doctor if:

- you have never been tested for hepatitis B.

- you know you have a current hepatitis B infection.
- you have had a previous hepatitis B infection.

Your doctor may order blood tests to see if you need hepatitis B treatment.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking MAVIRET.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

If you are taking any of the medicines in the table below, your doctor may need to change your dose of these medicines.

Medicines you must tell your doctor about before taking MAVIRET

Medicine	Purpose of the medicine
lovastatin pravastatin (Pravachol®) rosuvastatin (Crestor®)	to lower blood cholesterol
carbamazepine (Tegretol®) phenobarbital phenytoin (Dilantin®)	normally used for seizures
cyclosporine (Neoral®, Sandimmune®) tacrolimus (Prograf®)	to suppress the immune system
darunavir (Prezista®) efavirenz (Sustiva®, Atripla®) lopinavir/ritonavir (Kaletra®) rilpivirine (Edurant®, Complera®) ritonavir (Norvir®)	for HIV infection
digoxin (Lanoxin®)	for heart problems or high blood pressure
St John's Wort (<i>Hypericum perforatum</i>)	for mild depression
vitamin K antagonists (e.g., warfarin [Coumadin®])	to help reduce clots from forming in the blood

How to take MAVIRET:

- Take MAVIRET exactly as your doctor tells you. Do not change your dose or stop unless your doctor tells you to. If you reduce or miss a dose, the medicines may not be as effective against the virus.
- It is important that you do not miss or skip doses of MAVIRET during treatment.

- Swallow MAVIRET tablets whole. Do not chew, break, or crush MAVIRET tablets.

Usual adult and adolescent (12 to less than 18 years of age) dose:

- Take 3 MAVIRET tablets all at once each day (once daily) with food. The type of food is not important.
- MAVIRET is taken for either 8, 12 or 16 weeks. Your doctor will tell you exactly how long you need to take MAVIRET.

Overdose:

If you think you have taken too much MAVIRET, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you do miss a dose and it is:

- less than 18 hours from the time you usually take MAVIRET - take the missed dose with food as soon as possible. Then take your next dose at your usual time.
- more than 18 hours from the time you usually take MAVIRET - do not take the missed dose. Take your next dose as usual with food.

Do not take a double dose to make up for a forgotten dose.

If you vomit (throw up) and it has been less than 3 hours after taking MAVIRET, you should take another dose. If you vomit and it has been more than 3 hours after taking MAVIRET, do not take another dose.

What are possible side effects from using MAVIRET?

These are not all the possible side effects you may feel when taking MAVIRET. If you experience any side effects not listed here, contact your healthcare professional.

The most common side effects of MAVIRET are tiredness and headache. You could also have nausea (feeling sick in the stomach).

Potential serious side effects and what to do about them are listed in the table below.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
FREQUENCY UNKNOWN			
Angioedema: swelling of the face, hands, feet, genitals, tongue or throat, difficulty swallowing or breathing; swelling of the digestive tract which may cause diarrhea, nausea or vomiting			✓

If you have a troublesome symptom or feeling that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store between 2 and 30°C.
- Keep MAVIRET out of the reach and sight of children.

If you want more information about MAVIRET:

- Talk to your doctor.
- Find the most recent version of the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>), the manufacturer's website (www.abbvie.ca), or by calling 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

Last Revised: October 30, 2020

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