

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

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**.

If your child is taking MAVIRET, all of the information in this PATIENT MEDICATION INFORMATION applies to them. As their caregiver, please read this information before they start taking MAVIRET. Talk with your child's healthcare professional if you need any additional information on their condition and treatment.

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 children (3 years and older and weighing 12 kg or more) 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 3 years of age or weighing less than 12 kg.

How does MAVIRET work?

There are 2 medicines in MAVIRET: 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 Tablets?

Medicinal ingredients: glecaprevir, pibrentasvir.

Non-medicinal ingredients: colloidal silicon dioxide, copovidone (type K 28), croscarmellose sodium, hypromellose 2910, iron oxide red, lactose monohydrate, polyethylene glycol 3350, propylene glycol monocaprylate (type II), sodium stearyl fumarate, titanium dioxide and vitamin E polyethylene glycol succinate.

What do MAVIRET Tablets 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:

Tablet containing 100 milligrams of glecaprevir and 40 milligrams of pibrentasvir.

Granules in sachets containing 50 milligrams of glecaprevir and 20 milligrams of pibrentasvir. See the PATIENT MEDICATION INFORMATION for MAVIRET granules for further information about MAVIRET granules.

Do not use MAVIRET if:

- you are allergic to any of the ingredients in MAVIRET. (See the section "**What are the ingredients in MAVIRET Tablets?**" 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 ensure proper use, talk to your healthcare professional before you take MAVIRET. Talk about any health conditions or problems you may have, including if you:

- 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.

Liver Issues

Talk to your doctor if you had or have liver problems other than hepatitis C infection. Your doctor may order medical tests to determine how your liver is functioning. Tell your doctor right away if you experience symptoms of liver failure such as:

- abdominal pain or pressure, fluid in your abdomen

- bleeding or bruising more easily than normal
- confusion, difficulty concentrating, loss of consciousness, tiredness
- nausea, vomiting, diarrhea
- dark or bloody stools, dark or brown (tea coloured) urine
- yellowing of the skin and eyes

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.

The following may interact with 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.
- MAVIRET tablets and MAVIRET granules are not interchangeable.

Usual dose for adult, adolescent (12 to less than 18 years of age) or children weighing at least 45 kg:

- 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, or a person you are caring for, have taken too much MAVIRET, contact a 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 have when taking MAVIRET. If you experience any side effects not listed here, tell your healthcare professional.

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

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			✓
Hepatic decompensation and hepatic failure (liver failure): abdominal pain or pressure, fluid in your abdomen, bleeding or bruising more easily than normal,		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
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confusion, difficulty concentrating, loss of consciousness, tiredness, nausea, vomiting, diarrhea, dark or bloody stools, dark or brown (tea coloured) urine, yellowing of the skin and eyes			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) 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 out of reach and sight of children.

If you want more information about MAVIRET:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.abbvie.ca), or by calling 1-800-704-8271.

This leaflet was prepared by AbbVie Corporation.

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Atripla, Complera, Coumadin, Crestor, Dilantin, Edurant, Evotaz, Lanoxin, Lipitor, Neoral, Pradaxa, Pravachol, Prezista, Prograf, Reyataz, Rifadin, Rofact, Sandimmune, Sustiva and Tegretol are trademarks of their respective owners and are not trademarks of AbbVie Corporation. The makers of these brands are not affiliated with and do not endorse AbbVie or its products.

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How does MAVIRET work?

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

What are the ingredients in MAVIRET Granules?

Medicinal ingredients: glecaprevir, pibrentasvir.

Non-medicinal ingredients: colloidal silicon dioxide, copovidone (type K 28), croscarmellose sodium (in the glecaprevir granules only), hypromellose 2910, iron oxide red, iron oxide yellow, lactose monohydrate, polyethylene glycol/macrogol 3350, propylene glycol monocaprylate (type II), sodium stearyl fumarate, titanium dioxide and vitamin E (tocopherol) polyethylene glycol succinate.

What do MAVIRET Granules look like?

MAVIRET granules are pink and yellow, round, biconvex and approximately 2 millimeters in diameters.

MAVIRET comes in the following dosage forms:

Granules in sachets containing 50 milligrams of glecaprevir and 20 milligrams of pibrentasvir.

Tablets containing 100 milligrams of glecaprevir and 40 milligrams of pibrentasvir. See the PATIENT MEDICATION INFORMATION for MAVIRET tablets for further information about MAVIRET tablets.

Do not use MAVIRET if:

- you are allergic to any of the ingredients in MAVIRET. (See the section " **What are the ingredients in MAVIRET Granules in Sachets**" 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 ensure proper use, talk to your healthcare professional before you take MAVIRET. Talk about any health conditions or problems you may have, including if you:

- 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.
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- 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.

Liver Issues

Talk to your doctor if you or the person you are caring for had or have liver problems other than hepatitis C infection. Your doctor may order medical tests to determine how your liver is functioning. Tell your doctor right away if you or the person you are caring for experience symptoms of liver failure such as:

- abdominal pain or pressure, fluid in your abdomen

- bleeding or bruising more easily than normal
- confusion, difficulty concentrating, loss of consciousness, tiredness
- nausea, vomiting, diarrhea
- dark or bloody stools, dark or brown (tea coloured) urine
- yellowing of the skin and eyes

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.

The following may interact with 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
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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.
- MAVIRET tablets and MAVIRET granules are not interchangeable.

- **How to take a dose of MAVIRET oral granules or give it to your child. See detailed Instructions for Use for information.**
 - Give MAVIRET once a day at the same time or after a snack or meal.
 - Do not open the sachet until ready for use.
 - Hold the MAVIRET granules sachet with the cut line on top.
 - Tap the MAVIRET granules sachet gently to settle the granules.
 - Cut the MAVIRET sachet along the cut line.
 - Pour the granules into a bowl and check the sachet to make sure no granules remain.
 - Mix the granules with a small amount of recommended food and swallow (See Instructions for Use for list of recommended food).
 - Do not store any leftover MAVIRET mixture (oral granules mixed with food) for use at a later time.

Usual dose for children (3 to less than 12 years of age weighing at least 12 to less than 45 kg) :

- The usual dose for children 3 to less than 12 years of age will be based on a child's body weight. The child's doctor will decide what dose a child should receive.
- 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, or a person you are caring for, have taken too much MAVIRET, contact a 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 have when taking MAVIRET. If you experience any side effects not listed here, tell your healthcare professional.

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

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			✓
Hepatic decompensation and hepatic failure (liver failure): abdominal pain or pressure, fluid in your abdomen, bleeding or bruising more easily than normal, confusion, difficulty concentrating, loss of consciousness, tiredness, nausea, vomiting, diarrhea, dark or bloody stools, dark or brown (tea coloured) urine, yellowing of the skin and eyes		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) 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.

If you want more information about MAVIRET:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website (www.abbvie.ca), or by calling 1-800-704-8271.

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Instructions for Use

MAVIRET®

glecaprevir/pibrentasvir granules

Step 1. Get the number of sachets as advised by your child's doctor

Weight of child (kg)	Number of sachets once daily	Food Amount (approximate)
From 12 to less than 20 kg	3 sachets	About 1-2 teaspoons (5-10 ml) of recommended food listed in step 2
From 20 to less than 30 kg	4 sachets	
From 30 to less than 45 kg	5 sachets	

For children weighing 45 kg or more, talk to your child's doctor about giving MAVIRET tablets.

Do not give more than 5 sachets.



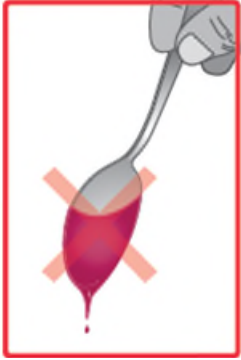

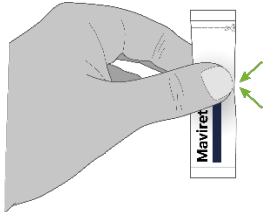
Step 2. Choose suitable food to mix with MAVIRET granules

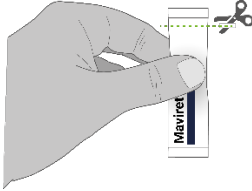

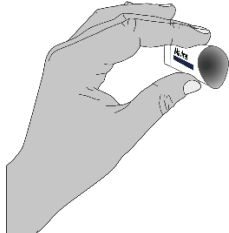
Suitable food should stick to the spoon. It must be soft, low in water content and can be swallowed without chewing.



Examples of recommended foods:

- Greek yogurt
- Cream cheese
- Peanut butter
- Chocolate hazelnut spread
- Thick jam
- Other food that sticks to the spoon

Note: in addition to the food used to mix the granules, MAVIRET should also be taken at the same time or straight after a meal or snack. The food used to mix the granules does not replace the meal or snack to take with MAVIRET.

	<p>Do not use food if it drips off a spoon as the medicine may dissolve quickly, taste bitter, and become less effective. Do not use food that your child is allergic to.</p> <p>Examples of foods not to use:</p> <ul style="list-style-type: none"> ✗ Liquids or watery food ✗ Apple sauce ✗ Food or liquid that is heated or frozen ✗ Bread or other food that requires chewing ✗ Non-Greek yogurt ✗ Baby food ✗ Food that drips off the spoon <p>For more information about suitable foods, contact your child’s doctor or pharmacist.</p>
	<p>Step 3. Gather materials</p> <p>Place the following on a clean surface:</p> <ul style="list-style-type: none"> ● Box with sachets in it ● Soft food ● Bowl to use for mixing ● Teaspoon ● Scissors
	<p>Step 4. Measure food</p> <ul style="list-style-type: none"> ● Place a small amount (1-2 teaspoons or 5-10 ml) of soft food into a bowl. ● The granules inside the sachets are very small, so placing food in the bowl first will help contain them.
	<p>Step 5. Prepare sachet</p> <ul style="list-style-type: none"> ● Look for the dotted line on the sachet to find the top end. ● Hold the sachet upright and tap the top of the sachet. Keep tapping until all the granules inside fall to the bottom. ● Feel top area of sachet thoroughly to make sure all granules are at the bottom.

	<p>Step 6. Cut top of sachet</p> <ul style="list-style-type: none"> ● Pinch the sachet in the center, above the granules inside. ● Use scissors to cut the top of the sachet completely off. <p>Be Careful: Granules are very small and can fall out easily.</p> <p>Use opened sachet immediately and do not store opened sachet.</p>
	<p>Step 7. Pour sachet</p> <ul style="list-style-type: none"> ● Make sure the sachet is fully open. ● Carefully pour all granules out of the sachet into the bowl of food. Granules are pink and yellow. ● Tap sachet to get all the granules out. ● Repeat for each sachet for your child's daily dose.
	<p>Step 8. Check sachet</p> <p>Look inside each sachet to make sure there are no granules left inside.</p> <p>Do not leave any granules behind as the medicine will not work as well if the full dose is not taken.</p>
	<p>Step 9. Mix</p> <ul style="list-style-type: none"> ● Use the teaspoon to gently stir the granules into the food. ● Do not crush the granules. If the granules are crushed, they will taste bitter. ● Do not store the mixture, give it to your child immediately. <p>If not given within 5 minutes, the mixture may taste bitter.</p> <p>If not given immediately (within 15 minutes), the medicine may be less effective. Throw away and start again.</p>

	<p>Step 10. Give the medicine</p> <ul style="list-style-type: none"> ● Scoop a small amount of mixture onto the teaspoon. ● Make sure your child swallows the mixture without chewing. ● Repeat until your child has taken all the mixture. ● If any granules are left, add more food and mix. Then finish the dose. ● Make sure your child takes the full dose of the medicine. <p>⚠ If your child misses a dose, see “Missed Dose” in the Patient Mediation Information for further information.</p>
	<p>Step 11. Confirm dose for tomorrow</p> <p>Check to make sure there are enough sachets for your child’s next dose of MAVIRET.</p> <p>For replacement sachets or to refill your prescription, contact your child’s doctor or pharmacist.</p>

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