

▼ This medicine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

MAVIRET®

Glecaprevir / Pibrentasvir

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MAVIRET.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor.

Keep this leaflet with the medicine.

You may need to read it again.

What MAVIRET is used for

MAVIRET is a tablet that contains two active substances called glecaprevir and pibrentasvir.

This medicine is used to treat chronic (long-lasting) hepatitis C virus (HCV) infection in adult patients.

This medicine belongs to a group of medicines called direct-acting antiviral agents.

This medicine works by stopping the hepatitis C virus from multiplying and infecting new cells. This allows the infection to be permanently eliminated from the body.

Ask your doctor if you have any questions about why it has been prescribed for you.

Your doctor may have prescribed it for another purpose.

This medicine is available only with a doctor's prescription.

Before you take MAVIRET

When you must not take it

Do not take MAVIRET if you have an allergy to:

- any medicine containing glecaprevir or pibrentasvir
- any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include:

- hives, skin rash or itching,
- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest,
- swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not take MAVIRET if you:

- have severe liver disease.

Do not take MAVIRET if you are taking the following medicines:

- atazanavir (for HIV infection)
- atorvastatin, simvastatin (for lowering cholesterol)

- dabigatran etexilate (for thinning the blood)
- ethinylloestradiol-containing medications (for contraception or hormone replacement therapy)
- rifampicin (for tuberculosis)

Do not give MAVIRET to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Do not take it after the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems other than hepatitis C infection,
- HIV infection,
- hepatitis B infection,
- a liver transplant

Tell your doctor or pharmacist if you are pregnant or trying to become pregnant.

It is not known if taking MAVIRET while you are pregnant will harm your unborn baby. Your doctor can

discuss the risks and benefits involved.

Tell your doctor or pharmacist if you are breastfeeding or are planning to breastfeed.

It is not known if MAVIRET can be passed to your baby in your breast milk. Your doctor can discuss the risks and benefits involved.

If you have not told your doctor or pharmacist about any of the above, tell them before you take MAVIRET.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Keep a list of your medicines to show your doctor or pharmacist.

Do not start taking a new medicine without telling your doctor or pharmacist that you are taking MAVIRET.

Some medicines and MAVIRET may interfere with each other. Your doctor or pharmacist can tell you if it is safe to take MAVIRET with other medicines.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- lovastatin, pravastatin or rosuvastatin, medicines used to lower blood cholesterol
- carbamazepine, used to treat epilepsy
- ciclosporin, used to suppress the immune system
- darunavir, ritonavir, efavirenz or lopinavir and ritonavir, used to treat HIV infection
- digoxin, used to treat heart problems
- St John's wort (*Hypericum perforatum*) used to treat mild depression

- Vitamin K antagonist, for example warfarin, used to thin the blood

These medicines may be affected by MAVIRET, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking MAVIRET.

How to take MAVIRET

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

It is important you follow the instructions your doctor provides about how to take MAVIRET and for how long.

Not taking the medicine as directed or stopping the medicine too early may cause you to not respond to the medicine and may affect your response to future treatments.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take and when to take it

Take 3 MAVIRET tablets once a day with food.

When to take it

Take MAVIRET at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take it

Swallow the tablets whole with a full glass of water.

Do not crush, chew or break the tablets.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Do not stop taking MAVIRET without first talking with your doctor.

It is important to keep taking your medicine even if you feel well.

If you forget to take it

It is important not to miss a dose of this medicine. If you 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 the dose that you missed.

This may increase the chance of getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for advice.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much MAVIRET. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using MAVIRET

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MAVIRET.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon that you are taking this medicine.

If you become pregnant while you are taking this medicine, tell your doctor or pharmacist immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop taking MAVIRET, or change the dosage, without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how MAVIRET affects you.

The effect of MAVIRET on your ability to drive or use machines is not known.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MAVIRET.

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are

not. You may need medical attention if you get some of the side-effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- feeling very tired
- headache
- nausea

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some people.

After using MAVIRET

Storage

Keep your tablets in the pack until it is time to take them.

Keep the medicine in a cool, dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine, or the medicine has passed its expiry date, ask your pharmacist what to

do with any medicine that is left over.

Product description

What it looks like

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

Ingredients

MAVIRET contains 100 mg of glecaprevir and 40 mg of pibrentasvir as active ingredients.

It also contains:

- copovidone
- tocofersolan
- colloidal anhydrous silica
- propylene glycol monocaprylate
- croscarmellose sodium
- sodium stearyl fumarate
- hypromellose 2910
- lactose monohydrate
- titanium dioxide
- macrogol 3350
- iron oxide red

MAVIRET contains lactose.

MAVIRET does not contain gluten.

Supplier

MAVIRET is supplied in Australia by:

AbbVie Pty Ltd

241 O'Riordan Street

Mascot NSW 2020 Australia

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