

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I taking Maviret?

Maviret contains the active ingredients glecaprevir and pibrentasvir. Maviret is used to treat acute (recently acquired) and chronic (long lasting) hepatitis C.

For more information, see Section [1. Why am I taking Maviret?](#) in the full CMI.

### 2. What should I know before I take Maviret?

Check the list of ingredients at the end of this CMI. Do not take Maviret if you have ever had an allergic reaction to any of them.

There are certain medicines that should not be taken together with Maviret.

Talk to your doctor before you take this medicine if he/she is not aware that you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take Maviret?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Maviret and affect how it works. Maviret may interfere with other medicines and affect how they work.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take Maviret?

#### Tablets

- Take 3 tablets all together, once every day. Take the tablets with food.
- Do not break, crush or chew the tablets. Swallow them whole with a full glass of water.

#### Granules

Mix the required amount of granules with recommended food. Take this once a day, before or after a snack or meal.

More instructions can be found in Section [4. How do I take Maviret?](#) in the full CMI.

### 5. What should I know while taking Maviret?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Call your doctor straight away if you become pregnant while taking Maviret.</li><li>• Keep all your doctor's appointments so that your progress can be checked.</li><li>• Remind any doctor or dentist you visit that you are taking Maviret.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking this medicine suddenly or change the dose without checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Maviret is expected to have little to no effect on the ability to drive or use machines.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• There is no information on the effects of taking Maviret with alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store Maviret in a cool dry place away from moisture, heat and sunlight.</li><li>• Keep your tablets in the pack until it is time to take them.</li></ul>

For more information, see Section [5. What should I know while taking Maviret?](#) in the full CMI.

### 6. Are there any side effects?

The reported side effects include feeling very tired or lacking energy (fatigue), headache and nausea.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. 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](http://www.tga.gov.au/reporting-problems).

# MAVIRET<sup>®</sup> (mav-i-ret)

Active ingredient(s): *Glecaprevir* (gle-cap-riv-ear) & *Pibrentasvir* (pib-rent-as-vear)

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking Maviret. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Maviret.**

Where to find information in this leaflet:

1. [Why am I taking Maviret?](#)
2. [What should I know before I take Maviret?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take Maviret?](#)
5. [What should I know while taking Maviret?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I taking Maviret?

Maviret contains the active ingredients *glecaprevir* and *pibrentasvir*.

Maviret is used to treat acute (recently acquired) and chronic (long lasting) hepatitis C in patients 3 years and older.

## 2. What should I know before I take Maviret?

### Warnings

**Do not take Maviret if:**

1. you are allergic to either *glecaprevir* or *pibrentasvir*, or any of the ingredients listed at the end of this leaflet.
2. you have moderate or severe liver disease.
3. you are taking any of the following medicines - *atazanavir*, *atorvastatin*, *simvastatin*, *dabigatran etexilate*, *ethinylestradiol*-containing products or *rifampicin*. See additional information under [Section 3. What if I am taking other medicines?](#)

**Check with your doctor if you:**

- have liver conditions, other than hepatitis C
- have HIV
- have hepatitis B
- have had a liver or kidney transplant
- have diabetes
- take any medicines for any other condition
- have any other medical conditions.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

Make sure your doctor is aware that you are pregnant or plan to become pregnant; or are breastfeeding or plan to do so.

## Use in children

- Do not give Maviret to a child younger than 3 years.

## 3. What if I am taking other medicines?

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

Some medicines may interfere with Maviret and affect how it works.

**Do not take the following medicines if you are taking Maviret:**

- *atazanavir* (a medicine used to treat HIV infection)
- *atorvastatin* (a medicine used for lowering cholesterol)
- *simvastatin* (a medicine used for lowering cholesterol)
- *dabigatran* (a medicine used to thin the blood)
- *ethinylestradiol* (in certain contraceptive pills and hormone replacement therapies)
- *rifampicin* (a medicine used to treat tuberculosis and other serious infections).

**Medicines that may increase the effect of Maviret include:**

- *atazanavir* (a medicine used to treat HIV infection, see above list of medicines to avoid while taking Maviret)
- *darunavir* (a medicine used to treat HIV infection)
- *lopinavir* (a medicine used to treat HIV infection)
- *ritonavir* (a medicine used to treat HIV infection)
- *ciclosporin* (a medicine for suppressing the immune system to treat conditions like rheumatoid arthritis, nephrotic syndrome, psoriasis, transplant rejection).

**Medicines that may reduce the effect of Maviret include:**

- *carbamazepine* (a medicine used to treat epilepsy to prevent convulsions, fits)
- *rifampicin* (a medicine used to treat tuberculosis and other serious infections)
- *St. John's Wort* (a herbal product used to improve mood)
- *efavirenz* (a medicine used to treat HIV infection).

#### Medicines where Maviret may increase their effect include:

- digoxin (a medicine used to treat certain heart conditions)
- dabigatran (a medicine used to thin the blood, see above list of medicines to avoid while taking Maviret)
- atorvastatin (a medicine used for lowering cholesterol, see above list of medicines to avoid while taking Maviret)
- simvastatin (a medicine used for lowering cholesterol, see above list of medicines to avoid while taking Maviret)
- pravastatin (a medicine used for lowering cholesterol)
- rosuvastatin (a medicine used for lowering cholesterol).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if Maviret can affect these, or if these affect Maviret.

## 4. How do I take Maviret?

### How much to take

#### Patients 12 years and older (Adolescents and Adults)

- Take three tablets altogether once every day.
- Do not break, crush or chew tablets.
- Take tablets during a meal or immediately after a meal.
- Take Maviret until your doctor tells you to stop.

#### Patients 3 to less than 12 years (Children)

Read the instructions for preparing and taking Maviret granules that are included inside the carton. These instructions are also available via the following hyperlink:

<https://www.medsinfo.com.au/media/veimavig>

Your child's doctor will prescribe the right Maviret dose. This is based on your child's weight.

Give the right dose of Maviret granules to your child once every day, just before or after a snack or meal.

Do not open the sachets until ready to use. Note: Opened sachets should be used immediately and not stored to use later.

Hold the sachet with the cut line on top.

Tap the sachet gently so all the granules inside fall to the bottom of the sachet.

Cut the sachet along the cut line.

Pour the granules into a bowl. Check the sachet to make sure no granules are left behind.

Mix the granules with a small amount (about 1-2 teaspoons or 5-10 mL) of recommended food e.g. greek yogurt, cream/soft cheese, peanut butter, chocolate hazelnut spread, thick jam. Do not crush the granules.

Make sure your child swallows the mixture of food and granules immediately (within 15 minutes of preparation), without chewing.

Do not store any leftover mixture i.e. granules mixed with food. Throw away any unused portion.

**The tablets and the granules cannot be used interchangeably.** A full course of treatment with tablets or a full course of treatment with granules is therefore required.

Please look for the QR code on the medicine pack. Scan this code with your smart phone for more information on Maviret.

### When to take Maviret

- Take Maviret at about the same time each day.

### If you forget to take Maviret

**If it is less than 6 hours until your next dose, skip the missed dose. Do not take a double dose to make up for a dose you missed.**

**If it is 6 hours or more until your next dose, take the missed dose and then take your next dose at the usual time.**

**If vomiting occurs within 3 hours of dosing, an additional dose of MAVIRET should be taken.**

**If vomiting occurs more than 3 hours after dosing, an additional dose of MAVIRET is not needed.**

### If you take too much Maviret

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there appear to be no signs of discomfort or poisoning.**

## 5. What should I know while taking Maviret?

### Things you should do

- Contact your doctor straight away if you become pregnant while taking Maviret.
- Keep all your doctor's appointments so that your progress can be checked.
- Remind any doctor or dentist you visit that you are taking Maviret.

### Things you should not do

- Do not stop taking this medicine suddenly or change the dose without checking with your doctor.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Maviret affects you.**

Maviret is expected to have little to no effect on the ability to drive and use machines.

## Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

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

Store them in a cool dry place away from moisture, heat or sunlight; for example:

- do not store them in the bathroom or near a sink, or
- do not store them in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Side effects

Side effects	What to do
<ul style="list-style-type: none"><li>• feeling very tired, lacking energy</li><li>• headache</li><li>• nausea</li><li>• itchy skin.</li></ul>	<b>Speak to your doctor if you have any of these side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing.</li></ul>	<b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

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

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What Maviret contains

#### Tablets

<b>Active ingredients (main ingredients)</b>	<ul style="list-style-type: none"><li>• glecaprevir</li><li>• pibrentasvir</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• copovidone</li><li>• tocopherol</li><li>• colloidal anhydrous silica</li><li>• propylene glycol monocaprylate</li><li>• croscarmellose sodium</li><li>• sodium stearyl fumarate</li><li>• hypromellose 2910</li><li>• lactose monohydrate</li><li>• titanium dioxide</li><li>• Macrogol 3350</li><li>• iron oxide red.</li></ul>

#### Granules

<b>Active ingredients (main ingredients)</b>	<ul style="list-style-type: none"><li>• glecaprevir</li><li>• pibrentasvir</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• copovidone</li><li>• tocopherol</li><li>• colloidal anhydrous silica</li><li>• propylene glycol monocaprylate</li><li>• croscarmellose sodium (glecaprevir granules only)</li><li>• sodium stearyl fumarate</li><li>• hypromellose 2910</li><li>• lactose monohydrate</li><li>• titanium dioxide</li><li>• Macrogol 3350</li><li>• iron oxide red (glecaprevir granules only)</li><li>• iron oxide yellow (pibrentasvir granules only)</li></ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

Maviret tablets and granules contains lactose and is gluten-free.

### **What Maviret looks like**

#### **Tablets**

Maviret tablets are pink, oblong and film-coated. They are curved on both sides and have the letters 'NXT' on one side.

Maviret is supplied in:

- a blister pack inside a carton (AUST R 284948);
- a bottle (AUST R 325401).

#### **Granules**

Each Maviret sachet contain round pink granules and round yellow granules.

Maviret granules is supplied in:

sachets inside a carton (AUST R 352573)

### **Who distributes Maviret?**

AbbVie Pty Ltd

241 O'Riordan Street

MASCOT NSW 2020

This leaflet was prepared in March 2026.

Version 11

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