

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking Maviret?

Maviret contains the active ingredients glecaprevir and pibrentasvir. Maviret is used to treat chronic 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 the CMI. Do not take Maviret if you have ever had an allergic reaction to, or cannot tolerate, any of them. Please note that Maviret tablets contain lactose.

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, or 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?

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

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?

Things you should do	 Call 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, dentist or pharmacist 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	Maviret is expected to have little to no effect on the ability to drive or use machines.	
Drinking alcohol	There is no information on the effects of taking Maviret with alcohol.	
Looking after your medicine	 Store Maviret in a cool dry place (below 30°C). Keep your tablets in the pack until it is time to take them. 	

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

6. Are there any side effects?

The most commonly 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.

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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?
- <u>5.</u> 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 chronic hepatitis C in patients 12 years and older.

2. What should I know before I take Maviret?

Warnings

Do not take Maviret if:

- you are allergic to either glecaprevir or pibrentasvir, or any of the ingredients listed at the end of this leaflet.
- 2. you have severe liver disease
- 3. you are taking atazanavir 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 intend to breastfeed.

Use in children

• Do not give Maviret to a child younger than 12 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; while Maviret may affect how other medicines work.

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

- atazanavir (a medicine used to treat HIV infection)
- rifampicin (a medicine used to treat tuberculosis and other serious infections).

Medicines that may <u>increase</u> 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 used for suppressing the immune system to treat various conditions).

Medicines that may <u>reduce</u> 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, see above list of medicines to avoid while taking Maviret)
- St. John's Wort (a herbal product used to improve mood)
- efavirenz (a medicine used to treat HIV infection).

Medicines where Maviret may <u>increase</u> their effect include:

- digoxin (a medicine used to treat certain heart conditions)
- dabigatran (a medicine used to thin the blood)
- atorvastatin, lovastatin, simvastatin, pravastatin, rosuvastatin (medicines used for lowering cholesterol)
- ethinyloestradiol (in certain contraceptive pills and hormone replacement therapies)
- fluindione, warfarin, or similar medicines used to thin the blood, known as Vitamin K blockers.

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

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4. How do I take Maviret?

How much to take

- Take three tablets all together once every day.
- Take tablets during a meal or immediately after a meal
- Do not break, crush or chew tablets. Swallow them whole with a full glass of water.
- Take Maviret until your doctor tells you to stop.

When to take Maviret

• Take Maviret at about the same time each day.

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

If you forget to take Maviret

If it is less than 6 hours until your next dose, skip the missed dose.

If it is more than 6 hours until your next dose, take the missed dose and then take your next dose at the usual time. Take the tablets during a meal or immediately after a meal.

Do not take a double dose to make up for a dose you missed.

If you take too much Maviret

You should immediately:

- phone the National Poisons Centre on 0800 POISON (0800 764 766), 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, dentist or pharmacist 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

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 (below 30°C) 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 your doctor advises that you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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
 feeling very tired, lacking energy headache nausea itchy skin 	Speak to your doctor if you have any of these side effects and they worry you.

Serious side effects

Serious side effects		What to do
•	swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing	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.

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.

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Reporting side effects

After you have received medical advice for any side effects you experience, you can report any side effects to https://nzphvc.otago.ac.nz/reporting/. 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

Active ingredients	glecaprevir
(main ingredient)	pibrentasvir
Other ingredients	Colloidal silicon dioxide
(inactive ingredients)	 Copovidone
, , , , , , , , , , , , , , , , , , , ,	 Croscarmellose sodium
	 Hypromellose
	Iron oxide red
	 Lactose monohydrate
	Macrogol 3350
	Propylene glycol
	monocaprylate
	 Sodium stearyl fumarate
	Titanium dioxide
	Tocofersolan
Potential allergens	lactose

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

Maviret tablets are gluten-free.

What Maviret looks like

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 blister strips inside a carton. The pack contains a total of 84 tablets (four packs of 21 tablets)It is also supplied in a plastic bottle containing 84 tablets.

Not all presentations may be available.

Who distributes Maviret?

Maviret is distributed in New Zealand by:

AbbVie Limited

6th Floor, 156-158 Victoria St

Wellington, 6011

New Zealand

Maviret®

Telephone: 0800 900 030

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