

Package leaflet: Information for the user

Maviret 100 mg/40 mg film-coated tablets glecaprevir/pibrentasvir

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take Maviret
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1. What Maviret is and what it is used for

Maviret is an antiviral medicine used to treat adults and children (3 years and older) with long-term ('chronic') hepatitis C. This is an infectious disease that affects the liver, caused by the hepatitis C virus. Maviret contains the active substances glecaprevir and pibrentasvir.

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

2. What you need to know before you take Maviret

Do not take Maviret if:

- you are allergic to glecaprevir, pibrentasvir or any of the other ingredients of this medicine (listed in section 6 of this leaflet).
- you have severe liver problems other than from hepatitis C.
- you are taking the following medicines:
 - atazanavir (for HIV infection)
 - atorvastatin or simvastatin (to lower blood cholesterol)
 - carbamazepine, phenobarbital, phenytoin, primidone (normally used for epilepsy)
 - dabigatran etexilate (to prevent blood clots)
 - ethinyl oestradiol-containing medicines (such as contraception medicines, including vaginal rings and tablets)
 - rifampicin (for infections)
 - St. John's wort (*Hypericum perforatum*), (herbal remedy used for mild depression).

Do not take Maviret if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Maviret.

Warnings and precautions

Talk to your doctor if you have the following because your doctor may want to check you more closely:

- liver problems other than hepatitis C
- current or previous infection with the hepatitis B virus
- diabetes. You may need closer monitoring of your blood glucose levels and/or adjustment of your diabetes medication after starting Maviret. Some diabetic patients have experienced low sugar levels in the blood (hypoglycaemia) after starting treatment with medicines like Maviret.

Blood tests

Your doctor will test your blood before, during and after your treatment with Maviret. This is so that your doctor can decide if:

- you should take Maviret and for how long
- your treatment has worked and you are free of the hepatitis C virus.

Children

Do not give this medicine to children under 3 years of age or weighing less than 12 kg. The use of Maviret in children under 3 years of age or weighing less than 12 kg has not yet been studied.

Other medicines and Maviret

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor or pharmacist before taking Maviret, if you are taking any of the medicines in the table below. The 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
ciclosporin, tacrolimus	to suppress the immune system
darunavir, efavirenz, lopinavir, ritonavir	for HIV infection
digoxin	for heart problems
fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin	to lower blood cholesterol
warfarin and other similar medicines*	to prevent blood clots

*Your doctor may need to increase the frequency of your blood tests to check how well your blood can clot.

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

Pregnancy and contraception

The effects of Maviret during pregnancy are not known. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine, as the use of Maviret in pregnancy is not recommended. Contraceptive medicines that contain ethinylestradiol must not be used in combination with Maviret.

Breast-feeding

Talk to your doctor before taking Maviret if you are breast-feeding. It is not known whether the two medicines in Maviret pass into breast milk.

Driving and using machines

Maviret should not affect your ability to drive or use any tools or machines.

Maviret contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

3. How to take Maviret

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will tell you how long you need to take Maviret for. Maviret tablets are intended for adults, children 12 years and older, or children weighing 45 kg or more. Maviret coated granules are intended for children aged 3 years to less than 12 years and weighing 12 kg to less than 45 kg.

How much to take

The recommended dose for adults, children aged 12 years and older, or children weighing at least 45 kg is three tablets of Maviret 100mg/40mg taken together, once a day.

Three tablets in one blister is the daily dose.

How to take

- Take the tablets with food.
- Swallow the tablets whole.
- Do not chew, crush or break the tablets as it may affect the amount of Maviret in your blood.

If you are sick (vomit) after taking Maviret it may affect the amount of Maviret in your blood. This may make Maviret work less well.

- If you vomit **less than 3 hours** after taking Maviret, take another dose.
- If you vomit **more than 3 hours** after taking Maviret, you do not need to take another dose until your next scheduled dose.

If you take more Maviret than you should

If you accidentally take more than the recommended dose, contact your doctor or go to the nearest hospital straight away. Take the medicine pack with you so that you can show the doctor what you have taken.

If you forget to take Maviret

It is important not to miss a dose of this medicine.

If you do miss a dose, work out how long it is since you should have last taken Maviret:

- If you notice **within 18 hours** of the time you usually take Maviret take the dose as soon as possible. Then take the next dose at your usual time.
- If you notice **18 hours or more** after the time you usually take Maviret, wait and take the next dose at your usual time. Do not take a double dose (two doses too close together).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist if you notice any of the following side effects:

Very common: may affect more than 1 in 10 people

- feeling very tired (fatigue)
- headache

Common: may affect up to 1 in 10 people

- feeling sick (nausea)
- diarrhoea
- feeling weak or lack of energy (asthenia)

Uncommon: may affect up to 1 in 100 people

- swelling of the face, lips, tongue, throat, abdomen, arms or legs

Not known: cannot be estimated from the available data

- itching

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Maviret

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'.

This medicine does not require any special storage.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Maviret contains

- The active substances are glecaprevir and pibrentasvir. Each tablet contains 100 mg of glecaprevir and 40 mg of pibrentasvir.
- The other ingredients are:
 - Tablet core: copovidone (Type K 28), vitamin E polyethylene glycol succinate, silica, anhydrous colloidal, propylene glycol monocaprylate (type II), croscarmellose sodium, sodium stearyl fumarate.
 - Tablet film-coating: hypromellose (E464), lactose monohydrate, titanium dioxide, macrogol 3350, iron oxide red (E172).

What Maviret looks like and contents of the pack

Maviret tablets are pink, oblong, curved on both sides (biconvex), film-coated tablets with dimensions of 18.8 mm x 10.0 mm and debossed on one side with 'NXT'.

Maviret tablets are packed into foil blisters, each containing 3 tablets. Maviret is available in a pack of 84 tablets as 4 cartons, each containing 21 film-coated tablets.

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