

## **Package leaflet: Information for the user**

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

**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**

1. What Maviret is and what it is used for
2. What you need to know before you take Maviret
3. How to take Maviret
4. Possible side effects
5. How to store Maviret
6. Contents of the pack and other information

#### **1. What Maviret is and what it is used for**

Maviret is an antiviral medicine used to treat adults and adolescents 12 years and older with long-term ('chronic') hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus). It 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

- HIV infection
- current or previous infection with the hepatitis B virus
- had liver or kidney transplant
- diabetes

### **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 12 years of age. The use of Maviret in children under 12 years of age 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.

<b>Medicines you must tell your doctor about before taking Maviret</b>	
<b>Medicine</b>	<b>Purpose of the medicine</b>
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 vitamin K antagonists*	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.

### **How much to take**

The recommended dose for adults and adolescents (12 to <18 years old) 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 or cut in half.
- 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)

**Frequency unknown:**

- swelling of the face, lips, tongue or throat (angioedema)
- itching (pruritus)

**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.

**5. How to store Maviret**

Store below 30°C.

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.

**Product Owner**

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