PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Maviret

Film-coated Tablets

Active ingredients and quantities:
Each tablet contains:
100 mg glecaprevir and 40 mg pibrentasvir.
See "Important information about some of the medicine's ingredients" in section 2.
For the list of inactive ingredients, please see section 6 "Further Information" in this leaflet.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for your ailment/ for you. Do not pass it on to others. It may harm them even if it seems to you that their ailment/ medical condition is similar.

Reactivation of hepatitis B:
Before starting treatment with Maviret, your doctor must perform blood tests for presence of a hepatitis B infection. If you have or have had a hepatitis B infection in the past, Maviret may cause reactivation of hepatitis B, which may, in certain cases, be fatal or cause serious liver problems (e.g., liver failure).
Reactivation of hepatitis B can occur during or after completing treatment with Maviret. You must be strictly monitored if you are at risk of reactivation of hepatitis B during or after Maviret treatment.

1. WHAT IS THE MEDICINE INTENDED FOR?

Maviret is an antiviral medicine used to treat adults and adolescents (ages 12 to 18) with long-term ('chronic') hepatitis C.

Therapeutic group:
Glecaprevir and pibrentasvir are antiviral substances.

Chronic hepatitis C is an infectious disease that affects the liver, caused by the hepatitis C virus. The medicine contains the active ingredients 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. BEFORE USING THE MEDICINE

Do not use the medicine if:
- you are sensitive (allergic) to the active ingredients (glecaprevir, pibrentasvir) or to any of the other ingredients contained in the medicine (for the list of inactive ingredients, see section 6).
- you have certain liver problems other than from hepatitis C.
- you are taking the following medicines:
  - atazanavir (to treat HIV infection)
  - atorvastatin or simvastatin (to lower blood cholesterol)
  - carbamazepine, phenobarbital, phenytoin, primidone (normally used for epilepsy)
  - dabigatran etexilate (to prevent blood clots)
  - ethinylestradiol-containing medicines (such as contraceptive medicines, including tablets, transdermal patches and vaginal rings)
  - rifampicin (to treat 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.

Special warnings regarding use of the medicine:
Before treatment with Maviret, tell the 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

If any of the above apply to you, or you are not sure, talk to your doctor, pharmacist, or nurse before taking this medicine.

Tests and Follow-up
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.

Drug interactions
If you are taking, or have recently taken, or might take other medicines including non-prescription medicines, nutritional supplements and herbal medicines, tell the doctor or pharmacist. Especially 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, breast-feeding and fertility
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. 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.

Important information about some of the medicine's ingredients
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.

Maviret contains sodium. This preparation contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen.
The dosage and treatment regimen will be determined by the doctor only.

Usual dosage
The usual dosage for adults and adolescents (ages 12 to 18) is three tablets of Maviret, taken together, once a day.
Three tablets in one blister is the daily dose.

Do not exceed the recommended dose.

How to take
- Take the tablets with food.
- Swallow the tablets whole.
- Do not crush/halve/chew the tablets as it may affect the amount of Maviret in your blood.

If you suffer from vomiting 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 took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

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 to make up for a missing dose.

Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your condition, do not stop treatment with the medicine without consulting the doctor.
Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them. If you have any further questions regarding the use of the medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Maviret may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
- **In people who had or have advanced liver problems before starting treatment with Maviret: rare risk of worsening liver problems, liver failure and death.** Your doctor will check you for signs and symptoms of worsening liver problems during treatment with Maviret. Tell your doctor right away if you have any of the following signs and symptoms: nausea, tiredness, yellowing of your skin or white part of your eyes, bleeding or bruising more easily than normal, confusion, dark or black or bloody stool, loss of appetite, diarrhea, dark or brown (tea-colored) urine, swelling or pain on the upper right side of your stomach area (abdomen), sleepiness, vomiting of blood, lightheadedness.

Tell your doctor or pharmacist if you notice any of the following side effects:
Very common side effects - effects that occur in more than 1 user in 10:
- feeling very tired (fatigue)
- headache

Common side effects - effects that occur in 1-10 users in 100:
- feeling sick (nausea)
- diarrhoea
- feeling weak or lack of energy (asthenia)
- increase in bilirubin levels (a laboratory test for liver function)

Uncommon side effects - effects that occur in 1-10 users in 1,000:
- swelling of the face, lips, tongue, throat, abdomen, arms or legs

Side effects of unknown frequency - effects whose frequency has not been determined yet:
- itching

If a side effect has occurred, if any of the side effects worsen or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects due to Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the carton package. The expiry date refers to the last day of that month.

Storage conditions:
- Store at a temperature below 30°C.
- 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. FURTHER INFORMATION

What Maviret contains
- In addition to the active ingredients, the medicine also contains:
  - Tablet core: copovidone (Type K 28), vitamin E polyethylene glycol succinate, colloidal silicon dioxide/silica, anhydrous colloidal, propylene glycol monocaprylate (type II), croscarmellose sodium, sodium stearyl fumarate.
  - Tablet film-coating: hypromellose (E464), lactose monohydrate, titanium dioxide, polyethylene glycol/macrogol 3350, iron oxide red (E172).

Maviret contains lactose and sodium. See section 2.

- **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 are 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.
- **Manufacturer name and address:** AbbVie Deutschland GmbH & Co. KG, Knollstrasse 67061, Ludwigshafen, Germany.
- **License holder and its address:** AbbVie Biopharmaceuticals Ltd., 4 Haharash St., Hod Hasharon, Israel.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 160-05-35323

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