Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is to be supplied by doctor's prescription only

Vemlidy®
Film-coated tablets

Active ingredient: each film-coated tablet contains -
Tenofovir alafenamide 25 mg

Each tablet contains 95 mg lactose monohydrate.
For the full list of inactive ingredients and allergens: See section 6: "*Additional Information*".

Read all of this leaflet carefully before you start taking this medicine.This leaflet contains a summary of the information about the medicine. If you have any further questions, ask your doctor or pharmacist.
This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their signs of illness are the same as yours.
The medicine is not intended for children under the age of 12 years.

1. What is the medicine intended for?

Vemlidy is used to **treat chronic (long-term) hepatitis B** in adults and adolescents 12 years of age and older, who weigh at least 35 kg.

Therapeutic Group: *antiviral medicine*, known as a *nucleotide reverse transcriptase inhibitor* (NtRTI).

Hepatitis B is an infection affecting the liver, caused by the hepatitis B virus. In patients with hepatitis B, this medicine controls the infection by stopping the virus from multiplying.

2. Before using the medicine

X Do not use the medicine if:
- **you are allergic** to tenofovir alafenamide or any of the other ingredients of this medicine listed in section 6.

→If this applies to you, **do not take Vemlidy and tell your doctor immediately.**

! Special warnings relating to the use of this medicine

Talk to your doctor or pharmacist before taking Vemlidy:

- **Take care not to pass on your hepatitis B to other people.** You can still infect others when taking this medicine. This medicine does not reduce the risk of passing on hepatitis B to others through sexual contact or blood contamination. You must continue to take precautions to avoid this. Discuss with your doctor the precautions needed to avoid infecting others.

- **Tell your doctor if you have a history of liver disease.** Patients with liver disease, who are treated for hepatitis B with antiviral medicines, have a higher risk of severe and potentially fatal liver complications. Your doctor may need to carry out blood tests to monitor your liver function.

- **Talk to your doctor or pharmacist if you have had kidney disease or if tests have shown problems with your kidneys, before or during treatment.** Before starting treatment and during treatment with Vemlidy, your doctor may order blood or urine tests to monitor how your kidneys work.

- **Talk to your doctor if you also have hepatitis C or D.** This medicine has not been tested on patients who have hepatitis C or D as well as hepatitis B.

- **Talk to your doctor if you also have HIV**. If you are not sure whether you have HIV, your doctor should offer you HIV testing before you start taking this medicine for hepatitis B.

→ If any of these apply to you, talk to your doctor before taking Vemlidy.

There is a possibility that you may experience kidney problems when taking Vemlidy over a long period of time (see *Special warnings relating to the use of this medicine*).

Other medicines and Vemlidy

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine, including medicines obtained without a prescription and dietary supplements. Vemlidy may interact with other medicines. As a result, the amounts of Vemlidy or other medicines in your blood may change. This may stop your medicines from working properly, or may make any side effects worse.

Medicines used in treating hepatitis B infection
You should not take this medicine with other medicines containing:
- **tenofovir alafenamide**
- **tenofovir disoproxil**
- **adefovir dipivoxil**

Other types of medicines
Talk to your doctor if you are taking:
- **antibiotics** used to treat bacterial infections including tuberculosis, containing:
  - rifabutin, rifampicin or rifapentine
- **antiviral medicines used to treat HIV**, such as:
  - ritonavir or cobicistat boosted darunavir, lopinavir or atazanavir
- **anticonvulsants** used to treat epilepsy, such as:
  - carbamazepine, oxcarbazepine, phenobarbital or phenytoin
- **herbal remedies** used to treat depression and anxiety, containing:
  - St. John's wort (*Hypericum perforatum*)
- **antifungal medicines** used to treat fungal infections, containing:
  - ketoconazole or itraconazole

→ Tell your doctor if you are taking these or any other medicines.

Using the medicine and food

Vemlidy film-coated tablets should be taken with food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Tell your doctor immediately if you become pregnant.

- **Do not breast-feed during treatment with Vemlidy.** It is recommended that you do not breast-feed to avoid passing tenofovir alafenamide or tenofovir to the baby through breast milk.

Driving and using machines

Vemlidy can cause dizziness. If you feel dizzy when taking Vemlidy, do not drive and do not use any tools or machines.

Children and adolescents

Do not give this medicine to children who are under 12 years old and weigh less than 35 kg. It has not been tested in children aged less than 12 years old and weighing less than 35 kg.

Important information about some ingredients of the medicine

Vemlidy contains lactose

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

Vemlidy contains sodium

This medicine 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 take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage and treatment is according to the physician's instructions only. The recommended dose is one tablet once a day with food. It is best to take Vemlidy with food to get the right levels of active substance in your body. Treatment should continue for as long as your doctor tells you. Usually this is for at least 6 to 12 months and may be for many years.

Do not exceed the recommended dose.
There is no information available regarding the crushing/splitting of the product.

If you take more Vemlidy than you should

If you accidentally take more than the recommended dose of Vemlidy you may be at increased risk of experiencing possible side effects with this medicine (see section 4, *Side effects*).

Contact your doctor or nearest emergency department immediately for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

If you forget to take Vemlidy

It is important not to miss a dose. If you do miss a dose, work out how long since you should have taken it.

- **If it is less than 18 hours** after you usually take Vemlidy, take it as soon as you can, and then take your next dose at its regular time.

- **If it is more than 18 hours** after you usually take Vemlidy, then do not take the missed dose. Wait and take the next dose at the regular time. **Do not take a double dose** to make up for a forgotten tablet.

If you are sick (vomit) less than 1 hour after taking Vemlidy, take another tablet. You do not need to take another tablet if you are sick (vomit) more than 1 hour after taking Vemlidy.

If you stop taking Vemlidy

Do not stop taking Vemlidy without your doctor's advice. Stopping treatment with Vemlidy may cause your hepatitis B to get worse. In some patients with advanced liver disease or cirrhosis, this could be life-threatening. If you stop taking this medicine, you will need regular health checks and blood tests for several months to check your hepatitis B infection.

- **Talk to your doctor** before you stop taking this medicine for any reason, particularly if you are experiencing any side effects or you have another illness.

- **Tell your doctor immediately** about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection.

- **Talk to your doctor** before you restart taking Vemlidy tablets.

Do not take medicines in the dark. Check the label and the dose <u>every time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Side effects

Like all medicines, this medicine also can cause side effects in some patients. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Very common
(may affect more than 1 in 10 people)
- Headache

Common
(may affect up to 1 in 10 people)
- Diarrhoea
- Being sick *(vomiting)*
- Feeling sick *(nausea)*
- Dizziness
- Stomach pain
- Joint pain *(arthralgia)*
- Rash
- Itchiness
- Feeling bloated
- Wind *(flatulence)*
- Feeling tired

Tests may also show:
- Increased level of a liver enzyme (ALT) in the blood

Uncommon
(may affect up to 1 in 100 people)
- Swelling of the face, lips, tongue or throat (*angioedema*)
- Hives *(urticaria)*

→ **If any of these side effects get serious tell your doctor.**

During HBV therapy there may be an increase in weight, fasting levels of blood lipids and/or glucose. Your doctor will test for these changes.

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

Reporting of side effects

You can report any side effects to the Ministry of Health by clicking on the link "Report side effects due to medical treatment" that is located on the Ministry of Health homepage (www.health.gov.il) which redirects to the online form for reporting side effects, or by clicking on the link: https://sideeffects.health.gov.il . You can also report any side effects directly to the registration holder via email: DrugSafety.Israel@gilead.com.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store the medicine

Store below 30°C.
Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use this medicine after the expiry date which is stated on the bottle and carton after {EXP}. The expiry date refers to the last day of that month. After first opening, use within 90 days.

Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

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. Additional information

What Vemlidy contains

The active substance is *tenofovir alafenamide.* Each Vemlidy film-coated tablet contains tenofovir alafenamide fumarate, equivalent to 25 mg of tenofovir alafenamide.
In addition to the active ingredient the medicine also contains: Lactose monohydrate: 95 mg.
Refer to section 2 "*Vemlidy contains lactose*".

The other ingredients are
Tablet core:
Lactose monohydrate, microcrystalline cellulose (E460(i)), croscarmellose sodium (E468), magnesium stearate (E470b).

Film-coating:
Polyvinyl alcohol (E1203), talc (E553b), macrogol/PEG (E1521), titanium dioxide (E171), iron oxide yellow (E172).

What Vemlidy looks like and contents of the pack

Vemlidy film-coated tablets are yellow, round, printed (or marked) with “GSI” on one side of the tablet and “25” on the other side of the tablet. It comes in bottles of 30 tablets (with a silica gel desiccant that must be kept in the bottle to help protect your tablets). The silica gel desiccant is contained in a separate sachet or canister and should not be swallowed.

The following pack size is available: outer carton containing 1 bottle of 30 film-coated tablets

Registration holder:
Gilead Sciences Israel Ltd.
4 HaHarash Street
Hod Hasharon 4524075
Israel

Manufacturer
Gilead Sciences Ireland UC
IDA Business & Technology Park
Carrigtohill
County Cork
Ireland

The medicine’s registration no. in the national register of medicines at the Ministry of Health: 35160

For simplicity and ease of reading, this leaflet was phrased in the masculine. Nevertheless, the medicine is intended for both sexes.

Revised in September 2022 according to MoH guidelines.
Reference: EU SmPC from August 2022.

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