

## Package leaflet: Information for the patient

### Vemlidy 25 mg film-coated tablets tenofovir alafenamide

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**

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

**If Vemlidy has been prescribed for your child, please note that all the information in this leaflet is addressed to your child (in this case please read “your child” instead of “you”).**

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

Vemlidy contains the active substance *tenofovir alafenamide*. This is an *antiviral medicine*, known as a *nucleotide reverse transcriptase inhibitor* (NtRTI).

Vemlidy is used to **treat chronic (long-term) hepatitis B** in adults and children 6 years of age and older, who weigh at least 25 kg. Hepatitis B is an infection affecting the liver, caused by the hepatitis B virus. In patients with hepatitis B, Vemlidy controls the infection by stopping the virus from multiplying.

#### **2. What you need to know before you take Vemlidy**

##### **Do not take Vemlidy**

- 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.**

##### **Warnings and precautions**

- **Take care not to pass on your hepatitis B to other people.** You can still infect others when taking this medicine. Vemlidy 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 tests to monitor how your kidneys work.
- **Talk to your doctor if you also have hepatitis C or D.** Vemlidy 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 Vemlidy 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 *Warnings and precautions*).

### Children and adolescents

**Do not give this medicine to children who are under 6 years old, or weighing less than 25 kg.** Vemlidy has not been tested in children aged less than 6 years old or weighing less than 25 kg.

**Bone problems.** Loss of bone mass has been reported in some children who received Vemlidy. The effects on long-term bone health and future fracture risk in children are uncertain. Your doctor will monitor this possible risk. Tell your doctor if any bone pain or fractures occur.

### Other medicines and Vemlidy

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

Do not take Vemlidy 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.**

### **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.

### **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 to take Vemlidy**

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

The recommended dose is **one tablet once a day with food.** 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.

### **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, Possible 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 of Vemlidy. 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 Vemlidy, 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 Vemlidy 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.

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.

### **Very common side effects**

*(may affect more than 1 in 10 people)*

- Headache

### **Common side effects**

*(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

### **Uncommon side effects**

*(may affect up to 1 in 100 people)*

- Swelling of the face, lips, tongue or throat (*angioedema*)
- Hives (*urticaria*)

*Tests may also show:*

- Increased level of a liver enzyme (ALT) in the blood

**→ 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.

### Reporting of side effects

**If you get any side effects, talk to your doctor, pharmacist or nurse.** This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the

*Yellow Card Scheme*

*Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store*

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

### 5. How to store Vemlidy

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 bottle and carton after {EXP}. The expiry date refers to the last day of that month.

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. Contents of the pack and other 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.

#### The other ingredients are

*Tablet core:*

Lactose monohydrate, microcrystalline cellulose (E460(i)), croscarmellose sodium (E468), magnesium stearate (E470b).

*Film-coating:*

Polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol (E1521), talc (E553b), 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. Vemlidy 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 sizes are available: outer cartons containing 1 bottle of 30 film-coated tablets and outer cartons containing 90 (3 bottles of 30) film-coated tablets. Not all pack sizes may be marketed.

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