Patient Information leaflet

SCHEDULING STATUS

S4

VEMLIDY 25 mg film-coated tablets

Tenofovir alafenamide

Contains sugar (Lactose 95 mg)

Read all of this leaflet carefully before you start taking VEMLIDY 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, pharmacist, nurse or healthcare provider.
- VEMLIDY has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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** infection of

the liver, caused by the hepatitis B virus in adults and children 6 years of age and older, who weigh at least 25 kg. 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 you are on treatment with other medicines containing tenofovir or adefovir dipivoxil**

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

Warnings and precautions

- **Too much lactic acid in your blood (lactic acidosis)** is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.

- **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 or urine 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.**

Children and adolescents

Do not give VEMLIDY to children who are under 6 years old, or weighing less than 25 kg. It 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 medicine. 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 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 your baby 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 has minor influence on the ability to drive and use machines. If you experience dizziness, you should not drive and use machines.

VEMLIDY can cause fatigue, headache, nausea and dizziness.

Important information about some of the ingredients of VEMLIDY:

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

Do not share medicines prescribed for you with any other person
Always take VEMLIDY 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**. 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.

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 (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. 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 VEMLIDY, ask your doctor or pharmacist.

4. Possible side effects

VEMLIDY can have side effects. Not all side effects reported for VEMLIDY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VEMLIDY, please consult your healthcare provider for advice.

Very common side effects

- Headache

Common side effects

- Diarrhoea
- Being sick (vomiting)
- Feeling sick (nausea)
- Dizziness
- Stomach pain
- Joint pain (arthralgia)
- Rash
- Itchiness
- Feeling bloated
- Wind (flatulence)
- Feeling tired

Uncommon side effects

- Swelling of the face, lips, tongue or throat, including difficulty breathing (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 side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the 6.04 Adverse Drug Reaction Reporting Form, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of VEMLIDY.

5. How to store VEMLIDY

Store all medicines out of reach of children.

Do not use after the expiry date stated on the label / carton / bottle. 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.

Store at or below 30 °C.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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, debossed 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 sizes are available: outer cartons containing 1 bottle of 30 film coated tablets.

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