PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TENEMINE

film-coated tablets

Tenofovir disoproxil fumarate 300 mg/ emtricitabine 200 mg

Contains sugar: Lactose monohydrate 136 mg

Read all of this leaflet carefully before you start taking TENEMINE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **TENEMINE** 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

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

1. What TENEMINE is and what it is used for

TENEMINE is a type of medicine called an HIV (human immunodeficiency virus) nucleoside analogue reverse transcriptase inhibitor (NRTI). **TENEMINE** contains 2 medicines, emtricitabine (200 mg) and tenofovir disoproxil fumarate (or tenofovir DF) (300 mg) combined in one pill.

Treatment for HIV Infection:

TENEMINE is used in adults in combination with other anti-HIV medicines to treat people with HIV infection

Treatment for Pre-Exposure Prophylaxis (PrEP):

To reduce the risk of getting HIV-1 in adults, **TENEMINE** is to be used in combination with safer sex practices and rigorous use at all times. This is called Pre-Exposure Prophylaxis or PrEP.

2. What you need to know before you take TENEMINE

Do not take TENEMINE:

- if you are hypersensitive (allergic) to tenofovir disoproxil fumarate or emtricitabine or any of the other ingredients contained in the **TENEMINE** tablets (listed in section 6).
- if you are pregnant or breastfeeding.
- if you have kidney problems or are on dialysis.

- If you are already taking any other tenofovir or emtricitabine containing medicines or medicines containing lamivudine because these medicines contain the same or similar active ingredients.
- If you are a female who is taking **TENEMINE** to prevent HIV infection and you become pregnant while taking **TENEMINE**.
- If you are HIV positive or if your HIV status is not known, when using **TENEMINE** to prevent HIV infection.
- If you are not fully committed to use **TENEMINE** every day for Pre-Exposure Prophylaxis.

See the section 1. What TENEMINE is and what it is used for, and talk to your healthcare provider for more information about how to prevent HIV infection.

Warnings and precautions

Take special care with TENEMINE:

- If you have bone problems.
- If you have liver problems including Hepatitis B Virus infection.
- If you have had kidney problems in the past or take other medicines that can cause kidney problems.
- If you are taking other medicines as **TENEMINE** may interact with these other medicines.
- **If you are also infected with the Hepatitis B Virus (HBV),** you need close medical follow up for several months after stopping treatment with **TENEMINE**. Follow-up includes medical examinations and blood tests to check for HBV that could be getting worse.

- **Patients with Hepatitis B Virus who take TENEMINE and then stop it, may get "flare-ups" of their hepatitis.** A "flare-up" is when the disease suddenly returns in a worse way than before. **TENEMINE** is not approved for the treatment of Hepatitis B Virus infection.

You should read the patient information leaflet of the other HIV medicines that you will be taking in combination with **TENEMINE**.

- Changes in body fat have been seen in some patients taking **TENEMINE** and other anti-HIV medicines. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen. The cause and long-term health effect of these conditions are not known at this time.
- Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking **TENEMINE** and other HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider if you start having any new symptoms after starting your HIV medicine.
- Some people who have taken medicine like **TENEMINE** have developed a serious condition called lactic acidosis (build-up of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital (see **Section 4 Possible side effects**).

The following side effects may be signs of lactic acidosis:

- deep rapid breathing
- drowsiness
- feeling sick (nausea), being sick (vomiting) and stomach pain

Some people who have taken medicines like **TENEMINE** have developed serious liver problems called hepatotoxicity, with liver enlargement (hepatomegaly) and fat in the liver (steatosis).

Any child exposed *in utero* to nucleoside and nucleotide analogues (like **TENEMINE**) even HIV negative children, should have clinical and laboratory follow up and should be fully investigated for possible mitochondrial dysfunction.

If you are diabetic, overweight or have high cholesterol, talk to your doctor.

Other important information to know before taking TENEMINE for HIV-1 treatment:

- You must stay on continuous HIV therapy to control HIV infection and decrease HIV-related illnesses.
- **TENEMINE does not cure HIV.** If you already have HIV or get HIV and take **TENEMINE** by itself without other medicines, you may develop resistance to **TENEMINE**. This means that the HIV virus may become harder to treat.
- **TENEMINE** does not lower your chance of passing HIV to other people through sexual contact, sharing needles, or being exposed to your blood. For your health and the health of others, it is important to always practice safe sex.
- You may still get opportunistic infections or other conditions that happen with HIV infection. Opportunistic infections are infections that develop because the immune system is weak.

Some of these conditions are different forms of tuberculosis infection, a form of pneumonia, herpes virus infections and a form of meningitis (infection of the protective membranes surrounding the brain and spinal cord).

Other important information to know before taking TENEMINE to help prevent you from getting HIV:

- **You must get tested to be sure you are HIV-negative.** It is important that you also get tested at least every 3 months as recommended by your healthcare provider while taking **TENEMINE**. Ask your partner to get tested. Know the HIV status of your partner.
- **TENEMINE** may not always keep you from getting HIV.
- **You must still practice safe sex at all times. Do not have any kind of sex without protection.** Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.
- **You must also use other prevention methods to keep from getting HIV.**
- Get information and support to help reduce risky sexual behaviour.
- Have fewer sexual partners.
- **Do not miss any doses of TENEMINE. Missing doses increases your risk of getting HIV.**

Other important information to know before taking TENEMINE to help prevent you from getting HIV or for HIV-1 treatment:

Avoid doing things that can increase your risk of spreading HIV infection to other people if you are HIV-infected or increase your risk of acquiring HIV if you are taking **TENEMINE** for prevention.

These include:

- Do not share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Tell your healthcare provider if you have any of the following symptoms within the last month before you start taking **TENEMINE** or at any time while taking **TENEMINE**:

- tiredness
- fever
- sweating a lot (especially at night)
- rash
- vomiting
- diarrhoea
- joint or muscle aches
- headache
- sore throat
- enlarged lymph nodes in the neck or groin.

These may be signs of HIV infection and you may need to have another test to diagnose HIV. Also, tell your healthcare provider if you think you were recently

exposed to the HIV virus. If you are already taking **TENEMINE** to prevent HIV-1 infection, your healthcare provider may tell you to stop taking **TENEMINE** until an HIV test confirms that you do not have HIV infection.

Other medicines and TENEMINE

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your healthcare professional if you take:

- Other medicines that contain tenofovir DF, emtricitabine or lamivudine, either alone or in combination. **TENEMINE should not be used with those medicines because they contain the same or similar active ingredients as TENEMINE (see Section 2. What you need to know before you take TENEMINE, do not take TENEMINE).**
- Medicines that contain didanosine. Tenofovir DF (a component of **TENEMINE**) may increase the amount of didanosine in your blood. **You may need to visit your healthcare professional more regularly if you are taking TENEMINE and didanosine together.** The dose of didanosine may also need to be reduced.
- Atazanavir sulphate or lopinavir and ritonavir co-formulation. These medicines may increase the amount of tenofovir DF (a component of **TENEMINE**) in your blood, which could result in more side effects. You may need to visit your healthcare professional more regularly if you are taking **TENEMINE** and atazanavir sulphate or lopinavir and ritonavir co-formulation together. **TENEMINE** may decrease the amount of atazanavir sulphate in your blood. If

you are taking **TENEMINE** and atazanavir sulphate together, you should also be taking ritonavir.

TENEMINE with food and drink:

TENEMINE may be taken with or without a meal. Take **TENEMINE** at the same time each day.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant o planning to have a baby, please consult your doctor, pharmacist or other healt provider for advice before taking this medicine.

Do not use **TENEMINE** if you are pregnant. The effects of **TENEMINE** on pregnant women or their unborn babies are not known.

- A reliable method of contraception should be used to avoid pregnancy while taking **TENEMINE**.
- Do not breastfeed if you are taking **TENEMINE**. Do not breastfeed if you have HIV. If you are a woman who has or will have a baby, talk to your healthcare provider about the best way to feed your baby. If your baby does not already have HIV, there is a chance that the baby can get HIV through breastfeeding.

Driving and using machines

TENEMINE can make you dizzy, so care should be taken when driving or using machinery.

TENEMINE contains lactose monohydrate

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take **TENEMINE**.

TENEMINE contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take TENEMINE

Do not share medicines prescribed for you with any other person.

Always take **TENEMINE** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Recommended dosage of TENEMINE tablets:

The usual dose for adults is one (1) **TENEMINE** tablet once a day.

Take **TENEMINE** at the same time each day.

Treatment of HIV:

If you take **TENEMINE** for the treatment of HIV infection, it should be used in combination with other anti-HIV medicines.

Prevention of HIV:

If you take TENEMINE to reduce the risk of getting HIV-1, you must also use other methods to reduce your risk of getting HIV. See Warnings and precautions, Take special care with TENEMINE.

Your doctor will tell you how long your treatment with **TENEMINE** will last. Do not stop treatment early.

If you have the impression that the effect of **TENEMINE** is too strong or too weak, talk to your doctor or pharmacist.

If you take more TENEMINE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take TENEMINE

It is important that you do not miss any doses. If you miss a dose of **TENEMINE**, take it as soon as possible that day and then take your next scheduled dose at its regular time. If it is almost time for your next dose, **do not** take 2 doses at the same time. Contact your healthcare provider or pharmacist if you are not sure what to do. Do not take more than one dose of **TENEMINE** in a day.

If you stop taking TENEMINE

You should not stop treatment unless your doctor instructs you to. When your **TENEMINE** supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood will increase if the medicine is stopped for even a short time. The virus may develop resistance to **TENEMINE** and become difficult to treat.

4. Possible side effects

TENEMINE can have side effects:

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

If any of the following happens, stop taking **TENEMINE** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing (angioedema);
- rash or itching;

- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **TENEMINE**.

You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Difficulty breathing;
- less urine than is normal for you;

  signs or symptoms of lactic acidosis (build-up of acid in the blood) e.g. feeling weak or tired, having unusual muscle pain, trouble breathing, stomach pain with nausea and vomiting, feeling cold (especially in your arms and legs), feeling dizzy and lightheaded and having a fast or irregular heartbeat;
- signs or symptoms of serious liver problems e.g. skin or white part of the eye turns yellow (jaundice), urine turns dark, stools turn light in colour, feeling sick to your stomach (nausea), have lower stomach area pain (abdominal pain) and not feeling like eating food for several days or longer;
- signs of softening of the bones (bone pain and sometimes resulting in fractures).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- Stomach pain;
- pain;

- abnormal physical weakness or lack of energy;
- diarrhoea;
- headache;
- nausea (feeling sick), vomiting;
- dizziness;
- difficulty sleeping, abnormal dreams;
- problems with digestion resulting in discomfort after meals, feeling bloated, flatulence;
- rashes (including red spots or blotches sometimes with blistering and swelling of the skin which may be allergic reactions), itching, changes in skin colour including darkening of the skin in patches;
- other allergic reactions e.g. wheezing, swelling or feeling lightheaded.

Blood tests may also show:

- Low white blood cell count (a reduced white blood cell count can make you more prone to infection);
- increased triglycerides (fatty acids), bile or sugar in the blood;
- increased creatine kinase (an enzyme resulting from breakdown of your muscles);
- increased amylase or lipase in the blood;
- increased liver enzymes.

The following side effects have been reported with unknown frequency:

- Back pain caused by kidney problems;

- anaemia (low red blood cell count), which may include symptoms e.g. fatigue, skin pallor, shortness of breath, light-headedness, dizziness, or a fast heartbeat;
- breakdown of muscle, muscle pain or weakness which may occur due to damage to the kidney tubule cells;
- inflammation of the pancreas which most commonly begins with abdominal pain in the middle or upper left part of the abdomen and may increase after eating or lying flat the back.

Blood and urine tests may also show:

- Decreases in potassium in the blood;
- decreases in phosphate in the blood;
- increased creatinine in your blood;
- changes to your urine.

This list of side effects is not complete. If you have questions about side effects, ask your healthcare provider. You should report any new or continuing symptoms to your healthcare provider right away. Your healthcare provider may be able to help you manage these side effects.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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 **TENEMINE**.

5. How to store TENEMINE

- Store all medicines out of reach of children.
- Store at or below 30 ºC.
- Store the tablets in the original container.
- Do not remove from the carton until required for use.
- Keep the bottle tightly closed.
- Do not store in bathrooms.
- Do not use after the expiry date stated on the label.
- 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 TENEMINE contains

The active substances are tenofovir disoproxil fumarate and emtricitabine.

Each film-coated tablet contains tenofovir disoproxil fumarate 300 mg and emtricitabine 200 mg

The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, film-coat {FD & C Blue # 2, hypromellose, titanium dioxide, triacetin}

What TENEMINE looks like and contents of the pack

Blue coloured, oval shaped, film-coated tablets debossed with “M117” on one side and plain on the other side.

TENEMINE is packed in high density polyethylene (HDPE) bottle pack comprising of white opaque wide mouth HDPE bottle with a white opaque polypropylene (PP) screw closure with desiccant in 28’s, 30’s and 100’s pack, in a carton.

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*Not all pack sizes may be marketed

TENEMINE is packed in a high-density polyethylene blue opaque HDPE bottle with a blue opaque polypropylene (PP) closure and with desiccant in 28’s and 30’s pack, in a carton.

TENEMINE is packed in a high-density polyethylene blue opaque HDPE bottle with a blue opaque polypropylene (PP) closure and with desiccant in 28’s and 30’s pack.

*Not all pack sizes may be marketed

Holder of Certificate of Registration

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