

Approved Patient Information Leaflet for Medicines for Human Use:

PREPETAM

SCHEDULING STATUS: S4

PREPETAM FILM-COATED TABLETS

Each PREPETAM film coated tablet contains 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil) and 200 mg of emtricitabine.

Contains sugar (lactose monohydrate)

Read all of this leaflet carefully before you start taking PREPETAM

- 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.
- PREPETAM 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.
- 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

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1. What PREPETAM is and what it is used for

PREPETAM is a type of medicine called an HIV (human immunodeficiency virus) nucleoside analogue reverse transcriptase inhibitor (NRTI).

PREPETAM contains 2 medicines, emtricitabine 200 mg and tenofovir disoproxil fumarate (tenofovir DF) 300 mg combined in one tablet. Both of these active substances are antiretroviral medicines used to treat HIV infection.

PREPETAM is used to treat HIV-1 Infections in adults, in combination with other antiretroviral medicines.

PREPETAM is also used as a Treatment for Pre-Exposure Prophylaxis (PrEP). To reduce the risk of getting HIV-1 in adults, PREPETAM 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 PREPETAM

Do not take PREPETAM

- if you are hypersensitive (allergic) to tenofovir disoproxil,-emtricitabine or any of the other ingredients of PREPETAM (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 PREPETAM to prevent HIV infection and you become pregnant while taking PREPETAM.

- If you are HIV positive or if your HIV status is not known, when using PREPETAM to prevent HIV infection.
- If you are not fully committed to use PREPETAM every day for Pre-Exposure Prophylaxis.

Talk to your healthcare provider for more information about how to prevent HIV infection.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking PREPETAM

Warnings and precautions

Take special care with PREPETAM

Tell your doctor or health care provider before being given PREPETAM:

- 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 PREPETAM 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 PREPETAM. Follow-up includes medical examinations and blood tests to check for HBV that could be getting worse.
- Patients with Hepatitis B Virus who take PREPETAM 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. PREPETAM is not approved for the treatment of Hepatitis B Virus infection.

You should read the patient information leaflet of the other antiretroviral medicines that you will be taking in combination with PREPETAM.

- Changes in body fat have been seen in some patients taking PREPETAM and other antiretroviral medicines. These changes may include an increased amount of fat in the upper back and neck (“buffalo hump”), breasts, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also occur. 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 PREPETAM and other antiretroviral 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 antiretroviral medicine.

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

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

- You must stay on continuous antiretroviral therapy to control HIV infection and decrease HIV-related illnesses.
- PREPETAM does not cure HIV. If you already have HIV or get HIV and take PREPETAM by itself without other medicines, you may develop resistance to PREPETAM. This means that the HIV virus may become harder to treat.
- PREPETAM 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 PREPETAM 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 PREPETAM. Ask your partner to get tested. Know the HIV status of your partner.
- PREPETAM 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 sex partners.
- **Do not miss any doses of PREPETAM. Missing doses increases your risk of getting HIV.**

Other important information to know before taking PREPETAM 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 PREPETAM 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 PREPETAM or at any time while taking PREPETAM:

- 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 PREPETAM to prevent HIV-1 infection, your healthcare provider may tell you to stop taking PREPETAM until an HIV test confirms that you do not have HIV-1 infection.

Other medicines and PREPETAM

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

The following medicines may affect how PREPETAM works, or PREPETAM may affect how they work:

- Other medicines that contain tenofovir DF, emtricitabine or lamivudine, either alone or in combination. PREPETAM should not be used with those medicines because they contain the same or similar active ingredients as PREPETAM (see “Do not take PREPETAM”).

- Medicines that contain didanosine. Tenofovir DF (a component of PREPETAM) may increase the amount of didanosine in your blood. You may need to visit your healthcare professional more regularly if you are taking PREPETAM 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 PREPETAM) in your blood, which could result in more side effects. You may need to visit your healthcare professional more regularly if you are taking PREPETAM and atazanavir sulphate or lopinavir and ritonavir coformulation together. PREPETAM may decrease the amount of atazanavir sulphate in your blood. If you are taking PREPETAM and atazanavir sulphate together, you should also be taking ritonavir.
- Ledipasvir and sofosbuvir or sofosbuvir and velpatasvir, or sofosbuvir/velpatasvir/voxilaprevir co-formulation or adefovir dipivoxil. These medicines used for a liver disease, called hepatitis C or B, may increase the amount of tenofovir DF (a component of PREPETAM) in your blood, which could result in more side effects.
- PREPETAM is mainly eliminated by your kidneys. Therefore, co-administration of medicines that reduce renal function should be avoided. These types of medicines include, but are not limited to adefovir, dipivoxil, cidofovir, aciclovir, valaciclovir, ganciclovir and valganciclovir.

Keep a complete list of all the medicines that you take. Make a new list when medicines are added or stopped. Give copies of this list to all of your

healthcare providers and pharmacist every time you visit your healthcare provider or fill a prescription.

Taking PREPETAM with food and drink

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

Pregnancy, breastfeeding and lactation

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking PREPETAM.

- Do not use PREPETAM if you are pregnant. The effects of PREPETAM on pregnant women or their unborn babies are not known.
- A reliable method of contraception should be used to avoid pregnancy while taking PREPETAM.
- Do not breastfeed your baby if you are taking PREPETAM. Do not breastfeed your baby 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

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

It is not always possible to predict to what extent PREPETAM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PREPETAM affects them.

PREPETAM contains Lactose monohydrate

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

3. How to take PREPETAM

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

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

The usual dose is one tablet once daily.

Your doctor will tell you how long your treatment with PREPETAM will last.

Do not stop treatment early. If you have the impression that the effect of PREPETAM is too strong or too weak, tell your doctor or pharmacist.

Treatment of HIV-1

If you take PREPETAM for the treatment of HIV-1 infection, it should be used in combination with other antiretroviral medicines.

Prevention of HIV

If you take PREPETAM to reduce the risk of getting HIV-1, you must also use other methods to reduce your risk of getting HIV. See “Take special care with PREPETAM”.

If you take more PREPETAM than you should

If you take more PREPETAM than prescribed by your doctor, contact a doctor or pharmacist immediately for advice. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take PREPETAM

It is important that you do not miss any doses. If you miss a dose of PREPETAM, 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 PREPETAM in a day.

If you stop taking PREPETAM

You should not stop treatment unless your doctor instructs you to. When your PREPETAM 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 PREPETAM and become difficult to treat.

4. Possible side effects

PREPETAM can have side effects.

Not all side effects reported for PREPETAM are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking PREPETAM, please consult your health care provider for advice.

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

- Difficulty breathing, swelling of the face, throat and tongue
- 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 very serious side effects. If you have them, you may have had a serious reaction to PREPETAM. 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:

Frequent

- 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

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 enzymes that helps with the metabolism of sugars and fats
- Increased liver enzymes.

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- 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.

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 or pharmacist. 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 PREPETAM.

5. How to store PREPETAM

Store all medicines out of reach of children

Store below 30 °C.

Protect the medicine from light.

Keep this medicine in the original container until required for use.

Keep the bottle tightly closed.

Discard 90 days after first opening.

Do not use this medicine after the expiry date which is stated on the carton.

The expiry date refers to the last day of that month.

Return all unused or expired medicine to your pharmacist.

Do not use if seal over bottle opening is broken or missing.

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

6. Contents of the pack and other information

What PREPETAM contains

The active substances of PREPETAM are emtricitabine and tenofovir disoproxil fumarate.

Each film-coated tablet contains 300 mg of tenofovir disoproxil fumarate (which is equivalent to 245 mg tenofovir disoproxil) and 200 mg of emtricitabine.

The other ingredients are Croscarmellose sodium, FD&C blue no.2/Indigo Carmine Aluminium lake (E132), hypromellose (hydroxypropyl methylcellulose), lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, titanium dioxide (E171), triacetin.

What PREPETAM looks like and contents of the pack

PREPETAM tablets are blue, capsule shaped, biconvex, film coated tablets, plain on both sides.

Bottle with silica gel sachet

30 Tablets - 120 CC White HDPE Bottle with 5 g silica gel desiccant sachet and white 38 mm non-CR closure. Seal the bottle by an Induction sealing process

Bottle with molecular sieve

30 Tablets - 120 CC White HDPE Bottle with 5 g molecular sieve desiccant sachet and white 38 mm non-CR closure. Seal the bottle by an Induction sealing process.

Pack size of 30's

Holder of Certificate of Registration

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