Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

DUOTEMTRIC

Emtricitabine 200 mg

Tenofovir disoproxil fumarate 300

This product contains sugar (lactose monohydrate 50 mg per tablet).

Read all of this leaflet carefully before you start taking DUOTEMTRIC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **DUOTEMTRIC** 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 **DUOTEMTRIC** is and what it is used for.
2. What you need to know before you take **DUOTEMTRIC**.
3. How to take **DUOTEMTRIC**.
4. Possible side effects.
5. How to store **DUOTEMTRIC**.
6. Contents of the pack and other information.

1. What DUOTEMTRIC is and what it is used for.

DUOTEMTRIC is a fixed dose combination of emtricitabine and tenofovir disoproxil fumarate. Both of these active substances are antiretroviral medicines which are used to treat HIV infection. Emtricitabine and tenofovir are antiviral agents belonging to a group of medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs). They work by interfering

with the normal working of an enzyme (reverse transcriptase) that is essential for the virus to reproduce itself.

DUOTEMTRIC is used for:

- ***Treatment for HIV Infection:*** **DUOTEMTRIC** in combination with other anti-HIV medicines are used in adults for the treatment of HIV-1 infection. **DUOTEMTRIC** is not a cure for HIV infection. While taking **DUOTEMTRIC** you may still develop infections or other illnesses associated with HIV infection.
- ***Treatment for Pre-Exposure Prophylaxis (PrEP)***: **DUOTEMTRIC** is also used to reduce the risk of getting HIV-1 infection, when used as daily treatment, together with safer sex practices (see Take special care with **DUOTEMTRIC**).

2. What you need to know before you take DUOTEMTRIC

Do not take ROSVATOR:

- If you have previously had an allergic reaction (hypersensitivity) to emtricitabine, tenofovir disoproxil fumarate, or any of the other ingredients of **DUOTEMTRIC** (an allergic reaction may include rash, itching, swelling of face, lips, or hands/feet or breathing difficulties).
- If you are pregnant or breastfeeding (see Pregnancy and Breast-feeding).
- If you have any kidney disease
- 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 HIV-1 positive or if your HIV-1 status is not known, when using **DUOTEMTRIC** to prevent HIV-1 infection.
- If you are not fully committed to use **DUOTEMTRIC** every day for Pre-Exposure Prophylaxis (PrEP).

Do not take **DUOTEMTRIC** tablets if any of the above applies to you. If you are not sure, please talk to your doctor or pharmacist before taking these tablets.

Warnings and precautions

Take special care with **DUOTEMTRIC**:

- If you have kidney problems.
- If you have bone problems.
- If you have liver problems including hepatitis B virus infection.
- If you are elderly (aged 65 years and over). Your doctor may suggest an appropriate dose for you.
- If you have had kidney problems in the past or you have taken other medicines that can cause kidney problems, your healthcare provider should do regular blood tests to check your kidneys.

Before taking DUOTEMTRIC to reduce the risk of getting HIV (PrEP):

DUOTEMTRIC can only help reduce your risk of getting HIV before you are infected.

- You must be HIV negative before you start to take **DUOTEMTRIC** to reduce the risk of getting HIV.
- You must get tested to make sure that you do not already have HIV infection.
- Do not take **DUOTEMTRIC** to reduce your risk unless you are confirmed to be HIV negative.
- People who do have HIV must take **DUOTEMTRIC** in combination with other medicines.
- Many HIV tests can miss a recent infection. If you get a flu-like illness, it could mean you have recently been infected with HIV.

These may be signs of HIV infection:

- tiredness
- fever
- joint or muscle aches
- headache
- vomiting or diarrhoea
- rash
- night sweats
- enlarged lymph nodes in the neck or groin

Tell your doctor about any flu-like illness – either in the month before starting **DUOTEMTRIC** or at any time while taking **DUOTEMTRIC**.

DUOTEMTRIC is not recommended in children under 12 years of age as safety and effectiveness of **DUOTEMTRIC** has not been established.

While taking DUOTEMTRIC to reduce the risk of getting HIV:

Take **DUOTEMTRIC** every day **to reduce your risk, not just when you think you have been at risk of HIV infection.** Do not miss any doses of **DUOTEMTRIC,** or stop taking it**.** Missing doses may increase your risk of getting HIV infection.

Get tested for HIV regularly.

- If you think you were infected with HIV, tell your doctor straight away. They may want to do more tests to make sure you are still HIV negative.
- **Just taking DUOTEMTRIC may not stop you getting HIV.**
    - Always practise safer sex. Use condoms to reduce contact with semen, vaginal fluids or blood.
    - Do not share personal items that can have blood or body fluids on them, such as toothbrushes and razor blades.
    - Do not share or re-use needles or other injection or drug equipment.
    - Get tested for other sexually transmitted infections such as syphilis and gonorrhoea. These infections make it easier for HIV to infect you.

Ask your doctor if you have any more questions about how to prevent HIV or spreading HIV to other people.

DUOTEMTRIC does not cure HIV infection or AIDS. The long-term effects of **DUOTEMTRIC** are not known at this time. People taking **DUOTEMTRIC** may still get infections that happen when their immune system is weak (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 pneumonia, herpes virus infections, and Mycobacterium avium complex (MAC) infection. It is very important that you see your healthcare provider regularly while taking **DUOTEMTRIC.**

DUOTEMTRIC 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 safer sex by using a latex or polyurethane condom or other barrier to lower the chance of sexual contact with semen, vaginal secretions, or blood. Never use or share dirty needles.

Once you start taking **DUOTEMTRIC,** look out for:

- Possible signs of lactic acidosis: Some people taking **DUOTEMTRIC** may develop 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.

Lactic acidosis:

Call your doctor right away if you get the following signs or symptoms of lactic acidosis:

- You feel very weak or tired.
- You have unusual (not normal) muscle pain.
- You have trouble breathing.
- You have stomach pain with nausea and vomiting.
- You feel cold, especially in your arms and legs.
- You feel dizzy or lightheaded.
- You have a fast or irregular heartbeat.
- You may be more likely to get lactic acidosis or liver problems if you are female, very overweight (obese), have been taking medicines, like **DUOTEMTRIC**, for a long time.

Serious liver problems:

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

Call your doctor right away if you get the following signs or symptoms of liver problems:

- Your skin or the white part of your eyes turns yellow (jaundice).
- Your urine turns dark.
- Your bowel movements (stools) turn light in color.

- You don't feel like eating food for several days or longer
- You feel nauseous.
- You have lower stomach area (abdominal) pain.

"Flare-ups" of Hepatitis B Virus infection, in which the disease suddenly returns in a worse way than before, can occur if you stop taking **DUOTEMTRIC**. Your healthcare provider will monitor your condition for several months after stopping **DUOTEMTRIC** if you have both HIV and HBV infection. **DUOTEMTRIC** is not for the treatment of Hepatitis B virus infection.

Changes in bone mineral density (thinning bones):

It is not known whether long term use of **DUOTEMTRIC** will cause damage to your bones. If you have had bone problems in the past, your healthcare provider may need to do tests to check your bone mineral density or may prescribe medicines to help your bone mineral density.

Changes in body fat have been seen in some patients taking **DUOTEMTRIC** 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.

Signs of inflammation or infection soon after you start taking **DUOTEMTRIC**: If you have advanced HIV infection (AIDS) and have an infection, you may develop symptoms of infection and inflammation or worsening of the symptoms of an existing infection once treatment with **DUOTEMTRIC** is started. These symptoms may indicate that your body's improved immune system is fighting infection. If you notice signs of inflammation or infection, tell your doctor immediately.

Important information about some of the ingredients of **DUOTEMTRIC:**

DUOTEMTRIC contains lactose monohydrate. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **DUOTEMTRIC**.

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

Other medicines and DUOTEMTRIC:

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines), DUOTEMTRIC may interact with these other medicines.

Tell your doctor especially if you are taking any of the following:

- Other medicines that contain lamivudine and zidovudine co-formulation; emtricitabine, lamivudine for HIV, lamivudine for HBV, abacavir sulfate and lamivudine co-formulation; abacavir sulfate; or tenofovir disoproxil fumarate. **DUOTEMTRIC** should not be used with these medicines.
- Medicines that contain didanosine. Tenofovir DF (a component of **DUOTEMTRIC**) may increase the amount of didanosine in your blood. You may need to be followed up more carefully if you are taking **DUOTEMTRIC** and didanosine together.
- Atazanavir sulfate and lopinavir/ritonavir. These medicines may increase the amount of tenofovir DF (a component of **DUOTEMTRIC**) in your blood, which could result in more side effects. You may need to be followed up more carefully if you are taking **DUOTEMTRIC** and atazanavir sulfate, lopinavir/ritonavir, ganciclovir, valacyclovir, valganciclovir, cidofovir, aciclovir, adefovir dipivoxil (used for viral infection).
- Non-steroidal anti-inflammatory drugs (NSAIDs); used to relieve bone or muscle pain.

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

Pregnancy, breast-feeding and fertility

Pregnancy

You must not take **DUOTEMTRIC** if you are pregnant, you think you might be pregnant or you are planning to become pregnant. A reliable method of contraception should be used to avoid being pregnant whilst taking **DUOTEMTRIC**.

If you become pregnant, you must contact your doctor, pharmacist or other healthcare professional for advice before taking **DUOTEMTRIC**.

Do not breast-feed during treatment with **DUOTEMTRIC**. It is unknown if the active substances in this medicine pass into human breast milk.

It is recommended that HIV infected women do not breast-feed their infants under any circumstances in order to avoid transmission of HIV to their new-born infant.

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Do not breast-feed during treatment with **DUOTEMTRIC**. It is unknown if the active substances in this medicine pass into human breast milk.

It is recommended that HIV infected women do not breast-feed their infants under any circumstances in order to avoid transmission of HIV to their new-born infant.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machinery:

DUOTEMTRIC can make you weak and dizzy, so care should be taken while driving or using machinery.

3. How to take DUOTEMTRIC :

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

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

Recommended dosage of **DUOTEMTRIC**:

The usual dose of **DUOTEMTRIC** is one tablet once a day with or without food.

If you have kidney problems, your healthcare provider will decide the dose for you.

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

If you take more DUOTEMTRIC than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. Take this leaflet or some tablets with you so that your doctor will know what you have taken.

If you forget to take DUOTEMTRIC

It is important that you do not miss a dose of **DUOTEMTRIC.**

If you notice within 12 hours of the time you usually take **DUOTEMTRIC,** take the tablet preferably with food as soon as possible. Then take the next dose at your usual time.

If you notice 12 hours or more after the time you usually take **DUOTEMTRIC**, forget about the missed dose. Wait and take the next dose, preferably with food, at your usual time.

If you vomit less than 1 hour after taking **DUOTEMTRIC**, take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking **DUOTEMTRIC**.

Effects when treatment with **DUOTEMTRIC** is stopped:

You should not stop treatment unless your doctor instructs you to. When your **DUOTEMTRIC** 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 may increase if the medicine is stopped for even a short time. The virus may develop resistance to emtricitabine + tenofovir DF and become harder to treat.

4. Possible side effects

DUOTEMTRIC can have side effects.

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

Possible serious side-effects

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

- **Allergic reactions** including**:**
  - shortness of breath, wheezing or difficult breathing;
  - swelling of the face, lips, tongue or other parts of the body;
  - rash, itching or hives on the skin.
- **Lactic acidosis** (excess lactic acid in the blood) is a rare but potentially life-threatening side effect. Lactic acidosis occurs more often in women particularly if they are overweight, and in people with liver disease. The following may be signs of lactic acidosis:
  - You feel very weak or tired;
  - You have unusual (not normal) muscle pain;
  - You have trouble breathing;
  - Deep rapid breathing;

- Drowsiness;
- You have stomach pain with nausea and vomiting;
- You feel cold, especially in your arms and legs;
- You feel dizzy or lightheaded;
- You have a fast or irregular heartbeat.

These are very serious side effects. If you have them, you may need urgent medical attention or hospitalisation.

Serious Side Effects:

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

- Serious liver problems including liver enlargement and fat in the liver.
- Once you start taking **DUOTEMTRIC,** look out for:
  - inflammation of the pancreas often with severe upper stomach pain, nausea and vomiting (pancreatitis);
  - numbness or weakness of the arms and legs (neuropathy), painful swelling in the arms or legs (peripheral neuritis), bone problems;
  - feeling of deep sadness and unworthiness (depressive disorder);
  - increase or decrease in the amount of urine passed, this may be a manifestation of kidney disease (renal failure, acute tubular necrosis, proximal renal tubulopathy and nephrogenic diabetes insipidus, fanconi syndrome);
  - tiredness, headaches, being short of breath when exercising, dizziness and looking pale (low number or red blood cells), frequent infections such as fever, severe chills, sore throat or mouth (low number of white blood cells);
  - Serious lung infection with fever, chills, shortness of breath, cough, phlegm and occasional blood (pneumonia).
- **Any signs of inflammation or infection**. In some patients with advanced HIV infection (AIDS) and a history of opportunistic infections (infections that occur in people with a weak immune system), signs and symptoms of inflammation from previous infection may occur soon after anti-HIV treatment is started. It is thought that these symptoms are due to an

improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.

- **Autoimmune disorders**, when the immune system attacks healthy body tissue, may also occur after you start taking medicines to treat HIV infection. Autoimmune disorders may occur many months after the start of treatment. Look out for any symptoms of infection or other symptoms such as:
    - muscle weakness;
    - weakness beginning in the hands and feet and moving up towards the trunk of the body;
    - palpitations, tremor or hyperactivity.

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 (winds);
- 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, but the frequency is unknown:

- Back pain caused by kidney problems;
- anaemia (low red blood cell count), which may include symptoms e.g. fatigue, skin pallor, shortness of breath, dizziness, or 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 in 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 or nurse. This includes any possible side effects not listed in this leaflet. 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 **DUOTEMTRIC**

5. How to store DUOTEMTRIC

Store at or below 25 °C, protected from moisture.

KEEP WELL CLOSED.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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 DUOTEMTRIC contains

DUOTEMTRIC contains emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg per tablet as active ingredients.

The other ingredients are:

Crospovidone, lactose monohydrate, microcrystalline cellulose, magnesium stearate, opadry yellow or opadry pink and sodium citrate.

What DUOTEMTRIC looks like and contents of the pack

White to off white, capsule shaped, film coated tablets debossed with 'RF14' on one side and plain on the other.

30 or 90 Tablets are packed into a white, opaque HDPE bottle together with a desiccant sachet and with a white polypropylene child resistance cap with a heat sea liner.

Each HDPE bottle contains 30 or 90 tablets. The bottle can be packed with or without a carton together with the package insert.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website