**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS** **S4**

**EFLOTELA** (Tablet)

**Fixed dose combination of**

**300 mg of tenofovir disoproxil fumarate,**

**300 mg of lamivudine, and 400 mg of efavirenz**

**Contains sugar (lactose monohydrate 218 mg)**

**Read all of this leaflet carefully before you start taking EFLOTELA**

- 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.
- **EFLOTELA** 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 EFLOTELA is and what it is used for

**EFLOTELA** is used in the treatment of acquired immune deficiency syndrome (AIDS) in adults over 18 years of age.

**EFLOTELA** will not cure or prevent HIV infection or AIDS; however it helps to keep the HIV virus from reproducing and to slow down the destruction of the immune system. **EFLOTELA** will not keep you from spreading HIV to other people.

## 2. What you need to know before you take EFLOTELA

**Do not take EFLOTELA:**

- If you are hypersensitive (allergic) to tenofovir disoproxil fumarate, lamivudine or efavirenz or to any of the other ingredients of **EFLOTELA**.
- If you have had liver problems when taking efavirenz previously.
- If you have severe liver problems.
- If you have moderate to severe kidney problems.
- If you are pregnant or breastfeeding your baby.
- If you are taking medicines containing any of the following: terfenadine, astemizole, cisapride, midazolam, triazolam, pimozide, bepridil, ergot alkaloids, St John's wort (hypericum perforatum), zalcitabine or with elbasvir/grazoprevir.

**Warnings and precautions**

Redistribution, accumulation or loss of body fat may occur. Contact your doctor if you notice changes in body fat.

Within the first few weeks of treatment with anti-HIV medicines, some people, particularly those that have been HIV positive for some time, may develop inflammatory reactions (e.g. pain, redness, swelling, high temperature) which may resemble an infection and may be

severe. It is thought that these reactions are caused by a recovery in the body's ability to fight infections, previously suppressed by HIV. If you become concerned about any new symptoms, or any changes in your health after starting HIV treatment, please discuss with your doctor.

If you experience joint aches and pain, joint stiffness or difficulty in movement, speak to your doctor as it could be a sign of bone problems.

**EFLOTELA** does not cure or prevent HIV infection and the chances of still developing infections or illness associated with HIV is possible.

The use of **EFLOTELA** does not reduce the risk of transmitting the virus to others through sexual contact or blood contamination.

**EFLOTELA** can cause a condition called lactic acidosis (excess of lactic acid in your blood), which causes nausea, vomiting, stomach ache, problems breathing, tiredness and weigh loss.

If you have hepatitis B or C, treatment with **EFLOTELA** can increase severe liver adverse reactions.

**Tell your doctor or healthcare provider before taking EFLOTELA:**

- If you have ever had mental illness or are using medicines for mental illness
- If you have ever had seizures or are taking medicines for seizures
- If you are older than 65 years of age
- If you have serious nervous system and psychiatric symptoms

**Other medicines and EFLOTELA**

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

Tell your doctor if you are taking any of the following medicines as they should not be taken with **EFLOTELA**:

- emtricitabine, lamivudine, indinavir, efavirenz, nelfinavir, saquinavir and didanosine (used to treat HIV infection)
- trimethoprim/sulphamethoxazole (used to treat fungal and bacterial infections) – especially if you have kidney problems
- terfenadine, astemizole, cisapride, midazolam, triazolam, pimozide, bepridil, ergot alkaloids (ergotamine, dihydroergotamine, ergonovine, methylergonovine)
- St John's wort hypericum perforatum), zalcitabine, elbasvir/grazoprevir

**EFLOTELA with food and drink**

Take **EFLOTELA** without food.

**Pregnancy and breastfeeding**

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 this medicine.

**EFLOTELA** should not be used if you are pregnant.

Barrier contraception should always be used in combination with other methods of contraception (for example, oral or other hormonal contraceptives). Women of childbearing potential should undergo pregnancy testing before initiation of **EFLOTELA.**

Women who are HIV-positive must not breast-feed because HIV infection can be passed on to the baby in breast-milk. If you are breast-feeding, or thinking about breast-feeding, talk to your doctor immediately.

**Driving and using machines**

**EFLOTELA** can make you dizzy and you can have other side-effects that may make you less alert. Do not drive or operate machinery if you are not feeling well.

**EFLOTELA contains lactose monohydrate**

**EFLOTELA** contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**3. How to take EFLOTELA**

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

Always take **EFLOTELA** 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 **EFLOTELA** tablet once daily taken orally on an empty stomach.

Your doctor will tell you how long your treatment with **EFLOTELA** will last. If you have the impression that the effect of **EFLOTELA** is too strong or too weak, tell your doctor or pharmacist.

**If you take more EFLOTELA than you should**

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

**If you forget to take EFLOTELA**

Do not take a double dose to make up for forgotten individual doses.

**If you stop taking EFLOTELA**

You should not stop treatment unless your doctor instructs you to. When your **EFLOTELA** 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 **EFLOTELA** and become harder to treat.

## 4. Possible side effects

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

If any of the following happens, stop taking **EFLOTELA** 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,
- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to **EFLOTELA**. You may need urgent medical attention or hospitalisation.

The following are signs of serious liver problems (hepatitis):

- Yellow discolouration of the skin and the white part of your eyeballs
- Darkening of your urine
- Your bowel movements turn lighter in colour
- You feel sick to your stomach (nausea)
- You have stomach pain

You may need urgent medical attention or hospitalisation.

The following are signs of a serious condition called lactic acidosis (build-up of acid in the blood). Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following**:**

- 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

This side effect can cause inflammation of the pancreas, liver and kidney failure, and has occasionally been fatal. Lactic acidosis also occurs more often in women, particularly if they are overweight. If you have liver disease, you may also be more at risk of getting this condition. While you are being treated with **EFLOTELA**, your doctor will monitor you closely for any signs that you may be developing lactic acidosis.

Tell your doctor if you notice any of the following:

*Frequent:*

- dizziness
- diarrhoea, nausea, vomiting, flatulence (wind)
- headache, insomnia (difficulty sleeping)
- cough, nose symptoms
- stomach pain or cramps
- rash, loss of hair
- joint pain, muscle problems

- fatigue (weakness), malaise (feel unwell), fever
- anxiety, depression
- abnormal dreams, disturbance in attention
- sleepiness
- itching

*Less frequent:*
- lactic acidosis (build-up of acid in the blood)
- shortness of breath
- Inflammation of the pancreas, which causes severe pain in the abdomen and back
- increases in enzymes produced by the liver, liver disease
- kidney problems
- asthenia (lack of energy)

- low white blood cell count, low red blood cell count, increased bruising or bleeding (thrombocytopenia), bone marrow stops making red blood cells (pure red cell aplasia)
- peripheral neuropathy (when the nerves carrying messages to and from the brain are damaged)
- rhabdomyolysis (muscle breaks down causing muscle pain, weakness, vomiting and confusion)
- allergy
- aggression, unrealistic feeling of wellbeing, false perceptions, mania, paranoia, suicide thoughts or attempts
- agitation, memory loss, loss of muscle coordination, abnormal coordination, confusion, fits, abnormal thinking, blurred vision
- erythema multiforme (skin eruption)
- increased size of male breasts

*Frequency not known:*

- myopathy (muscle weakness and wasting), osteomalacia (rickets)
- kidney inflammation

**Changes in body fat**. Changes in body fat develop in some patients taking **EFLOTELA**. These changes may include an increased amount of fat in the upper back and neck ("buffalo hump"), in the breasts and around the trunk. Loss of fat from the legs, arms and face may also happen. The cause and long-term health effects of these fat changes are not known.

**Opportunistic infections**. Signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed 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. If you notice any symptoms of infection, please inform your doctor immediately.

**Osteonecrosis** (death of bone tissue caused by loss of blood supply to the bone). You must contact your doctor if you experience joint aches and pain, joint stiffness or difficulty in movement.

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 **EFLOTELA**.

## 5. How to store EFLOTELA

Store all medicines out of reach of children.

Store at or below 25 °C. Store in the original container.

Do not remove from the carton until required for use. Keep the bottles tightly closed.

## 6. Contents of the pack and other information

### What EFLOTELA contains

The active substances are tenofovir disoproxil fumarate 300 mg, lamivudine 300 mg and efavirenz 400 mg per tablet.

The other ingredients are:

Microcrystalline cellulose, croscarmellose sodium, ferric oxide, hydroxypropyl cellulose, magnesium stearate, sodium lauryl sulfate.

Contains sugar (lactose monohydrate 218 mg).

Film coat: Opadry II White {macrogol, polyvinyl alcohol, talc, titanium dioxide.

### What EFLOTELA looks like and contents of the pack

A white to off-white, film-coated, oval, biconvex, beveled edge tablet debossed with M on one side and TLE on the other side.

Tablet dimensions: 21,4 x 10,8 mm, thickness 8,25 mm.

Round, wide mouth, white, high density polyethylene (HDPE) bottle with white opaque polypropylene cap along with desiccant. Pack size: 30 tablets.

Blue high-density polyethylene (HDPE) bottle with blue opaque polypropylene cap along with desiccant. Pack size: 30 tablets.

The HDPE bottle may be placed in an outer cardboard carton.

**Holder of Certificate of Registration**

VIATRIS HEALTHCARE (PTY) LTD

4 Brewery Street,

Isando, Gauteng,

1601

Republic of South Africa

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