PATIENT INFORMATION LEAFLET FOR

TRILEF

SCHEDULING STATUS:

S4

TRILEF film coated tablets

Efavirenz 400 mg, Lamivudine 300 mg and Tenofovir disoproxil fumarate 300 mg

Contains sugar: 133,070 mg of lactose for DC (Tablettose® 80) per tablet

This medicine contains less than 1 mmol sodium (23 mg) per tablet

(9,701 mg sodium per tablet), that is to say essentially “sodium-free”.

Read all of this leaflet carefully before you start taking TRILEF

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

6. Contents of the pack and other information

1. What TRILEF is and what it is used for

TRILEF film coated tablets is used in the treatment of acquired immune deficiency syndrome (AIDS) in adults over 18 years of age.

TRILEF 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.

TRILEF will not keep you from spreading HIV to other people.

2. What you need to know before you take TRILEF

Do not take TRILEF if you:

- are hypersensitive (allergic) to tenofovir disoproxil fumarate, lamivudine or efavirenz or to any of the other ingredients of TRILEF (see **section 6**)
- have had liver problems when taking efavirenz previously
- have severe liver problems
- 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.

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

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

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

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

Tell your doctor or healthcare provider before taking TRILEF:

- 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 TRILEF

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 TRILEF:

- 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.

TRILEF with food and drink

Take TRILEF 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.

TRILEF 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 TRILEF.

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

TRILEF 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.

TRILEF contains 133,070 mg of Lactose for DC (Tablettose® 80) per tablet

TRILEF contains Lactose. 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 TRILEF

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

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

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

If you take more TRILEF 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 TRILEF

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

If you stop taking TRILEF

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

4. Possible side effects

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

If any of the following happens, stop taking TRILEF 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 TRILEF. 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 TRILEF, 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 TRILEF.

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 or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of TRILEF.

5. How to store TRILEF

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original container.

Do not remove from the carton until required for use.

Keep the container tightly closed.

6. Contents of the pack and other information

What TRILEF contains:

The active substances are Efavirenz 400 mg, Lamivudine 300 mg and Tenofovir disoproxil fumarate 300 mg, per tablet.

The other ingredients are Croscarmellose Sodium (Ac-di-sol), Hydroxy propyl cellulose (Klucel LF), Insta Moist-shield AQUA -II (A22G01178) Yellow, Lactose for DC (Tablettose® 80), Magnesium Stearate (Vegetable grade), Microcrystalline Cellulose (Avicel PH 101), Sodium Lauryl Sulfate, Starch 1500 (Pregelatinised Starch), and Yellow oxide of iron.

Contains sugar: 133,070 mg of Lactose for DC (Tablettose® 80) per tablet

Film coat: Insta Moist-shield AQUA -II (A22G01178) Yellow: Lecithin (E322), Polyethylene Glycol (E1521), Polyvinyl Alcohol (E1203), Talc (E553b), Titanium dioxide (E171) and Yellow iron oxide (E172)

What TRILEF looks like and contents of the pack

TRILEF is yellow coloured, oblong shaped, biconvex, film coated tablet with “T4” debossed on one side and plain on other side.

TRILEF film coated tablets are packed as either 28's, 30's or 90's into a white high-density polyethylene (HDPE) container with a white polypropylene screw cap, together with a 3 g silica gel bag in a carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Mispel Street

Bellville

7530

Customer Care: 080 222 6662

This leaflet was last revised in:

Not applicable

Registration number:

TRILEF: 56/20.2.8/0483.482

Access to the corresponding professional information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:

The QR Code to be generated and included after approval