PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

PROPRIETARY NAME AND DOSAGE FORM
TEEVIR (film-coated tablets)
Tenofovir disoproxil fumarate 300 mg, efavirenz 600 mg, emtricitabine 200 mg
Contains sugar (lactose monohydrate 120 mg per tablet).

Read all of this leaflet carefully before you start taking TEEVIR
- 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.
- TEEVIR 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 TEEVIR is and what it is used for
2. What you need to know before you take TEEVIR
3. How to take TEEVIR
4. Possible side effects
5. How to store TEEVIR
6. Contents of the pack and other information

1. What TEEVIR is and what it is used for
TEEVIR is used to treat Human Immunodeficiency Virus (HIV-1) infection. HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). TEEVIR can be given alone or in combination with other antiretrovirals.

2. What you need to know before you take TEEVIR
Do not take TEEVIR:
- If you are allergic to tenofovir disoproxil fumarate or emtricitabine or efavirenz or any of the other ingredients contained in the tablets (See "What TEEVIR contains", for a complete list of ingredients)
- If you have severe liver disease
- If you are currently taking any of the following medicines:
  - astemizole (used to treat hay fever and other allergies)
  - bepridil (used to treat heart disease)
  - cisapride (used to treat heart burn)
  - ergot alkaloids (used to treat migraines and cluster headaches)
  - midazolam and triazolam (used to help you sleep)
  - pimozide (used to treat certain mental conditions)
  - St John's Wort (*Hypericum perforatum*) (a herbal remedy used for depression and anxiety)
  - voriconazole (used to treat fungal infections)

If you are taking any of these medicines, tell your doctor immediately. Taking these medicines with TEEVIR could cause serious or life-threatening side effects or stop these medicines from working properly.
- If you have kidney problems or are undergoing kidney dialysis treatment
- If you are pregnant or planning to become pregnant
- If you are breast-feeding your baby
- If you are younger than 18 years of age as safety and efficacy has not been established in paediatric and adolescent patients

Do not take TEEVIR if you are already taking lamivudine/zidovudine, lamivudine, abacavir sulphate/lamivudine, abacavir sulphate/lamivudine/zidovudine, tenofovir disoproxil fumarate, efavirenz,

emtricitabine or adefovir dipivoxil because these medicines contain the same or similar active ingredients.

Warnings and precautions
Take special care with TEEVIR:

- If you have bone problems, including previous bone breaks
- If you have liver problems, including hepatitis B infection
- 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 that 65 years of age
- If you are taking other medicines, as TEEVIR may interact with these other medicines
- If you use medicines that may affect your kidney function since use of such medicines in combination with TEEVIR will require careful monitoring of your kidney function. Speak to your doctor about this.
- If you have serious nervous system and psychiatric symptoms

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

To protect other people from becoming infected with HIV:

- use a condom when you have oral or penetrative sex
- do not risk blood transfer – for example, do not share needles

Children and adolescents
Do not give TEEVIR to children who are younger than 18 years of age as safety and efficacy has not been established in paediatric and adolescent patients.

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

The following medicines should not be taken with TEEVIR:

- Other products which contain tenofovir disoproxil fumarate, efavirenz, emtricitabine, or lamivudine either alone or as combination pills. TEEVIR should not be used with those medicines because they contain the same or similar active ingredients as found in TEEVIR.
- Adefovir dipivoxil for the treatment of Hepatitis B infection due to the increased risk of kidney damage if combined with TEEVIR.
- Medicines that contain didanosine (another antiretroviral). Tenofovir disoproxil fumarate (a component of TEEVIR) may increase the amount of didanosine in your blood, and the risk of side effects.
- Atazanavir sulphate or atazanavir/ritonavir in a combination pill. These medicines may increase the amount of tenofovir disoproxil fumarate (a component of TEEVIR) in the blood, which could result in more side effects
- St John's Wort
- Astemizole, cisapride, midazolam, triazolam, or ergot derivatives as efavirenz (a component of TEEVIR) could prevent break down of these medicines and may cause side effects such as abnormal heart rhythm and breathing problems.
- Other medicines used for HIV infection: amprenavir, indinavir, lopinavir/ritonavir combination pill, ritonavir, or saquinavir
- Medicines used to treat fungal infections (antifungals): Itraconazole and ketoconazole since no dosage recommendations are available when used in combination with TEEVIR.
- Voriconazole

- Medicines called calcium channel blockers could be affected by TEEVIR if taken together. These include diltiazem, and other calcium channel blockers such as verapamil, felodipine, nifedipine and nicardipine

- Medicines such as cidofovir, acyclovir, valacyclovir, ganciclovir and valganciclovir. These compete for excretion by the kidney
- Selective serotonin reuptake inhibitors (SSRI's) for the treatment of depression.
- Medicines used to lower blood fats (also called statins): atorvastatin, simvastatin and pravastatin. TEEVIR can reduce the amount of statins in your blood.
- Medicines used to treat convulsions/seizures (anticonvulsants): carbamazepine, phenytoin and phenobarbital. TEEVIR can reduce the amount of anticonvulsant medicine in your blood. Carbamazepine can reduce the amount of efavirenz, one of the components of TEEVIR, in your blood
- Medicines used to treat bacterial infections, including tuberculosis and AIDs-related infections: clarithromycin, rifabutin and rifampicin.
- Indinavir (another antiretroviral)
- Hormonal contraceptives (e.g. the pill or contraceptive implant). Because the potential for efavirenz, one of the components of TEEVIR, to interact with hormonal contraceptives has not been fully studied, a reliable method of barrier contraception (e.g. a condom) should always be used in addition to the hormonal contraceptive (see Pregnancy and breast-feeding)
- Methadone, a medicine used to treat opiate addiction
- Sertraline, a medicine used to treat depression

TEEVIR with food and drink
TEEVIR must be swallowed whole with water on an empty stomach.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think 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.
TEEVIR is contraindicated in pregnancy.
Do not breast feed your baby if you are taking TEEVIR.

Driving and using machines
TEEVIR may cause dizziness which can affect your ability to drive a car or operate machines.

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

3. HOW TO TAKE TEEVIR
Do not share medicines prescribed for you with any other person.
Always take TEEVIR exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one tablet taken once daily without food.
Take TEEVIR at bedtime which will make some side effects less bothersome

Your doctor will tell you how long your treatment with **TEEVIR** will last.
Do not run out of TEEVIR tablets. The virus in your blood may increase and the virus may become harder to treat.
If you have the impression that the effect of TEEVIR is too strong or too weak, tell your doctor or pharmacist.

If you take more TEEVIR 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 TEEVIR
Do not take a double dose to make up for forgotten individual doses.
Do not miss a dose of TEEVIR.
If you miss a dose of TEEVIR take it as soon as you remember.

If you stop taking TEEVIR
You should not stop treatment unless your doctor instructs you to. When your TEEVIR supply starts to run low, get more from your healthcare provider or pharmacy. This is very important as 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 TEEVIR and become harder to treat.

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

If any of the following happens, stop taking TEEVIR and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Swelling of the mouth, face, lips or tongue
- Difficulty in swallowing or breathing

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

Lactic acidosis (build up of an 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 weak and tired
- You have unusual muscle pain
- You have stomach pain with nausea and vomiting
- You feel cold especially in your arms and legs
- You feel dizzy and lightheaded
- You have a fast and irregular heartbeat

These could be a sign of lactic acidosis. Lactic acidosis can be a medical emergency and may need to be treated in hospital.

Serious liver problems (hepatotoxicity), with liver enlargement (hepatomegaly) and fat in the liver (steatosis)
Call your doctor right away if you get any of the following signs of liver problems:
- 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

Worsening of hepatitis B virus infection
TEEVIR tablets are not for use to treat chronic hepatitis B virus (HBV) infection. If you have hepatitis B virus (HBV) infection and take TEEVIR tablets, your HBV may get worse (flare-up) if you stop taking TEEVIR tablets. A “flare-up” is when your HBV infection suddenly returns in a worse way than before.

Serious psychiatric problems
Some patients may experience severe depression, strange thoughts, and thoughts of suicide or angry behaviour while taking TEEVIR. Contact your doctor right away if you think you are having these psychiatric symptoms.

Kidney problems
Should you notice blood in your urine, have difficulty or painful urination, and pain in the lower back, contact your doctor immediately.

Other side-effects include:
Frequent side effects:
Headache
Asthenia (low muscle strength)
Increased cough
Rhinitis (stuffy nose)

Nausea
Diarrhoea
Vomiting
Dizziness
Problems concentrating
Sleepiness
Inability to sleep
Rash
Itch
Increased sweating
Fatigue (lack of energy)
Pain

Less frequent side effects:
Neuritis (inflammation of a nerve causing pain)
Paraesthesia (pins and needles)
Peripheral neuropathy (weakness, numbness and pain from nerve damage, usually in the hands and feet)
Depression
Abnormal dreams
Abdominal pain (belly ache)
Dyspepsia (indigestion)
Changes in skin colour
Arthralgia (joint pain)
Myalgia (muscle pain)
Anorexia (loss of appetite)
Flatulence (gas)
Liver problems
Hypoaesthesia (decreased sense of touch)

The following side effects are reported but the frequency is not known:
Neutropenia (low number of white blood cells)
Anaemia (low number of red blood cells)
Lactic acidosis (low acidity in the bloodstream)
A high level of a certain type of fat (triglycerides) in the blood
Hyperglycaemia (high blood sugar levels)
Blood in urine
Allergic reactions
Increased levels of phosphate in the blood
Anxiety
Chest pain
Lung infection
Difficulty breathing
Pancreatitis (inflammation of the pancreas causing belly ache)
Inflammation of the liver
Back pain
Kidney problems
Fever
Weight loss
Weight gain
Problems with balance and coordination
Fits
Tremor (shaking)
Amnesia (memory loss)
Increased appetite
Confusion
Impotence (loss of male sexual ability)
Changes in sexual drive
Neuralgia (nerve pain)
Speech problems

Vertigo (spinning sensation)
Apathy (lacking emotion)
Emotional behaviour
Seeing things that aren't there
Problems with eye sight
Ringing or buzzing noise in the ears
Reddening of the skin
Palpitations (fast, irregular heartbeat)
Tachycardia (fast heartbeat)
Asthma
Sinusitis
Gastritis (stomach inflammation)
Gastro-enteritis (stomach flu)
Gastro-oesophageal reflux (stomach acid irritates the food pipe lining)
Constipation
Malabsorption (poor absorption of nutrients)
Change in sense of taste
Acne
Hair loss
Eczema (itchy inflammation of the skin)
Infection of the pockets from which hair grows (follicles)
Seborrhea (scaly patches and red skin, mainly on the scalp)
Skin peeling
Erythema multiforme (skin or mouth lesions that have a pink-red centre surrounded by a pale ring border and an outer pink-red ring)
Nail problems
Stevens-Johnson syndrome (Flu-like symptoms appear first. A painful rash that spreads and blisters follow)
Myopathy (muscle disease resulting in muscular weakness)
Alcohol intolerance
Flu-like symptoms
Malaise (general sense of being unwell)
Fainting
Redistribution/accumulation of body fat

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. 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 TEEVIR.

5. How to store TEEVIR
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 bottle tightly closed.

6. Contents of the pack and other information
What TEEVIR contains
The active substances are tenofovir disoproxil fumarate 300 mg, efavirenz 600 mg and emtricitabine 200 mg, per tablet.
The other ingredients are:
Croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate.
Film coat: black iron oxide, iron oxide red, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide.

What TEEVIR looks like and contents of the pack
Pink coloured, capsule-shaped, film-coated tablets, debossed with "M171" on one side and plain on the other side.debossed with M on one side of the tablet and TD1 on the other side.

TEEVIR is packed in high density polypropylene (HDPE) bottle pack comprising of white or blue, opaque, wide mouth HDPE bottle with a white or blue opaque polypropylene (PP) screw closure with desiccant sachet or desiccant canister, packed in an outer carton in 28's and 30's.
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