SCHEDULING STATUS S4

TELATRI 50 mg/ 300 mg/ 300 mg film coated tablets

Dolutegravir, Lamivudine and Tenofovir disoproxil fumarate

Contains sugar: Mannitol 144,5 mg per tablet

WARNING:

LACTIC ACIDOSIS (A BUILD UP OF LACTIC ACID IN THE BODY) AND SEVERE, POTENTIALLY FATAL LIVER COMPLICATIONS (LIVER ENLARGEMENT), HAVE BEEN REPORTED WITH THE USE OF NUCLEOSIDE ANALOGUES ALONE OR IN COMBINATION WITH OTHER ANTIRETROVIRALS (see 'Take special care with TELATRI').

TELATRI IS NOT USED FOR THE TREATMENT OF CHRONIC HEPATITIS B VIRUS (HBV) INFECTION. IT IS NOT KNOWN IF TELATRI IS SAFE AND EFFECTIVE IN PEOPLE WHO HAVE BOTH HUMAN IMMUNODEFICIENCY VIRUS (HIV) AND HBV INFECTION. IF YOU HAVE BOTH HUMAN IMMUNODEFICIENCY VIRUS AND HEPATITIS B VIRUS INFECTION, YOUR HBV INFECTION MAY GET WORSE IF YOU STOP TAKING TELATRI. IN THIS CASE, YOUR DOCTOR SHOULD CLOSELY MONITOR YOUR LIVER FUNCTION FOR AT LEAST SEVERAL MONTHS AFTER YOU HAVE STOPPED TAKING TELATRI. IF APPROPRIATE, YOUR DOCTOR MAY

START YOU ON ANTI-HEPATITIS B TREATMENT (see 'Take special care with TELATRI').

Read all of this leaflet carefully before you start taking TELATRI

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

TELATRI contains three active ingredients used to treat human immunodeficiency virus (HIV) infection: tenofovir, lamivudine and dolutegravir *(known as anti-retrovirals)*. Tenofovir and lamivudine are nucleoside analogue reverse transcriptase inhibitors (*NRTIs*), and dolutegravir is an integrase inhibitor (*INI*).

TELATRI is used to treat HIV-1 infection in adults aged 18 years or over.

2. What you need to know before you take TELATRI Do not take TELATRI :

- if you are hypersensitive (allergic) to lamivudine, tenofovir disoproxil fumarate,

dolutegravir or any of the other ingredients of **TELATRI**

- if you are taking another medicine called dofetilide or pilsicainide (to treat heart conditions)
- if you are taking a medicine called metformin (to treat diabetes)
- if you have moderate or severe liver disease
- if you have kidney problems
- if you are talking a medicine containing adefovir dipivoxil (to treat chronic hepatitis B)
- if you are taking a medicine called didanosine (to treat HIV infection)

Warnings and precautions

Take special care with TELATRI:

- **If you develop rash**. Some people taking dolutegravir (one of the ingredients of **TELATRI**) **have had allergic reactions**.

- **Take care not to infect other people.** HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor on the precautions needed to avoid infecting other people. This medicine does not reduce the risk of passing on hepatitis B virus (HBV) to others through sexual contact or blood contamination. You must continue to take precautions to avoid this. 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, don't share needles.

- **Talk to your doctor or pharmacist if you have had kidney disease or if tests have shown problems with your kidneys.** Before starting treatment, your doctor may carryout blood tests to assess your kidney function. **TELATRI** may affect your kidney functions during treatment.

  TELATRI is not usually taken with other medicines that can damage your kidneys (see **'other medicines and TELATRI'**). If this is unavoidable, your doctor will monitor your kidney functions once a week.

- **Joint pain, stiffness and bone problems.** Some adult patients with HIV taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). People may be more likely to get this condition:
  - if they have been taking combination therapy for a long time
  - if they are also taking anti-inflammatory medicines called corticosteroids
  - if they drink alcohol
  - if their immune systems are very weak
  - if they are overweight

  Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms tell your doctor.

  Bone problems (sometimes resulting in fractures) may also occur due to damage to kidney tubule cells (**also see section 4, 'Possible side effects'**).

- **Talk to your doctor if you have a history of liver disease, including hepatitis.** Patients with liver disease including chronic hepatitis B or C, who are

treated with antiretrovirals, have a higher risk of severe and potentially fatal liver complications. If you have hepatitis B infection, your doctor will carefully consider the best treatment for you. If you have a history of liver disease or chronic hepatitis B infection, your doctor may conduct blood tests to monitor your liver function. If you have hepatitis B infection, you should not stop treatment without instructions from your doctor, as you may have a recurrence of your hepatitis. This recurrence may be more severe if you have serious liver disease.

Look out for infections. If you have advanced HIV (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 this medicine is started (*opportunistic infections*). Such infections may have been "silent" and not detected by the weak immune system before treatment was started. After starting treatment, the immune system becomes stronger, and may attack the infections, which can cause symptoms of infection or inflammation. Symptoms usually include fever, plus some of the following: headache, stomach ache, difficulty breathing. These symptoms may indicate that your body's improved immune system is fighting infection. Look out for signs of inflammation or infection soon after you start taking this medicine. If you notice signs of inflammation or infection, **tell your doctor at once.**

In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders (such a Graves' disease) may occur many months after the start of treatment. If you notice 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, rapid or irregular heartbeat (palpitations), tremor or excessive restlessness and movement (hyperactivity), **please inform your doctor immediately to seek necessary treatment.**
Don't take other medicines for the infection without your doctor's advice.

- **Lactic acidosis**. Females, particularly if very overweight, and patients with liver disease may be more at risk of getting a rare, but serious side effect called lactic acidosis, a build-up of lactic acid in the body. It can cause enlargement of the liver, fatty liver and has occasionally been fatal. It usually develops after a few months of treatment. Deep rapid breathing, drowsiness, and non-specific symptoms such as nausea, vomiting and stomach pain, might indicate the development of this condition. While you are being treated with this medicine your doctor or health care provider will monitor you for any signs that you may be developing lactic acidosis.

- **Pancreatitis.** Inflammation of the pancreas has been observed in some patients receiving lamivudine (one of the ingredients of **TELATRI**). However, it is unclear whether this is due to treatment with the medicinal product or to HIV disease. The symptoms of this are abdominal pain, nausea and vomiting. If you develop these symptoms you should contact your doctor for advice.

- **Talk to your doctor or pharmacist if you are over 65 years of age.**

- **Redistribution or accumulation of body fat** including central obesity may occur in patients receiving combination antiretroviral treatment. Contact your doctor if you notice changes in body fat.

- **Combination therapy for HIV can cause**:
    - increased levels of lactic acid in the blood, which can lead to lactic acidosis
    - increased levels of sugar and fats (triglycerides and cholesterol) in the blood
    - resistance to insulin (so if you are diabetic, you may have to change your insulin dose to control your blood sugar).

- **Care should be taken in children whose mothers took class of anti- HIV drugs known as nucleoside and nucleotide analogues during pregnancy**. Variable degree of mitochondrial dysfunction (characterised by decreased blood cells, disorders of metabolism, late onset neurological disorders) have been reported in such children.

- **You should not take** medicines containing lamivudine, tenofovir or emtricitabine.

- During HIV therapy there may be an **increase in weight and in levels of blood lipids and glucose**. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

While you are taking TELATRI, you will need regular blood tests.

For as long as you are taking **TELATRI**, your doctor will arrange regular blood tests to check for side effects. There is more information about these side effects in this leaflet. **See 'Possible side effects'**.

TELATRI does not cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. It also increases the number of CD4 cells in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

Other medicines and TELATRI

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

- **Do not take TELATRI if you are:**
    - already taking other medicines containing tenofovir disoproxil fumarate, tenofovir alafenamide, emtricitabine or lamivudine (medicines used to treat HIV infection or hepatitis B infection)
    - taking dofetilide or pilsicainide (used to treat heart conditions) or metformin (used to treat diabetes)
    - taking high doses of co-trimoxazole (an antibiotic)
    - taking cladribine (used to treat hairy cell leukaemia)
    - taking medicines containing adefovir dipivoxil (a medicine used to treat chronic hepatitis B)
    - taking medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol).
    - taking medicines containing didanosine (for HIV infection) [taking this medicine with other antiviral medicines that contain didanosine can raise the levels of didanosine in your blood and may reduce CD4 cell counts. Rarely, inflammation of the pancreas and lactic acidosis (excess lactic acid in the blood), which sometimes caused death, have been reported when medicines containing tenofovir disoproxil fumarate and didanosine were taken together].

- **It is very important to tell your doctor if you are taking other medicines that may damage your kidneys.**

  These include:

  - aminoglycosides, vancomycin (for bacterial infection)
  - amphotericin B, pentamidine (for fungal infection)
  - foscarnet, ganciclovir, acyclovir, valaciclovir, valganciclovir or cidofovir (for viral infection)
  - interleukin-2 (to treat cancer)
  - tacrolimus (for suppression of the immune system).

- **Some medicines can affect how TELATRI works, or make it more likely that you will have side effects. This medicine can also affect how some other medicines work**. Tell your doctor if you are taking any of the medicines in the following list:

  - medicines called antacids (to treat indigestion and heartburn). Do not take an antacid during the 6 hours before you take this medicine, or for at least 2 hours after you take it
  - calcium supplements, iron supplements and multivitamins. Do not take a calcium supplement, iron supplement or multivitamin during the 6 hours before you take this medicine, or for at least 2 hours after you take it
  - etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine, tipranavir/ritonavir, zalcitabine, atazanavir, indinavir, lopinavir/ritonavir, abacavir or atazanavir/ritonavir (to treat HIV infection)
  - isoniazid, rifampicin [to treat tuberculosis (TB) and other bacterial infections]
  - phenytoin and phenobarbital (to treat epilepsy)
  - oxcarbazepine and carbamazepine (to treat epilepsy or bipolar disorder)

- St. John's wort (*Hypericum perforatum*) [herbal remedy to treat depression]
- ledipasvir/sofosbuvir or sofosbuvir/velpatasvir (to treat hepatitis C infection).

Tell your doctor or pharmacist if you are taking any of these. Your doctor may decide to adjust your dose or that you need extra check-ups.

TELATRI with food and drink TELATRI can be taken with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant, or if you are planning to have a baby:

→ **Talk to your doctor** about the risks and benefits of taking **TELATRI**.

Taking **TELATRI** at the time of becoming pregnant or during the first six weeks of pregnancy, may increase the risk of a type of birth defect, called neural tube defect, such as spina bifida (malformed spinal cord).

If you could get pregnant while receiving **TELATRI**:

→ **Talk to your doctor** and discuss whether there is a need for contraception, such as condom or pills.

Tell your doctor immediately if you become pregnant or are planning to become pregnant. Your doctor will review your treatment. Do not stop taking **TELATRI** without consulting your doctor, as this may harm you and your unborn child.

Breast-feeding

Women who are HIV-positive must not breast-feed because the HIV infection can be passed on to the baby in breast milk.

A small amount of the ingredient in **TELATRI** can pass into your breast milk. If you are breast-feeding, or thinking about breast-feeding:

→ **Talk to your doctor immediately.**

TELATRI contains mannitol and may have a mild laxative effect.

Driving and using machines

This medicine can make you dizzy and have other side effects that make you less alert. Don't drive or operate machinery unless you are sure your alertness has not been affected.

3. How to take TELATRI

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

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

The usual dose is:

Adults *(aged 18 years or over)*:

1 tablet each day with or without food.

Always take the dose recommended by your doctor. This is to make sure that your medicine is fully effective, and to reduce the risk of developing resistance to the treatment. Do not change the dose unless your doctor tells you to.

Swallow **TELATRI** whole with water.

Use in children and adolescents

TELATRI is not for children and adolescents under 18 years of age.

Your doctor will tell you how long your treatment with **TELATRI** will last. Do not stop treatment unless your doctor advises you to.

If you have the impression that the effect of **TELATRI** is too strong or too weak, tell your doctor or pharmacist.

If you take more TELATRI than you should

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

Take the tablet container with you so that you can easily describe what you have taken.

If you forget to take TELATRI

If you miss a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with TELATRI is stopped:

Don't stop **TELATRI** without advice from your doctor. Take **TELATRI** for as long as your doctor recommends. If you have stopped taking **TELATRI** for any reason, particularly because you think you are having side effects or for other illness, it is important that you contact your doctor before restarting. In some cases your doctor will ask you to restart **TELATRI** in a place where you will be able to get ready access to medical care if needed.

It is important to take **TELATRI** once daily on a regular dosing schedule and to avoid missing doses as it can also result in the development of resistance.

4. Possible side effects

TELATRI can have side effects.

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

When you are being treated for HIV, it can be hard to tell whether a symptom is a side effect of this medicine or other medicines you are taking, or an effect of the HIV disease itself. So it is very important to talk to your doctor about any changes in your health.

In addition to the side effects listed below for this medicine, other conditions can develop during combination therapy for HIV. It is important to read the information in this section under the heading 'Other possible side effects of combination therapy for HIV'.

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

- allergic reactions (symptoms include skin rash, fever, lack of energy, swelling, sometimes of the face or mouth *(angioedema)*, causing difficulty in breathing, muscle or joint aches)
- lactic acidosis (excess lactic acid in the blood). Symptoms include deep, rapid breathing, drowsiness, feeling sick, vomiting and stomach pain
- pain in the abdomen (stomach), caused by inflammation of the pancreas *(pancreatitis)*
- yellow skin or eyes, itching, or pain in the abdomen (stomach) caused by

inflammation of the liver *(hepatitis)*

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

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

Frequent

- changes to your urine and back pain caused by kidney problems, including kidney failure
- passing a lot of urine and feeling thirsty

Less Frequent

- breakdown of muscle fibers and pain in muscles *(rhabdomyolysis)*
- softening of the bones (with bone pain and sometimes resulting in fractures), which may occur due to damage to kidney tubule cells
- inflammation of the kidney
- fatty liver
- decrease in the number of cells involved in blood clotting *(thrombocytopenia)*
- low red blood cell count, which can make you tired and out of breath *(anaemia)* or low white blood cell count which could make you more prone to infection *(neutropenia)*
- an inflammatory condition which may develop as the immune system becomes stronger *(immune reconstitution syndrome)*

Frequency unknown

- failure of the bone marrow to produce new red blood cells *(pure red cell aplasia)*

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

Tell your doctor if you notice any of the following:

Frequent side effects

- headache
- loss of appetite *(anorexia)*
- heartburn
- dizziness
- loose stools
- *nausea*
- *vomiting*
- rash, itching
- feeling weak
- decreases in phosphate in the blood
- difficulty in sleeping (*insomnia*)
- cough
- irritated or runny nose
- wind (*flatulence*)
- stomach pain or cramps
- hair loss
- joint pain
- feeling tired
- fever

- feeling generally unwell *(malaise)*
- abnormal dreams
- anxiety
- feelings of deep sadness and unworthiness *(depression)*
- increase in the level of liver enzymes/ liver problems
- increase in the level of enzymes produced in the muscles (*creatine phosphokinase, creatinine*)
- increased levels of lactate in the blood
- abnormally high levels of protein in the urine *(proteinuria)*

Less Frequent side effects

- muscle pain and discomfort
- muscle weakness
- suicidal thoughts and behaviours (particularly in patients who have had depression or mental health problems before)
- decrease in potassium in the blood
- muscle pain or weakness *(myopathy)*
- increase in an enzyme called amylase
- tingling or numbness of the arms, legs, hands or feet
- increased amount of fat in upper back and neck *(lipodystrophy)*
- decrease in bone mineral density

The breakdown of muscle, softening of the bones (with bone pain and sometimes resulting in fractures), muscle pain, muscle weakness and decreases in potassium or phosphate in the blood may occur due to damage to kidney tubule cells.

Frequency not known

- stomach discomfort
- shortness of breath

Other possible side effects of combination therapy for HIV:

Combination therapy such as **TELATRI** may cause other conditions to develop during HIV treatment (see **'Take special care with TELATRI'**).

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: Suspected adverse reactions can also be reported directly to the HCR via email: pharmacovigilance.africasme@sunpharma.com or Tel: +27(0) 12 643 2000

By reporting side effects, you can help provide more information on the safety of **TELATRI**.

5. How to store TELATRI

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from moisture and light.

Keep in the original container until required for use.

Keep the container tightly closed.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewage systems (e.g. toilet)

6. Contents of the pack and other information

What TELATRI contains

TELATRI contains three active substances. The active substances are dolutegravir sodium equivalent to dolutegravir 50 mg, lamivudine 300 mg and tenofovir disoproxil fumarate 300 mg.

The other ingredients are: Croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose, povidone, sodium starch glycolate. The tablets are film-coated with a coating material Opadry II 85F580019 (White) containing macrogol/PEG, polyvinyl alcohol-part hydrolyzed, talc, and titanium dioxide.

What TELATRI looks like and contents of the pack

White to off-white film coated, caplet shaped tablets plain on both side.

Contents of the pack:

The film coated tablets are packed in a white opaque HDPE bottle pack of 28's, 30's, 84's and 90's with 3 g silica or 5 g silica as desi**c**cant and a white opaque polypropylene screw cap with an induction seal liner; with or without a carton.

Holder of Certificate of Registration

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