SCHEDULING STATUS: **S4**

ADCO TENOFOVIR 300 mg (Tablets)
Tenofovir disoproxil fumarate 300 mg equivalent to 245 mg of tenofovir disoproxil
Contains sugar (163,998 mg lactose monohydrate per tablet)

WARNING:
ADCO TENOFOVIR 300 mg MAY LEAD TO SERIOUS PROBLEMS WITH YOUR LIVER OR CAUSE TOO MUCH ACID IN YOUR BLOOD. IF LEFT UNTREATED, THIS MAY EVEN CAUSE DEATH. THE SAFETY AND EFFECTIVENESS OF ADCO TENOFOVIR 300 mg IN PATIENTS WHO ARE INFECTED WITH BOTH HUMAN IMMUNODEFICIENCY VIRUS (HIV) AND HEPATITIS B VIRUS (HBV) HAS NOT BEEN ESTABLISHED.
ADCO TENOFOVIR 300 mg SHOULD NOT BE USED FOR THE TREATMENT OF CHRONIC HBV INFECTION. YOU SHOULD BE CLOSELY MONITORED BY YOUR DOCTOR FOR SEVERAL MONTHS IF YOU ARE INFECTED WITH HBV AND DISCONTINUE THE USE ADCO TENOFOVIR 300 mg.

Read all of this leaflet carefully before you start taking ADCO TENOFOVIR 300 mg

- 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.
- ADCO TENOFOVIR 300 mg 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 ADCO TENOFOVIR 300 mg is and what it is used for

ADCO TENOFOVIR 300 mg is an antiretroviral medicine and is used in the treatment of the infection caused by the human immunodeficiency virus (HIV). HIV is the virus that causes acquired immunodeficiency syndrome (AIDS). ADCO TENOFOVIR 300 mg must always be used in combination with other antiretroviral medicines.

2. What you need to know before you take ADCO TENOFOVIR 300 mg

ADCO TENOFOVIR 300 mg is not a cure for HIV infection or AIDS. People taking

ADCO TENOFOVIR 300 mg may still develop infections or other illnesses associated with HIV disease and AIDS. It is therefore important that you remain under the supervision of your doctor while taking ADCO TENOFOVIR 300 mg. ADCO TENOFOVIR 300 mg does not reduce the risk of passing HIV to others through sexual contact or blood contamination. You should use appropriate precautions.

Do not take ADCO TENOFOVIR 300 mg:

- If you have ever had an allergic reaction to tenofovir, or any of the other ingredients in this tablet (listed in section 6).
- If you have kidney failure.
- If you have chronic hepatitis B virus infection.
- If you are pregnant or breastfeeding.
- If you are already taking an antiretroviral medicine that contains a combination of emtricitabine and tenofovir disoproxil fumarate because ADCO TENOFOVIR 300 mg contains one of the active ingredients in these medicines.
- If you are already taking another medicine that contains tenofovir.
- If you are taking a medicine that contains adefovir dipivoxil.

Warnings and precautions

Take special care with ADCO TENOFOVIR 300 mg:

- Make sure you tell your doctor if you have any of the following medical problems: Kidney disease, liver disease or hepatitis B virus infection. If you have kidney problems, your doctor may need to monitor your kidney function before you start taking and while you are taking ADCO TENOFOVIR 300 mg.
- Make sure you tell your doctor if you are using any of the following medicines together with ADCO TENOFOVIR 300 mg as your doctor may need to change the dose or how often you use one or both of the medicines: Didanosine, atazanavir, lopinavir-ritonavir combination and other medicines that are toxic to the kidneys (see "*Other medicines and ADCO TENOFOVIR 300 mg*").
- ADCO TENOFOVIR 300 mg may cause bone abnormalities. Your doctor will monitor if you have a history of bone fractures or have osteoporosis, and you may need to take calcium and vitamin D supplements.
  Tell your doctor if you experience any problems with your bones or muscles, including bone or muscle pain, muscle weakness, joint stiffness or find it difficult to move (see section 4: "*Possible side effects*").
- Treatment with ADCO TENOFOVIR 300 mg has been associated with a change in body fat seen as an accumulation of fat on the stomach and back, and loss of fat on the face, arms and legs.
- Look out for infections. If you have advanced HIV infection (AIDS) and have an infection, you may develop symptoms of such an infection (or worsening of the symptoms of an existing infection) once you start taking ADCO TENOFOVIR 300 mg. This may indicate that your body's improved immune system is fighting the infection. If you notice signs of infection, tell your doctor at once (see section 4: "*Possible side effects*").

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 HIV. Such immune problems may occur many months after you have started taking ADCO TENOFOVIR 300 mg. If you notice any symptoms such as palpitations, tremor or hyperactivity, tell your doctor immediately.

- If you are over the age of 65 years, you may be more sensitive to the effects of ADCO TENOFOVIR 300 mg. Your doctor will monitor you more carefully.

Children and adolescents

The safety and effectiveness of ADCO TENOFOVIR 300 mg in children and adolescents younger than 18 years of age is not known.

Other medicines and ADCO TENOFOVIR 300 mg

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

Tell your doctor if any of the below applies to you:

- ADCO TENOFOVIR 300 mg should be used with caution with didanosine, as the blood levels of didanosine may be increased. The didanosine dose may need to be reduced.
- ADCO TENOFOVIR 300 mg should not be taken with other medicines that may damage your kidneys. These include: Acyclovir, adefovir dipivoxil, aminoglycosides, amphotericin B, cidofovir, foscarnet, ganciclovir, interleukin-2, pentamidine, vancomycin, valacyclovir and valganciclovir.
- ADCO TENOFOVIR 300 mg blood levels may be increased when taken with atazanavir and lopinavir-ritonavir combination, and should be used with caution.
  ADCO TENOFOVIR 300 mg may decrease the amount of atazanavir in your blood. If you take ADCO TENOFOVIR 300 mg and atazanavir together, you should also be taking ritonavir.
- Blood levels of lamivudine and indinavir may be decreased when it they are taken together with ADCO TENOFOVIR 300 mg.
- Non-steroidal anti-inflammatory medicines (NSAIDs): when these medicines are used at a high dose or many NSAIDs are used together, there is a risk of serious kidney problems when used together with ADCO TENOFOVIR 300 mg. Speak to your health care provider for alternative medicines that can be used. Examples of NSAIDs include aspirin, diclofenac and ibuprofen.
- The blood levels of ADCO TENOFOVIR 300 mg can be increased when used with ledipasvir and sofosbuvir or sofosbuvir and velpatasvir, or a combination of sofosbuvir, velpatasvir and voxilaprevir co-formulation. These medicines are used for a liver problems like hepatitis C and can cause an increase in side effects of ADCO TENOFOVIR 300 mg if taken with ADCO TENOFOVIR 300 mg.

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.

Pregnancy: ADCO TENOFOVIR 300 mg should not be used during pregnancy. You should use adequate contraceptive methods. Avoid falling pregnant while using
ADCO TENOFOVIR 300 mg.

Breastfeeding: ADCO TENOFOVIR 300 mg should not be used while breastfeeding.

Driving and using machines
It is not always possible to predict to what extent ADCO TENOFOVIR 300 mg may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which ADCO TENOFOVIR 300 mg affects you.

ADCO TENOFOVIR 300 mg can cause dizziness which can affect your ability to drive or use machines. Therefore, you should not drive, use machinery or perform any tasks that require concentration until you are certain that ADCO TENOFOVIR 300 mg does not affect your ability to do so safely.

ADCO TENOFOVIR 300 mg contains lactose monohydrate and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
ADCO TENOFOVIR 300 mg contains less than 1 mmol sodium (23 mg) tablet; that is to say it is essentially ‘sodium-free’.

3. How to take ADCO TENOFOVIR 300 mg
Do not share medicines prescribed for you with any other person.

Always take ADCO TENOFOVIR 300 mg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of ADCO TENOFOVIR 300 mg is as follows:
1 tablet (300 mg) once daily, with or without food. Do not chew the tablet.

It is important that you take ADCO TENOFOVIR 300 mg exactly as directed by your doctor. Your doctor will tell you how long your treatment with ADCO TENOFOVIR 300 mg will last. Even if you feel better, do not stop taking ADCO TENOFOVIR 300 mg without talking to your doctor.

If you have the impression that the effect of ADCO TENOFOVIR 300 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more ADCO TENOFOVIR 300 mg than you should

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

If you forget to take ADCO TENOFOVIR 300 mg
Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects
ADCO TENOFOVIR 300 mg can have side effects.
Not all side effects reported for ADCO TENOFOVIR 300 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO TENOFOVIR 300 mg, please consult your health care provider for advice.

If any of the following happens, stop taking ADCO TENOFOVIR 300 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, tongue 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 allergic reaction to ADCO TENOFOVIR 300 mg. You may need urgent medical attention or hospitalisation.

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

- signs and symptoms of **lactic acidosis**. Lactis acidosis is a build-up of lactic acid in the blood and is a serious side effect that infrequently occurs in patients taking medicines like ADCO TENOFOVIR 300 mg. It can be a medical emergency that needs to be treated in the hospital. Call your doctor right away if you experience any of the following signs or symptoms of lactic acidosis:
    - trouble breathing.
    - feeling weak or tired.
    - feeling and/or being sick (nausea and/or vomiting) with stomach pain.
    - unexplained weight loss.
- signs and symptoms of **severe liver problems**, including:
    - skin or the white part of your eyes turns yellow (known as jaundice).
    - dark urine.
    - bowel movements (stools) turn light in colour.
    - loss of appetite (you don’t feel like eating food).
    - feeling and/or being sick (nausea and/or vomiting) with lower stomach pain.

  These symptoms may indicate serious liver problems including worsening of your Hepatitis B infection. Patients who take ADCO TENOFOVIR 300 mg and have an underlying Hepatitis B infection may get “flare-ups” of their hepatitis infection (infection suddenly gets worse than before) when treatment with ADCO TENOFOVIR 300 mg is stopped.

- signs and symptoms of **kidney problems**, including:
    - passing lots or less urine.
    - fluid retention, causing swelling in your legs, ankles or feet.
    - feeling tired or weak.
    - muscle cramps.
    - shortness of breath.

  The breakdown of muscle, muscle pain, muscle weakness and decreases in potassium or phosphate in the blood may occur due to damage to kidney cells.
- signs and symptoms of **bone problems**, including:
    - bone or joint pain.
    - fractures (bone break).
    - stiffness of the joints or difficulty in moving.

  ADCO TENOFOVIR 300 mg can cause softening of the bones by decreasing the bone mineral density.
- signs and symptoms of **infection**, including:
    - fever.
    - cough.
    - feeling generally unwell.

  Changes in your immune system can happen when an HIV-infected person starts taking antiretroviral medicines (known as Immune Reconstitution Syndrome). Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your health care provider right away if you start having any new symptoms after you start taking ADCO TENOFOVIR 300 mg.
- signs and symptoms of **pancreatitis** (inflammation of the pancreas), including:
    - upper stomach pain, which can spread to your back.
    - swelling and tenderness of your stomach.
    - nausea and/or vomiting (feeling and/or being sick).
    - fever.
- seizures (fits).
- shortness of breath.

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

Other possible side effects of ADCO TENOFOVIR 300 mg are:

Frequent side effects:

- difficulty in sleeping (insomnia).
- headache, dizziness.
- diarrhoea, nausea (feeling sick), vomiting (being sick), stomach pain, bloated stomach (swelling), flatulence (passing gas).
- skin rash.
- decrease in bone mass (bone mineral density).
- feeling weak (lack of energy) or tired.
- weight loss.
- pain including back or chest pain.

- increase in liver enzymes (picked up with a blood test).

Less frequent side effects:
- loss of appetite.
- fatty liver disease (fat build-up in the liver).

Side effects for which the frequency is unknown:
- anaemia (low levels of red blood cells or haemoglobin levels that can cause tiredness, shortness of breath and pale skin) or a decrease in white blood cell count (both of which are picked up with a blood test).
- changes in body fat including increased fat in the upper back and neck (known as “buffalo hump”), breasts and around the main part of your body (trunk); loss of fat from the legs, arms and face may also happen.
- increase in cholesterol or fats in the blood (picked up with a blood test).
- insulin resistance (the body does not respond as it should to insulin) and increased blood sugar levels.
- abnormal behaviour, depression, anxiety.
- increased muscle tone causing muscle stiffness.
- peripheral neuropathy causing muscle weakness or pins and needles (or pain) in the arms, legs, hands or feet.
- indigestion.
- sweating, itchy skin.
- increase in certain body enzymes including amylase and creatine phosphokinase, that is picked up with a blood test.

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 ADCO TENOFOVIR 300 mg.

5. How to store ADCO TENOFOVIR 300 mg
Store all medicines out of reach of children.
Store at or below 30 °C.
Store in the original container and keep the container in the outer carton.
The container should be tightly closed.
Protect from light and moisture.
Do not store in bathrooms.
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 ADCO TENOFOVIR 300 mg contains

The active substance is tenofovir disoproxil fumarate.
Each ADCO TENOFOVIR 300 mg tablet contains tenofovir disoproxil fumarate 300 mg, equivalent to 245 mg of tenofovir disoproxil.

The other ingredients in the tablet are: croscarmellose sodium, FD&C blue #2 / Indigo carmine aluminium lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, titanium dioxide and triacetin.

What ADCO TENOFOVIR 300 mg looks like and contents of the pack

ADCO TENOFOVIR 300 mg is light blue, almond-shaped, film-coated tablets debossed with 'H' on one side and '123' on the other side.

ADCO TENOFOVIR 300 mg tablets are packed in:

- 28, 30, 56, 60, 100, 500 or 1000 tablets packed in a white plastic container with plastic lid. Rayon coil and a silica gel desiccant are included in the container.
- 28 and 30 tablets are packed in a white opaque HDPE container with a white opaque polypropylene ribbed, plastic cap with continuous threading and with plain surface on top with induction sealing wad. Purified rayon coil and a silica gel desiccant are placed in the container.

Not all pack sizes or types are necessarily marketed.

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