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, opaque HDPE container with a white, child-resistant, ribbed plastic closure with a pulp liner. Purified rayon coil and a silica gel desiccant are placed 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.

Holder of Certificate of Registration

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PASIËNT INLIGTINGSBILJET

SKEDULERING STATUS: S4

ADCO TENOFOVIR 300 mg (Tablette)
Tenofovirdisoproksielfumaraat 300 mg gelykstaande aan 245 mg tenofovirdisoproksiel
Bevat suiker (163,998 mg laktosemonohidraat per tablet)

WAARSKUWING:
ADCO TENOFOVIR 300 mg KAN LEI TOT ERNSTIGE PROBLEME MET U LEWER, OF TE VEEL SUUR IN U BLOED VEROORSAAK. INDIEN DIT NIE BEHANDEL WORD NIE, KAN DIT SELFS DIE DOOD VEROORSAAK. DIE VEILIGHEID EN DOELTREFFENDHEID VAN ADCO TENOFOVIR 300 mg BY PASIËNTE WAT BESMET IS MET BEIDE MENSLIKE IMMUNITEITSGEBREKSVIRUS (MIV) EN HEPATITIS B-VIRUS (HBV) IS NIE VASGESTEL NIE.
ADCO TENOFOVIR 300 mg MOET NIE GEBRUIK WORD VIR DIE BEHANDELING VAN CHRONIESE HBV-INFEKSIE NIE. U MOET VIR 'N AANTAL MAANDE NOUKEURIG DEUR U DOKTER GEMONITOR WORD INDIEN U MET HBV BESMET IS EN DIE GEBRUIK ADCO TENOFOVIR 300 mg STAAK.

Lees hierdie hele biljet noukeurig deur voor u ADCO TENOFOVIR 300 mg begin neem
- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- ADCO TENOFOVIR 300 mg is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat is in hierdie biljet

1. Wat ADCO TENOFOVIR 300 mg is en waarvoor dit gebruik word
ADCO TENOFOVIR 300 mg is 'n antiretrovirale medisyne en word gebruik in die behandeling van die infeksie wat veroorsaak word deur die menslike immuniteitsgebreksvirus (MIV). MIV is die virus wat verworwe immuniteitsgebreksindroom (VIGS) veroorsaak. ADCO TENOFOVIR 300 mg moet altyd in kombinasie met ander antiretrovirale medisyne gebruik word.

2. Wat u moet weet voordat u ADCO TENOFOVIR 300 mg neem

ADCO TENOFOVIR 300 mg kan nie MIV-infeksie of VIGS genees nie. Mense wat ADCO TENOFOVIR 300 mg neem kan steeds infeksies of ander siektes ontwikkel wat verband hou met MIV-siekte en VIGS. Dit is dus belangrik dat u voortdurend onder u dokter se sorg bly terwyl u ADCO TENOFOVIR 300 mg neem. ADCO TENOFOVIR 300 mg verminder nie die risiko van die oordrag van HIV na andere deur seksuele kontak of bloedbesmetting nie. U moet toepaslike voorsorgmaatreëls tref.

Moenie ADCO TENOFOVIR 300 mg neem nie:

- Indien u al ooit 'n allergiese reaksie op tenofovir gehad het, of enige van die ander bestanddele in hierdie tablet (gelys in afdeling 6).
- Indien u nierversaking het.
- Indien u chroniese hepatitis B-virusinfeksie het.
- Indien u swanger is of borsvoed.
- Indien u reeds 'n antiretrovirale medisyne neem wat 'n kombinasie van emtrisitabien en tenofovirdisoproksielfumaraat bevat omdat ADCO TENOFOVIR 300 mg een van die aktiewe bestanddele in hierdie medisyne bevat.
- Indien u reeds 'n ander medisyne neem wat tenofovir bevat.
- Indien u 'n medisyne neem wat adefovirdipivoksiel bevat.

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met ADCO TENOFOVIR 300 mg:

- Maak seker dat u die dokter ingelig het indien u enige van die volgende mediese probleme het: Niersiekte, lewersiekte of hepatitis B-virusinfeksie. Indien u nierprobleme het, moet u dokter dalk u nierfunksie monitor voordat u ADCO TENOFOVIR 300 mg begin neem, en terwyl u dit neem.
- Maak seker dat u die dokter ingelig het indien u enige van die volgende medisyne saam met ADCO TENOFOVIR 300 mg gebruik, aangesien u dokter dalk die dosis moet verander, of hoe gereeld u een of albei van die medisyne gebruik: Didanosien, atazanavir, lopinavir-ritonavir kombinasie en ander medisyne wat giftig is vir die niere (sien "*Ander medisyne en ADCO TENOFOVIR 300 mg*").
- ADCO TENOFOVIR 300 mg kan beenafwykings veroorsaak. U dokter sal monitor of u 'n geskiedenis van beenfrakture het, of indien u osteoporose het, en u sal dalk kalsium- en vitamien D-aanvullings moet neem.
  Lig u dokter in indien u enige probleme met u bene of spiere ervaar, insluitend been- of spierpyn, spierswakheid, gewrigstyfheid of dit moeilik vind om te beweeg (sien afdeling 4: "*Moontlike newe-effekte*").
- Behandeling met ADCO TENOFOVIR 300 mg is geassosieer met 'n verandering in liggaamsvet wat opgemerk word as 'n ophoping van vet op die maag en rug, en verlies van vet op die gesig, arms en bene.
- Wees op die uitkyk vir infeksies. Indien u gevorderde MIV-infeksie (VIGS) het en 'n infeksie het, kan u simptome van so 'n infeksie ontwikkel (of verergering van die simptome van 'n bestaande infeksie) sodra u ADCO TENOFOVIR 300 mg begin neem. Dit kan aandui dat u liggaam se verbeterde immuunstelsel die infeksie beveg. Indien u tekens

van infeksie opmerk, lig u dokter dadelik in (sien afdeling 4: "*Moontlike newe-effekte*"). Outo-immuunafwykings ('n toestand wat voorkom wanneer die immuunstelsel gesonde liggaamsweefsel aanval) kan ook voorkom nadat u medisyne vir die behandeling van MIV begin neem het. Sulke immuunprobleme kan baie maande nadat u ADCO TENOFOVIR 300 mg begin neem het. Indien u enige simptome soos hartkloppings, bewerasies of hiperaktiwiteit opmerk, lig u dokter dadelik in.
- Indien u ouer indien 65 jaar is, kan u meer sensitief wees vir die gevolge van ADCO TENOFOVIR 300 mg. U dokter sal u noukeuriger monitor.

Kinders en adolessente
Die veiligheid en doeltreffendheid van ADCO TENOFOVIR 300 mg by kinders en adolessente jonger as 18 jaar is nie bekend nie.

Ander medisyne en ADCO TENOFOVIR 300 mg
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem (dit sluit alle komplementêre of tradisionele medisyne in).

Lig u dokter in indien enige van die onderstaande op u van toepassing is:
- ADCO TENOFOVIR 300 mg moet versigtig gebruik word saam met didanosien, aangesien die bloedvlakke van didanosien verhoog kan word. Die didanosien-dosis moet dalk verminder word.
- ADCO TENOFOVIR 300 mg moet nie saam met ander medisyne geneem word wat u niere kan beskadig nie. Dit sluit in: Asiklovir, adefovirdipivoksiel, aminoglikosiede, amfoterisien B, sidofovir, foskarnet, gansiklovir, interleukin-2, pentamidien, vankomisien, valasiklovir en valgansiklovir.
- ADCO TENOFOVIR 300 mg bloedvlakke kan verhoog word wanneer dit saam met atasanavir en lopinavir-ritonavir kombinasie geneem word, en moet versigtig gebruik word.
  ADCO TENOFOVIR 300 mg kan die hoeveelheid atasanavir in u bloed verminder. Indien u ADCO TENOFOVIR 300 mg en atasanavir saam neem, moet u ook ritonavir neem.
- Bloedvlakke van lamivudien en indinavir kan verlaag word wanneer dit saam met ADCO TENOFOVIR 300 mg geneem word.
- Nie-steroïed anti-inflammatoriese medisyne (NSAIM's): wanneer hierdie medisyne teen 'n hoë dosis gebruik word, of baie NSAIM's saam gebruik word, is daar 'n risiko van ernstige nierprobleme wanneer dit saam met ADCO TENOFOVIR 300 mg gebruik word. Raadpleeg u gesondheidsorgverskaffer vir alternatiewe medisyne wat gebruik kan word. Voorbeelde van NSAIM's sluit in aspirien, diklofenak en ibuprofeen.
- Die bloedvlakke van ADCO TENOFOVIR 300 mg kan verhoog word wanneer dit saam met ledipasvir en sofosbuvir of sofosbuvir en velpatasvir gebruik word, of 'n kombinasie van sofosbuvir, velpatasvir en voxilaprevir kombinasie-formulering. Hierdie medisyne word gebruik vir lewerprobleme soos hepatitis C en kan 'n toename in newe-effekte van ADCO TENOFOVIR 300 mg veroorsaak indien dit saam met ADCO TENOFOVIR 300 mg geneem word.

Swangerskap en borsvoeding
Indien u swanger is of borsvoed, dink u kan swanger wees of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.

Swangerskap: ADCO TENOFOVIR 300 mg moet nie tydens swangerskap gebruik word nie. U moet voldoende voorbehoedingsmetodes gebruik. Vermy om swanger te raak tydens die gebruik van ADCO TENOFOVIR 300 mg.

Borsvoeding: ADCO TENOFOVIR 300 mg moet nie tydens borsvoeding gebruik word nie.

Bestuur en gebruik van masjinerie
Dit is nie altyd moontlik om te voorspel in watter mate ADCO TENOFOVIR 300 mg met u daaglikse aktiwiteite kan inmeng nie. U moet seker maak dat u nie bestuur of masjinerie hanteer voordat u bewus is van die mate waartoe ADCO TENOFOVIR 300 mg u beïnvloed nie.

ADCO TENOFOVIR 300 mg kan duiseligheid veroorsaak wat u vermoë om te bestuur of masjinerie te hanteer kan beïnvloed. Daarom moet u nie bestuur, masjinerie hanteer of enige take verrig wat konsentrasie vereis, totdat u seker is dat ADCO TENOFOVIR 300 mg nie u vermoë om dit veilig te doen, beïnvloed nie.

ADCO TENOFOVIR 300 mg bevat laktosemonohidraat en natrium
Indien u deur u dokter ingelig is dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u hierdie medisyne neem.
ADCO TENOFOVIR 300 mg bevat minder as 1 mmol natrium (23 mg) per tablet; dit wil sê dit is in wese 'natriumvry'.

3. Hoe om ADCO TENOFOVIR 300 mg te neem
Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.

Neem altyd ADCO TENOFOVIR 300 mg presies soos u dokter of apteker u ingelig het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Die gewone dosis ADCO TENOFOVIR 300 mg is soos volg:
1 tablet (300 mg) een keer per dag, met of sonder kos. Moenie die tablet kou nie.

Dit is belangrik dat u ADCO TENOFOVIR 300 mg neem presies soos voorgeskryf deur u dokter. U dokter sal u inlig hoe lank u behandeling met ADCO TENOFOVIR 300 mg sal duur. Selfs indien u beter voel, moenie ophou om ADCO TENOFOVIR 300 mg te neem sonder om u dokter te raadpleeg nie.

Indien u die indruk het dat die effek van ADCO TENOFOVIR 300 mg te sterk of te swak is,

raadpleeg u dokter of apteker.

Indien u meer ADCO TENOFOVIR 300 mg neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Indien u vergeet om ADCO TENOFOVIR 300 mg te neem
Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

4. Moontlike newe-effekte
ADCO TENOFOVIR 300 mg kan newe-effekte hê.
Nie alle newe-effekte wat vir ADCO TENOFOVIR 300 mg aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u ADCO TENOFOVIR 300 mg neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van ADCO TENOFOVIR 300 mg en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond, tong of keel, wat dit moeilik kan maak om te sluk of asem te haal;
- veluitslag of jeukerigheid;
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige allergiese reaksie op ADCO TENOFOVIR 300 mg gehad. U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:
- tekens en simptome van **laktiese asidose**. Laktiese asidose is 'n opbou van melksuur in die bloed en is 'n ernstige newe-effek wat selde voorkom by pasiënte wat medisyne soos ADCO TENOFOVIR 300 mg gebruik. Dit kan 'n mediese noodgeval wees wat in die hospitaal behandel moet word. Skakel dadelik u dokter indien u enige van die volgende tekens of simptome van laktiese asidose ervaar:
    - probleme met asemhaling.
    - swak of moeg voel.
    - naar voel en/of opgooi (naarheid en/of braking) met maagpyn.
    - onverklaarbare gewigsverlies.
- Tekens en simptome van **ernstige lewerprobleme**, insluitend:
    - vel of die wit deel van u oë word geel (bekend as geelsug).
    - donker urien.
    - dermbewegings (stoelgang) word lig van kleur.
    - verlies aan eetlus (u is nie lus om kos te eet nie).
    - Naar voel en/of opgooi (naarheid en/of braking) met laer maagpyn.

  Hierdie simptome kan dui op ernstige lewerprobleme, insluitend verergering van u

Hepatitis B-infeksie. Pasiënte wat ADCO TENOFOVIR 300 mg neem en 'n onderliggende hepatitis B-infeksie het, kan "opvlamming" van hul hepatitis-infeksie kry (infeksie word skielik erger as voorheen) wanneer behandeling met ADCO TENOFOVIR 300 mg gestaak word.

- tekens en simptome van **nierprobleme**, insluitend:
    - die uitskei van baie meer of minder urien.
    - vloeistofretensie, wat swelling in u bene, enkels of voete veroorsaak.
    - moeg of swak voel.
    - spierkrampe.
    - kortasem.

  Die afbraak van spiere, spierpyn, spierswakheid en afname in kalium of fosfaat in die bloed kan voorkom as gevolg van skade aan nierselle.
- tekens en simptome van **beenprobleme**, insluitend:
    - been- of gewrigspyn.
    - frakture (beenbreuk).
    - styfheid van die gewrigte of probleme om te beweeg.

  ADCO TENOFOVIR 300 mg kan die bene laat versag deur die beenmineraaldigtheid te verlaag.
- tekens en simptome van **infeksie**, insluitend:
    - koors.
    - hoes.
    - oor die algemeen onwel voel.

  Veranderinge in u immuunstelsel kan plaasvind wanneer 'n MIV-besmette persoon antiretrovirale medisyne begin neem (bekend as Immuunrekonstitusiesindroom). U immuunstelsel kan sterker word en infeksies begin beveg wat al lank in u liggaam versteek is. Lig u gesondheidsorgverskaffer dadelik in indien u enige nuwe simptome begin kry nadat u ADCO TENOFOVIR 300 mg begin neem het.
- tekens en simptome van **pankreatitis** (inflammasie van die pankreas), insluitend:
    - maagpyn aan die bokant, wat na u rug kan versprei.
    - swelling en gevoeligheid van u maag.
    - naarheid en/of braking (naar voel en/of opgooi).
    - koors.
- stuipaanvalle (toevalle).
- kortasem.

Hierdie is alles ernstige newe-effekte. U sal dalk dringend mediese hulp nodig hê.

Ander moontlike newe-effekte van ADCO TENOFOVIR 300 mg is:

Gereelde newe-effekte:

- probleme met slaap (insomnia).
- hoofpyn, duiseligheid.
- diarree, naarheid (naar voel), braking (opgooi), maagpyn, opgeblaasde maag (swelling), winderigheid (winde laat).
- veluitslag.

- afname in beenmassa (beenmineraaldigtheid).
- swak voel (gebrek aan energie) of moeg.
- gewigsverlies.
- pyn, insluitend rug- of borspyn.
- toename in lewerensieme (opgetel met 'n bloedtoets).

Minder gereelde newe-effekte:
- verlies aan eetlus.
- vetterige lewersiekte (vet wat opbou in die lewer).

Newe-effekte waarvan die frekwensie onbekend is:
- bloedarmoede (lae vlakke van rooibloedselle of hemoglobienvlakke wat moegheid, kortasem en bleek vel kan veroorsaak) of 'n afname in witbloedseltelling (wat albei met 'n bloedtoets opgespoor word).
- veranderinge in liggaamsvet, insluitend verhoogde vet in die boonste area van die rug en nek (bekend as "buffelskof"), borste en rondom die grootste deel van u liggaam (romp); verlies van vet van die bene, arms en gesig kan ook voorkom.
- toename in cholesterol of vette in die bloed (opgespoor met 'n bloedtoets).
- insulienweerstandigheid (die liggaam reageer nie op insulien soos dit moet nie), en verhoogde bloedsuikervlakke.
- abnormale gedrag, depressie, angs.
- verhoogde spiertonus wat spierstyfheid veroorsaak.
- perifere neuropatie wat spierswakheid of naalde-en-spelde gevoel (of pyn) in die arms, bene, hande of voete veroorsaak.
- slegte spysvertering.
- sweet, jeukerige vel.
- toename in sekere ensieme in die liggaam, insluitend amilase en kreatienfosfokinase, wat met 'n bloedtoets opgetel word.

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die vorm "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van ADCO TENOFOVIR 300 mg te verskaf.

5. Hoe om ADCO TENOFOVIR 300 mg te bêre
Bêre alle medisyne buite bereik van kinders.
Bêre teen of benede 30 °C.

Bêre in die oorspronklike houer en hou die houer in die buitenste kartonboksie.
Die houer moet dig gesluit wees.
Beskerm teen lig en vog.
Moenie in badkamers bêre nie.
Moenie gebruik ná die vervaldatum wat op die etiket vermeld word nie.
Neem alle ongebruikte medisyne terug na u apteker.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat ADCO TENOFOVIR 300 mg bevat

Die aktiewe bestanddeel is tenofovirdisoproksielfumaraat.
Elke ADCO TENOFOVIR 300 mg tablet bevat tenofovirdisoproksielfumaraat 300 mg, gelykstaande aan 300 mg tenofovirdisoproksiel.

Die ander bestanddele in die tablet is: natriumkruiskarmellose, FD&C blou #2 / Indigo karmyn aluminium lak-kleursel, hipromellose, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, voorafgegelatiniseerde stysel, titaandioksied en triasetien.

Hoe ADCO TENOFOVIR 300 mg lyk en die inhoud van die verpakking

ADCO TENOFOVIR 300 mg is ligblou, amandelvormige, filmbedekte tablette met 'H' aan die een kant gegraveer en '123' aan die ander kant.

ADCO TENOFOVIR 300 mg tablette is verpak in:

- 28, 30, 56, 60, 100, 500 of 1000 tablette verpak in 'n wit, ondeursigtige HDPE-houer met 'n wit, kinderbestande, geriffelde plastiekdop met 'n pulpvoering. Gesuiwerde rayon-wattebal en 'n silikajel-droogmiddel word in die houer geplaas.
- 28 en 30 tablette word verpak in 'n wit ondeursigtige HDPE-houer met 'n wit ondeursigtige polipropileen geriffelde plastiekdop met aaneenlopende skroeflyn en met 'n gewone oppervlak bo-op met induksie-verseëling. Gesuiwerde rayon-wattebal en 'n silikajel-droogmiddel word in die houer geplaas.

Nie alle verpakkingsgroottes of -tipes word noodwendig bemark nie.

Houer van Sertifikaat van Registrasie

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