PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

TENOBINE, 200 mg/300 mg, film-coated tablets
Emtricitabine 200 mg and Tenofovir disoproxil fumarate 300 mg
Contains sugar: lactose monohydrate 90 mg

Read all of this leaflet carefully before you start taking TENOBINE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- TENOBINE 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 TENOBINE is and what it is used for
2. What you need to know before you take TENOBINE
3. How to take TENOBINE
4. Possible side effects
5. How to store TENOBINE
6. Contents of the pack and other information

1. What TENOBINE is and what it is used for

TENOBINE belongs group of medicine called Antimicrobial (chemotherapeutic) agents and Antiviral agents. It is a type of medicine called an HIV (human immunodeficiency virus) nucleoside analogue reverse transcriptase inhibitor (NRTI). TENOBINE contains 2 medicines, emtricitabine and tenofovir disoproxil fumarate (tenofovir DF) combined in one tablet.
Both of these active substances are antiretroviral medicines used to treat HIV infection.

TENOBINE used for treatment of HIV infection

TENOBINE is used for the treatment of HIV infection in adults in combination with other antiretroviral medicines.

TENOBINE used for treatment of Pre-Exposure Prophylaxis (PrEP)

TENOBINE is also used to decrease the risk of getting HIV-1 in adults when used at the same time as safe sex practices and if rigorous use at all times is adhered to. This is called Pre-Exposure Prophylaxis (PrEP).

2. What you need to know before you take TENOBINE

Do not take TENOBINE

- If you have ever had an allergic reaction to emtricitabine or tenofovir disoproxil fumarate or any of the other ingredients in TENOBINE (listed in section 6).
- If you are pregnant or breastfeeding.
- If you have moderate to severe kidney disease
- Safety and efficacy in paediatric patients less than 18 years of age have not been established.
- If you are taking other medicines containing tenofovir, emtricitabine or containing lamivudine because these medicines have similarities in active ingredients.
- If you are HIV positive or if your HIV status is unknown (only when using TENOBINE to prevent HIV infection).
- If you are not committed to taking TENOBINE everyday exactly as instructed by your health care provider, when using TENOBINE to prevent HIV infection.

Talk to your health care provider for more information on how to prevent HIV infection, including safe sex practices.

Warnings and precautions

Take special care with TENOBINE

WARNING:

TENOBINE MAY LEAD TO SERIOUS PROBLEMS WITH YOUR LIVER OR CAUSE TOO MUCH ACID IN YOUR BLOOD (KNOWN AS LACTIC ACIDOSIS). IF LEFT UNTREATED, THIS MAY EVEN CAUSE DEATH (SEE POSSIBLE SIDE EFFECTS FOR SIGNS AND SYMPTOMS OF LACTIC ACIDOSIS). THE SAFETY AND EFFICACY OF TENOBINE IN PATIENTS WHO ARE INFECTED WITH BOTH HUMAN IMMUNODEFICIENCY VIRUS (HIV) AND HEPATITIS B VIRUS (HBV) HAVE NOT BEEN ESTABLISHED. TENOBINE 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 OF TENOBINE.

- If you are unwell or notice any symptoms, abdominal pain, nausea, vomiting, notify your doctor immediately. Because of the effects of TENOBINE on the liver, your doctor will do blood tests before starting treatment and during treatment to monitor your liver function. Depending on the results, your doctor may decide to discontinue treatment.
- Liver disease. TENOBINE can cause LIFE-THREATENING LIVER TOXICITY. It may result in a condition called lactic acidosis. If you are feeling unwell, consult your doctor.
- Some people who have taken medicines like TENOBINE have developed serious liver problems called hepatotoxicity, with liver enlargement (hepatomegaly) and fat in the liver (steatosis).
- If you have, or previously had, a hepatitis B infection of the liver. TENOBINE may make the infection worse and is not to be used in patients who have both hepatitis B infection and HIV infection.
- If you also have hepatitis B, you will need close medical follow up for many months after stopping treatment with TENOBINE. Medical tests will include blood tests to check if your hepatitis B infection is getting worse.
- “Flare-ups” of hepatitis B virus infection, in which the disease suddenly returns in a worse way than before, can occur if you stop taking TENOBINE. Your health care provider will monitor your condition for several months after stopping TENOBINE.
- Kidney problems: If you have had kidney problems in the past or take other medicines that can cause kidney problems, your health care provider should do regular blood tests to check your kidneys.
- If you have bone problems, tenofovir disoproxil may also cause loss of bone mass. Overall, the effects of tenofovir disoproxil on long term bone health and future fracture risk in adult and paediatric patients are uncertain.
- If you are taking other medicines, certain medicines interact with TENOBINE and may cause undesirable effects; tell your health care professional about all of the medicines that you are taking.
- If you are taking other medicine for your HIV infection, you should read the patient information leaflet for each medicine before taking TENOBINE.
- Some patients taking TENOBINE, as well as other antiretroviral medicines, may develop changes in body fat. Changes include deposition of fat in the upper back and neck (known

as a “buffalo hump”), breast and abdomen. Loss of fat from the legs, arms and face may also occur. The cause of this problem is not known.

- Changes in your immune system known as Immune Reconstitution Syndrome may occur when you start taking TENOBINE and other antiretroviral medicines. You may become sick as your immune system becomes stronger and starts to fight previously latent infections. Tell your health care provider if you have any new symptoms after starting medicine TENOBINE.

Two conditions called lactic acidosis (built up of acid in the blood) and severe liver disease have occurred with the use of TENOBINE. These conditions may result in death (see possible side effects).

If a baby was exposed to TENOBINE *in utero*, even if they are born HIV-negative, they should have medical tests to ensure that they do not have mitochondrial dysfunction.

Please inform your health care provider if you are diabetic, overweight or if you have high cholesterol before starting TENOBINE.

Important information when taking TENOBINE to treat HIV infection

- You must remain on treatment for HIV in order to control the HIV infection as well as HIV related diseases.
- TENOBINE must not be taken by itself without other medicines for HIV-infection as this may lead to you developing resistance to TENOBINE which makes the HIV-infection more difficult to treat.
- TENOBINE does not reduce the risk of passing HIV to others through sexual contact or blood contamination. You should use appropriate precautions (including practicing safe sex at all times).
- TENOBINE is not a cure for HIV infection or AIDS. People taking TENOBINE may still develop opportunistic infections or other illnesses associated with HIV disease and AIDS. Opportunistic infections are infections that develop because the immune system is weak. It is therefore important that you remain under the supervision of your doctor while taking TENOBINE.

Important information when taking TENOBINE to prevent HIV infection (PrEP):

- You will need to have an HIV-test to ensure that you are HIV-negative before starting TENOBINE. You will also need to be tested every 3 months while taking TENOBINE. You should also ask your partner to be tested; you should know your partner's HIV status.

- It is possible that TENOBINE may not always keep you from contracting HIV.
- **You must always practice safe sex. Do not have any kind of sex without using protection**. Always use a condom to decrease the chance of coming into contact with semen, vaginal secretions or blood.
- **You must also use other preventative measures to keep from getting HIV**.
- Ask your health care professional for information and support regarding reducing risk sexual behaviour.
- Having fewer sexual partners will reduce your risk of contracting HIV.
- **Never miss a dose of TENOBINE**. Missing a dose may increase your risk of contracting HIV.

Other important information to know before taking TENOBINE to help prevent you from getting HIV or for HIV treatment:

You should be cautious at all times to reduce the risk of the spread of HIV infection. Such precautions include:

- Do not share or re-use needles or any other injection equipment.
- Do not share personal items that could possibly have blood or other body fluids on them, such as a toothbrush or razor blade.
- Do not have any form of sex without protection. Always use a condom.

Tell your health care provider if you have any of the following symptoms, which may indicate an infection, within the previous month before you start taking TENOBINE or at any time while taking TENOBINE:

- Tiredness,
- Fever,
- A lot of sweating (especially at night),
- Rash,
- Vomiting,
- Diarrhoea,
- Joint or muscle aches and pain,
- Headache,
- Sore throat,
- Enlarged lymph nodes in the neck or groin.

If you have any of these symptoms you may need to have another HIV test.

You should also tell your health care provider if you were possibly exposed to the HIV virus recently. If you are already taking TENOBINE for prevention of HIV infection, your health care provider may tell you to stop taking TENOBINE until an HIV test confirms that you are still HIV negative.

Other medicines and TENOBINE

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

There may be an interaction with the following types of medicines:

- Medicines that are toxic to the kidney or that are eliminated by the kidney. This may include acyclovir, adefovir dipivoxil, cidofovir, ganciclovir, valacyclovir or valganciclovir:
- **Taking TENOBINE with other medicines that can damage your kidneys**: it is especially important to tell your doctor if you are taking any of these medicines, including
    - aminoglycosides (for bacterial infection)
    - amphotericin B (for fungal infection)
    - foscarnet (for viral infection)
    - ganciclovir (for viral infection)
    - pentamidine (for infections)
    - vancomycin (for bacterial infection)
    - interleukin-2 (to treat cancer)
    - cidofovir (for viral infection)
    - non-steroidal anti-inflammatory drugs
    - (NSAIDs, to relieve bone or muscle pains)
- If you are taking another antiviral medicine called a protease inhibitor to treat HIV, your doctor may order blood tests to closely monitor your kidney function.
- It is also important to tell your doctor if you are taking ledipasvir/sofosbuvir, sofosbuvir/velpatasvir or sofosbuvir/velpatasvir/voxilaprevir to treat hepatitis C infection.
- Taking TENOBINE with other medicines containing didanosine (for treatment of HIV infection): Taking TENOBINE 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 causes death, have been reported when medicines containing tenofovir disoproxil and didanosine were taken together. Your doctor will carefully consider whether to treat you with combinations of tenofovir and didanosine.

- TENOBINE may decrease the blood levels of the anti-HIV medication indinavir and atazanavir. If you are taking TENOBINE and atazanavir sulphate together, you should also be taking ritonavir. It may increase the blood levels of the following antiviral medicines: didanosine and abacavir. Your doctor will decide if any dosage adjustments are needed.
- Medicines containing lamivudine and lamivudine itself should not be taken with TENOBINE as there are similarities between emtricitabine and lamivudine.
- Lopinavir and ritonavir combination causes increased blood levels of tenofovir. Your doctor will monitor co-administration of these two medicines.

It may be helpful to keep a list of all the medicines that you are taking. Whenever you go to see your doctor or pharmacist, take this list with so that he/she can assess all your medicines in-line with TENOBINE usage.

TENOBINE with food and drink

TENOBINE may be taken with or without a meal. It is important to take TENOBINE at the same time every day.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking TENOBINE.

- Do not use TENOBINE if you are pregnant. The effects of TENOBINE on pregnant women and their unborn babies are unknown.
- You should use a reliable form of contraception to avoid becoming pregnant while taking TENOBINE.
- Do not breastfeed your baby while taking TENOBINE. If you have a baby, talk to your health care provider about the best way to feed your baby. There is a chance that your baby can contract HIV through your breast milk if you are HIV positive and breastfeeding.

Driving and using machines

TENOBINE can make you dizzy; if you feel dizzy while taking TENOBINE you should take care when driving and using machinery.

It is not always possible to predict to what extent TENOBINE may interfere with daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TENOBINE affects them.

TENOBINE contains lactose monohydrate

TENOBINE contains lactose monohydrate. Patients with rare hereditary conditions of lactose or galactose intolerance should not take TENOBINE.

TENOBINE contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take TENOBINE

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

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

- The recommended dose is one tablet of TENOBINE (emtricitabine 200 mg and tenofovir DF 300 mg) taken once daily, with or without food.
- The tablet should be taken at the same time each day.
- If you have kidney problems your doctor will adjust your dose.
- Swallow the TENOBINE tablet whole with water.
- Do not chew the tablet.
- Using TENOBINE as directed should give you the best chance to delay the development of resistance to TENOBINE.

Treatment of HIV

When taking TENOBINE for the treatment of HIV, it should be used in combination with other anti-HIV medicines.

Prevention of HIV

When using TENOBINE to prevent contraction of HIV, you must also strictly adhere to other methods of reducing your risk of HIV contraction, including practicing safe sex (see Take special care with TENOBINE).

Your doctor will tell you how long your treatment with TENOBINE will last. Do not stop treatment early because your infection will no longer be controlled.

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

If you take more TENOBINE than you should

Do not take more than prescribed by your doctor; to do so may increase the chance of side effects.

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 TENOBINE

It is important that you do not miss any doses. Do not take a double dose to make up for forgotten individual doses. Take the next dose as soon as possible. Contact your health care provider or pharmacist if you are not sure what to do.

If you stop taking TENOBINE

Even if you feel better, do not stop taking TENOBINE without talking to your doctor.

You should not stop treatment unless your doctor instructs you to. When your TENOBINE supply starts to run low, get more from your health care 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 TENOBINE and become harder to treat.

4. Possible side effects

TENOBINE can have side effects.

Not all side effects reported for TENOBINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TENOBINE, please consult your doctor, pharmacist or other health care professional for advice.

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

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.
- Serious liver problems: Some patients who have taken medicines like TENOBINE have developed serious liver problems called hepatotoxicity, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Call your doctor right away if you get the following signs or symptoms of liver problems:

- your skin or the white part of your eyes turns yellow, also called jaundice,
- your urine turns dark,
- your bowel movements (stools) turn light in colour,
- you don't feel like eating food for several days or longer,
- you feel sick to your stomach (nausea),
- you have lower stomach area (abdominal) pain.

Lactic acidosis: Some patients who have taken medicine like TENOBINE (nucleoside analogues) have developed a serious condition called lactic acidosis (build-up of acid in the blood).
Lactic acidosis can be a medical emergency and may need to be treated in the hospital. Call your doctor right away if you get the following signs or symptoms of lactic acidosis:

- 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 light headed,
- you have a fast or irregular heartbeat.

You may be more likely to get lactic acidosis or liver problems if you are female, very overweight (obese), or have been taking nucleoside analog medicines, like TENOBINE, for a long time.

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

- signs or symptoms of serious liver problems (described above),
- signs or symptoms of lactic acidosis (described above),
- less urine than is normal for you,
- softening of your bones (such as bone pain and fractures).

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

- Nausea (feeling sick), vomiting (being sick),
- Abdominal cramps or stomach pains,

- Headache,
- General pain,
- Dizziness,
- Tiredness (including feeling weak and having low energy levels),
- Difficulty sleeping and abnormal dreams, low mood,
- Problems with digestion resulting in discomfort after meals, feeling flatulence or wind,
- Diarrhoea,
- Weight loss,
- Skin rashes (including spots and blotches, and sometimes blistering and swelling which may be an allergic reaction), itching, changes in skin colour (including darkening patches),
- Other allergic reactions such as wheezing and feeling lightheaded,
- Loss of bone mass.

Frequent side effects that show up on blood tests include the following:

- Low white blood cell count (which may dispose you to infections),
- Increased fatty acids (related to cholesterol), bile or sugar,
- Increased creatinine kinase (which indicates muscle breakdown),
- Increased amylase or lipase (enzymes used for food digestion),
- Increased liver enzymes (indicating liver damage),
- Decreases in phosphate in the blood,
- High blood sugar levels,
- Increased creatine kinase.

Tell your doctor if you notice any of the following:

Less frequent side effects

- Back pain, indicating kidney problems,
- Anaemia (low red blood cell count, signs and symptoms include tiredness, pale skin, dizziness, fast heartbeat),
- Breakdown of muscle (signs and symptoms include muscle pain and weakness),
- Inflamed pancreas (signs and symptoms include middle to upper left quadrant abdominal pain which increases after eating or lying down),
- Low potassium in blood,
- Cough, nasal congestion, runny nose and sneezing.

- Shortness of breath, chest pain, lung infection.
- Pain in the abdomen (tummy) caused by inflammation of the pancreas.

Side effects of less frequency that show up on blood and urine tests include the following:

- Changes to your urine.

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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
By reporting side effects, you can help provide more information on the safety of TENOBINE.

5. How to store TENOBINE

- Store all medicines out of reach of children.
- Store in a cool, dry place, at or below 30 °C.
- Protect from light and moisture.
- Store in the original container.
- Do not store in bathrooms.
- Do not use after the expiry date stated on the label or carton.
- 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 TENOBINE contains

The active substances of TENOBINE are emtricitabine and tenofovir disoproxil fumarate.
Each film-coated tablet contains 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate (tenofovir DF).
The other ingredients are:
Croscarmellose sodium, magnesium stearate, microcrystalline cellulose, pregelatinised starch, lactose monohydrate (Pharmatose 200M)

Coating excipients:

Opadry II Blue (coating) contains: hypromellose 15 Cp, FD&C blue #2/ indigo carmine aluminium lake, lactose monohydrate, titanium dioxide (CI 77891), Triacetin.

What TENOBINE looks like and contents of the pack

TENOBINE film-coated tablets are blue, capsule shaped, tablets debossed with 'H' on one side and '124' on the other side.

TENOBINE are packed in securitainers sizes of 28's, 30's, 56's or 60's in a white, opaque HDPE container with a white, ribbed plastic closure with continued threading with a pulp liner.

Not all pack sizes may be marketed.

HOLDER OF THE CERTIFICATE OF REGISTRATION

Adcock Ingram Limited
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Customer Care: 0860 ADCOCK / 232625

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Registration number

TENOBINE: 44/20.2.8/0837

SKEDULERINGSTATUS: **S4**

TENOBINE, 200 mg/300 mg, filmbedekte tablette
Emtrisitabien 200 mg en Tenofovirdisoproksielfumaraat 300 mg
Bevat suiker: laktosemonohidraat 90 mg

Lees hierdie hele biljet noukeurig deur voordat u TENOBINE begin neem

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter of u apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- TENOBINE is aan u persoonlik voorgeskryf en u moenie 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 TENOBINE is en waarvoor dit gebruik word
2. Wat u moet weet voordat u TENOBINE neem
3. Hoe om TENOBINE te neem
4. Moontlike newe-effekte
5. Hoe om TENOBINE te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat TENOBINE is en waarvoor dit gebruik word

TENOBINE behoort aan groep medisyne genaamd Antimikrobiese (chemoterapeutiese) middels en Antivirale middels. Dit is 'n tipe medisyne wat 'n MIV (menslike immuniteitsgebrekvirus) nukleosiedanaloog omgekeerde transkriptase-inhibeerder (NRTI) genoem word. TENOBINE bevat 2 medisynes, emtrisitabien en tenofovirdisoproksiel-fumaraat (tenofovir DF) gekombineer in een tablet.

Albei hierdie aktiewe bestanddele is antiretrovirale medisyne wat gebruik word om MIV-infeksie te behandel.

TENOBINE wat gebruik word vir die behandeling van MIV-infeksie

TENOBINE word gebruik vir die behandeling van MIV-infeksie by volwassenes in kombinasie met ander antiretrovirale medisyne.

TENOBINE wat gebruik word vir die behandeling van Voorblootstellingsprofilakse (PrEP)
TENOBINE word ook gebruik om die risiko om MIV-1 te verwerf by volwassenes te verminder wanneer dit tesame met veilige sekspraktyke gebruik word en indien streng gebruik te alle tye nagekom word. Dit word Voorblootstellingsprofilakse (PrEP) genoem.

2. Wat u moet weet voordat u TENOBINE neem

Moenie TENOBINE neem nie

- Indien u al ooit 'n allergiese reaksie op emtrisitabien of tenofovirdisoproksielfumaraat, of enige van die ander bestanddele in TENOBINE (gelys in afdeling 6) gehad het.
- Indien u swanger is of borsvoed.
- Indien u matige tot ernstige niersiekte het
- Veiligheid en doeltreffendheid by pediatriese pasiënte jonger as 18 jaar is nie vasgestel nie.
- Indien u ander medisyne gebruik wat tenofovir, emtrisitabien of lamivudien bevat, omdat hierdie medisyne ooreenkomste in aktiewe bestanddele het.
- Indien u MIV-positief is of indien u MIV-status onbekend is (slegs wanneer TENOBINE gebruik word om MIV-infeksie te voorkom).
- Indien u nie daartoe verbind is om TENOBINE elke dag te neem presies soos deur u gesondheidsorgverskaffer voorgeskryf is nie, in die geval van die neem van TENOBINE om MIV-infeksie te voorkom.

Raadpleeg u gesondheidsorgverskaffer vir meer inligting oor hoe om MIV-infeksie te voorkom, insluitend veilige sekspraktyke.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met TENOBINE

WAARSKUWING:
TENOBINE KAN LEI TOT ERNSTIGE PROBLEME MET U LEWER, OF KAN TE VEEL SUUR IN U BLOED VEROORSAAK (BEKEND AS MELKSUURASIDOSE). INDIEN DIT NIE BEHANDEL WORD NIE, KAN DIT SELFS DIE DOOD VEROORSAAK (SIEN MOONTLIKE NEWE-EFFEKTE VIR TEKENS EN SIMPTOME VAN MELKSUURASIDOSE). DIE VEILIGHEID EN DOELTREFFENDHEID VAN TENOBINE BY PASIËNTE WAT BESMET IS MET BEIDE MENSLIKE IMMUNITEITSGEBREKVIRUS (MIV) EN HEPATITIS B-VIRUS

(HBV) IS NIE VASGESTEL NIE. TENOBINE MOET NIE GEBRUIK WORD VIR DIE BEHANDELING VAN CHRONIESE HBV-INFEKSIE NIE. U MOET VIR 'N PAAR MAANDE NOUKEURIG DEUR U DOKTER GEMONITOR WORD INDIEN U MET HBV BESMET IS, EN DIE GEBRUIK VAN TENOBINE STAAK.

- Indien u siek is of enige simptome, buikpyn, naarheid, braking opmerk, stel u dokter dadelik in kennis. As gevolg van die uitwerking van TENOBINE op die lewer, sal u dokter bloedtoetse doen voordat daar met behandeling begin word, en tydens behandeling, om u lewerfunksie te monitor. Afhangende van die resultate, kan u dokter besluit om behandeling te staak.
- Lewersiekte. TENOBINE kan LEWENSGEVAARLIKE LEWERTOKSISITEIT veroorsaak. Dit kan lei tot 'n toestand wat melksuurasidose genoem word. Indien u sleg voel, raadpleeg u dokter.
- Sommige persone wat medisyne soos TENOBINE geneem het, het ernstige lewerprobleme ontwikkel wat hepatotoksisiteit genoem word, met lewervergroting (hepatomegalie) en vet in die lewer (steatose).
- Indien u 'n hepatitis B-infeksie van die lewer het, of voorheen gehad het. TENOBINE kan die infeksie vererger en moet nie gebruik word by pasiënte wat beide hepatitis B-infeksie en MIV-infeksie het nie.
- Indien u ook hepatitis B het, sal u noukeurige mediese opvolging vir baie maande nodig hê nadat u die behandeling met TENOBINE gestaak het. Mediese toetse sal bloedtoetse insluit om te kyk of u hepatitis B-infeksie erger word.
- "Opvlammings" van hepatitis B-virusinfeksie, waartydens die siekte skielik op 'n meer ernstige manier terugkeer as voorheen, kan voorkom indien u ophou om TENOBINE te neem. U gesondheidsorgverskaffer sal u toestand vir 'n paar maande monitor nadat u TENOBINE gestaak het.
- Nierprobleme: Indien u in die verlede nierprobleme gehad het, of ander medisyne neem wat nierprobleme kan veroorsaak, moet u gesondheidsorgverskaffer gereelde bloedtoetse doen om u niere na te gaan.
- Indien u beenprobleme het, kan tenofovirdisoproksiel ook verlies aan beenmassa veroorsaak. Oor die algemeen is die uitwerking van tenofovirdisoproksiel op langtermyn beengesondheid en toekomstige fraktuurrisiko by volwasse en pediatriese pasiënte onseker.

- Indien u ander medisyne gebruik. Sekere medisyne is in wisselwerking met TENOBINE en kan ongewenste effekte veroorsaak; lig u gesondheidsorg kundige in van al die medisyne wat u neem.
- Indien u ander medisyne vir u MIV-infeksie neem, moet u die pasiënt inligtingsbiljet vir elke medisyne lees voordat u TENOBINE neem.
- Sommige pasiënte wat TENOBINE neem, sowel as ander antiretrovirale medisyne, kan veranderinge in liggaamsvet ontwikkel. Veranderinge sluit in die neerlegging van vet in die boonste rug en nek (bekend indien 'n "buffelskof"), bors en buik. Verlies aan vet van die bene, arms en gesig kan ook voorkom. Die oorsaak van hierdie probleem is nie bekend nie.
- Veranderinge in u immuunstelsel, bekend as Immuun-rekonstitusiesindroom, kan voorkom wanneer u TENOBINE en ander antiretrovirale medisyne begin neem. U kan siek word namate u immuunstelsel sterker word en voorheen latente infeksies begin beveg. Lig u gesondheidsorgverskaffer in indien u enige nuwe simptome het nadat u die medisyne TENOBINE begin gebruik het.

Twee toestande genaamd melksuurasidose (opgebou van suur in die bloed) en ernstige lewersiekte het voorgekom met die gebruik van TENOBINE. Hierdie toestande kan tot die dood lei (sien moontlike newe-effekte).
Indien 'n baba in die baarmoeder aan TENOBINE blootgestel is, selfs al word hulle MIV-negatief gebore, moet hulle mediese toetse ondergaan om te verseker dat hulle nie mitochondriale disfunksie het nie.
Stel asseblief u gesondheidsorgverskaffer in kennis indien u diabeet is, oorgewig is, of indien u hoë cholesterol het voordat u TENOBINE begin gebruik.

Belangrike inligting wanneer TENOBINE geneem word om MIV-infeksie te behandel

- U moet op behandeling vir MIV bly om die MIV-infeksie sowel as MIV-verwante siektes te beheer.
- TENOBINE moet nie alleen geneem word sonder ander medisyne vir MIV-infeksie nie, aangesien dit daartoe kan lei dat u weerstand teen TENOBINE ontwikkel, wat die MIV-infeksie moeiliker maak om te behandel.
- TENOBINE verminder nie die risiko om MIV aan ander oor te dra deur seksuele kontak of bloedbesmetting nie. U moet toepaslike voorsorgmaatreëls gebruik (insluitend die beoefening van veilige seks te alle tye).

- TENOBINE is nie 'n geneesmiddel vir MIV-infeksie of VIGS nie. Mense wat TENOBINE neem, kan steeds opportunistiese infeksies of ander siektes ontwikkel wat verband hou met MIV-siekte en VIGS. Opportunistiese infeksies is infeksies wat ontwikkel omdat die immuunstelsel swak is. Dit is dus belangrik dat u onder toesig van u dokter bly terwyl u TENOBINE neem.

Belangrike inligting wanneer TENOBINE geneem word om MIV-infeksie te voorkom (PrEP):

- U sal 'n MIV-toets moet ondergaan om te verseker dat u MIV-negatief is voordat u TENOBINE begin gebruik. U sal ook elke 3 maande getoets moet word terwyl u TENOBINE neem. U moet ook u maat vra om getoets te word; u moet die MIV-status van u maat ken.
- Dit is moontlik dat TENOBINE u nie altyd daarvan weerhou om MIV op te doen nie.
- **U moet altyd veilige seks beoefen. Moenie enige soort seks hê sonder om beskerming te gebruik nie**. Gebruik altyd 'n kondoom om die kans om met semen, vaginale afskeidings of bloed in aanraking te kom, te verminder.
- **U moet ook ander voorkomende maatreëls gebruik om te verhoed dat u MIV kry**.
- Vra u gesondheidsorg kundige vir inligting en ondersteuning rakende die vermindering van riskante seksuele gedrag.
- Om minder seksmaats te hê, sal u risiko verminder om MIV op te doen.
- **Moet nooit 'n dosis TENOBINE oorslaan nie**. Die oorslaan van ‘n dosis kan u risiko verhoog om MIV op te doen.

Ander belangrike inligting om te weet voordat u TENOBINE neem om te voorkom dat u MIV kry, of vir MIV-behandeling:

U moet te alle tye versigtig wees om die risiko van die verspreiding van MIV-infeksie te verminder. Sulke voorsorgmaatreëls sluit in:

- Moenie naalde of enige ander inspuitingstoerusting deel of hergebruik nie.
- Moenie persoonlike items deel wat moontlik bloed of ander liggaamsvloeistowwe op kan hê nie, soos 'n tandeborsel of skeermeslem.
- Moenie enige vorm van seks sonder beskerming hê nie. Gebruik altyd 'n kondoom.

Lig u gesondheidsorgverskaffer in indien u enige van die volgende simptome het, wat kan dui op 'n infeksie, binne die vorige maand voordat u TENOBINE begin neem het, of enige tyd terwyl u TENOBINE neem:

- Moegheid,
- Koors,
- Baie sweet (veral snags),
- Veluitslag,
- Braking,
- Diarree,
- Gewrigs- of spierseerheid en -pyn,
- Hoofpyn,
- Keelseer,
- Vergrote limfknope in die nek of lies.

Indien u enige van hierdie simptome ervaar, moet u dalk nog 'n MIV-toets doen.

U moet ook u gesondheidsorgverskaffer inlig indien u moontlik onlangs aan die MIV-virus blootgestel is. Indien u reeds TENOBINE neem vir die voorkoming van MIV-infeksie, kan u gesondheidsorgverskaffer u aanraai om op te hou om TENOBINE te neem totdat 'n MIV-toets bevestig dat u steeds MIV-negatief is.

Ander medisyne en TENOBINE

Lig altyd u gesondheidsorg kundige in indien u enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

Daar kan 'n interaksie met die volgende soorte medisyne wees:

- Medisyne wat giftig is vir die nier of wat deur die nier uitgeskei word. Dit kan asiklovir, adefovirdipivoksiel, sidofovir, gansiklovir, valasiklovir of valgansiklovir insluit.
- **Die neem van TENOBINE saam met ander medisyne wat u niere kan beskadig**: dit is veral belangrik om u dokter te vertel indien u enige van hierdie medisyne neem, insluitend
    - aminoglikosiede (vir bakteriële infeksie)
    - amfoterisien B (vir swaminfeksie)
    - foskarnet (vir virusinfeksie)
    - gansiklovir (vir virusinfeksie)
    - pentamidien (vir infeksies)
    - vankomisien (vir bakteriële infeksie)
    - interleukien-2 (om kanker te behandel)
    - sidofovir (vir virusinfeksie)
    - nie-steroïed anti-inflammatoriese middels (NSAIMs, om been- of spierpyne te verlig)

- Indien u 'n ander antivirale medisyne genaamd 'n protease inhibeerder neem om MIV te behandel, kan u dokter bloedtoetse bestel om u nierfunksie noukeurig te monitor.
- Dit is ook belangrik om u dokter in te lig indien u ledipasvir/sofosbuvir, sofosbuvir/velpatasvir of sofosbuvir/velpatasvir/voksilaprevir neem om hepatitis C-infeksie te behandel.
- Die neem van TENOBINE saam met ander medisyne wat didanosien bevat (vir die behandeling van MIV-infeksie): Die neem van TENOBINE saam met ander antivirale medisyne wat didanosien bevat, kan die vlakke van didanosien in u bloed verhoog en kan CD4-seltellings verminder. Inflammasie van die pankreas en melksuurasidose (oortollige melksuur in die bloed), wat soms die dood veroorsaak, is selde aangemeld wanneer medisyne wat tenofovirdisoproksiel en didanosien bevat, saam geneem is. U dokter sal dit noukeurig oorweeg of u met kombinasies van tenofovir en didanosien behandel moet word.
- TENOBINE kan die bloedvlakke van die anti-MIV-medikasie indinavir en atazanavir verlaag. Indien u TENOBINE en atazanavirsulfaat tegelykertyd neem, moet u ook ritonavir neem. Dit kan die bloedvlakke van die volgende antivirale medisyne verhoog: didanosien en abasavir. U dokter sal besluit of enige dosisaanpassings nodig is.
- Lamivudien, en medisyne wat lamivudien bevat, moet nie saam met TENOBINE geneem word nie, aangesien daar ooreenkomste tussen emtrisitabien en lamivudien is.
- Lopinavir en ritonavir kombinasie veroorsaak verhoogde bloedvlakke van tenofovir. U dokter sal gelyktydige toediening van hierdie twee medisyne monitor.

Dit kan nuttig wees om 'n lys te hou van al die medisyne wat u neem. Wanneer u ook al u dokter of apteker gaan spreek, neem hierdie lys saam sodat hy/sy al u medisyne kan evaluaeer in ooreenstemming met die gebruik van TENOBINE.

TENOBINE saam met kos en drank

TENOBINE kan met of sonder 'n maaltyd geneem word. Dit is belangrik om TENOBINE elke dag op dieselfde tyd te neem.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies voordat TENOBINE geneem word.

- Moenie TENOBINE gebruik indien u swanger is nie. Die uitwerking van TENOBINE op swanger vroue en hul ongebore babas is onbekend.

- U moet 'n betroubare vorm van voorbehoeding gebruik om te verhoed dat u swanger raak terwyl u TENOBINE neem.
- Moenie u baba borsvoed terwyl u TENOBINE neem nie. Indien u 'n baba het, raadpleeg u gesondheidsorgverskaffer oor die beste manier om u baba te voed. Daar is 'n kans dat u baba MIV deur u borsmelk kan opdoen indien u MIV-positief is en borsvoed.

Bestuur en gebruik van masjinerie

TENOBINE kan u duiselig maak; indien u duiselig voel terwyl u TENOBINE neem, moet u versigtig wees wanneer u bestuur en masjinerie gebruik.

Dit is nie altyd moontlik om te voorspel in watter mate TENOBINE met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet verseker dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle bewus is van die mate waartoe TENOBINE hulle raak nie.

TENOBINE bevat laktosemonohidraat

TENOBINE bevat laktosemonohidraat. Pasiënte met seldsame oorerflike toestande van laktose- of galaktose onverdraagsaamheid moet nie TENOBINE neem nie.

TENOBINE bevat natrium

Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per tablet, dit wil sê in wese 'natriumvry'.

3. Hoe om TENOBINE te neem

Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.

Neem altyd TENOBINE presies soos u dokter of apteker u ingelig het. Raadpleeg u dokter of apteker indien u nie seker is nie.

- Die aanbevole dosis is een tablet TENOBINE (emtrisitabien 200 mg en tenofovir DF 300 mg) wat een keer per dag geneem word, met of sonder kos.
- Die tablet moet elke dag op dieselfde tyd geneem word.
- Indien u nierprobleme het, sal u dokter u dosis aanpas.
- Sluk die TENOBINE tablet heel met water.
- Moenie die tablet kou nie.
- Deur TENOBINE te gebruik soos aangedui behoort u die beste kans te gee om die ontwikkeling van weerstandigheid teen TENOBINE uit te stel.

Behandeling van MIV
Wanneer TENOBINE geneem word vir die behandeling van MIV, moet dit in kombinasie met ander anti-MIV-medisyne gebruik word.

Voorkoming van MIV
Wanneer u TENOBINE gebruik vir die voorkoming van MIV oordrag, moet u ook streng by ander metodes hou om u risiko van MIV-oordrag te verminder, insluitend die beoefening van veilige seks (sien Wees veral versigtig met TENOBINE).
U dokter sal u inlig hoe lank u behandeling met TENOBINE sal duur. Moenie die behandeling vroeg stop nie, want u infeksie sal nie meer beheer word nie.
Indien u die indruk het dat die effek van TENOBINE te sterk of te swak is, raadpleeg u dokter of apteker.

Indien u meer TENOBINE neem as wat u moes
Moenie meer neem as wat deur u dokter voorgeskryf is nie; deur dit te doen, kan die kans op newe-effekte verhoog.
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 TENOBINE te neem
Dit is belangrik dat u geen dosisse oorslaan nie. Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie. Neem die volgende dosis so gou as moontlik. Kontak u gesondheidsorgverskaffer of apteker indien u nie seker is wat om te doen nie.

Indien u ophou om TENOBINE te neem
Selfs al voel u beter, moenie ophou om TENOBINE te neem sonder om u dokter te raadpleeg nie.
U moet nie die behandeling stop nie, tensy u dokter u opdrag gee om dit te doen. Wanneer u voorraad TENOBINE begin min raak, kry meer daarvan vanaf u gesondheidsorgverskaffer of apteek. Dit is baie belangrik omdat die hoeveelheid virus in u bloed kan toeneem indien die medisyne selfs vir 'n kort tydjie gestaak word. Die virus kan weerstand teen TENOBINE ontwikkel en moeiliker word om te behandel.

4. Moontlike newe-effekte

TENOBINE kan newe-effekte hê.

Nie alle newe-effekte wat vir TENOBINE aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak, of indien u enige ongewenste gevolge ervaar terwyl u TENOBINE neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies.

Indien enige van die volgende gebeur, staak TENOBINE en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- swelling van u hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
- veluitslag of jeukerigheid,
- floute.
- Ernstige lewerprobleme: Sommige pasiënte wat medisyne soos TENOBINE geneem het, het ernstige lewerprobleme ontwikkel wat hepatotoksisiteit genoem word, met lewervergroting (hepatomegalie) en vet in die lewer (steatose). Bel u dokter dadelik indien u die volgende tekens of simptome van lewerprobleme kry:
    - u vel of die wit deel van u oë word geel, ook genoem geelsug,
    - u urien word donker,
    - u stoelgang (feses) word lig van kleur,
    - u is vir 'n paar dae of langer nie lus om kos te eet nie,
    - u voel baie naar op die maag (naarheid),
    - u het pyn op die laer maagarea (abdominale pyn).

Melksuurasidose: Sommige pasiënte wat medisyne soos TENOBINE (nukleosiedanaloë) geneem het, het 'n ernstige toestand genaamd melksuurasidose (opbou van suur in die bloed) ontwikkel.

Melksuurasidose kan 'n mediese noodgeval wees en moet dalk in die hospitaal behandel word. Bel u dokter dadelik indien u die volgende tekens of simptome van melksuurasidose kry:

- u voel baie swak of moeg,
- u het ongewone (abnormale) spierpyn,
- u sukkel om asem te haal,
- u het maagpyn met naarheid en braking,
- u voel koud, veral in u arms en bene,

- u voel duiselig of lighoofdig,
- u het 'n vinnige of onreëlmatige hartklop.

U kan meer geneig wees om melksuurasidose of lewerprobleme te kry indien u vroulik is, baie oorgewig is (vetsugtig), of al lank nukleosied-analoog medisyne, soos TENOBINE, neem.

Lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:

- tekens of simptome van ernstige lewerprobleme (hierbo beskryf),
- tekens of simptome van melksuurasidose (hierbo beskryf),
- minder urien as wat normaal vir u is,
- versagting van u bene (soos beenpyn en frakture).

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

Lig u dokter in indien u enige van die volgende opmerk

Gereelde newe-effekte

- Naarheid (naar voel), braking (opgooi),
- Abdominale krampe of maagpyne,
- Hoofpyn
- Algemene pyn,
- Duiseligheid
- Moegheid (insluitend swak voel en lae energievlakke),
- Probleme met slaap en abnormale drome, lae bui,
- Probleme met spysvertering wat lei tot ongemak na etes, opgeblaas voel of winderigheid,
- Diarree
- Gewigsverlies
- Veluitslag (insluitend kolle en vlekke, en soms blase en swelling wat 'n allergiese reaksie kan wees), jeukerigheid, veranderinge in velkleur (insluitend donkerder kolle),
- Ander allergiese reaksies soos hygende asemhaling en lighoofdigheid,
- Verlies aan beenmassa.

Gereelde newe-effekte wat op bloedtoetse verskyn, sluit die volgende in:

- Lae witbloedseltelling (wat u geneig kan maak tot infeksies),
- Verhoogde vetsure (verwant aan cholesterol), gal of suiker,
- Verhoogde kreatinienkinase (wat spierafbraak aandui),

- Verhoogde amilase of lipase (ensieme wat gebruik word vir voedselvertering),
- Verhoogde lewerensieme (dui op lewerskade),
- Afname in fosfaat in die bloed,
- Hoë bloedsuikervlakke,
- Verhoogde kreatien kinase.

Lig u dokter in indien u enige van die volgende opmerk:

Minder gereelde newe-effekte

- Rugpyn, wat nierprobleme aandui,
- Bloedarmoede (lae rooibloedseltelling, tekens en simptome sluit in moegheid, bleek vel, duiseligheid, vinnige hartklop),
- Afbraak van spiere (tekens en simptome sluit spierpyn en swakheid in),
- Ontsteekte pankreas (tekens en simptome sluit in pyn in die middel tot boonste linker abdominale kwadrant wat toeneem nadat u geëet of gelê het),
- Lae kalium in bloed,
- Hoes, geblokte neus, loopneus en nies.
- Kortasem, borspyn, longinfeksie.
- Pyn in die buik (maag) veroorsaak deur inflammasie van die pankreas.

Newe-effekte van laer frekwensie wat op bloed- en urientoetse verskyn, sluit die volgende in:

- Veranderinge in u urien.

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 of verpleegkundige. Dit sluit in enige moontlike newe-effekte wat nie in hierdie biljet gelys word nie. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word.

Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van TENOBINE te verskaf.

5. Hoe om TENOBINE te bêre

- Bêre alle medisyne buite bereik van kinders.

- Bêre op 'n koel, droë plek, teen of benede 30 °C.
- Beskerm teen lig en vogtigheid.
- Bêre in die oorspronklike houer.
- Moenie in badkamers bêre nie.
- Moenie gebruik ná die vervaldatum wat op die etiket of karton 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 TENOBINE bevat

Die aktiewe bestanddele van TENOBINE is emtrisitabien en tenofovirdisoproksielfumaraat.
Elke filmbedekte tablet bevat 200 mg emtrisitabien en 300 mg tenofovirdisoproksielfumaraat (tenofovir DF).
Die ander bestanddele is:
Natriumkruiskarmellose, magnesiumstearaat, mikrokristallyne sellulose, voorafgegelatiniseerde stysel, laktosemonohidraat (“Pharmatose 200M”)

Bedekkingshulpstowwe:
“Opadry II” Blou (bedekking) bevat: hipromellose 15 Cp, FD&C blou #2/ indigokarmyn aluminium lak, laktosemonohidraat, titaniumdioksied (CI 77891), “Triacetin”.

Hoe TENOBINE lyk en die inhoud van die verpakking

TENOBINE filmbedekte tablette is blou, kapsuul-vormige tablette met 'H' aan die een kant gegraveer en '124' aan die ander kant.
TENOBINE word verpak in veiligheidshouers in hoeveelhede van 28's, 30's, 56's of 60's in 'n wit, ondeursigtige HDPE-houer met 'n wit, geriffelde plastieksluiting met aaneenlopende skroefdraad met 'n pulpvoering.
Nie alle verpakkingsgroottes mag dalk bemark word nie.

HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

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