PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

EMTEN tablets

Tenofovir disoproxil fumarate 300 mg and emtricitabine 200 mg.

Sugar free

Read all of this leaflet carefully before you start taking EMTEN

- 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.
- EMTEN 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 EMTEN is and what it is used for

EMTEN helps to block enzymes that are needed for the HIV virus to multiply.

Treatment for HIV infection

EMTEN is used with other anti-HIV medicines (antiretrovirals), to treat people that are infected with the human immuno-deficiency virus (HIV). HIV is the virus that causes acquired immune deficiency syndrome (AIDS).

Treatment for Pre-Exposure Prophylaxis (PrEP)

To reduce the risk of getting HIV-1 in adults, EMTEN is to be used in combination with safer sex practices and rigorous use at all times. This is called Pre-Exposure Prophylaxis or PrEP.

2. What you need to know before you take EMTEN

Do not take EMTEN:

- if you are hypersensitive (allergic) to tenofovir disoproxil fumarate, emtricitabine or to any of the ingredients contained in EMTEN (see section 6),
- if you have moderate to severe renal (kidney) problems (see Warnings and Precautions),
- If you are HIV positive or if your HIV status is not known, when using EMTEN to prevent HIV infection.
- If you are not fully committed to use EMTEN every day for Pre-Exposure Prophylaxis.
- If you are pregnant or breastfeeding (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Special care should be taken with EMTEN: (Please inform your doctor)

- if you experience lipodystrophy and metabolic abnormalities (if you pick up weight on your body, lose weights on your arms, legs and face and if your blood sugar and cholesterol levels increase).

- if you are over 65 or under 18 years of age.
- if you have a history of liver disease including hepatitis B or C.
- if after taking EMTEN you start suffering from possible Immune Reconstitution Inflammatory Syndrome (IRIS). IRIS is a reaction where your immune system begins to recover, but then responds to a previously acquired opportunistic infection with an overwhelming inflammatory response that can make the symptoms of the infection worse.
- if you develop any signs of infection and inflammation, as you may continue to develop other complications of HIV. You need to remain under close observation by your healthcare professional and your CD4 count and viral load will still need to be monitored.
- if you are sexually active appropriate precautions should be taken as EMTEN does not prevent the risk of transmission of HIV to others.
- if after taking EMTEN, you start suffering the possible symptoms of lactic acidosis (deep, rapid breathing, drowsiness, stomach pain, nausea and vomiting).
- mitochondrial dysfunction: signs of this is lactic acidosis (build-up of an acid in the blood), blood disorders and peripheral neuropathy (persistent numbness, tingling or pain in the feet and/or hands).
- if you develop abdominal pain, nausea and vomiting as this could be symptoms of pancreatitis.
- If you have any bone problems as some patients taking EMTEN can develop bone diseases. Contact your doctor if you experience joint pain, joint stiffness or difficulty in movement.
- If you are suffering from kidney problems or have had kidney problems in the past or are taking medicines that can cause kidney problems.

Other medicines and EMTEN

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

It is important to tell your healthcare provider if you are taking any of the following:

- Any other antiretroviral medicines.
- Didanosine taken with tenofovir (a component of EMTEN) may increase the amount of didanosine in your blood, which could result in more side effects.
- Atazanavir sulphate or lopinavir and ritonavir co-formulation. These medicines may increase the amount of tenofovir (a component of EMTEN) in your blood, which could result in more side effects.
- Lamivudine and zidovudine co-formulation, lamivudine and abacavir sulphate as these medicines should not be used with EMTEN.

Pregnancy, breastfeeding and fertility

Pregnancy and Breastfeeding

You should not take EMTEN if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, 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.

A reliable method of contraceptive should be used to avoid pregnancy while taking EMTEN.

Driving and using machines

Dizziness, impaired concentration and drowsiness may occur when taking EMTEN. If this happens, do not drive or use machines that require you to be alert.

3. How to take EMTEN

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

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

The usual dose is one tablet once daily taken orally with or without food.

Dosage for Pre-Exposure Prophylaxis

The dose of EMTEN in HIV-1 uninfected adults is one tablet once daily taken orally with or without food.

To reduce the risk of getting HIV-1, your partner must use a condom.

Your doctor will tell you how long your treatment with EMTEN will last. Do not stop early because resistance can develop and EMTEN will no longer work for you. If you have the impression that the effect of EMTEN is too strong or too weak, tell your doctor or pharmacist.

If you take more EMTEN than you should

If you accidently take too many EMTEN tablets, contact your doctor or nearest emergency rooms for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

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

If you forget to take EMTEN

If you forget to take EMTEN, take the missed dose right away, unless it is almost time for the next dose. Do not double the next dose. Carry on with your regular dosing schedule.

Effects when treatment with EMTEN is stopped

Even if you feel better, do not stop taking EMTEN without consulting your doctor first, as the amount of HIV in your blood may increase.

4. Possible side effects

EMTEN can have side effects.

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

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

Lactic acidosis (too much lactic acid in the blood) is a less frequent but very serious side effect that can be fatal. The following may be signs of lactic acidosis:

- you have deep rapid breathing
- you feel drowsy
- you feel sick (nausea) or are sick (vomiting) and have stomach pain

Serious liver problems

Some people taking medicine like EMTEN have developed serious liver problems called liver toxicity, with liver enlargement (hepatomegaly) and fat in the liver (steatosis).

The following side effects may be signs of liver problems:

- your skin or white part of your eye turns yellow (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 have lower stomach area (abdominal) pain

"Flare-ups" of Hepatitis B (HBV infection)

Some people who have had HBV and stop taking EMTEN can have the HBV suddenly return in a worse way than before. Your healthcare provider will monitor your condition for several months after stopping EMTEN if you have both HIV and HBV infection. Your healthcare provider may recommend that you be given treatment for your HBV.

Severe allergic reactions

- swelling of the hands, feet, face, skin or other tissues,
- 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 EMTEN. You may need urgent medical attention or hospitalisation.

Other possible serious side effects

The following side effects can occur **frequently:**

Headache, dizziness nausea, vomiting, diarrhoea, abdominal pain, flatulence, bloatidness, upset stomach, rash, itchy skin, increase in your blood creatinine kinase, low blood phosphate level, increased amylase levels, increased serum lipase levels, skin discolouration, low white

blood cell count, increased levels of bilirubin in the blood, increased dilute urination, Increased blood sugar levels, increased triglyceride levels in the blood, weakness, pain.

The following side effects can occur **less frequently:**

Sleep disturbances (strange dreams, lack of sleep), muscular weakness, muscle pain, back pain, low blood count, blood in the urine, inflammation of the kidneys, kidney blockage, kidney failure, increased liver enzyme levels, inflammation of the liver, fatty liver, inflammation of the pancreas, swelling of the deep layers of the skin, low blood potassium levels.

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 EMTEN.

5. How to store EMTEN

- Store at or below 25 °C
- Keep HDPE containers tightly closed
- Keep the blisters in the outer carton until required for use
- KEEP OUT OF REACH OF CHILDREN

6. Contents of the pack and other information

What EMTEN contains

The active substances are tenofovir disoproxil fumarate 300 mg and emtricitabine 200 mg.

The other ingredients are:

- croscarmellose sodium
- magnesium stearate
- microcrystalline cellulose
- Pregelatinised starch

EMTEN is coated with Opadry AMB white 80W68912 which contains:

- polyvinyl alcohol
- soya lecithin
- talc
- titanium dioxide (CI 77891)
- xanthum gum

What EMTEN looks like and contents of the pack

White to off white, modified capsule shaped, film-coated tablets, debossed with “EM” on one side and “144” on the other side of the tablet.

<u>HDPE containers:</u>

28 or 30 tablets are packed in a 75 cc, white opaque, wide mouth round, HDPE container and closed with a 38 mm, white opaque, polypropylene child resistant closure. Each HPDE container contains a HDPE canister containing silica gel.

<u>Blister:</u>

Silver aluminium-aluminium foil blisters containing 10 tablets per blister strip.

Pack size: 30’s – Three blister strips are packed in a cardboard carton.

Holder of Certificate of Registration

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