WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

Information for the patient

Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets[1]
Emtricitabine/Tenofovir

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness seem to be the same as yours.
- If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets is and what it is used for

Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets is a treatment for Human Immunodeficiency Virus (HIV) infection in adults and adolescents over 10 years of age weighing more than 30 kg.
To prevent the virus from becoming resistant Emtricitabine/Tenofovir DF200 mg/300 mg Tablets should always be given in combination with at least one other antiretroviral medicine.

Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets is used to reduce the risk of getting HIV-1 infection in adults and adolescents who are not HIV infected (i.e. HIV-negative) and are at high risk of getting infected with HIV. This is called oral pre-exposure prophylaxis (PrEP).
It should be used in combination with safer sex practices (see section 2).

Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets contains the active substances *emtricitabine* and *tenofovir disoproxil* . Both of these are *antiretroviral* medicines for the treatment of HIV infection. Emtricitabine is a *nucleoside reverse transcriptase inhibitor*. Tenofovir is a *nucleotide reverse transcriptase inhibitor.* Both active substances work by interfering with the normal working of an enzyme (reverse transcriptase) that is essential for the virus to reproduce itself.

2. What you need to know before you take Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets

Do not take Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets:
If you are allergic (hypersensitive) to emtricitabine, tenofovir, tenofovir disoproxil fumarate or any of the other ingredients of Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets listed at the end of this leaflet.

[1]Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

If this applies to you, tell your health care provider immediately and don't take Emtricitabine /Tenofovir DF 200 mg/300 mg Tablets

Before taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets to reduce the risk of getting HIV:
Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets can only help reduce your risk of getting HIV **before** you are infected.

- **You must be HIV negative before you start to take** Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets **to reduce the risk of getting HIV**. You must get tested to make sure that you do not already have HIV infection. Do not take Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets to reduce your risk unless you are confirmed to be HIV negative. People who do have HIV must take Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets in combination with other drugs.
- **Many HIV tests can miss a recent infection.** If you get a flu-like illness, it could mean you have recently been infected with HIV. These may be signs of HIV infection:
  - tiredness
  - fever
  - joint or muscle aches
  - headache
  - vomiting or diarrhoea
  - rash
  - night sweats
  - enlarged lymph nodes in the neck or groin
  - **Tell your health care provider about any flu-like illness** – either in the month before starting Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets, or at any time while taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets.

Warnings and precautions

While taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets **to reduce the risk of getting HIV:**

- Do not miss any doses of Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets, or stop taking it. Missing doses may increase your risk of getting HIV infection.
- Get tested for HIV regularly.
- If you think you were infected with HIV, tell your health care provider straight away. More tests may be necessary to make sure you are still HIV negative.
- **Just taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets may not stop you getting HIV**.
- Always practice safer sex. Use condoms to reduce contact with semen, vaginal fluids, or blood.
- Do not share personal items that can have blood or body fluids on them, such as toothbrushes and razor blades.
- Do not share or re-use needles or other injection or drug equipment.
- Get tested for other sexually transmitted infections such as syphilis and gonorrhoea. These infections make it easier for HIV to infect you.

Ask your health care provider if you have any more questions about how to prevent getting HIV or spreading HIV to other people.

While taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets **to treat HIV or to reduce the risk of getting HIV:**

- **Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets may affect your kidneys**. Before and during treatment, your health care provider may order blood tests to measure kidney function. Tell your health care provider if you have had kidney disease, or if tests have shown kidney problems. If you have kidney problems, your health care provider may advise you to stop taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets or, if you already have HIV, to take Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets less frequently. Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets is not recommended if you have severe kidney disease or are on dialysis.

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

- **Talk to your health care provider if you have a history of liver disease, including hepatitis.** Patients infected with HIV who also have liver disease (including chronic hepatitis B or C), who are treated with antiretrovirals, have a higher risk of severe and potentially fatal liver complications. If you have hepatitis B or C, your health care provider will carefully consider the best treatment regimen for you.

  - **Know your hepatitis B virus (HBV) infection status** before starting Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets. If you have HBV, there is a serious risk of liver problems when you stop taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets, whether or not you also have HIV. It is important not to stop taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets without talking to your health care provider: see section 3, If you stop taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets.

- **Talk to your health care provider if you are over 65.** Emtricitabine/tenofovir disoproxil fumarate has not been studied in patients over 65 years of age.

- **This medicine is not a cure for HIV infection.** While taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets you may still develop infections or other illnesses associated with HIV infection. You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your health care provider the precautions needed to avoid infecting other people.

Children
Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets is not for use in children under 10 years of age.

Other medicines and Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets

Do not take Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets if you are already taking other medicines that contain the components of Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets (emtricitabine and tenofovir disoproxil fumarate) or any other antiviral medicines that contain tenofovir, tenofovir alafenamide, lamivudine or adefovir dipivoxil.

Taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets **with other medicines that can damage your kidneys:** it is especially important to tell your health care provider 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 pain)

If you are taking another antiviral medicine called a protease inhibitor to treat HIV, your health care provider may order blood tests to closely monitor your kidney function.
It is also important to tell your health care provider if you are taking ledipasvir/sofosbuvir to treat hepatitis C infection.

Taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets **with other medicines containing didanosine (for treatment of HIV infection):** Taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets 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 fumarate and didanosine were taken together. Your health care provider will carefully consider whether to treat you with combinations of tenofovir and didanosine.

➢ **Tell your health care provider** if you are taking any of these medicines. Tell your health care provider if you are taking, have recently taken or might take any other medicines.

Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets **with food and drink**

You can take Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets with food or between meals.

Pregnancy, breast-feeding and fertility
If you become pregnant or are planning to become pregnant, you must contact your health care provider to discuss the potential benefits and risks of taking this medicine to you and your child. Be sure to tell your health care provider immediately if you are or may be pregnant.

If you are interested in breastfeeding your baby, you should discuss the risks and benefits with your health care provider.

Driving and using machines
Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets can cause dizziness. If you feel dizzy while taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets, **do not drive** and do not use any hazardous tools or machines.

Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets contains lactose.
If you have been told by your health care provider that you have an intolerance to some sugars, contact your health care provider before taking this medicinal product.

3. How to take Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets

Always take Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets and the doses exactly as your health care provider has told you. This is to make sure that your medicine is and remains fully effective. You should check with your health care provider if you are not sure. Do not change the dose unless your health care provider tells you to.

The dose for adolescents and adults is **one tablet each day**.

You can take Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets with food or between meals. Swallow Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets whole with water or another liquid.

When used for HIV-treatment:
This product is not for use by children under 10 years of age or adolescents weighing less than 30 kg.

When used for reducing the risk of getting HIV-1 infection:
This product is not for use by children under 10 years of age or adolescents weighing less than 35 kg.

For treatment of established HIV-infection:
Your health care provider will prescribe Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets with at least one other antiretroviral medicine. Please refer to the patient information leaflets of the other antiretrovirals for guidance on how to take those medicines.

If your health care provider decides to stop one of the components of Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets or change the dose of this medicine, you may be given emtricitabine and/or tenofovir separately instead of the combined medicine or other medicines for the treatment of HIV infection.

If you have problems with your kidneys, your health care provider may advise you to take Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets less frequently.

If you take more Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets than you should:
If you accidentally take too many Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets, contact your health care provider or nearest emergency department for advice. Take the tablet container with you so that you can easily describe what you have taken.

If you forget to take Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets:
It is important not to miss a dose of Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets. If you miss a dose of this medicine, take it as soon as you can, and then take your next dose at its regular time. However, if your next dose is due within 6 hours, do not take the missed dose. Wait and take the next dose at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you vomit less than 1 hour after taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets, take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking this medicine.

If you stop taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets:
Don’t stop taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets without your health care provider’s advice. Stopping Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets may reduce the effectiveness of the treatment. Talk to your health care provider before you stop taking Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets for any reason, particularly if you are experiencing any side effects, have another illness, or if you think you are no longer at risk of getting infected with HIV.
Contact your health care provider before you restart taking Emtricitabine/Tenofovir DF 200 mg/ 300 mg Tablets

If you have hepatitis B or HIV and hepatitis B together (co-infection), it is very important not to stop your Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets treatment without talking to your health care provider first. Some patients have had blood tests or symptoms indicating that their hepatitis has got worse after stopping this medicine. You may require blood tests for several months after stopping treatment. Tell your health care provider immediately about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection.

If you have any further questions on the use of this product, ask your health care provider.

4. Possible side effects

Like all medicines, this medicine can cause side effects. Possible side effects of this medicine are listed below but they affect people differently and not everybody gets them.

The following side effects have been observed in patients who were treated for HIV-1 infection.

Possible serious side effects:

- **Lactic acidosis** (excess lactic acid in the blood) is a rare but potentially life-threatening side effect. Lactic acidosis occurs more often in women, particularly if they are overweight, and in people with liver disease. The following may be signs of lactic acidosis:
  - deep rapid breathing
  - drowsiness
  - feeling sick (nausea), being sick (vomiting)
  - stomach pain

➢ **If you think you may have lactic acidosis, get medical help immediately.**

- **Any signs of inflammation or infection**. In some patients with advanced HIV infection (AIDS) and a history of opportunistic infections (infections that occur in people with a weak immune system), signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is thought that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.
- **Autoimmune disorders**, when the immune system attacks healthy body tissue, may also occur after you start taking medicines to treat HIV infection. Autoimmune disorders may occur many months after the start of treatment. Look out for any symptoms of infection or other symptoms such as:
- muscle weakness
- weakness beginning in the hands and feet and moving up towards the trunk of the body
- palpitations, tremor or hyperactivity

➢ **If you notice these or any symptoms of inflammation or infection, get medical help immediately.**

Possible side effects:

Very common side effects
(may affect more than 1 in 10 people)

- diarrhoea, being sick (vomiting), feeling sick (nausea)
- dizziness, headache
- rash
- feeling weak

Tests may also show:

- decreases in phosphate in the blood
- increased creatine kinase

Common side effects
(may affect up to 1 in 10 people)

- pain, stomach pain
- difficulty sleeping, abnormal dreams

- problems with digestion resulting in discomfort after meals, feeling bloated, flatulence
- rashes (including red spots or blotches sometimes with blistering and swelling of the skin), which may be allergic reactions, itching, changes in skin colour including darkening of the skin in patches
- other allergic reactions, such as wheezing, swelling or feeling light-headed

Tests may also show:

- low white blood cell count (a reduced white blood cell count can make you more prone to infection)
- increased triglycerides (fatty acids), bile or sugar in the blood
- liver and pancreas problems

Uncommon side effects
(may affect up to 1 in 100 people)

- pain in the abdomen (tummy) caused by inflammation of the pancreas
- swelling of the face, lips, tongue or throat
- anaemia (low red blood cell count)
- breakdown of muscle, muscle pain or weakness which may occur due to damage to the kidney tubule cells

Tests may also show:

- decreases in potassium in the blood
- increased creatinine in your blood
- changes to your urine

Rare side effects
(may affect up to 1 in 1,000 people)

- Lactic acidosis (see *Possible serious side effects*)
- fatty liver
- yellow skin or eyes, itching, or pain in the abdomen (tummy) caused by inflammation of the liver
- inflammation of the kidney, passing a lot of urine and feeling thirsty, kidney failure, damage to kidney tubule cells
- softening of the bones (with bone pain and sometimes resulting in fractures)
- back pain caused by kidney problems

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

- **If you notice any of the side effects listed above or if any of the side effects get serious**, talk to your health care provider.

The frequency of the following side effects is not known.

- **Bone problems**. Some patients taking combination antiretroviral medicines such as Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). Taking this type of medicine for a long time, taking corticosteroids, drinking alcohol, having a very weak immune system, and being overweight, may be some of the many risk factors for developing this disease.

Signs of osteonecrosis are:

- joint stiffness
- joint aches and pains (especially of the hip, knee and shoulder)
- difficulty with movement

- **If you notice any of these symptoms tell your health care provider.**

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

Adults not infected with HIV and using tenofovir disoproxil fumarate/emtricitabine to reduce the risk of getting HIV-1 infection experienced in clinical trials no side effects other than those described above.
The following side effects were reported in at least 2% of the participants and occurred slightly more frequently in the treatment group (as compared to placebo):
Headache, abdominal pain, weight decrease and syphilis (a sexually transmitted infection).

Reporting of side effects
If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets

Do not store above 30 ºC. Store in original container.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets contains

The active substance(s) are 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate (TDF) equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir.

The other ingredients are:
Core tablet: Microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, pregelatinized starch, magnesium stearate

Film coat: Hypromellose, lactose monohydrate, titanium dioxide, triacetin and FD&C Blue # 2 / Indigo carmine aluminum lake.

What Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets looks like and contents of the pack
Emtricitabine/Tenofovir DF 200 mg/300 mg Tablets are blue coloured, capsule shaped, film coated tablet, debossed with ‘I’ on one side and ‘45’ on the other side.

The primary packs are:
- White opaque HDPE bottle secured with a white polypropylene child resistant cap. The bottle pack includes a canister containing silica gel desiccant. Pack sizes: 30 and 100 tablets.

- Alu-Alu blister cards containing 10 tablets. 3 or 10 cards per box.

Supplier and Manufacturer

Supplier
Micro Labs Limited
27, Race Course Road
Bangalore - 560001, Karnataka
India
Tel: +91-80-2237 0451 to 2237 0457
Fax: +91-80-2237 0463

Manufacturer
Micro Labs Limited
Plot No: S-155 to S-159 & N1
Phase III & IV
Verna Industrial Estate
Verna, Goa- 403722
India

For any information about this medicine, contact the supplier:

This leaflet was prepared in May 2017
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Detailed information on this medicine is available on the World Health Organization (WHO) web site: https://extranet.who.int/prequal/.