APPROVED BY THE MINISTRY OF HEALTH ON JUNE 2022

Information for patient about Teva preparations Emtricitabine/Tenofovir Disoproxil

Emtrivir Teva*
which contains Emtricitabine/Tenofovir Disoproxil fumarate
Emtricitabine/Tenofovir Teva*
which contains Emtricitabine/Tenofovir Disoproxil Phosphate,
for the indication of pre-exposure prophylaxis (PrEP) treatment
for human immunodeficiency virus (HIV-1)

החברה הישראלית לרפואת איידס

הוועד למלחמה באיידס
ISRAEL AIDS TASK FORCE

* For ease of reading, throughout the document, the name Emtricitabine/Tenofovir will refer to either Emtrivir Teva or Emtricitabine/Tenofovir Teva

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This brochure contains important safety information and guidelines on taking Emtricitabine/Tenofovir for pre-exposure prophylaxis (prevention) against human immunodeficiency virus (HIV). Read it carefully and keep it for future reference.

The purpose of this brochure is to complete the information in the consumer's leaflet.
For full information about Emtricitabine/Tenofovir, refer to the consumer's leaflet enclosed with the drug package.
If you have additional questions, please ask the doctor or pharmacist.

Emtricitabine/Tenofovir, which contains the substances emtricitabine and tenofovir disoproxil, is a prescription product, designed to reduce the risk of HIV infection in adults, together with safe sexual conduct.

What you should know before and while taking Emtricitabine/Tenofovir in order to reduce the risk for HIV infection

- Emtricitabine/Tenofovir for the indication of PrEP is designed to reduce the risk of HIV-1 infection, but only in patients who tested negative for the virus before starting Emtricitabine/Tenofovir.
- Mutations in HIV-1 that are resistant to Emtricitabine/Tenofovir were detected in people who were infected with HIV, but did not know it, and took Emtricitabine/Tenofovir without any other medication to treat their HIV infection. Therefore, you must test negative for HIV-1 infection before starting Emtricitabine/Tenofovir for PrEP. You must also repeat the HIV test at least every 3 months in order to make sure that your HIV status remains negative while on PrEP.

Do not take Emtricitabine/Tenofovir unless you were tested and found negative for HIV.

- Do not start or continue Emtricitabine/Tenofovir for PrEP if signs and/or symptoms of an acute HIV infection appear. Therefore, tell your doctor if you've experienced symptoms of the flu in the month prior to initiation of PrEP or at any time during PrEP administration.
- If you have engaged in a sexual interaction that might have put you at risk of HIV-1 infection, it is important that you know the signs and symptoms which might indicate recent HIV infection:
  - » Tiredness
  - » Fever
  - » Joint or muscle aches
  - » Headache
  - » Vomiting or diarrhea
  - » Rash
  - » Night sweats
  - » Enlarged lymph nodes in the neck or groin

Take Emtricitabine/Tenofovir according to the approved dosing regimen, which is one tablet a day, every day.

- Take Emtricitabine/Tenofovir as instructed by your doctor.
  If you are unsure, ask your doctor or pharmacist.
- The recommended dosing regimen is one tablet a day, every day, and preferably with food. Do not take Emtricitabine/Tenofovir at a different dosing regimen or stop it without recommendation from your doctor. Skipping doses or irregular intake of the product increases the risk for HIV-1 infection and resistance to treatment with the Emtricitabine/Tenofovir in case of HIV-1 infection.
- **You must have routine HIV tests, at least every 3 months while taking Emtricitabine/Tenofovir for PrEP.**
- If there is suspicion that you may have

become infected with HIV, inform the doctor immediately. The doctor will run a test to reconfirm that you are negative for the HIV-1 infection before you continue Emtricitabine/Tenofovir.

Take Emtricitabine/Tenofovir every day, not only when you think you are at a risk for an HIV infection.

- Do not skip doses or stop treatment without informing the doctor.
- Skipping a dose might put you at an increased risk for HIV infection.
- If you forget to take Emtricitabine/Tenofovir and less than 12 hours have passed from the time you usually take Emtricitabine/Tenofovir, take the tablet as soon as possible, preferably with food. Take the next dose at your usual time.
- If more than 12 hours have passed from the time you usually take Emtricitabine/Tenofovir, do not take the tablet and take the next dose at your usual time.
- If you vomited less than an hour after taking the tablet, take another tablet. Do not take Emtricitabine/Tenofovir if the vomiting took place more than an hour after intake.

Take action in order to remain HIV negative while taking Emtricitabine/Tenofovir

Emtricitabine/Tenofovir alone is not a complete regimen for the treatment of HIV infection and does not protect against infection with other sexually transmitted diseases.

• Use Emtricitabine/Tenofovir with other measures for preventing infection, including engaging in safe sexual conduct.

This includes:

- » Using a condom to reduce contact with semen, vaginal fluids or blood
- » Not sharing needles, syringes or other medical equipment
- » Getting checked routinely for other sexually transmitted diseases such as syphilis, chlamydia and gonorrhea is recommended, since these infections increase the risk of getting infected with HIV.
- » Requesting information and support on reducing sexual conduct that might put you at a higher risk for an HIV infection.

Know your hepatitis B (HBV) infection status before starting Emtricitabine/Tenofovir for PrEP

- If you have a background of hepatitis B infection, there is a substantial risk for an acute flare up of hepatitis and the aggravation of hepatic diseases after stopping Emtricitabine/Tenofovir.
- Therefore, if you have a hepatitis B infection, inform your doctor before treatment initiation and if you want to stop Emtricitabine/Tenofovir.
- If you are negative for hepatitis B, it is recommended that you get the vaccine against hepatitis B before beginning Emtricitabine/Tenofovir.

Emtricitabine/Tenofovir's side effects

- As with all medical products, Emtricitabine/Tenofovir may cause side effects.
- The most common side effects of the product include:
  - » Diarrhea
  - » Being sick (Vomiting)
  - » Feeling sick (Nausea)
  - » Dizziness
  - » Headache
  - » Rash
  - » Feeling weak

  Tests also show:
  - decreases in phosphate in the blood
  - increased creatine kinase (an enzyme that may indicate muscle damage)
- Emtricitabine/Tenofovir may also cause serious side effects, including new renal (kidney) effects and the worsening of existing kidney disease as well as bone

effects. Therefore, before and while taking Emtricitabine/Tenofovir for PrEP, you will have to undergo tests to check kidney function. Inform the doctor if you have a kidney disease, abnormal kidney function tests or if you are taking additional drugs.

- Bone problems (which can show up as persistent or worsening bone pain and sometimes with fractures) may also occur due to damage to the kidneys. Tell your doctor if you have bone pain or fractures.
- Drugs containing a nucleotide analog, including Emtricitabine/Tenofovir, might cause lactic acidosis (excess lactic acid in the blood). Fast and deep breathing, drowsiness and non-specific symptoms such as nausea, vomiting and stomach pains may be signs of this condition. Sometimes, this rare but serious side effect can be life threatening. Lactic acid increase is more common in women, especially in case of obesity. There is also a high risk of developing this condition if you have liver disease. If you feel these symptoms, see a doctor immediately.
- Patients with a chronic liver disease, including hepatitis B or C, who are treated with antiretroviral products, are at a higher risk for developing serious hepatic (liver) complications which might be life threatening. If you have an underlying liver disease (including hepatitis B, C), inform the doctor before starting treatment.
- Inform the doctor if you experience a side effect which does not go away or one of the side effects specified in the patient leaflet.
- Refer to Emtricitabine/Tenofovir's patient leaflet for the full information about the product's side effects.

Pregnancy and breastfeeding

- The information about safety of use Emtricitabine/Tenofovir during pregnancy is limited but does not indicate the formation of defects or toxic effects on the fetus.
- If you are pregnant, may be pregnant or are planning a pregnancy, inform the doctor.
- If you have taken Emtricitabine/Tenofovir during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child.
- **Do not breastfeed while taking Emtricitabine/Tenofovir**. This is because the active substances in this medicine pass into human breast milk and the effect on the baby is uncertain.

Reporting side effects:

Side effects can be reported to the Ministry of Health using the online form for side effect reporting that is found in the Ministry of Health homepage:
www.health.gov.il

or via the link:
https://sideeffects.health.gov.il

or through the registration holder:
safety.israel@teva.co.il

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