PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Emtricitabine/Tenofovir Teva

Film-coated tablets

Composition
Each film-coated tablet contains:
Emtricitabine 200 mg
Tenofovir disoproxil (as phosphate) 245 mg
For information on the inactive and allergenic ingredients, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Further information".

Read the leaflet carefully in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

The medicine is intended for adults above the age of 18 years.

In addition to the leaflet, there is also a Patient Safety Information Booklet for Emtricitabine Tenofovir Teva. This booklet contains important safety information that you should know and adhere to before commencing treatment and during treatment with the medicine. Read both the Patient Safety Information Booklet and the patient leaflet before starting to use the preparation. The booklet should be kept for further reference if necessary.

1. WHAT IS THE MEDICINE INTENDED FOR?

Emtricitabine Tenofovir Teva is a treatment for human immunodeficiency virus (HIV) infection in adults aged 18 years and over in combination with other antiretroviral medicines.

Therapeutic group:
Antiviral reverse transcriptase inhibitors.
Emtricitabine Tenofovir Teva **contains two active substances**, emtricitabine and tenofovir disoproxil. Both of these active substances are antiretroviral medicines used to treat HIV infection. Emtricitabine is a *nucleoside reverse transcriptase* inhibitor and tenofovir is a *nucleotide reverse transcriptase* inhibitor. However, both medicines are generally known as nucleoside reverse transcriptase inhibitors (NRTIs) and they act by interfering with the normal activity of an enzyme (reverse transcriptase) that is essential for the replication process of HIV.

- **Emtricitabine Tenofovir Teva is used to treat human immunodeficiency virus 1 (HIV-1) infection, in adults aged 18 years and over.**
  - Emtricitabine Tenofovir Teva should always be used in combination with other medicines to treat HIV infection.
  - Emtricitabine Tenofovir Teva can be taken instead of separately taking emtricitabine and tenofovir disoproxil in the same dosages.

This medicine does not cure HIV infection. While taking Emtricitabine Tenofovir Teva, you may still develop infections or other illnesses associated with HIV infection.

- **Emtricitabine Tenofovir Teva is also used to reduce the risk of contracting HIV-1 infection in adults**, when the medicine is taken as a daily treatment, together with safe sexual behavior:

See section 2 for a list of precautionary measures to take against contracting HIV-1.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- You are sensitive (allergic) to emtricitabine, tenofovir, tenofovir disoproxil or to any of the additional ingredients contained in the medicine medicine (listed in section 6).

If any of these apply to you, tell the doctor immediately.

Special warnings regarding use of the medicine
Before using Emtricitabine Tenofovir Teva, to reduce the risk of contracting HIV:
Emtricitabine Tenofovir Teva can help you reduce the risk of contracting HIV, only if you are **not yet** infected.

- **Before beginning treatment with Emtricitabine Tenofovir Teva, you should not be a carrier of HIV, to reduce the risk of contracting HIV**. You have to be tested to confirm that you are not already a carrier of HIV. Do not take the medicine to reduce the risk unless you have confirmed that you are not an HIV carrier. HIV carriers must take Emtricitabine Tenofovir Teva in combination with other medicines.
- **Many HIV tests may not diagnose recent infection**. If you have a flu-like illness, it could mean you have recently been infected with HIV. Signs that could be indicative of HIV infection are:
  tiredness; fever; muscle or joint aches; headaches; vomiting or diarrhea; rash; night sweats; enlarged lymph nodes in the neck or groin

Inform your doctor about any flu-like illness – either during the month before starting treatment with Emtricitabine Tenofovir Teva, or at any time while taking the medicine.

Warnings and precautions
While taking Emtricitabine Tenofovir Teva to reduce the risk of contracting HIV:

- Take Emtricitabine Tenofovir Teva every day **in order to reduce the risk, not only when you think you have been at risk of contracting HIV**. Do not miss any Emtricitabine Tenofovir Teva doses or stop taking the medicine. Missing doses may increase your risk of contracting HIV.
- Get tested for HIV regularly.
- Report to the doctor immediately if you think you were infected with HIV. The doctor may perform additional tests to make sure you are not an HIV carrier.
- **Taking Emtricitabine Tenofovir Teva alone may not stop you from contracting the virus**. Therefore, you must take the following steps:
  - Always practice safe sexual behavior. Use a condom to reduce contact with seminal fluid, vaginal secretions or blood.
  - Do not share personal items that could have blood or body fluids on them, such as toothbrushes and razor blades.
  - Do not share or re-use needles, other injection or medical devices.
  - Get tested for other sexually transmitted diseases such as syphilis and gonorrhea. These infections make it easier for the HIV virus to infect you.

Consult the attending doctor if you have any more questions about how to prevent contracting HIV or infecting other people with HIV.

While taking Emtricitabine Tenofovir Teva to treat HIV or to reduce the risk of contracting HIV:

- **Emtricitabine Tenofovir Teva may affect the kidneys**. Before starting, as well as during treatment, the doctor may refer you for blood tests to assess kidney function. Tell the doctor if you have had kidney disease, or if the tests indicated a kidney problems. If you have kidney problems, the doctor may instruct you to stop taking the medicine or, if you are an HIV carrier, the doctor may instruct you to take the medicine less frequently. Emtricitabine Tenofovir Teva is not recommended if you have severe kidney disease or if you are being treated with dialysis.
- Tell your doctor if you suffer from osteoporosis, have a history of bone fractures or if you have problems with your bones.
  Bone problems (which appear as prolonged or worsening bone pain that sometimes result in fractures) may also occur due to damage to kidney tubule cells (see section 4 "*Side effects*"). Tell your doctor if you have bone pain or fractures.
  Tenofovir disoproxil may also cause a reduction in bone mass. Pronounced bone loss was seen in clinical studies when patients were treated with tenofovir disoproxil in combination with a boost of protease inhibitors.
  Overall, the effects of tenofovir disoproxil on long-term bone health and future fracture risk in adults are uncertain.
- **Talk to the doctor if you have a history of liver disease, including hepatitis**. Patients with both HIV and liver disease (including chronic hepatitis B or C), treated with antiretroviral drugs, are at higher risk of developing potentially fatal liver complications. If you have hepatitis B or C, the doctor will carefully consider the best treatment regimen for you.
- **Know the status of your hepatitis B virus (HBV) infection** before starting to take Emtricitabine Tenofovir Teva. If you have hepatitis B, there is a serious risk of liver problems when discontinuing Emtricitabine Tenofovir Teva, whether or not you have HIV. It is important not to stop taking Emtricitabine Tenofovir Teva without consulting a doctor: see section 3 *"Do not stop taking Emtricitabine Tenofovir Teva"*.
- **Consult the doctor if you are over 65 years of age**. The medicine has not been studied in patients over 65 years of age.

Children and adolescents
Emtricitabine Tenofovir Teva is not intended for use in children and adolescents under 18 years of age.

Drug interactions
Do not take Emtricitabine Tenofovir Teva if you are already taking other medicines that contain the ingredients of Emtricitabine Tenofovir Teva (emtricitabine and tenofovir disoproxil) or any other antiviral medicine containing tenofovir alafenamide, lamivudine or adefovir dipivoxil.
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Taking Emtricitabine Tenofovir Teva together with other medicines that can damage your kidneys: It is especially important to tell the doctor if you are taking other medicines, including:
- aminoglycosides (to treat bacterial infection)
- amphotericin B (to treat fungal infection)
- foscarnet (to treat viral infection)
- ganciclovir (to treat viral infection)
- pentamidine (to treat infections)
- vancomycin (to treat bacterial infection)
- interleukin-2 (to treat cancer)
- cidofovir (to treat viral infection)
- non-steroidal anti-inflammatory drugs (NSAIDs; to relieve bone or muscle pain)

If you are taking another antiviral medicine called a protease inhibitor to treat HIV, the doctor may refer you for blood tests to closely monitor your kidney function.
It is important to tell the doctor if you are taking ledipasvir/sofosbuvir, sofosbuvir/velpatasvir or sofosbuvir/velpatasvir/voxilaprevir to treat hepatitis C infection.
Taking Emtricitabine Tenofovir Teva with other medicines containing didanosine (for treatment of HIV infection): Taking Emtricitabine Tenofovir Teva together with other antiviral medicines that contain didanosine may raise the levels of didanosine in the blood and reduce CD4 cell count. Rarely, inflammation of the pancreas and lactic acidosis (excess lactic acid in the blood), which sometimes cause death, have been reported when medicines containing tenofovir disoproxil and didanosine were taken at the same time. The doctor will carefully consider whether to treat you with combinations of tenofovir and didanosine.
Tell the doctor if you are taking any of these medicines. If you are taking or if you have recently taken any other medicines, or if you may take any other medicines, tell the doctor or pharmacist.

Use of the medicine and food
When possible, Emtricitabine Tenofovir Teva should be taken with food.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you might be pregnant, or plan to become pregnant, consult with the doctor or pharmacist before taking any medicine.
If you have taken Emtricitabine Tenofovir Teva during pregnancy, the doctor may ask you to have regular blood tests and other diagnostic tests performed to monitor the development of your child. In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV virus outweighed the risk of side effects.

- **Do not breastfeed during treatment with Emtricitabine Tenofovir Teva,** since the active ingredients in this medicine pass into breast milk.
- Breastfeeding is not recommended in women living with HIV because HIV infection can be passed on to the baby in breast milk.
- If you are breastfeeding, or are thinking about breastfeeding, **you should discuss it with your doctor as soon as possible.**

Driving and operating machinery
Emtricitabine Tenofovir Teva may cause dizziness. If you feel dizzy when taking the medicine, **do not drive** or operate tools or machinery.

Important information about some of the ingredients of the medicine
This medicine contains less than 23 mg sodium per tablet and is therefore considered "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the preparation dosage and treatment regimen.

The recommended dosage of Emtricitabine Tenofovir Teva for treatment of HIV or to reduce the risk of contracting HIV is:
Adults: one tablet per day.
When possible, Emtricitabine Tenofovir Teva should be taken with food.

Do not exceed the recommended dose.
In the case of difficulty swallowing, the tablet may be crushed with the tip of a teaspoon (or divided into smaller pieces, but be sure to swallow all the parts of the tablet immediately), then mix the powder in about 100 ml (half a cup) of water, orange juice or grape juice and drink immediately.

- **Always take the dosage recommended by the doctor** to ensure that the medicine is fully effective and to reduce the risk of developing resistance to treatment. Do not change the dosage without instruction from a doctor.
- **If you are being treated for HIV infection**, your doctor will prescribe Emtricitabine Tenofovir Teva together with other antiretroviral medicines. Please read the patient leaflet of the other antiretroviral medicines for guidance on how to take those medicines.
- **If you are an adult taking Emtricitabine Tenofovir Teva to reduce the risk of contracting HIV**, take Emtricitabine Tenofovir Teva every day, not only when you think you may be at risk for contracting HIV.

Refer to your doctor for any question regarding prevention of contraction of HIV or preventing infection of other people with HIV.

If you took a higher dosage of Emtricitabine Tenofovir Teva than required
If you accidentally took a higher dosage of Emtricitabine Tenofovir Teva than required, refer to a doctor or proceed to the closest hospital emergency room and consult with them. Bring the package of the medicine with you so you will be able to easily describe what you have taken.

If you missed a dose
It is important not to miss any dose of Emtricitabine Tenofovir Teva.
If you realized within 12 hours of the time that you usually take Emtricitabine Tenofovir Teva, take the tablet as soon as possible, preferably with food. Then take the next dose at the regular time.
If you realized 12 hours or more after the time that you usually take Emtricitabine Tenofovir Teva, do not take the missed dose. Wait and take the next dose at the regular time, preferably with food.
If you vomited within less than one hour after taking Emtricitabine Tenofovir Teva, take another tablet. If you vomited more than one hour after taking Emtricitabine Tenofovir Teva, there is no need to take another tablet.

Do not stop taking Emtricitabine Tenofovir Teva

- **If you are taking Emtricitabine Tenofovir Teva for treatment of HIV**, stopping administration of the tablets may reduce the effectiveness of the anti-HIV therapy recommended by the doctor.
- **If you are taking Emtricitabine Tenofovir Teva to reduce the risk of contracting HIV**, do not stop taking Emtricitabine Tenofovir Teva, any doses. Stopping use of the medicine or missing a dose may increase the risk of contracting HIV.

Do not stop taking Emtricitabine Tenofovir Teva without consulting the doctor.

- **If you have hepatitis B infection**, it is particularly important not to stop the treatment with Emtricitabine Tenofovir Teva without first consulting a doctor. You may need to undergo blood tests for several months after stopping treatment. In some patients with advanced liver disease or cirrhosis, stopping treatment is not recommended, as this may lead to worsening of the hepatitis, which could be life-threatening.
  Tell the doctor immediately about new or unusual symptoms that occurred after you stopped treatment, especially symptoms that you associate with the hepatitis B infection.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Emtricitabine Tenofovir Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Tell the doctor if you have any of the following side effects:

Possible severe side effects: tell the doctor immediately

- **Lactic acidosis** (excess lactic acid in the blood) is a rare side effect. However, it may be life-threatening. Lactic acidosis occurs more frequently in women, especially if they are overweight, and in people with liver disease. Possible signs of lactic acidosis:
  - deep and rapid breathing
  - sleepiness
  - nausea, vomiting
  - abdominal pain

If you think you may have lactic acidosis, refer for medical treatment immediately.

- **Any sign of inflammation or infection**. In some patients with an 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. The hypothesis is that these symptoms occur due to an improvement in the body's immune response, which enables the body to fight infections that were present but with no observable symptoms.
- **Autoimmune disorders**, a condition in which the immune system attacks healthy body tissues, which may occur even after you start taking medicines to treat the HIV infection. Autoimmune disorders may develop many months after starting treatment. Pay attention to any symptoms of infection or other symptoms such as:
  - muscle weakness
  - weakness that starts in the palms of the hands and soles of the feet and moves up towards the trunk of the body
  - palpitations, tremor or hyperactivity

If you notice these symptoms or any other sign of inflammation or infection, refer for medical care immediately.

Possible side effects:
Very common side effects (*may affect more than one in 10 patients*):
- diarrhea, nausea, vomiting
- dizziness, headache
- rash
- feeling weak

Blood tests may also indicate:
- a decrease in blood level of phosphorus
- an increase in level of creatine kinase

Common side effects (*may affect up to 1 in 10 patients*):
- pain, abdominal pain
- insomnia, abnormal dreams
- problems with digestion that cause discomfort after meals, feeling bloated, flatulence
- rashes (including red spots or large red patches, sometimes with blisters and swelling of the skin), which may be allergic reactions, itching, changes in skin color, including formation of dark patches on the skin
- other allergic reactions, such as wheezing, swelling or feeling lightheaded
- loss of bone mass

Tests may also indicate:
- low white blood cell count (a reduced white blood cell count may make you more prone to infections)
- high triglycerides (fatty acids), bile or sugar level in the blood
- liver and pancreas problems

Uncommon side effects (*may affect up to one in 100 patients*):
- abdominal pain caused by inflammation of the pancreas
- swelling of the face, lips, tongue or throat
- anemia (low red blood cell count)
- muscle breakdown, muscle pain or weakness, which may occur due to damage to the kidney tubule cells

Tests may also indicate:
- decrease in blood potassium levels
- increase in blood creatinine levels
- changes in the urine

Rare side effects (*may affect up to one in 1,000 patients*):
- lactic acidosis (see *"Possible severe side effects"*)
- fatty liver
- yellowing of the skin or eyes, itching or abdominal pain caused by inflammation of the liver
- inflammation of the kidneys, increased urination and thirst, kidney failure, damage to kidney tubule cells
- softening of the bones (with bone pain. Sometimes this condition causes fractures)
- back pain caused by kidney problems

Damage to kidney tubule cells which may be associated with muscle breakdown, bone softening (with bone pain, and sometimes the condition causes fractures), muscle pain, muscle weakness and decreased blood potassium or phosphorus levels.
If you noticed any side effect that appears in this leaflet, or if any of the side effects worsen, inform the doctor or pharmacist.
The frequency of the following side effects is unknown:

- **Bone problems**. Some patients taking combined antiretroviral medicines, such as Emtricitabine Tenofovir Teva, may develop a bone disease called osteonecrosis (death of bone tissue caused by decreased blood supply to the bone). Taking such medicines for a long time, taking corticosteroids, alcohol consumption, a very weak immune system, and being overweight are some of the many risk factors for developing this disease. The signs of osteonecrosis are:
  - joint stiffness
  - joint pain and aches (especially of the hip, knee and shoulder)
  - movement difficulties

If you notice any of these symptoms, tell the doctor.
During treatment with medicines for HIV, there may be an increase in weight and in levels of blood lipids and glucose. This is partly due to restored health and lifestyle, and in the case of blood lipids, this is sometimes associated with the HIV medicines themselves. The doctor will conduct tests to detect these changes.
If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- **Store below 25°C.**
- **Store in the original package in order to protect from moisture.**
- The bottle package: The medicine may be used for up to 60 days after first opening the bottle and no later than the medicine expiry date.
  Please note: The bottle contains a desiccant. Do not swallow! Leave the desiccant in the bottle and close the bottle tightly after each use!
- Do not discard medicines into the wastewater or household waste bin. Consult with the pharmacist on how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:
Mannitol, Low-substituted hydroxypropyl cellulose, Microcrystalline cellulose, Sodium stearyl fumarate, Polyvinyl alcohol, Titanium dioxide, Macrogol, Hypromellose, Talc, Iron oxide yellow, Indigo carmine aluminium lake/FD&C Blue.
What the medicine looks like and the contents of the package:
Green to light green, oval-shaped film-coated tablets, debossed with "ET" on one side and plain on the other side.
Pack sizes: 30 or 90 tablets in a tray (blister) package. 30 or 90 tablets in a bottle with a desiccant.
Not all package sizes may be marketed.
Name of Manufacturer and License Holder and Address: Teva Israel Ltd., 124 Devorah HaNevi'a St., Tel Aviv 6944020
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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 162.68.35319

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