PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Tenofovir Teva

Film-coated tablets

Active ingredient

Each film-coated tablet contains:
Tenofovir Disoproxil (as fumarate) 245 mg

For information on inactive and allergenic ingredients, see in section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read this leaflet carefully in its entirety before using this medicine, as it contains information that is important for you. This leaflet contains essential information about the medicine. If you have further questions, refer to the doctor or pharmacist. Keep this leaflet; you may need to read it again.
This medicine was prescribed for you only. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar to yours. If you experience side effects, refer to a doctor or pharmacist even if you experience side effects that are not mentioned in the leaflet (see section 4).

The medicine is not intended for children below 12 years of age.
If Tenofovir Teva was prescribed for your child, please note that all the information in this leaflet is intended for your child (in this case, read "your child" instead of "you").

1. WHAT IS THE MEDICINE INTENDED FOR?

- Tenofovir Teva is intended for treatment of HIV (human immunodeficiency virus) in adults and children above 12 years of age.
- Tenofovir Teva is also used to treat chronic hepatitis B, hepatitis B virus (HBV) infection in adults. It is not known whether Tenofovir Teva is safe and effective in treating hepatitis B virus in children under 18 years of age.

Therapeutic group:
A systemic antiviral medicine; nucleoside and nucleotide reverse transcriptase inhibitors.

Tenofovir Teva contains the active ingredient tenofovir disoproxil. This active ingredient is an antiretroviral or a retrovirus inhibitor intended to treat infection with HIV, HBV or both together. Tenofovir is a nucleotide reverse transcriptase inhibitor, known as NRTI, and acts by interfering with the normal activity of enzymes (reverse transcriptase in HIV; DNA polymerase in hepatitis B), which are essential for replication of the viruses themselves. In the case of HIV, Tenofovir Teva must always be taken in combination with other medicines to treat HIV infection. You do not have to have HIV to receive treatment with Tenofovir Teva for HBV.
This medicine does not cure HIV. During the course of treatment with Tenofovir Teva, you may still develop infections or other illnesses associated with HIV. You can also still transmit HIV or HBV to others; therefore, it is important to take precautionary measures to prevent infection of other people.

2. BEFORE USING THE MEDICINE:

Do not use the medicine if:

- You are sensitive (allergic) to tenofovir, tenofovir disoproxil or to any of the additional ingredients contained in this medicine, listed in section 6.

If the above condition applies to you, **tell the doctor immediately and do not take Tenofovir Teva.**

Special warnings regarding use of the medicine:
Consult the doctor or pharmacist before taking Tenofovir Teva.

- **Take care not to infect other people.** Even when taking this medicine, you can still pass on HIV, although the risk is lowered by effective antiretroviral therapy. Consult the doctor regarding the precautions needed to avoid infecting other people. Tenofovir Teva does not reduce the risk of passing on HBV to others through sexual contact or contaminated blood. You must continue to take precautions to avoid this.
- **Inform the doctor or pharmacist if you have had kidney disease or if tests have revealed kidney problems.** Tenofovir Teva should not be given to adolescents with kidney problems. Before starting treatment, the doctor can refer you to blood tests to assess your kidney function. Tenofovir Teva may damage the kidneys during the course of treatment. The doctor may refer you for blood tests during the course of treatment to monitor kidney function. If you are an adult, the doctor may advise you to take the tablets less often. Do not reduce the prescribed dosage, unless the doctor has told you to do so.
  Tenofovir Teva is usually not taken together with other medicines that can damage your kidneys (see "Other medicines and Tenofovir Teva"). If this is unavoidable, the doctor will monitor your kidney function once a week.
- **Bone problems.** Some adult patients with HIV taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, and increased body mass index, are among the many possible factors for developing this disease. Signs of osteonecrosis include joint stiffness, aches and pains (especially of the hip, knee and shoulder) and movement difficulties. If you notice any of these symptoms, tell your doctor.
  Bone problems (manifesting by prolonged or worsening bone pain and sometimes resulting in fractures) may also occur due to damage to kidney tubule cells (see in 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 boosted protease inhibitor.
  Overall, the effects of tenofovir disoproxil on long term bone health and future fracture risk in adult and pediatric patients are uncertain.
  Tell your doctor if you know you suffer from osteoporosis. Patients with osteoporosis are at a higher risk for fractures.
- **Talk to the doctor if you have a history of liver disease, including hepatitis.** Patients with 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 a hepatitis B infection, your doctor will carefully consider the best treatment for you. If you have a history of liver disease or chronic hepatitis B infection, your doctor may conduct blood tests to monitor your liver function.
- **Look out for infections.** If you have advanced HIV infection (AIDS) and have an infection, you may develop symptoms of infection and inflammation or worsening of the symptoms of an existing infection once treatment with Tenofovir Teva is started. These symptoms may indicate that your immune system has improved and is fighting the infection. Look out for onset of signs of inflammation or infection immediately after you start taking Tenofovir Teva. If you notice any sign of inflammation or infection, **inform your doctor immediately.**
  In addition to opportunistic infections, autoimmune diseases (a condition in which the immune system attacks healthy body tissues) may also occur after you start taking medicines to treat HIV infection. Autoimmune diseases may develop many months after the start of treatment. If you notice 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, inform the doctor immediately in order to receive the necessary treatment.
- **Tell the doctor or pharmacist if you are over 65 years of age.** Tenofovir has not been studied in patients over 65 years of age. If you are older than 65 years of age and were prescribed Tenofovir Teva, the doctor will monitor you carefully.

Other medicines and Tenofovir Teva:
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

- If you have both HBV and HIV, and you are starting to take Tenofovir Teva, **do not stop taking any anti-HIV medicine** prescribed for you by the doctor.
- **Do not take Tenofovir Teva** if you are already taking other medicines containing tenofovir disoproxil or tenofovir alafenamide. Do not take Tenofovir Teva together with medicines containing adefovir dipivoxil (a medicine used to treat chronic hepatitis B).
- **It is particularly important to tell the doctor if you are taking other medicines that may damage the kidneys,** including:
  - aminoglycosides, pentamidine or vancomycin (to treat bacterial infection)
  - amphotericin B (to treat fungal infection)
  - foscarnet, ganciclovir, cidofovir (to treat viral infection)
  - interleukin-2 (to treat cancer)
  - adefovir dipivoxil (to treat HBV)
  - tacrolimus (to suppress the immune system)
  - non-steroidal anti-inflammatory drugs (NSAIDs, to relieve bone or muscle pain).
- **Other medicines containing didanosine (to treat HIV infection):** Taking Tenofovir Teva 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 caused death, have been reported when medicines containing tenofovir disoproxil and didanosine were taken together. The doctor will carefully consider whether to treat you with combinations of tenofovir and didanosine.
- 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.

Use of the medicine and food:
Take Tenofovir Teva with food (for example, a meal or a snack).

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult the doctor or pharmacist before taking the medicine.

- **If you have taken Tenofovir Teva** during pregnancy, the doctor may request that you perform regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took nucleotide reverse transcriptase inhibitors (NRTIs) during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.
- If you are an HBV carrier, and your baby has been given treatment to prevent hepatitis B transmission at birth, you can breastfeed your infant, but first talk to your doctor to get more information.
- If you are an HIV carrier, do not breastfeed, in order to prevent passing the virus to the baby through the breast milk.

Driving and operating machinery:
Tenofovir Teva may cause dizziness. If you feel dizzy when taking Tenofovir Teva, **do not drive or ride a bicycle** and do not operate dangerous instruments or machinery.

Children and adolescents:
Tenofovir Teva tablets are suitable for:

- **Adolescents with an HIV-1 infection, aged 12 to less than 18 years, who weigh at least 35 kg.**

Tenofovir Teva is not suitable for the following groups:

- Not for children under the age of 12 with an HIV-1 infection
- Not for children under the age of 18 with an HBV infection

Information regarding the dosage appears in section 3, "How should you use the medicine?".

Important information about some of the ingredients of the medicine:
Tenofovir Teva contains lactose.
Consult a doctor before taking Tenofovir Teva. If you have been told by your doctor that you have an intolerance to any sugars, refer to your doctor before taking this 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 about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:

- **To treat HIV-1 or HBV in adults:** 1 tablet each day with food (for example, a meal or a snack).
- **To treat HIV-1 in adolescents aged 12 to less than 18 years who weigh at least 35 kg:** 1 tablet each day with food (for example, a meal or a snack).

Do not exceed the recommended dose.
Take the medicine once a day, with a glass of water, with food.
Do not halve in the absence of a score line.
In the event of particular difficulty in swallowing, the tablet can be crushed using the tip of a spoon. Afterwards, mix the powder with approximately 100 ml (half a cup) of water, orange juice or grape juice and drink immediately.

- **Always take the dosage recommended by the doctor.** This way you can ensure that your medicine will be effective, and you will reduce your risk of developing resistance to the treatment. Do not change the dose without instructions from the doctor.
- **If you are an adult and have problems with your kidneys,** the doctor may advise you to take Tenofovir Teva less frequently.
- If you have HBV, your doctor may suggest that you undergo an HIV test to see if you have both HBV and HIV.

For instructions on how to take other antiretrovirals, refer to the patient information leaflets of those medicines.

Tests and follow-up
Tenofovir Teva can have an effect on the kidneys. Before starting to use the medicine, the doctor will refer you for blood tests to assess your kidney and liver functions.
During the course of treatment with this medicine, it is recommended to perform blood tests to assess kidney function, and, depending on the results, the attending doctor may instruct you to take Tenofovir Teva 245 mg less frequently.
Also see section 2 "Special warnings regarding use of the medicine", section 3 "If you have hepatitis B or HIV and hepatitis B together (co-infection)" and section 4 "Side effects".

If you take a higher Tenofovir Teva dosage than required
If you accidentally took too many Tenofovir Teva tablets, you may be at increased risk of experiencing possible side effects with this medicine (see section 4 "Side effects").
If you took an overdose or if a child has accidentally swallowed the medicine, contact your doctor or the emergency room of a hospital and consult with them. Bring the bottle of tablets with you so that you can easily describe what you have taken.

If you forget to take Tenofovir Teva
It is important not to miss a Tenofovir Teva dose. If you miss a dose, work out how long since you should have taken it.

- **If less than 12 hours** have elapsed from the usual dosing time, take the medicine as soon as possible and then take the next dose at the regular time.
- **If more than 12 hours have elapsed** from the time you were supposed to take the medicine, skip the forgotten dose. Wait and take the next dose at the regular time. Do not take a double dose to compensate for a forgotten tablet.

If you vomited within less than 1 hour of taking Tenofovir Teva, take another tablet. If you vomited more than one hour after taking Tenofovir Teva, there is no need to take an additional tablet.

If you stop taking Tenofovir Teva
Do not stop taking Tenofovir Teva without consulting the doctor. Discontinuation of Tenofovir Teva may reduce the effectiveness of the treatment recommended by the doctor.
If you have hepatitis B or HIV together with hepatitis B (co-infection), it is very important not to stop treatment with Tenofovir Teva without first consulting the doctor. Some of the patients who stopped taking the medicine showed worsening of their hepatitis, as observed in blood tests or symptoms experienced by the patients. You may need to perform blood tests for a few months after stopping the treatment. Discontinuation of treatment is not recommended for some patients with advanced liver disease or cirrhosis, since discontinuation of treatment may cause worsening of hepatitis.

- Speak with the doctor before you discontinue to take Tenofovir Teva for any reason, especially if you experience any side effects or if you have an additional illness.
- Inform the doctor immediately of new or unusual symptoms after you have discontinued treatment, especially symptoms associated with hepatitis B infection.
- Refer to the doctor before you resume taking Tenofovir Teva tablets.

Do not take medicines in the dark! Check the label and the dose each time you take 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

During HIV therapy, 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 doctor will perform tests to detect these changes.
As with any medicine, use of 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.

Possible serious side effects: tell the doctor immediately
Lactic acidosis (excess lactic acid in the blood) is a **rare** (can affect up to one patient in every 1,000 patients) but serious side effect that can be fatal. The following side effects may be signs of lactic acidosis:

- deep, rapid breathing
- sleepiness
- nausea, vomiting and stomach pain

If you think that you may have **lactic acidosis, refer to a doctor immediately.**

Other possible serious side effects
The following side effects are **uncommon** (can affect up to one patient in every 100 patients):

- **abdominal pain** caused by inflammation of the pancreas
- damage to kidney tubule cells

The following side effects are **rare** (can affect up to one patient in every 1,000 patients):

- inflammation of the kidneys, **passing a lot of urine and thirst**
- **changes to the urine and back pain** caused by kidney problems, including kidney failure
- softening of the bones (accompanied by **bone pain**, sometimes this condition leads to fractures), which may occur due to damage to kidney tubule cells
- **fatty liver**

If you think that you have one of these serious side effects, tell the doctor.

Most common side effects
The following side effects are **very common** (can affect at least 10 patients in every 100 patients):

- diarrhea, vomiting, nausea, dizziness, rash, feeling weak

Tests may also show:

- decrease in phosphate levels in the blood

Other possible side effects
The following side effects are **common** (can affect up to 10 patients in every 100 patients):

- headache, abdominal pain, feeling tired, feeling bloated, flatulence

Tests may also show:

- liver problems

The following side effects are **uncommon** (can affect up to one patient in every 100 patients):

- breakdown of muscle, muscle pain or weakness

Tests may also show:

- decrease in potassium levels in the blood
- increased creatinine levels in the blood
- pancreatic problems

Muscle breakdown, softening of the bones (accompanied by bone pain, sometimes this condition leads to fractures), muscle pain, muscle weakness and a decrease in potassium or phosphate levels in the blood may occur due to damage to kidney tubule cells.
The following side effects are **rare** (can affect up to one patient in every 1,000 patients):

- abdominal pain caused by inflammation of the liver
- swelling of the face, lips, tongue or throat

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
In addition, side effects can be reported directly to the license holder via email:
Safety.Israel@tevapharm.com
You can help provide further information about the safety of the medicine by reporting side effects.

5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine and any other medicine must be kept in a safe place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use this medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Store in a dry place, below 25°C.**
- **The medicine can be used for up to 60 days after first opening the bottle and no later than the expiry date.**
- **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. Consult the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Microcrystalline cellulose, Lactose monohydrate, Sodium starch glycolate, Magnesium stearate, Polyvinyl alcohol (E1203), Colloidal anhydrous silica, Titanium dioxide (E171), Macrogol (E1521), Talc, Indigo carmine aluminium lake, Carmine (E120).

What the medicine looks like and the contents of the package:
Tablet shape: light-blue to blue, oblong, film-coated tablet. '93' appears on one side of the tablet and '7104' appears on the other side.
The package contains a bottle with 30 tablets.

Name of Manufacturer and License Holder and its Address: Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 150.91.33867
This leaflet was revised in August 2022 according to MOH guidelines.

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