

PATIENT INFORMATION LEAFLET

HEPA-TAF 25 mg film coated tablet

It is taken orally.

Active ingredient: Each film-coated tablet contains 31.09 mg tenofovir alafenamide fumarate equivalent to 25 mg tenofovir alafenamide.

Excipients: Lactose monohydrate (obtained from cow's milk), Microcrystalline cellulose, Croscarmellose sodium, Colloidal anhydrous silica, Magnesium stearate, Polyvinyl alcohol (E1203), Polyethylene glycol/Macrogol (E1521), Talc (E553b), Titanium dioxide (E171), Yellow iron oxide (E172), Red iron oxide (E172).

Before you start using this medicine, read this PATIENT INFORMATION LEAFLET carefully because it contains important information for you.

- *Keep this leaflet. You may need to read again*
- *If you have other questions, please consult your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *During the use of this medicine, tell your doctor that you are using this medicine when you go to the doctor or hospital*
- *Follow exactly what is written in this instruction. Do not use **high or low doses** other than the dose recommended to you about the medicine.*

In this leaflet:

- 1. What is HEPA-TAF and what is it used for?***
- 2. Thing to consider before using HEPA-TAF***
- 3. How to use HEPA-TAF?***
- 4. What are the possible side effects?***
- 5. Storage of HEPA-TAF***

Headings are included.

1. What is HEPA-TAF and what is it used for?

HEPA-TAF is available in the form of film-coated tablets. Each film-coated tablet contains tenofovir alafenamide fumarate equivalent to 25 mg tenofovir alafenamide as the active ingredient. This medication is an antiviral medication known as nucleotide reverse transcriptase inhibitor (NtRTI).

HEPA-TAF, film-coated tablets are yellow, round, film-coated tablets. HEPA-TAF is available in high density polyethylene (HDPE) bottles of 30 tablets (each bottle contains a silica gel desiccant and polyester cotton to protect your tablets and should not be removed from the bottle). Silica gel desiccant is contained in a separate sachet and should not be swallowed.

HEPA-TAF is used to **treat chronic (long-term) hepatitis B** in adults and adolescents 12 years of age and older who weigh at least 35 kg. Hepatitis B is an infection that affects the liver, caused by the Hepatitis B virus. In patients with hepatitis B, HEPA-TAF controls the infection by stopping the virus from multiplying.

2. Thing to consider before using HEPA-TAF

DO NOT USE HEPA-TAF in the following situations

If,

- You are allergic to tenofovir alafenamide or any of the other ingredients of this medicine.

If this applies to you, **do not take HEPA-TAF and tell your doctor immediately.**

USE HEPA-TAF WITH CARE in the following situations

- **Be careful not to pass your hepatitis B to others.** There is a possibility that you may infect others while taking this medicine. HEPA-TAF does not reduce the risk of transmitting hepatitis B to others through sexual contact or blood. You should continue to take precautions to avoid this. Discuss with your doctor the precautions necessary to avoid infecting other people.
- **If you have a history of liver disease, talk to your doctor.** Patients with liver disease and being treated with antiviral medications for hepatitis B are at higher risk for severe and potentially fatal liver complications. Your doctor may need to do blood tests to monitor your liver function.
- **If you have kidney disease or if tests show kidney problems before or after**

treatment, talk to your doctor or pharmacist. Your doctor may order blood tests before and during treatment with HEPA-TAF to monitor how your kidneys are working.

- **If you have hepatitis C or hepatitis D, talk to your doctor.** HEPA-TAF has not been tested in patients with hepatitis C or hepatitis D as well as hepatitis B.
- **If you also have HIV, talk to your doctor.** If you are not sure whether you have HIV, your doctor should recommend that you get tested for HIV before you start taking HEPA-TAF for hepatitis B.
- Stopping HEPA-TAF treatment may cause your hepatitis B to worsen. If you stop taking HEPA-TAF, you will need regular checkups and blood tests for several months to check your hepatitis B infection. If appropriate, you may need to start treatment again.

If any of these apply to you, **talk to your doctor before taking HEPA-TAF.**

There is a possibility that you may experience kidney problems when using HEPA-TAF for a long time (see USE HEPA-TAF WITH CARE in the following situations).

Children and adolescents

Do not give this medicine to children under 12 years of age and whose body weight is less than 35 kg.

HEPA-TAF has not been tested in children younger than 12 years and weighing less than 35 kg.

Using HEPA-TAF with food and drink

HEPA-TAF should be taken with food.

Pregnancy

Consult your doctor or pharmacist before using this medication.

If you are pregnant, think you may be pregnant, or are planning to have a baby, consult your doctor or pharmacist before taking this medicine. If you become pregnant, notify your doctor immediately.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

Do not breastfeed during HEPA-TAF treatment. It is recommended that you do not breast-feed to prevent tenofovir alafenamide or tenofovir from passing to the baby through breast milk.

Driving and using machines

HEPA-TAF may cause dizziness. If you feel dizzy while taking HEPA-TAF, do not drive or use any tools or machines.

Important information about some excipients contained in HEPA-TAF

HEPA-TAF contains lactose. If you have been told by your doctor that you are intolerant to some sugars, contact your doctor before taking this medicinal product.

Use with other drugs

Tell your doctor or pharmacist if you are using, have recently taken, or might take any other medication. HEPA-TAF may interact with other medications. As a result, the amounts of HEPA-TAF or other medications in your blood may change. This may prevent medications from working properly or worsen side effects.

Medicines used to treat hepatitis B infection

You should not take HEPA-TAF with other medicines containing the following substances:

- **tenofovir alafenamide**
- **tenofovir disoproxil**
- **adefovir dipivoxil**

Other types of medications

Talk to your doctor if you are using any of the following medications:

- **Antibiotics** used to treat bacterial infections such as tuberculosis, including:
 - rifabutin, rifampicin or rifapentine
- **Antiviral drugs** used to treat HIV, such as:
 - darunavir, lopinavir, or atazanavir boosted with ritonavir or cobicistat
- **Anticonvulsants** used to treat epilepsy, such as:
 - carbamazepine, oxcarbazepine, phenobarbital or phenytoin
- Herbal remedies used to treat depression and anxiety, including:
 - St. John's wort (*Hypericum perforatum*)

- **Antifungal medications** used to treat fungal infections, including:
 - ketoconazole or itraconazole

If you are using any of these medications or any other medications, inform your doctor.

If you are currently using or have recently used any prescription or non-prescription medication, please inform your doctor or pharmacist about them.

3. How to use HEPA-TAF?

Always take this medication exactly as your doctor tells you. If you are not sure, consult your doctor or pharmacist.

Instructions for proper use and dosage/frequency of application:

Recommended dosage for adults: The recommended dose is **one tablet per day with food**. Treatment should continue as long as your doctor tells you. Treatment usually takes at least 6 to 12 months and can last for years.

Application route and method:

It is taken orally. HEPA-TAF should be taken with food.

Different age groups:

- **Use in children:** Do not give this medicine to children under 12 years of age or whose body weight is less than 35 kg.
- **Use in the elderly:** No dosage adjustment of HEPA-TAF is required in patients aged 65 years and over.

Special use cases:

Kidney/Liver failure:

If you have problems with your kidneys or liver, see: *Part 2, Precautions before using HEPA-TAF*

If you have the impression that the effect of HEPA-TAF is too strong or weak, talk to your doctor or pharmacist.

If you use more HEPA-TAF than you should:

If you have used more HEPA-TAF than you should, talk to a doctor or pharmacist.

If you accidentally take more HEPA-TAF than the recommended dose, your risk of experiencing possible side effects from this medicine may increase (See Section 4, Possible side effects).

Contact your doctor or nearest emergency room immediately for advice. Keep the tablet bottle with you so you can easily explain what you are taking.

If you forget to use HEPA-TAF

Do not take a double dose to make up for forgotten doses.

It is important not to miss a dose of HEPA-TAF. If you miss a dose, calculate how long has passed since the missed dose.

- **If less than 18 hours have passed** since you normally take HEPA-TAF, take it as soon as possible and take your next dose on time.
- **If 18 hours or more have passed** since you normally take HEPA-TAF, do not take the missed dose. Wait and take the next dose on time. **Do not take a double dose** to make up for a forgotten tablet.
- **If you vomit less than 1 hour after taking HEPA-TAF**, take another tablet. If you vomit more than 1 hour after taking HEPA-TAF, you do not need to take another tablet.

Effects that may occur when treatment with HEPA-TAF is stopped

Do not stop taking HEPA-TAF without consulting your doctor. Stopping treatment with HEPA-TAF may cause your hepatitis B disease to worsen. Discontinuation of the drug may be life-threatening in some patients with advanced liver disease or cirrhosis. If you stop taking HEPA-TAF, you should have regular checkups and blood tests for several months to check your hepatitis B infection.

Before you stop taking HEPA-TAF for any reason, especially if you experience side effects or if you have another disease, **talk to your doctor.**

- After stopping treatment, **report any new or unusual symptoms to your doctor immediately**, especially symptoms you associate with hepatitis B infection.
- **Talk to your doctor** before you start taking HEPA-TAF tablets again.

If you have any other questions about the use of this medicine, you can ask your doctor or pharmacist.

4. What are the possible side effects?

Like all medicines, side effects may occur in people who are sensitive to the substances contained in HEPA-TAF.

Side effects are classified as shown in the following categories:

- Very common : It can be seen in at least one in 10 patients.
- Common : It can be seen in less than 1 in 10 patients, but in more than 1 in 100 patients.
- Uncommon : It may occur in less than 1 in 100 patients, but in more than 1 in 1,000 patients.
- Rare : It can be seen in less than 1 in 1,000 patients, but in more than 1 in 10,000 patients.
- Very Rare : It can be seen in less than 1 in 10,000 patients, but in more than 1 in 10,000 patients.
- Unknown : It cannot be predicted based on the available data.

Very common

- Headache

Common

- Diarrhea
- Vomiting
- Nausea
- Dizziness
- Stomach ache
- Joint pain (arthralgia)
- Rash
- Itching
- Feeling bloated
- Gas (bloating)
- Feeling tired

Uncommon

- Swelling of the face, lips, tongue or throat (angioedema)

- Hives (urticaria)

Tests may also show:

- Increased level of a liver enzyme (ALT) in the blood

If any of these side effects become serious, tell your doctor.

During HBV treatment, increases in weight, fasting blood lipids and/or glucose levels may occur. Your doctor will test for these changes.

If you experience any side effects not mentioned in this instruction manual, inform your doctor or pharmacist.

Reporting side effects

If you experience any side effects, whether listed in the instructions for use or not, talk to your doctor, pharmacist or nurse. Also, report the side effects you encounter to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effect Reporting" icon on the website www.titck.gov.tr or by calling the side effect reporting line at 0800 314 00 08. By reporting any side effects that occur, you will contribute to obtaining more information about the safety of the medicine you are using.

5. Storage of HEPA-TAF

Keep HEPA-TAF in its packaging and out of sight and reach of children.

Store at room temperature below 25°C and in its original packaging to protect from moisture.

Keep the bottle tightly closed.

Use in accordance with expiration dates.

Do not use HEPA-TAF after the expiration date on the packaging.

If you notice any defects in the product and/or its packaging, do not use HEPA-TAF.

Each bottle contains a silica gel desiccant to protect your tablets and should not be removed from the bottle or swallowed.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment, Urbanization and Climate Change.

Marketin Authorization Holder: Drogan İlaçları San. ve Tic. A.Ş.

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Manufacturing site: Drogan İlaçları San. ve Tic. A.Ş.

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