

TAFLON 25mg Film Coated Tablets

Tenofovir Alafenamide Fumarate 25mg

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1. What TAFLON is used for

TAFLON 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 affecting the liver, caused by the hepatitis B virus.

2. How TAFLON works

TAFLON contains the active substance *tenofovir alafenamide*. This is an *antiviral medicine*, known as a *nucleotide reverse transcriptase inhibitor* (NRTI).

In patients with hepatitis B, TAFLON controls the infection by stopping the virus from multiplying.

3. Before you use TAFLON

- When you must not use it

Do not take TAFLON

- **If you are allergic** to tenofovir alafenamide, or any of the other ingredients of this medicine (listed in section 8)

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

- Before you start to use it

Warnings and precautions

- **Take care not to pass on your hepatitis B to other people.** You can still infect others when taking this medicine. TAFLON does not reduce the risk of passing on hepatitis B to others through sexual contact or blood contamination. You must continue to take precautions to avoid this. Discuss with your doctor the precautions needed to avoid infecting others.

- **Tell your doctor if you have a history of liver disease.** Patients with liver disease, who are treated for hepatitis B with antiviral medicines, have a higher risk of severe and potentially fatal liver complications. Your doctor may need to carry out blood tests to monitor your liver function.
- **Talk to your doctor or pharmacist if you have had kidney disease or if tests have shown problems with your kidneys, before or during your treatment.** Before starting treatment and during treatment, your doctor may order blood tests to monitor how your kidneys work.
- **Talk to your doctor if you also have hepatitis C or D.** TAFLON has not been tested on patients who have hepatitis C or D as well as hepatitis B.
- **Talk to your doctor if you also have HIV.** If you are not sure whether you have HIV, your doctor should offer you HIV testing before you start taking TAFLON for hepatitis B.

If any of these apply to you, **talk to your doctor before taking TAFLON.**

Children and adolescents:

Do not give this medicine to children who are under 12 years old or weigh less than 35 kg. TAFLON has not been tested in children aged less than 12 years old or weighing less than 35 kg.

- Taking other medicines
Other medicines and TAFLON

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. TAFLON may interact with other medicines. As a result, the amounts of TAFLON or other medicines in your blood may change. This may stop your medicines from working properly, or may make any side effects worse.

Medicines used in treating hepatitis B infection

Do not take TAFLON with other medicines containing:

- tenofovir alafenamide
- tenofovir disoproxil
- adefovir dipivoxil

Other types of medicines

Talk to your doctor if you are taking:

- **antibiotics** used to treat bacterial infections including tuberculosis, containing:
 - rifabutin, rifampicin or rifapentine
- **antiviral medicines used to treat HIV**, such as:
 - ritonavir or cobicistat boosted darunavir, lopinavir or atazanavir
- **anticonvulsants** used to treat epilepsy, such as:
 - carbamazepine, oxcarbazepine, phenobarbital or phenytoin
- **herbal remedies** used to treat depression and anxiety, containing:
 - St. John's wort (*Hypericum perforatum*)
- **antifungal medicines** used to treat fungal infections, containing:
 - ketoconazole or itraconazole

Tell your doctor if you are taking these or any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

- Tell your doctor immediately if you become pregnant.
- **Do not breast-feed during treatment with TAFLON.** It is recommended that you do not breast-feed to avoid passing tenofovir alafenamide or tenofovir to the baby through breast milk.

TAFLON contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

TAFLON contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4. How to take TAFLON

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

-How much and how long to use it:

The recommended dose is one tablet once a day with food. Treatment should continue for as long as your doctor tells you. Usually this is for at least 6 to 12 months and may be for many years.

-If you forget to take TAFLON

It is important not to miss a dose of TAFLON. If you do miss a dose, work out how long since you should have taken it.

- **If it is less than 18 hours** after you usually take TAFLON, take it as soon as you can, and then take your next dose at its regular time.
- **If it is more than 18 hours** after you usually take TAFLON, then do not take the missed dose. Wait and take the next dose at the regular time. **Do not take a double dose** to make up for a forgotten tablet.

If you are sick (vomit) less than 1 hour after taking TAFLON, take another tablet. You do not need to take another tablet if you are sick (vomit) more than 1 hour after taking TAFLON.

-If you take more TAFLON than you should (overdose)

If you accidentally take more than the recommended dose of TAFLON you may be at increased risk of experiencing possible side effects with this medicine (see section 6, for side effects).

Contact your doctor or nearest emergency department immediately for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

5. While you are taking TAFLON

-Things you must do:

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure

-Things you must not do:

If you stop taking TAFLON

Do not stop taking TAFLON without your doctor's advice. Stopping treatment with TAFLON may cause your hepatitis B to get worse. In some patients with advanced liver disease or cirrhosis, this could be life-threatening. If you stop taking TAFLON, you will need regular health checks and blood tests for several months to check your hepatitis B infection.

- **Talk to your doctor** before you stop taking TAFLON for any reason, particularly if you are experiencing any side effects or you have another illness.
- **Tell your doctor immediately** about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection.
- **Talk to your doctor** before you restart taking TAFLON tablets.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

-Things to be careful of

Driving and using machines

TAFLON can cause dizziness. If you feel dizzy when taking TAFLON, do not drive and do not use any tools or machines.

6. Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effect

- Headache

Common side effects

- Diarrhoea
- Being sick (vomiting)
- Feeling sick (nausea)
- Dizziness
- Stomach pain
- Joint pain (arthralgia)
- Rash
- Itchiness
- Feeling bloated
- Wind (flatulence)
- Feeling tired

Uncommon side effects

- 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 get serious tell your doctor.

During HBV therapy there may be an increase in weight, fasting levels of blood lipids and/or glucose. Your doctor will test for these changes.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my/ (Consumers → Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

By reporting side effects you can help provide more information on the safety of this medicine.

7. Storage and Disposal of TAFLON

-Storage

Preserve in tightly closed container, store not above 30°C at dry place.

-Disposal

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

8. Product Description

- What TAFLON looks like and contents of the pack:

TAFLON are yellow, round, film coated tablets with white or off-white cores.

The following pack size is available: outer cartons containing 1 bottle of 30 film-coated tablets.

-What TAFLON contains:

The active substance is tenofovir alafenamide. Each TAFLON film coated tablet contains tenofovir alafenamide fumarate, equivalent to 25 mg of tenofovir alafenamide

The other ingredients are

Tablet core:

Croscarmellose Sodium, Lactose
Monohydrate, Microcrystalline
Cellulose, Magnesium Stearate.

Film-coating:

Polyvinyl alcohol, talc, polyethylene
glycol, titanium dioxide, yellow iron
oxide non-irradiated.

-MAL number(s):

MAL24106013AZ

**9. Manufacturer and Product
Registration Holder**

Manufacturer

Shijiazhuang Lonzeal Pharmaceuticals
Co., Ltd.
Industrial Zone,
Shenze (No. 16 West Ring Road),
Shijiazhuang, Hebei Province,
052560, P.R. China.

Product Registration Holder

Medispec (M) Sdn Bhd
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10. Date of revision

07/02/2025

Serial number

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