



1.5.3 Patient Information Leaflet (PIL) or Package Insert

Tenofovir Alafenamide Tablets 25 mg

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

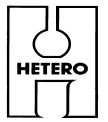
1. What are Tenofovir alafenamide tablets
2. What you need to know before you take Tenofovir Alafenamide Tablets
3. How to take Tenofovir Alafenamide Tablets
4. Possible side effects
5. How to store Tenofovir Alafenamide Tablets
6. Contents of the pack and other information

1. What Are Tenofovir Alafenamide Tablets

Tenofovir alafenamide is a prescription medicine used to treat chronic (long-lasting) hepatitis B virus (HBV) in adults with stable (compensated) liver disease.

- Tenofovir alafenamide may lower the amount of HBV in your body.
- Tenofovir alafenamide may improve the condition of your liver.

It is not known if Tenofovir alafenamide is safe and effective in children under 18 years of age.



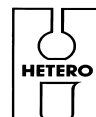
2. What You Need To Know Before You Take Tenofovir Alafenamide Tablets

- have HIV-1 infection. Your healthcare provider may test you for HIV-1 infection before you start Tenofovir alafenamide. If you have both HBV and HIV-1, and you only take Tenofovir alafenamide, the HIV-1 virus may develop resistance and become harder to treat.
- have end stage renal disease (ESRD).
- are pregnant or plan to become pregnant. It is not known if Tenofovir alafenamide will harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with Tenofovir alafenamide.
- **Pregnancy Registry:** There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. It is not known if Tenofovir alafenamide passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines may affect how Tenofovir alafenamide works. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine. You can ask your healthcare provider or pharmacist for a list of medicines that interact with Tenofovir alafenamide.

Do not start a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take Tenofovir alafenamide with other medicines.



3. How to take Tenofovir Alafenamide Tablets

- Take Tenofovir alafenamide exactly as your healthcare provider tells you to take it.
- Take Tenofovir alafenamide 1 time each day.
- Take Tenofovir alafenamide with food.
- If you are on dialysis, on your dialysis days, take your daily dose of Tenofovir alafenamide following dialysis.
- Do not change your dose or stop taking Tenofovir alafenamide without first talking with your healthcare provider. Stay under a healthcare provider's care when taking Tenofovir alafenamide.
- Do not miss a dose of Tenofovir alafenamide.
- If you take too much Tenofovir alafenamide, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your Tenofovir alafenamide supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because your HBV infection may get worse (flare-up) if you stop taking Tenofovir alafenamide.

4. Possible side effects

Tenofovir alafenamide can cause serious side effects, including: Worsening of hepatitis B infection. Your hepatitis B (HBV) infection may become worse (flare-up) if you take Tenofovir alafenamide and then stop taking it. A "flare-up" is when your HBV infection suddenly returns in a worse way than before. Do not run out of Tenofovir alafenamide. Refill your prescription or talk to your healthcare provider before your Tenofovir alafenamide is all gone.

Do not stop taking Tenofovir alafenamide without first talking to your healthcare provider.

If you stop taking Tenofovir alafenamide, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection.



Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking Tenofovir alafenamide.

New or worse kidney problems, including kidney failure. Your healthcare provider should do blood and urine tests to check your kidneys when starting and during treatment with Tenofovir alafenamide. Your healthcare provider may tell you to stop taking Tenofovir alafenamide if you develop new or worse kidney problems.

Too much lactic acid in your blood (lactic acidosis). Too much lactic acid is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.

Severe liver problems. In rare cases, severe liver problems can happen that can lead to death. Tell your healthcare provider right away if you get these symptoms: skin or the white part of your eyes turns yellow, dark "tea-colored" urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-area pain.

The most common side effect of Tenofovir alafenamide is headache. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Tenofovir alafenamide. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

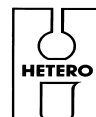
5. How to store Tenofovir Alafenamide Tablets

- Store Tenofovir alafenamide below 86 °F (30 °C).
- Keep Tenofovir alafenamide in its original container.
- Keep the container tightly closed.
- Tenofovir alafenamide comes in a child-resistant package.

General information about the safe and effective use of Tenofovir alafenamide

Medicines are sometimes prescribed for purposes other than those listed in a Patient

Hetero Labs Limited, India



Information leaflet. Do not use Tenofovir alafenamide for a condition for which it was not prescribed. Do not give Tenofovir alafenamide to other people, even if they have the same symptoms you have. It may harm them. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Tenofovir alafenamide that is written for health professionals.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Tenofovir Alafenamide Tablets 25 mg contains

The active substance is Tenofovir alafenamide hemifumarate

Each film coated tablet contains Tenofovir alafenamide 25 mg equivalent to 28.043 mg of Tenofovir alafenamide hemifumarate.

The other ingredients are:

- Lactose Monohydrate,(Supertab 11SD) Microcrystalline Cellulose (Avicel PH 102), Croscarmellose sodium (Ac-di-sol), Magnesium stearate (Ligamed MF-2-V-VEG), Magnesium stearate (Ligamed MF-2-V-VEG), Opadry II Pink 85F94172, HIS Purified Water,

What Tenofovir Alafenamide 25 mg looks like and contents of the pack

Pink, round, biconvex, film-coated tablets de-bossed with "H" on one side and "T25" on the other side.

Tenofovir Alafenamide Tablets 50 mg / 200 mg / 25 mg are available in:

Container pack: 30's HDPE container and 100's HDPE container

Marketing Authorization Holder and Manufacturer

Marketing Authorisation Holder:

Name: Hetero Labs Limited

Business Address: 7-2-A2, Hetero Corporate,
Industrial Estates,

Hetero Labs Limited, India



Sanath Nagar,
Hyderabad-500 018
Telangana.

Country: INDIA

Manufacturer:

Name: Hetero Labs Limited (Unit-V)
Address: SY. No.: 439, 440, 441 & 458, TSIIC Pharma SEZ,
Polepally Village, Jadcherla Mandal, Mahaboob Nagar Dist.,
Telangana

Country: INDIA
Phone: + 91 -8542-238400
Fax: + 91 -8542-238404
E-Mail : contact@heterodrugs.com