

Patient Information

Tenofovir Disoproxil Fumarate Tablets (ten OF oh vir dye soe PROX il FUE ma rate)

Read this Patient Information before you start taking tenofovir disoproxil fumarate tablets and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is the most important information I should know about tenofovir disoproxil fumarate tablets?

Tenofovir disoproxil fumarate tablets can cause serious side effects, including:

- **Worsening of your Hepatitis B infection.** Your hepatitis B virus (HBV) infection may become worse (flare-up) if you take tenofovir disoproxil fumarate tablets and then stop it. A “flare-up” is when your HBV infection suddenly returns in a worse way than before.
 - o **Do not** let your tenofovir disoproxil fumarate tablets run out. Refill your prescription or talk to your healthcare provider before your tenofovir disoproxil fumarate is all gone.
 - o **Do not** stop taking tenofovir disoproxil fumarate tablets without first talking to your healthcare provider.
 - o If you stop taking tenofovir disoproxil fumarate tablets, your healthcare provider will need to check your health often and do blood tests regularly to check your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking tenofovir disoproxil fumarate tablets.

Talk to your doctor about taking an HIV test before starting treatment with tenofovir disoproxil fumarate tablets for chronic hepatitis B. You should also get a test for HBV if you are taking tenofovir disoproxil fumarate tablets for treatment of HIV.

What are tenofovir disoproxil fumarate tablets?

Tenofovir disoproxil fumarate tablet is a prescription medicine used:

- with other antiviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) in people 2 years of age and older.
 - o When used with other HIV medicines, tenofovir disoproxil fumarate tablets may reduce the amount of HIV in your blood (called “viral load”). Tenofovir disoproxil fumarate tablets may also help to increase the number of CD4 (T) cells in your blood which help fight off other infections. Reducing the amount of HIV and increasing the CD4 (T) cell count may improve your immune system. This may reduce your risk of death or infections that can happen when your immune system is weak (opportunistic infections).
 - o **Tenofovir disoproxil fumarate tablets does not cure HIV infection or AIDS.** People taking tenofovir disoproxil fumarate tablets may still develop infections or other conditions associated with HIV infection.
 - o You must stay on continuous HIV therapy to control infection and decrease HIV-related illnesses.
 - o It is very important that you stay under the care of your healthcare provider.
 - o HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).
 - o It is not known if tenofovir disoproxil fumarate tablets are safe and effective for the treatment of HIV-1 infection in children under the age of 2 years.
- to treat chronic (long-lasting) hepatitis B virus (HBV) in people 12 years of age and older.
 - o Tenofovir disoproxil fumarate tablets may lower the amount of HBV in your body.
 - o Tenofovir disoproxil fumarate tablets may improve the condition of your liver.
 - o It is not known if tenofovir disoproxil fumarate tablets are safe and effective for treatment of chronic hepatitis B in children under the age of 12 years.

What should I tell my healthcare provider before taking tenofovir disoproxil fumarate tablets?

Before you take tenofovir disoproxil fumarate tablets, tell your healthcare provider if you:

- have liver problems, including hepatitis B (HBV) infection.
- have kidney problems.
- have bone problems.
- have any other medical conditions, including HIV infection.
- are pregnant or plan to become pregnant. It is not known if tenofovir disoproxil fumarate tablets will harm your unborn baby.

Pregnancy Registry. There is a pregnancy registry for women who take antiviral medicines during pregnancy. Its purpose is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. **Do not breastfeed if you are taking tenofovir disoproxil fumarate tablets.** Tenofovir passes into your breast milk. You should not breastfeed because of the risk of passing HIV to your baby. Talk to your healthcare provider about the best way to feed your baby.

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

Some medicines may affect how tenofovir disoproxil fumarate tablets work.

- 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 disoproxil fumarate tablets.
- **Do not start a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take tenofovir disoproxil fumarate tablets with other medicines.

How should I take tenofovir disoproxil fumarate tablets?

- See "What is the most important information I should know about tenofovir disoproxil fumarate tablets?"
- Take tenofovir disoproxil fumarate tablets exactly as your healthcare provider tells you to take them.
- Take tenofovir disoproxil fumarate tablets at the same time every day.
- For adults and children 12 years of age and older, the usual dose of tenofovir disoproxil fumarate tablets is one 300 mg tablet each day.
- If you are an adult with kidney problems, your healthcare provider may tell you to take tenofovir disoproxil fumarate tablets less often.
- For children 2 to 12 years of age, your healthcare provider will prescribe the right dose of tenofovir disoproxil fumarate tablets based on your child's body weight.
- Tell your healthcare provider if your child has problems with swallowing tablets.
- Take tenofovir disoproxil fumarate tablets by mouth, with or without food.
- Do not miss a dose of tenofovir disoproxil fumarate tablets. If you miss a dose of tenofovir disoproxil fumarate tablets, take the missed dose as soon as you remember. If it is almost time for your next dose of tenofovir disoproxil fumarate tablets, do not take the missed dose. Take the next dose of tenofovir disoproxil fumarate tablets at your regular time.
- If you take too much tenofovir disoproxil fumarate, call your local poison control center or go right away to the nearest hospital emergency room.

What are the possible side effects of tenofovir disoproxil fumarate tablets?

Tenofovir disoproxil fumarate tablets may cause serious side effects, including:

- See "What is the most important information I should know about tenofovir disoproxil fumarate tablets?"
- **New or worse kidney problems, including kidney failure,** can happen in some people who take tenofovir disoproxil fumarate tablets. Your healthcare provider should do blood tests to check your kidneys before you start treatment with tenofovir disoproxil fumarate tablets. If you have had kidney

problems in the past or need to take another medicine that can cause kidney problems, your healthcare provider may need to do blood tests to check your kidneys during your treatment with tenofovir disoproxil fumarate tablets.

- **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.

- **Bone problems** can happen in some people who take tenofovir disoproxil fumarate tablets. Bone problems include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do additional tests to check your bones.

- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider if you start having new symptoms after starting your HIV medicine.

The most common side effects in all people who take tenofovir disoproxil fumarate tablets are:

- nausea
- rash
- diarrhea
- headache
- pain
- depression
- weakness

In some people with advanced HBV-infection, other common side effects may include:

- sleeping problems
- itching
- vomiting
- dizziness
- fever

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 disoproxil fumarate tablets. 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.

How should I store tenofovir disoproxil fumarate tablets?

- Store tenofovir disoproxil fumarate tablets at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
- Do not use tenofovir disoproxil fumarate tablets if the seal over the bottle opening is broken or missing.
- Keep the bottle tightly closed.

Keep tenofovir disoproxil fumarate tablets and all medicines out of the reach of children.

General information about tenofovir disoproxil fumarate tablets:

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use tenofovir disoproxil fumarate tablets for a condition for which it was not prescribed. Do not give tenofovir disoproxil fumarate tablets to other people, even if they have the same condition you have. It may harm them.

Avoid doing things that can spread HIV-1 or HBV infection to others.

- **Do not share or re-use needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes and**

razor blades.

• **Do not have any kind of sex without protection.** Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

A vaccine is available to protect people at risk for becoming infected with HBV. You can ask your healthcare provider for information about this vaccine.

This leaflet summarizes the most important information about tenofovir disoproxil fumarate tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about tenofovir disoproxil fumarate tablets that is written for health professionals.

For more Information call Hetero Labs Limited at 1-866-495-1995.

What are the ingredients in tenofovir disoproxil fumarate tablets?

Active Ingredient: tenofovir disoproxil fumarate

Inactive Ingredients:

Tenofovir disoproxil fumarate tablets: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose and pregelatinized starch.

Tablet Coating:

The tablets are coated with opadry II white which contains hypromellose, lactose monohydrate, titanium dioxide and triacetin.

This Patient Information has been approved by the U.S. Food and Drug Administration.



Manufactured for:
Camber Pharmaceuticals, Inc.
Piscataway, NJ 08854.
By: HETEROTM
HETERO LABS LIMITED
22-110, I.D.A., Jeedimetla,
Hyderabad – 500 055, India.

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