

PATIENT INFORMATION
Tenofovir Disoproxil Fumarate
(ten-of-oh-vir dye-soe-prox-il fue-ma-rate)

Tablets

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 Hepatitis B virus infection (HBV). Your healthcare provider will test you for HBV and HIV before starting treatment with tenofovir disoproxil fumarate tablets. **If you have HBV infection and take tenofovir disoproxil fumarate tablets your HBV may get worse (flare-up) if you stop taking tenofovir disoproxil fumarate tablets.** A “flare-up” is when your HBV infection suddenly returns in a worse way than before.

- **Do not** run out of tenofovir disoproxil fumarate tablets. Refill your prescription or talk to your healthcare provider before your tenofovir disoproxil fumarate tablets are all gone.
- **Do not** stop taking tenofovir disoproxil fumarate tablets without first talking to your healthcare provider.
- 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.

For more information about side effects, see “What are the possible side effects of tenofovir disoproxil fumarate tablets.

What are Tenofovir Disoproxil Fumarate Tablets?

Tenofovir disoproxil fumarate tablets are a prescription medicine that is used to:

- treat HIV-1 infection when used with other anti-HIV-1 medicines in adults and children 2 years of age and older who weigh at least 22 pounds (10 kg). HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).
- treat HBV infection in adults and children 2 years of age and older who weigh at least 22 pounds (10 kg). It is not known if tenofovir disoproxil fumarate tablets is safe and effective in children under 2 years of age.

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

Before you take tenofovir disoproxil fumarate tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems, including (HBV) infection.
- have kidney problems or receive kidney dialysis treatment
- have bone problems
- have HIV infection

- are pregnant or plan to become pregnant. Tell your healthcare provider if you become pregnant during treatment with tenofovir disoproxil fumarate.

Pregnancy Registry. There is a pregnancy registry for women who take tenofovir disoproxil fumarate during pregnancy. The purpose of this registry 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. Tenofovir disoproxil fumarate can pass to your baby in your breast milk.
 - Do not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - If you take tenofovir disoproxil fumarate tablets for treatment of HBV infection, 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 non-prescription medicines, vitamins, and herbal supplements.

Some medicines may interact with tenofovir disoproxil fumarate.

- 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?

- Take tenofovir disoproxil fumarate tablets exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking tenofovir disoproxil fumarate tablets without first talking with your healthcare provider. Stay under a healthcare provider's care when taking disoproxil fumarate tablets.
- Take tenofovir disoproxil fumarate tablets at the same time every day.
- For adults and children 2 years of age and older who weigh at least 77 pounds (35 kg), the usual dose of tenofovir disoproxil fumarate tablets is one 300 mg tablet each day.
- For children 2 years of age and older who weigh between 37 pounds (17 kg) and 77 pounds (35 kg), your healthcare provider will prescribe the right dose of tenofovir disoproxil fumarate tablets based on your child's body weight.
- Adults and children 2 years of age and older who weigh at least 22 pounds (10 kg) and who are unable to swallow tenofovir disoproxil fumarate tablets whole, may take tenofovir disoproxil fumarate powder. Your healthcare provider will prescribe the right dose of tenofovir disoproxil fumarate powder based on your or your child's body weight.
- Tell your healthcare provider if you or 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. Missing a dose lowers the amount of medicine in your blood. Refill your tenofovir disoproxil fumarate tablets

prescription before you run out of medicine.

- If you take too much tenofovir disoproxil fumarate tablets, 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?

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.** Your healthcare provider should do blood and urine tests to check your kidneys before you start and during treatment with tenofovir disoproxil fumarate tablets. Your healthcare provider may tell you to take tenofovir disoproxil fumarate tablets less often, or to stop taking tenofovir disoproxil fumarate tablets if you get new or worse kidney problems.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when an HIV-1 infected person starts 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 right away if you start having new symptoms after starting your tenofovir disoproxil fumarate tablets for the treatment of HIV-1 infection
- **Bone problems** can happen in some children or adults who take tenofovir disoproxil fumarate tablets. Bone problems include bone pain, or softening or thinning of bones, which may lead to fractures. Your healthcare provider may need to do tests to check your bones or your child’s bones.
- **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 effects in all people taking 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:

- fever
- itching
- vomiting
- stomach-area pain
- dizziness
- sleeping problems

These are not all the possible side effects of tenofovir disoproxil fumarate tablets. 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 room temperature between 68°F to 77°F (20°C to 25°C).
- Keep tenofovir disoproxil fumarate tablets in the original container.
- Keep the bottle tightly closed.

- Do not use tenofovir disoproxil fumarate tablets if the seal over the bottle opening is broken or missing.

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

General information about the safe and effective use of 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. You can ask your pharmacist or healthcare provider for information about tenofovir disoproxil fumarate tablets that is written for health professionals.

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.

What are the ingredients in tenofovir disoproxil fumarate tablets?

Active Ingredient: tenofovir disoproxil fumarate

Inactive Ingredients:

Tenofovir disoproxil fumarate tablets: anhydrous lactose, calcium stearate, colloidal silicon dioxide and crospovidone.

Tablet Coating:

FD&C Blue No. 2 lake 12 to 14%, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.

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