

Medication Guide

Emtricitabine and Tenofovir Disoproxil Fumarate Tablets (em’ trye sye’ ta been and ten of’ oh vir dye’’ soe prox’ il fue’ ma rate)

Read this Medication Guide before you start taking emtricitabine and 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 to your healthcare provider about your medical condition or your treatment.

This Medication Guide provides information about **two different ways** that emtricitabine and tenofovir disoproxil fumarate tablets may be used. See the section “**What are emtricitabine and tenofovir disoproxil fumarate tablets?**” for detailed information about how emtricitabine and tenofovir disoproxil fumarate tablets may be used.

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

Emtricitabine and 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 before start or when you start treatment with emtricitabine and tenofovir disoproxil fumarate tablets. If you have HBV infection and take emtricitabine and tenofovir disoproxil fumarate tablets, your HBV may get worse (flare-up) if you stop taking emtricitabine and 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 emtricitabine and tenofovir disoproxil fumarate tablets. Refill your prescription or talk to your healthcare provider before your emtricitabine and tenofovir disoproxil fumarate tablets are all gone.
 - Do not stop taking emtricitabine and tenofovir disoproxil fumarate tablets without first talking to your healthcare provider.
 - If you stop taking emtricitabine and tenofovir disoproxil fumarate tablets, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection, or give you a medicine to treat hepatitis B. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking emtricitabine and tenofovir disoproxil fumarate tablets.

For more information about side effects, see the section “What are the possible side effects of emtricitabine and tenofovir disoproxil fumarate tablets?”.

Other important information for people who take emtricitabine and tenofovir disoproxil fumarate tablets to help reduce their risk of getting human immunodeficiency virus-1 (HIV-1) infection, also called pre-exposure prophylaxis or “PrEP”:

Before taking emtricitabine and tenofovir disoproxil fumarate tablets to reduce your risk of getting HIV-1:

- **You must be HIV-1 negative to start emtricitabine and tenofovir disoproxil fumarate tablets. You must get tested to make sure that you do not already have HIV-1 infection.**
- **Do not take emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PrEP unless you are confirmed to be HIV-1 negative.**
- Some HIV-1 tests can miss HIV-1 infection in a person who has recently become infected. If you have flu-like symptoms, you could have recently become infected with HIV-1. Tell your healthcare provider if you had a flu-like illness within the last month before starting emtricitabine and tenofovir disoproxil fumarate tablets or at any time while taking emtricitabine and tenofovir disoproxil fumarate tablets. Symptoms of new HIV-1 infection include:
 - tiredness
 - fever
 - joint or muscle aches
 - headache
 - sore throat
 - vomiting or diarrhea
 - rash
 - night sweats
 - enlarged lymph nodes in the neck or groin

While you are taking emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PrEP:

- **Emtricitabine and tenofovir disoproxil fumarate tablets do not prevent other sexually transmitted infections (STIs). Practice safer sex by using a latex or polyurethane condom to reduce the risk of getting STIs.**
- **You must stay HIV-negative to keep taking emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PrEP.**
 - Know your HIV-1 status and the HIV-1 status of your partners.
 - Ask your partners with HIV-1 if they are taking anti-HIV-1 medicines and have an undetectable viral load. An undetectable viral load is when the amount of virus in the blood is too low to be measured in a lab test. To maintain an undetectable viral load, your partners must keep taking HIV-1 medicines every day. Your risk of getting HIV-1 is lower if your partners with HIV-1 are taking effective treatment.
 - Get tested for HIV-1 at least every 3 months or when your healthcare provider tells you.
 - Get tested for other STIs such as syphilis, chlamydia, and gonorrhea. These infections make it easier for HIV-1 to infect you.
 - If you think you were exposed to HIV-1, tell your healthcare provider right away. They may want to do more tests to be sure you are still HIV-1 negative.
 - Get information and support to help reduce sexual risk behaviors.
 - Do not miss any doses of emtricitabine and tenofovir disoproxil fumarate tablets. Missing doses increases your risk of getting HIV-1 infection.

- If you do become HIV-1 positive, you need more medicine than emtricitabine and tenofovir disoproxil fumarate tablets alone to treat HIV-1. Emtricitabine and tenofovir disoproxil fumarate tablets by itself are not a complete treatment for HIV-1.

If you have HIV-1 and take only emtricitabine and tenofovir disoproxil fumarate tablets, over time your HIV-1 may become harder to treat.

What are emtricitabine and tenofovir disoproxil fumarate tablets?

Emtricitabine and tenofovir disoproxil fumarate tablets are a prescription medicine that may be used in two different ways. Emtricitabine and tenofovir disoproxil fumarate tablets are used:

- to treat HIV-1 infection when used with other anti-HIV-1 medicines in adults and children who weigh at least 37 pounds (at least 17 kg).
- for HIV-1 PrEP to reduce the risk of getting HIV-1 infection in adults and adolescents who weigh at least 77 pounds (at least 35 kg).

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

Emtricitabine and tenofovir disoproxil fumarate tablets contain the prescription medicines emtricitabine and tenofovir disoproxil fumarate.

It is not known if emtricitabine and tenofovir disoproxil fumarate tablets for treatment of HIV-1 infection is safe and effective in children who weigh less than 37 pounds (17 kg).

It is not known if emtricitabine and tenofovir disoproxil fumarate tablets are safe and effective in reducing the risk of HIV-1 infection in people who weigh less than 77 pounds (35 kg).

For people taking emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PrEP:

Do not take emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PrEP if:

- **you already have HIV-1 infection.** If you are HIV-1 positive, you need to take other medicines with emtricitabine and tenofovir disoproxil fumarate tablets to treat HIV-1. Emtricitabine and tenofovir disoproxil fumarate tablets by itself is not a complete treatment for HIV-1.
- **you do not know your HIV-1 infection status.** You may already be HIV-1 positive. You need to take other HIV-1 medicines with emtricitabine and tenofovir disoproxil fumarate tablets to treat HIV-1.

Emtricitabine and tenofovir disoproxil fumarate tablets can only help reduce your risk of getting HIV-1 **before** you are infected.

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

Before taking emtricitabine and 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
- are pregnant or plan to become pregnant. It is not known if emtricitabine and tenofovir disoproxil fumarate tablets can harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with emtricitabine and tenofovir disoproxil fumarate tablets.
 - **Pregnancy Registry:** There is a pregnancy registry for people who take emtricitabine and tenofovir disoproxil fumarate tablets 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. Emtricitabine and tenofovir disoproxil fumarate can pass to your baby in your breast milk.
 - Do not breastfeed if you have HIV-1 or if you think you have recently become infected with HIV-1 because of the risk of passing HIV-1 to your baby.
 - If you take emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PrEP, 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 interact with emtricitabine and tenofovir disoproxil fumarate tablets. 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 emtricitabine and 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 emtricitabine and tenofovir disoproxil fumarate tablets with other medicines.

How should I take emtricitabine and tenofovir disoproxil fumarate tablets?

- Take emtricitabine and tenofovir disoproxil fumarate tablets exactly as your healthcare provider tells you to take them. If you take emtricitabine and tenofovir disoproxil fumarate tablets to treat HIV-1 infection, you need to take other HIV-1 medicines. Your healthcare provider will tell you what medicines to take and how to take them.
- Take emtricitabine and tenofovir disoproxil fumarate tablets 1 time each day with or without food.
- Children who take emtricitabine and tenofovir disoproxil fumarate tablets are prescribed a lower strength tablet than adults. Children should swallow the emtricitabine and tenofovir disoproxil fumarate tablet. Tell your healthcare provider if your child cannot swallow the tablet, because they may need a different HIV-1 medicine.

- Your healthcare provider will change the dose of emtricitabine and tenofovir disoproxil fumarate tablets as needed based on your child's weight.
- Do not change your dose or stop taking emtricitabine and tenofovir disoproxil fumarate tablets without first talking with your healthcare provider. Stay under a healthcare provider's care when taking emtricitabine and tenofovir disoproxil fumarate tablets. Do not miss a dose of emtricitabine and tenofovir disoproxil fumarate tablets.
- If you take too much emtricitabine and tenofovir disoproxil fumarate, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your emtricitabine and tenofovir disoproxil fumarate tablets supply starts to run low, get more from your healthcare provider or pharmacy.
 - o If you are taking emtricitabine and tenofovir disoproxil fumarate tablets for treatment of HIV-1, the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to emtricitabine and tenofovir disoproxil fumarate tablets and become harder to treat.
 - o If you are taking emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PrEP, missing doses increases your risk of getting HIV-1 infection.

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

Emtricitabine and tenofovir disoproxil fumarate tablets may cause serious side effects, including:

- **See “What is the most important information I should know about emtricitabine and 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 emtricitabine and tenofovir disoproxil fumarate tablets. Your healthcare provider may tell you to take emtricitabine and tenofovir disoproxil fumarate tablets less often, or to stop taking emtricitabine and tenofovir disoproxil fumarate tablets if you get new or worse kidney problems.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when taking medicines to treat HIV-1 infection. 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 any new symptoms after starting your HIV-1 medicine.
- **Bone problems** can happen in some people who take emtricitabine and 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.
- **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 of emtricitabine and tenofovir disoproxil fumarate tablets for treatment of HIV-1 include:

- diarrhea
- nausea
- tiredness
- headache
- dizziness
- depression
- problems sleeping
- abnormal dreams
- rash

Common side effects in people who take emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PrEP include:

- headache
- stomach-area (abdomen) pain
- decreased weight

These are not all the possible side effects of emtricitabine and 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 emtricitabine and tenofovir disoproxil fumarate tablets?

- Store emtricitabine and tenofovir disoproxil fumarate tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep emtricitabine and tenofovir disoproxil fumarate tablets in its original container.
- Keep the container tightly closed.
- Do not use emtricitabine and tenofovir disoproxil fumarate tablets if seal over bottle opening is broken or missing.

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

General information about emtricitabine and tenofovir disoproxil fumarate tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use emtricitabine and tenofovir disoproxil fumarate tablets for a condition for which it was not prescribed. Do not give emtricitabine and tenofovir disoproxil fumarate tablets to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about emtricitabine and tenofovir disoproxil fumarate tablets that is written for health professionals.

What are the ingredients in emtricitabine and tenofovir disoproxil fumarate tablets?

Active ingredients: emtricitabine and tenofovir disoproxil fumarate

Inactive ingredients: pregelatinized starch (maize), lactose monohydrate, microcrystalline cellulose, croscarmellose sodium and magnesium stearate. The tablets are coated with Opadry II White which contains hypromellose, lactose monohydrate, titanium dioxide and triacetin.

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

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