

Important Safety Information for Adults Who Don't Have HIV

This booklet is for adults taking emtricitabine/tenofovir disoproxil fumarate to reduce the risk of getting HIV-1 infection. A separate booklet is available for adolescents taking emtricitabine/tenofovir disoproxil fumarate to reduce the risk of getting HIV-1 infection.

If you are taking emtricitabine/tenofovir disoproxil fumarate to treat HIV-1, please see the Medication Guide for other important information.

Emtricitabine/tenofovir disoproxil fumarate to reduce the risk of getting HIV-1 infection

Emtricitabine/tenofovir disoproxil fumarate is a prescription medicine to reduce the chance of getting HIV-1 infection in adults and adolescents weighing at least 77 pounds (at least 35 kg) when used with safer sex practices. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

This medicine, to reduce the risk of getting HIV-1 infection, is meant for individuals who are:

- HIV negative, and
- At risk for getting HIV-1 infection through sex

This medicine should only be used to reduce the risk of getting HIV-1 infection as part of a complete prevention strategy that includes safer sex practices and regular testing for HIV-1.

- The medicine works better to reduce the risk of getting HIV-1 infection when the medicines are in your bloodstream *before* you are exposed to HIV-1
- You need to take the medicine every day, not just when you think you have been exposed
- Just taking the medicine alone may not keep you from getting HIV-1 infection

You must be HIV negative to start taking this medicine. You must get tested to make sure that you do not already have HIV-1 infection. Do not take this medicine to reduce the risk of getting HIV-1 infection unless you are confirmed to be HIV negative.

The most important information you should know about this medicine (emtricitabine/tenofovir disoproxil fumarate)

If you have hepatitis B virus (HBV) infection and take this medicine, your HBV may get worse (flare-up) if you stop taking this medicine. A “flare-up” is when your HBV infection suddenly returns in a worse way than before.

- Your healthcare provider will test you for HBV before starting treatment with this medicine
- Do not stop taking this medicine without first talking to your healthcare provider
- If you stop taking this medicine, 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 medication to treat HBV

Tell your healthcare provider about any new or unusual symptoms you have after you stop taking this medicine.

Before taking this medicine (emtricitabine/tenofovir disoproxil fumarate) to reduce your risk of getting HIV-1 infection:

- **You must be HIV negative to start this medicine.** You must get tested to make sure that you do not already have HIV-1 infection
- Many 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 this medicine or at any time while taking it. 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 this medicine (emtricitabine/tenofovir disoproxil fumarate) to reduce your risk of getting HIV-1 infection:

- **Just taking this medicine alone may not keep you from getting HIV-1 infection**
- **You must continue using safer sex practices** while you are taking this medicine to reduce your risk of getting HIV-1 infection
- **You must stay HIV-1 negative to keep taking this medicine to reduce your risk of infection**
 - Know your HIV-1 status and the HIV-1 status of your partner(s)
 - Practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal fluids, or blood
 - Ask your partner(s) with HIV-1 if they are taking anti-HIV-1 medicine 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 partner(s) must keep taking anti-HIV-1 medicine every day. Your risk of getting HIV-1 is lower if your partner(s) 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 sexually transmitted infections, 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. Your healthcare provider may want to do more tests to be sure you are still HIV negative
 - Get information and support to help reduce risky sexual behavior
 - Have fewer sex partners
 - Do not miss any doses of this medicine. Missing doses may increase your risk of getting HIV infection

- If you do become HIV positive, you need more medicines to treat HIV-1 infection. This medicine by itself is not a complete treatment for HIV-1 infection
 - If you have HIV-1 and take only this medicine, over time your HIV-1 infection may become harder to treat

See the section **“Things you should avoid while taking this medicine (emtricitabine/tenofovir disoproxil fumarate)”** and talk to your healthcare provider for more information about how to prevent HIV-1 infection.

Things you should avoid while taking this medicine (emtricitabine/tenofovir disoproxil fumarate)

There are things you should avoid while taking this medicine that can increase your risk of getting infected with HIV-1. While taking this medicine:

- Do NOT have any kind of sex without protection. Always practice safer sex. Use latex or non-latex condoms, except lambskin, to reduce contact with semen, vaginal fluids, or blood
- Do NOT share personal items that can have blood or body fluids on them, such as toothbrushes and razor blades
- Do NOT share or reuse needles or other injection equipment

Ask your healthcare provider if you have any questions about how to prevent getting infected with HIV-1.

Do not take this medicine (emtricitabine/tenofovir disoproxil fumarate) to reduce the risk of getting HIV-1 infection if...

- **You already have HIV-1 infection.** If you are HIV positive, you need to take other medicines with this medicine to treat HIV-1. This medicine by itself is not a complete treatment for HIV-1 infection
- **You do not know your HIV-1 infection status.** You may already be HIV positive. You need to take other HIV-1 medicines with this medicine to treat HIV-1 infection

Things to tell your healthcare provider before taking this medicine (emtricitabine/tenofovir disoproxil fumarate)

Before taking this medicine, 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**
 - Tell your healthcare provider if you become pregnant during treatment with this medicine
 - **Pregnancy Registry:** There is a pregnancy registry for women who take medicines to treat or prevent HIV-1 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.** This medicine can pass to your baby in your breast milk
 - Do not breastfeed if you think you may have recently become infected with HIV-1 because of the risk of passing HIV-1 to your baby
 - If you take this medicine to reduce the risk of getting HIV-1, 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 this medicine. 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 this medicine
- Do not start a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take this medicine with other medicines

How to take this medicine (emtricitabine/tenofovir disoproxil fumarate)

- Take this medicine exactly as your healthcare provider tells you to take it
- Take this medicine 1 time each day with or without food
- Take this medicine at the same time each day to help keep the medicine blood levels constant
- Do not miss a dose of this medicine. Missing a dose lowers the amount of medicine in your blood. Refill your prescription before you run out of medicine
- Do not change your dose or stop taking this medicine without first talking with your healthcare provider. Stay under a healthcare provider's care when taking this medicine
- If you take too much of this medicine, call your healthcare provider or go to the nearest hospital emergency room right away

Possible side effects of this medicine (emtricitabine/tenofovir disoproxil fumarate)

This medicine may cause serious side effects, including:

- See *“The most important information you should know about this medicine (emtricitabine/tenofovir disoproxil fumarate)”*
- **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 this medicine. Your healthcare provider may tell you to stop taking it if you get 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
- **Bone problems** can happen in some people who take this medicine. 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

You can find this booklet and other important information about emtricitabine/tenofovir disoproxil fumarate to reduce the risk of getting HIV-1 infection at www.ftc-tdf-preprems.com or call **1-800-625-7471**.

Reference: TRUVADA [package insert]. Foster City, CA: Gilead Sciences, Inc; 2018.