

Medication Guide
TRUVADA® (tru-VAH-dah)
(emtricitabine and tenofovir disoproxil fumarate)
Tablets

Read this Medication Guide before you start taking TRUVADA 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.

What is the most important information I should know about TRUVADA?

TRUVADA can cause serious side effects, including:

1. Build-up of an acid in your blood (lactic acidosis). Lactic acidosis is a serious medical emergency that can lead to death.

Lactic acidosis can be hard to identify early, because the symptoms could seem like symptoms of other health problems. **Call your healthcare provider right away if you get the following symptoms which could be signs of lactic acidosis:**

- feeling very weak or tired
- unusual muscle pain
- trouble breathing
- stomach pain with
 - nausea
 - vomiting
- feel cold, especially in your arms and legs
- feel dizzy or lightheaded
- have a fast or irregular heartbeat

2. Severe liver problems. Severe liver problems can happen in people who take TRUVADA. In some cases these liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis) when you take TRUVADA. **Call your healthcare provider right away if you get the following symptoms:**

- your skin or the white part of your eyes turns yellow (jaundice)
- dark “tea-colored” urine
- light-colored bowel movements (stools)
- loss of appetite for several days or longer
- nausea
- stomach pain

You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight (obese), or have been taking TRUVADA for a long time.

3. Worsening of your hepatitis B infection. If you have hepatitis B virus (HBV) infection it may become worse (flare-up) if you take TRUVADA and then stop it. A “flare-up” is when your HBV infection suddenly returns in a worse way than before.

- Do not run out of TRUVADA. Refill your prescription or talk to your healthcare provider before your TRUVADA is all gone.

- Do not stop taking TRUVADA without first talking to your healthcare provider.
- If you stop taking TRUVADA, 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 TRUVADA.

For more information about side effects, see the section “**What are the possible side effects of TRUVADA?**”

Before taking TRUVADA to help prevent you from getting HIV:

- **You must get tested to be sure you are HIV-negative.** It is important that you also get tested at least every 3 months as recommended by your healthcare provider while taking TRUVADA. **Do not take TRUVADA to reduce the risk of getting HIV unless you are confirmed to be HIV-negative.**
- Tell your healthcare provider if you have any of the following symptoms within the last month before you start taking TRUVADA or at any time while taking TRUVADA:
 - tiredness
 - fever
 - sweating a lot (especially at night)
 - rash
 - vomiting
 - diarrhea
 - joint or muscle aches
 - headache
 - sore throat
 - enlarged lymph nodes in the neck or groin

These may be signs of HIV infection and you may need to have a different kind of test to diagnose HIV. Also, tell your healthcare provider if you think you were exposed to the HIV virus. If you are already taking TRUVADA to prevent HIV-1 infection, your healthcare provider may tell you to stop taking TRUVADA until an HIV test confirms that you do not have HIV-1 infection.

- **TRUVADA by itself is not a complete treatment for HIV.** If you already have HIV or get HIV and take TRUVADA by itself without other medicines, you may develop resistance to TRUVADA. This means that the HIV virus may become harder to treat.
- **Just taking TRUVADA may not keep you from getting HIV. TRUVADA does not always prevent HIV.**
- **You must still practice safer sex at all times. Do not have any kind of sex without protection.** Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.
- **You must also use other prevention methods to keep from getting HIV.**
 - Know your HIV status and the HIV status of your partners. While taking TRUVADA, get tested at least every 3 months for HIV, as recommended by your healthcare provider. Ask your partners to get tested.
 - Get tested for other sexually transmitted infections such as syphilis and gonorrhea. These infections make it easier for HIV to infect you.
 - Get information and support to help reduce risky sexual behavior.
 - Have fewer sex partners.

- **Do not miss any doses of TRUVADA. Missing doses increases your risk of getting HIV.**
- **See the section “What is TRUVADA?” and talk to your healthcare provider for more information about how to prevent HIV infection.**

What is TRUVADA?

TRUVADA contains the prescription medicines emtricitabine (EMTRIVA®) and tenofovir disoproxil fumarate (VIREAD®). TRUVADA is used:

- with other antiviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) in adults and children age 12 years and older. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).
- **with safer sex practices at all times**, to reduce the risk of getting HIV-1 in men who have sex with men who are at high risk of getting infected with HIV-1 through sex, and heterosexual couples where one partner has HIV-1 and the other does not. This is called Pre-Exposure Prophylaxis or PrEP.

It is not known if TRUVADA is safe and effective in children with HIV-1 infection who are under 12 years of age or who weigh less than 77 pounds.

When used with other HIV medicines to treat HIV-1 infection, TRUVADA may help:

- Reduce the amount of HIV in your blood. This is called “viral load.”
- Increase the number of CD4+ (T) cells in your blood that help fight off other infections.
- Reducing the amount of HIV and increasing the CD4+ (T) cells in your blood may help improve your immune system. This may reduce your risk of death or infections that can happen when your immune system is weak (opportunistic infections).

TRUVADA does not cure HIV infection or AIDS. If you have HIV infection, you must stay on continuous HIV therapy to control HIV infection and decrease HIV-related illnesses.

Avoid doing things that can increase your risk of getting HIV infection or spreading HIV infection to other people:

- 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 safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your healthcare provider if you have any questions on how to prevent getting HIV infection or spreading HIV infection to other people.

Who should not take TRUVADA?

Do not take TRUVADA to prevent HIV infection if you are HIV positive or if your HIV status is not known.

What should I tell my healthcare provider before taking TRUVADA?

See “What is the most important information I should know about TRUVADA?”

Before taking TRUVADA, tell your healthcare provider if you:

- have liver problems including hepatitis B virus infection
- have kidney problems or receive kidney dialysis treatment
- have bone problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if TRUVADA can harm your unborn baby.

If you are a female who is taking TRUVADA to prevent HIV infection and you become pregnant while taking TRUVADA, talk to your healthcare provider about whether you will continue taking TRUVADA.

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 to your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. Do not breastfeed if you take TRUVADA.
 - You should not breastfeed if you have HIV because of the risk of passing HIV to your baby.
 - TRUVADA can pass to your baby in 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 non-prescription medicines, vitamins, and herbal supplements. TRUVADA may affect the way other medicines work, and other medicines may affect how TRUVADA works.

Do not take TRUVADA if you also take:

- other medicines that contain tenofovir or emtricitabine (ATRIPLA, COMPLERA, EMTRIVA, VIREAD)
- medicines that contain lamivudine (Combivir, Epivir, Epivir-HBV, Epzicom, Trizivir)
- adefovir (HEPSERA)

Especially tell your healthcare provider if you take:

- didanosine (VIDEX EC)
- atazanavir (REYATAZ)
- lopinavir with ritonavir (KALETRA)

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take TRUVADA?

- Take TRUVADA exactly as prescribed.
- **Do not change your dose or stop taking TRUVADA without first talking with your healthcare provider.** Stay under a healthcare provider's care when taking TRUVADA.
- TRUVADA is usually taken 1 time each day. If you have kidney problems, your healthcare provider may tell you to take TRUVADA less often.
- **When used to treat HIV-1 infection, TRUVADA is always used with other HIV-1 medicines.**
- **If you take TRUVADA to reduce the risk of getting HIV-1, you must also use other methods to reduce your risk of getting HIV. See “What is the most important information I should know about TRUVADA?”**
- Take TRUVADA by mouth, with or without food.
- Take TRUVADA at the same time each day.
- If you miss a dose of TRUVADA, take it as soon as you remember that day. Do not take more than 1 dose of TRUVADA in a day. Do not take 2 doses at the same time to make up for a missed dose. Call your healthcare provider or pharmacist if you are not sure what to do.
- It is important that you do not miss any doses of TRUVADA or your other HIV-1 medicines.
- When your TRUVADA supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because 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 TRUVADA and become harder to treat.
- If you take too much TRUVADA, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of TRUVADA?

TRUVADA may cause the following serious side effects, including:

- **See “What is the most important information I should know about TRUVADA?”**
- **New or worse kidney problems**, including kidney failure. 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 before you start and while you are taking TRUVADA. Your healthcare provider may tell you to take TRUVADA less often, or to stop taking TRUVADA if you have kidney problems.
- **Bone problems** can happen in some people who take TRUVADA. Bone problems include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do tests to check your bones.
- **Changes in body fat can happen in people who take HIV medicines.** These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these problems are not known.

- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when an HIV-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 any new symptoms after starting your HIV medicine.

The most common side effects of TRUVADA in people with HIV-1 infection include:

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

Common side effects in people who take TRUVADA to prevent HIV-1 infection include:

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

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 TRUVADA. 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 TRUVADA?

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

Keep TRUVADA and all other medicines out of reach of children.

General information about TRUVADA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TRUVADA for a condition for which it was not prescribed. Do not give TRUVADA to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about TRUVADA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about TRUVADA that is written for health professionals. For more information, call 1-800-445-3235 or go to www.TRUVADA.com.

What are the ingredients in TRUVADA?

Active ingredients: emtricitabine and tenofovir disoproxil fumarate

Inactive ingredients: Croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and pregelatinized starch (gluten free). The tablets are coated with Opadry II Blue Y-30-10701 which contains FD&C Blue #2 aluminum lake, hydroxypropyl methylcellulose 2910, lactose monohydrate, titanium dioxide, and triacetin.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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