



Truvada

WHAT IS TRUVADA?

Truvada is a drug used as part of [antiretroviral therapy \(ART\)](#) and as [pre-exposure prophylaxis \(PrEP\)](#). Truvada contains two [antiretroviral drugs \(ARVs\)](#) combined in one tablet:

- [emtricitabine \(FTC, Emtriva\)](#)
- [tenofovir disoproxil fumarate \(tenofovir DF, TDF, Viread\)](#)

The FDA approved Truvada in 2004 as a PrEP medication to reduce the risk of getting HIV and as an ARV for people with HIV infection. Generic versions have been approved for sale under the [President's Emergency Plan for AIDS Relief \(PEPFAR\)](#). Truvada is manufactured by [Gilead Sciences](#).

The drugs in Truvada, emtricitabine and tenofovir DF, are [nucleoside reverse transcriptase inhibitors \(NRTIs\)](#). NRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used in combination with other ARVs to treat HIV infection, Truvada may help:

- Reduce the amount of HIV in your blood. This is called [viral load](#).
- Increase the number of [CD4 cells](#) in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting [opportunistic infections \(OIs\)](#) that can happen when your immune system is weak. [Read more about viral suppression](#).

Truvada [does not cure](#) HIV infection or [AIDS](#). You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE TRUVADA?

Truvada is a prescription two-drug fixed-dose combination medication that may be used in two different ways. Truvada is used:

- to treat HIV infection in adults and children who weigh at least 37 pounds (17 kg), in combination with other ARVs
- as HIV PrEP to reduce the risk of getting HIV infection in adults and adolescents who weigh at least 77 pounds (35 kg)

The safety and effectiveness of Truvada for treatment of HIV infection has not been established in children who weigh less than 37 pounds (17 kg). The safety and effectiveness of Truvada as PrEP for reducing the risk

of HIV infection has not been established in people who weigh less than 77 pounds (35 kg). Truvada has not been carefully studied in the elderly (65 years of age and older).

All people with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. [Read more about U.S. ART guidelines.](#)

Truvada provides two drugs in one pill. It can be more convenient to use Truvada than some other combinations of drugs that must be taken separately or at different times of the day. This could mean fewer missed doses and better control of HIV. **Truvada must be used in combination with other ARVs for the treatment of HIV infection.**

WHO SHOULD NOT TAKE TRUVADA?

Do not take Truvada if you are allergic to emtricitabine, tenofovir DF, or any of the ingredients in this drug.

Do not take Truvada for HIV PrEP if you already have HIV or you do not know your HIV infection status. You must be HIV-negative to start Truvada. Truvada can only help reduce your risk of getting HIV infection before you are infected. You must [get tested](#) to make sure that you do not already have HIV infection before taking Truvada for PrEP. If you have HIV, you need to take other ARVs with Truvada to treat HIV infection. Truvada by itself is not a complete treatment for HIV. If you have HIV and take only Truvada, over time your HIV may become harder to treat.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING TRUVADA?

Before you take Truvada, tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have liver problems, including [hepatitis B virus \(HBV\)](#) infection
- Have [kidney problems](#) or receive kidney dialysis treatment
- Have bone problems

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with Truvada. It is not known if Truvada can harm your unborn baby. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. [Read more about pregnancy and HIV.](#)

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with Truvada. Truvada can pass to your baby in your breastmilk. Do not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop

working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. [Read more about HIV drug resistance.](#)

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS TRUVADA TAKEN?

Truvada is taken by mouth as a tablet. Truvada tablets are available in 4 dose strengths:

- 100/150 mg: 100 mg of emtricitabine and 150 mg of tenofovir DF
- 133/200 mg: 133 mg of emtricitabine and 200 mg of tenofovir DF
- 167/250 mg: 167 mg of emtricitabine and 250 mg of tenofovir DF
- 200/300 mg: 200 mg of emtricitabine and 300 mg of tenofovir DF

Take Truvada at the same time each day with or without food.

Treatment of HIV infection:

The recommended dosage of Truvada for treatment of HIV infection in adults and children who weigh at least 77 pounds (35 kg) is one tablet (200/300 mg) once daily. The recommended dosage of Truvada for treatment of HIV infection in children weighing between 37-76 pounds (17-34 kg) varies based on the child's weight.

If you take Truvada to treat HIV infection, you need to take other ARVs. Your healthcare provider will tell you what medicines to take and how to take them.

HIV PrEP:

The recommended dosage of Truvada for HIV PrEP in HIV-negative adults and adolescents who weigh at least 77 pounds (35 kg) is one tablet (200/300 mg) once daily.

Before taking Truvada for HIV PrEP:

- You must be HIV-negative to start Truvada. You must [get tested](#) to make sure that you do not already have HIV infection.
- Do not take Truvada for HIV PrEP unless you are confirmed to be HIV-negative.
- Some HIV tests can miss HIV infection in a person who has recently become infected. If you have flu-like symptoms, you could have recently become infected with HIV. Tell your healthcare provider if you had a flu-like illness within the last month before starting Truvada or at any time while taking Truvada. Symptoms of new HIV 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 Truvada for HIV PrEP:

- Truvada does not prevent other sexually transmitted infections (STIs). Practice safer sex by using a [condom](#) to reduce the risk of getting STIs.
- You must stay HIV-negative to keep taking Truvada for HIV PrEP.
 - Know your HIV status and the HIV status of your partners.
 - Ask your partners with HIV if they are taking HIV 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 medicines every day. Your risk of getting HIV is lower if your partners with HIV are taking effective treatment.
 - Get tested for HIV 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 to be transmitted.
 - If you think you were exposed to HIV, tell your healthcare provider right away. They may want to do more tests to be sure you are still HIV-negative.
 - Get information and support to help [reduce sexual risk behaviors](#).
 - Do not miss any doses of Truvada. Missing doses increases your risk of getting HIV infection.
- If you do become HIV-positive, you need more medicine than Truvada alone to treat HIV. Truvada by itself is not a complete treatment for HIV.

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary [side effects](#) such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of Truvada for HIV treatment are [diarrhea](#), nausea, [tiredness](#), headache, dizziness, [depression](#), problems sleeping, abnormal dreams, and rash.

The most common side effects of Truvada for HIV PrEP are headaches, stomach-area (abdomen) pain, and decreased weight.

Truvada can cause serious side effects including:

Worsening of HBV infection. Your healthcare provider will test you for HBV before starting treatment with Truvada. If you have HBV infection and take Truvada your HBV may get worse (flareup) if you stop taking Truvada. A flare-up is when your HBV infection suddenly returns in a worse way than before. Do not stop taking Truvada without first talking to your healthcare provider. Do not run out of Truvada. Refill your prescription or talk to your healthcare provider before your Truvada is all gone. 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, or give you a medication to treat HBV. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking Truvada.

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 Truvada. Your healthcare provider may tell you to take Truvada less often or to stop taking Truvada if you develop new or worse kidney problems.

Immune Reconstitution Inflammatory Syndrome (IRIS). [IRIS](#) is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting treatment with Truvada.

Bone problems. [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). [Lactic acidosis](#) is a serious but rare medical emergency that can cause death. Tell your healthcare provider right away if you develop any of these symptoms:

- Weakness or being more tired than usual
- Being short of breath or fast breathing
- Cold or blue hands and feet
- Fast or abnormal heartbeat
- Unusual muscle pain
- Stomach pain with nausea and vomiting
- Feel dizzy or lightheaded

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:

- Your skin or the white part of your eyes turns yellow
- Dark or “tea-colored” urine
- Light-colored stools (bowel movements)
- Loss of appetite for several days or longer
- Nausea
- Stomach-area pain

You may be more likely to get lactic acidosis or serious liver problems if you are assigned female at birth (AFAB) or are very overweight (obese).

These are not all the possible side effects of Truvada. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES TRUVADA REACT WITH OTHER DRUGS?

All ARVs can [interact](#) with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take Truvada with other medicines.

MORE INFORMATION

Visit the [Truvada website](#).

Visit the [Truvada PrEP website](#).

Visit the [Truvada healthcare professional website](#).

Download the full [Prescribing Information](#).

Download the [Important Facts](#) information sheet about Truvada for PrEP.

Download the [Truvada Medication Guide](#).

Apply for the [Gilead Advancing Access Program](#).

Read more about PrEP at [pleasePrEPme.org](#)

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