

TRUVADA AS PrEP:

WHAT YOU SHOULD KNOW BEFORE MAKING THE DECISION

WHAT IS TRUVADA?

Truvada is a pill that contains two antiretroviral medicines (ARVs): 200mg of emtricitabine (FTC) and 300mg of tenofovir (TDF).

ARVs are drugs used mainly for treatment of HIV infection.

Treatment of HIV with ARVs is called antiretroviral therapy (ART). A standard ART uses at least three (3) ARVs to help reduce the ability of HIV virus from making more HIV in a person's body and stop the virus from doing more damage to a person's health.

WHAT IS TRUVADA USED FOR?

Truvada, marketed by Gilead Science, was approved in 2004 for treatment of HIV infection in adults and children 12 years and older. The U.S. Food and Drug Administration (FDA) recently approved a generic version of Truvada by Strides Arcolab Limited in 2013. A generic version of Truvada contains the same kind and same amount of chemical as the Truvada produced by Gilead Science. Generic medicines are cheaper and more affordable for most people.

Truvada is also the first drug to be approved by the U.S. Food and Drug Administration (FDA) for the prevention of HIV infection for adults with high risk of HIV infection¹. This type of use of Truvada is called *PrEP* (*pre-exposure prophylaxis*).

HOW IS TRUVADA USED?

Truvada is taken orally, once daily and with or without food for both HIV treatment and PrEP.

When used in HIV treatment, Truvada must be taken **with** at least one other HIV drug. Truvada combined with efavirenz (EFV) and Truvada combined with nevirapine (NVP) are two of the four preferred first-line ART regimens for those who are starting HIV treatment for the first time recommended by the World Health Organization (WHO).

When used as PrEP, Truvada is taken **without** other HIV drugs.

WHAT IS PrEP?

PrEP is similar to the other types of prophylaxis (e.g. taking a drug, getting vaccinated) that a person can use to prevent or reduce their chance of becoming infected with a disease (e.g. malaria) **before** they are exposed to the disease.

PrEP is a new HIV prevention method that can be used by people who are HIV-negative, it requires that they take Truvada everyday to reduce their risk of becoming infected with HIV.

It is important to remember that FDA requires a person to *take Truvada everyday and use other HIV preventative strategies*, such as safer-sex practices, consistent and correct condom use when using Truvada as PrEP. Truvada is **NOT** approved as a prevention strategy to be used alone (e.g. without the use of condoms), it is not for single use (e.g. whenever a person needs it) and it is not 100 percent effective in the prevention of HIV infection.

Truvada has shown different levels of effectiveness in preventing HIV infection in high-risk men who have sex with men (MSM)², heterosexual sero-discordant couples³ and injecting drug users⁴ in clinical trials. On the other hand, a clinical trial on Truvada as PrEP in women, including female sex workers was stopped early in 2011 because Truvada did not reduce women's risk of becoming HIV infected⁵. Researchers later found that those women weren't taking Truvada regularly but there are no reports on why they did not take the drug, so we still do not know if Truvada can work in the real world that sex workers live and work in.

WHAT ARE THE SIDE EFFECTS OF TRUVADA?

The most common side effects of Truvada are:

- Headache
- Nausea
- Diarrhea
- Vomiting
- Loss of appetite
- Depression
- Insomnia
- Abnormal dreams
- Rash

Just like any other ARVs, Truvada can also cause serious side effects. Some of these side effects are:

1. **Lactic acidosis** – build-up of lactic acid in your blood. This happens when cells in your body receive too little oxygen. Lactic acidosis is a serious medical condition that can lead to death.

² Nam aidsmap. *The iPrEX Study*. Available: <http://www.aidsmap.com/The-iPrEx-study/page/1746640/>

³ Nam aidsmap. *The Partners PrEP trial*. Available: <http://www.aidsmap.com/The-Partners-PrEP-trial/page/2213106/>

⁴ U.S. CDC. (2013). *Press release: Study finds first evidence that PrEP can reduce HIV risk among people who inject drugs*. Available: <http://www.cdc.gov/nchhstp/newsroom/2013/PrEP-Study-Press-Release.html>

⁵ U.S. CDC. *Pre-Exposure Prophylaxis (PrEP)*. Available: <http://www.cdc.gov/hiv/prevention/research/prep/>

¹ FDA approval in July 2012.

2. **Severe liver problems**, including “fatty” (steatosis) and “enlarged” (hepatomegaly) liver can happen in people who take Truvada. In some situation, these liver problems can lead to death. If you are a women and very overweight, or if you have been taking Truvada for a long time, you will have increased risk of liver problems.
3. **Increased creatinine level** is a sign of possible kidney damage. If you had kidney problems before, you need to tell your doctor and check the condition your kidney through a laboratory test [creatinine level] before starting Truvada.
4. **Decreased bone mineral density**, a condition known as osteopenia, has also been found in those taking Truvada⁶. If you think you have low bone density problem (e.g. have osteoporosis, easily fractured or broken bones) you need to inform your doctor.
5. If you are infected with hepatitis B virus (HBV), your **HBV infection may get worse** if you take Truvada and then stop it. In certain cases, it could be life threatening. This is an important issue if you are considering and taking Truvada as PrEP. If you have hepatitis B or suspect you have hepatitis B, you need to inform your doctor.
6. Tenofovir in Truvada can cause **increased fat levels** (cholesterol and triglycerids) **in the blood and abnormal body shape changes**. This is seen when people loose fat in their face, arms and legs and gain more fat around their tummy, breasts and neck. These conditions cannot be changed back to normal even after a person stops taking Truvada.

TRUVADA AS PrEP - WHO IS IT INTENDED FOR?

If you are HIV-negative and at high risk for HIV infection because you are (one or more of the below):

- With a HIV-positive sexual partner
- With frequent partner change or multiple sexual partners
- With partner(s) at high risk of HIV infection
- With other HIV risk factors (e.g. presence or frequent sexual transmitted infection (STI))
- Unable to (consistently) use other preventive measures such as correct use of condoms

ISSUES TO CONSIDER ON TRUVADA AS PrEP:

1. **SAFETY:** Long-term use of any medication, including Truvada, may have serious long-term side effects. Although clinical studies to-date have not found any serious [no significant] health and behavioral safety issues in those MSM and sero-discordant couples that took Truvada to

prevent HIV infection. HOWEVER, those studies only looked at immediate and short-term safety issues and have not been able to include any long-term safety study.

In other words, we know that if you have health problems such as liver, kidney and low bone mineral density, taking Truvada can make your health worse. BUT we do not know what might happen to your body if you are healthy (e.g. no liver problem) and if you take Truvada for a long period of time.

2. **EFFECTIVENESS:** For Truvada to work in reducing your risk of HIV infection, you must take it once a day, everyday and at the scheduled time – this means you must have a good adherence in taking the drug.

Your ability to have good adherence may be influenced by issues such as you cannot handle the short-term drug side effects (e.g. headaches, vomiting, etc.), your work schedule (e.g. busy and forget to take med), you ran out of or forget to bring Truvada, etc.

3. **RESISTANCE:** Drug-resistant HIV variants have been found in people who took Truvada as PrEP⁷. It has been suggested that a possible contributing factor to the development of drug-resistance in this group of people was that those individuals were already infected with HIV (e.g. during window period) prior to starting PrEP.

Having drug-resistant HIV means that those people will not be able to use some of the ARVs to treat their HIV infection because those ARVs will not work against the kind of HIV virus they have in their bodies.

Being drug-resistant is a serious problem if you live in an area/country where only few types of ARVs are available – treatment might not be available or work well for you if you become HIV infected.

4. **ACCESS TO AND SUSTAINABILITY:** Because Truvada needs to be taken everyday and for a long period of time, it is important that if you choose to take it you will be able to get it easily, continuously and without interruption.

If you have to pay for Truvada yourself (e.g. not free from government, research or insurance program), you should have a plan in case you cannot get/afford the medicine later on.

⁶ At least one clinical trial conducted involving HIV-positive patients using tenofovir [combined with efaviren and lamivudine] founded the drug caused decreases in bone mineral density at the hip and spine.

⁷ Gilead Science, Inc. 2013. *Safety Information Fact Sheet For Prescribers About Truvada for a Pre-exposure Prophylaxis Indication*. Available: http://start.truvada.com/content/pdf/Safety_Information_Fact_Sheet.pdf