

What is PrEP?

Pre-exposure prophylaxis (PrEP) is a HIV prevention method in which people who are HIV-negative take HIV treatment drugs (antiretrovirals – ARVs) daily to reduce their risk of becoming HIV-infected.

How does PrEP work?

The idea behind PrEP is that if an HIV-negative person takes certain ARV pills on a regular schedule before they are exposed to HIV through sex, they may be protected from HIV infection. PrEP is not 100 percent effective and does not protect against other sexually transmitted infection (STI) such as gonorrhea, syphilis or chlamydia, therefore PrEP should be used in conjunction with condoms.



What is Truvada®?

Truvada® is an ARV drug combination of TDF (Viread) and emtricitabine (FTC). The FDA approved daily oral Truvada® for PrEP in July, 2012. To date Truvada® is the only ARV approved by the FDA for HIV prevention in adults. Truvada® is currently available for doctors to prescribe for use as PrEP.

Has there been research on PrEP?

At least seven PrEP studies have either recently been completed, or are currently underway in a total of 13 countries involving over 20,000 people with diverse risk behaviors. In 2010, the iPrEx study published results that showed the daily use of oral Truvada® reduced the risk of HIV infection by 44% in HIV-negative men who have sex with men (MSM) and transgender women. The study found participants who had more Truvada® in their body were better protected than those who did not take the pills daily. In 2011, two additional studies also found Truvada® effective in reducing HIV infection among heterosexual men and women.

Two different studies have shown that PrEP is not effective if it is not taken as prescribed. The VOICE study, which evaluated oral and topical PrEP, and Fem-PrEP, which evaluated oral use of Truvada® as PrEP, were both conducted with heterosexual women in Africa. Neither study showed that PrEP worked with those study participants because a majority of the participants did not take the drug as instructed.

How effective is Truvada® as PrEP?

The level of HIV protection varies widely depending on how consistently PrEP is used. Those who adhere well to the daily dosing regimen have significantly greater levels of protection (up to 90%) than those who do not. Other than low adherence, no factors have been identified that appear to influence the effectiveness of PrEP in reducing sexual transmission of HIV.

How should Truvada® be taken?

The following steps must be taken before you start taking PrEP:

- You must have HIV risk reduction counseling
- A negative HIV test
- Test for hepatitis B, kidney function and sexually transmitted infections (STIs)



While taking PrEP, you should visit the doctor at least every three months to receive additional drug, test for HIV and an evaluation for side effects, ongoing HIV risk counseling and to discuss any problems that you may be having with drug adherence.

The recommended dose of Truvada® for PrEP is:

- one tablet taken by mouth daily,
- at about the same time every day,
- with or without food.

If you miss a dose of Truvada® your doctor may advise you to take the missed pill as soon as you remember on that same day, but to not take more than one dose of Truvada® in a 24 hour period. Your doctor may also advise that if you miss a dose, and it is almost time for your next dose, to wait and take the next dose at your regular time. Contact your medical provider as soon as possible if you take more than one pill of Truvada® a day. If it is after hours, consider contacting the nearest hospital emergency room.

What are side effects of Truvada®?

Truvada® may have side effects and you should consult a medical provider if you have any concerns. Allergic reactions include; fever, rash, upset stomach, vomiting, loose or watery stools, achiness. Other possible side effects include; runny nose, gas, itching, headache, dizziness, depression, increased cough, muscle pain or weakness, sleeping problems, darkening of the palms and or soles, bone pain or broken bones.

Who should take PrEP?

If you're HIV-negative and trying to stay that way, PrEP might be right for you. Some questions to consider:

- Is your main sexual partner HIV-positive? In other words, are you part of a mixed-status couple?
- Has a man — especially an HIV-positive man, or a man whose status you're not sure about penetrated you during anal sex ("topped" you) without a condom recently?
- Have you been treated recently for an STI such as gonorrhea?
- Have you used PEP more than once in the past year?
- Do you use alcohol and/or drugs heavily; or, does your sex partner(s)?
- Do you exchange sex for money, housing or other needs; or, does your sex partner(s)?
- Has your partner threatened you with violence or physically harmed you recently?

If you answer "yes" to any of these then you should consider discussing PrEP with your doctor.

Who should not take PrEP?

People who have symptoms of acute HIV infection (symptoms similar to the flu) or who have kidney disease or reduced kidney health should not use PrEP.

Where can I get PrEP?

PrEP can only be prescribed by a medical provider. Some insurance companies cover the cost of PrEP. The Truvada® for PrEP Medication Assistance Program assists eligible HIV-negative adults in the United States obtain access to Truvada® who do not have insurance. Call 1-855-330-5479 to find out if you are eligible.

How should Truvada® be stored?

Truvada® should be stored at room temperature in its original container. The container should be kept tightly closed and out of the reach of children. Do not give Truvada® prescribed to you to other people.

Where can I get additional information on Truvada®?

Additional information on Truvada® can be found on the following websites:

- http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf
- <http://www.cara-online.org/services/health/HIVAIDSDRUGSTruvada.html>
- <http://hivinfo.us/truvada.html>

What is HPTN?

The HIV Prevention Trials Network (HPTN) is a worldwide collaborative clinical trials network that brings together investigators, ethicists, community and other partners to develop and test the safety and efficacy of interventions designed to prevent the acquisition and transmission of HIV. HPTN studies evaluate new HIV prevention interventions and strategies in populations and geographical regions that bear a disproportionate burden of infection. HPTN receives its funding from three NIH institutes: the National Institute of Allergy and Infectious Diseases, the National Institute of Mental Health and the National Institute on Drug Abuse.

What PrEP research is the HIV Prevention Trials Network conducting?

The HPTN is currently conducting three PrEP studies:

- **HPTN 067/ADAPT** is looking at the use of non-daily PrEP and hopes to identify PrEP pill-taking schedules that participants are more likely to follow and determine if these schedules influence healthier sexual practices.
- **HPTN 069/ACTG 5305/NEXT-PrEP** is studying the safety and acceptability of four different drug combinations when used as PrEP by men who have sex with men and when used by women.
- **HPTN 073** is a demonstration study designed to see if Black men who have sex with men (BMSM) are willing to use Truvada and gather feedback from their PrEP taking experience.

To learn more about the HIV Prevention Trials Network, visit www.hptn.org or follow on Facebook: www.facebook.com/HIVptn/ or Twitter: [www.twitter.com/HIVptn](https://twitter.com/HIVptn).