

## One Daily Pill Can Help Prevent HIV

TRUVADA for PrEP<sup>™</sup> together with safer sex practices can mean better protection.

TRUVADA for PrEP is a prescription medicine that can help reduce the risk of getting HIV-1 through sex when used together with safer sex practices.

- TRUVADA for PrEP is only for adults who have a higher chance of getting HIV-1 through sex.
- You must be HIV-negative before you start taking TRUVADA for PrEP.

## Ask a healthcare provider about HIV prevention and if TRUVADA for PrEP is right for you.

Please see brochure pocket for Important Facts about TRUVADA for PrEP, including important warnings on the risk of drug resistance if you become HIV-positive and only take TRUVADA and worsening of hepatitis B infection.

## Change the way you think about HIV and prevention



That's one reason why knowing your HIV prevention options is so important to your health. Because HIV is spread through body fluids, practicing safer sex can help prevent the spread of the virus. Some effective safer sex practices include using condoms consistently and correctly, getting tested regularly for HIV and other sexually transmitted infections (STIs), and knowing the HIV status of your partners.

There's also an additional prevention option available for people who are HIV-negative and at higher risk for infection. It's called PrEP. When used with safer sex practices, it can help reduce the chances of HIV infection.



PrEP stands for pre-exposure prophylaxis. Prophylaxis is the action taken in order to prevent disease.

# TRUVADA for PrEP<sup>™</sup> can provide increased protection against HIV

TRUVADA for PrEP, along with safer sex practices, can help give you added protection from HIV. If you're wondering whether TRUVADA for PrEP is right for you, here are some important things to know:

## What is TRUVADA for PrEP (Pre-exposure Prophylaxis)?

TRUVADA for PrEP is a prescription medicine that is used together with safer sex practices to help reduce the risk of getting HIV-1 through sex. This use is only for HIV-negative adults who are at high risk of getting HIV-1. To help determine your risk of getting HIV-1, talk openly with your healthcare provider about your sexual health.

## Before and after you start TRUVADA for PrEP

- You must be HIV-negative to take TRUVADA for PrEP:
  - Get tested for HIV-1 before you start taking TRUVADA for PrEP and at least every 3 months while taking it
- If you have HIV-1, you must take more medicines than TRUVADA alone to treat HIV-1
- It's one pill, taken once a day, every day. You can take it with or without food, and it should always be used with safer sex practices such as:
  - Condoms and lube
  - Talking with your partners about their status
  - Getting tested regularly for HIV and other STIs
  - Understanding situations that increase your chances of getting HIV

Ask a healthcare provider about HIV prevention and if TRUVADA for PrEP is right for you.



# What is the most important information I should know about TRUVADA for PrEP<sup>™</sup>?

#### **Before taking TRUVADA for PrEP:**

- You must be HIV-negative before you start taking TRUVADA for PrEP. You must get tested to make sure that you do not already have HIV-1. Do not take TRUVADA to reduce the risk of getting HIV-1 unless you are confirmed to be HIV-negative.
- 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 or at any time while taking TRUVADA for PrEP. Symptoms of new HIV-1 infection include tiredness, fever, joint or muscle aches, headache, sore throat, vomiting, diarrhea, rash, night sweats, and/or enlarged lymph nodes in the neck or groin.

#### While taking TRUVADA for PrEP:

- You must continue to use safer sex practices. Just taking TRUVADA for PrEP may not keep you from getting HIV-1.
- You must stay HIV-negative to keep taking TRUVADA for PrEP:
  - Get tested for HIV-1 at least every 3 months.
  - If you think you were exposed to HIV-1, tell your healthcare provider right away.
- To further help reduce your risk of getting HIV-1:
  - Know your HIV status and the HIV status of your partners.
  - Get tested for other sexually transmitted infections. Other infections make it easier for HIV to infect you.

- Get information and support to help reduce risky sexual behavior, such as having fewer sex partners.
- Do not miss any doses of TRUVADA. Missing doses may increase your risk of getting HIV-1 infection.
- If you do become HIV-1 positive, you need more medicine than TRUVADA alone to treat HIV-1. TRUVADA by itself is not a complete treatment for HIV-1. If you have HIV-1 and take only TRUVADA, your HIV-1 may become harder to treat over time.

#### **TRUVADA can cause serious side effects:**

 Worsening of hepatitis B (HBV) infection. TRUVADA is not approved to treat HBV. If you have HBV and stop taking TRUVADA, your HBV may suddenly get worse. Do not stop taking TRUVADA without first talking to your healthcare provider, as they will need to monitor your health.

#### Who should not take TRUVADA for PrEP?

- Do not take TRUVADA for PrEP if you:
  - Already have HIV-1 infection or if you do not know your HIV-1 status. If you are HIV-1 positive, you need to take other medicines with TRUVADA to treat HIV-1. TRUVADA by itself is not a complete treatment for HIV-1. If you have HIV-1 and take only TRUVADA, your HIV-1 may become harder to treat over time.
  - Also take certain medicines to treat hepatitis B infection.



## Is TRUVADA for PrEP<sup>™</sup> right for you?

TRUVADA for PrEP can help reduce the chance of HIV infection in HIV-negative people when used with safer sex practices. It's a daily medication for adults who have higher chances of getting HIV through sex.

## You might be at higher risk for getting HIV if you are:

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#### Having sex with someone who is HIV-positive

Having sex in a geographic area or within a sexual network where HIV is more common, *and* any of the following are true about you:



Have or have had a sexually transmitted infection (STI) like syphilis, gonorrhea, or chlamydia



Ever have sex without condoms



Have many sexual partners



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- Exchange sex for drugs, food, money, or shelter
- Use recreational drugs or are dependent on alcohol

Have ever been in prison

Have sexual partners whose HIV status is not known, and who would fall into one of the above categories

For more information about the rate of HIV in your area, visit AIDSVU.org.

## Who should not take TRUVADA for PrEP

TRUVADA for PrEP is not for people who are HIV-positive or don't know their HIV status. It's also not for people taking certain medicines to treat hepatitis B infection. Before starting TRUVADA for PrEP, you have to be tested for HIV to confirm that you are negative.

If you think you might have been exposed to HIV before starting or while taking TRUVADA for PrEP, let your healthcare provider know right away. TRUVADA by itself is not a complete treatment for HIV—in fact, taking TRUVADA alone to treat HIV can make HIV harder to treat now and in the future.

Talk to a healthcare provider to learn more about steps you can take to prevent HIV.





## Studies show that TRUVADA for PrEP<sup>™</sup> helps protect against HIV

In two clinical studies, TRUVADA for PrEP, along with safer sex practices, helped reduce the chances of HIV infection. The first study followed HIV-negative men second followed male-female partners where one partner was HIV-positive and the other was not. During the studies, all participants were instructed to use safer sex practices, including condoms. They also received monthly HIV testing and counseling on safer sex practices.



Studies show that **TRUVADA for PrEP works** better when it is taken every day as directed.

## Further analysis of the studies

After the initial studies were completed and the results were known, researchers looked at a sample of people who were assigned to take TRUVADA in the studies. They wanted to know if people who had TRUVADA in their body were better protected against HIV than those who did not.

In both studies, people with TRUVADA in their body\* were less likely to get HIV, compared to those with no TRUVADA in their body. This kind of analysis, called a "post-hoc analysis," should be interpreted with caution because it was not one of the original goals of either study.

\*Whether or not people had TRUVADA in their body was determined by testing blood samples that were collected during the studies.

#### **STUDY 1**

## Men who have sex with men and transgender women who have sex with men:



in people who took **TRUVADA vs placebo**  TO TAKE TRUVADA

FURTHER ANALYSIS OF A

SAMPLE OF PEOPLE ASSIGNED



in people who had TRUVADA in their body vs those who didn't\* • Number of people who who were assigned to take TRUVADA: 1.251

• Number of people who took a placebo (sugar pill): 1,248

\*92% reduction was seen in a sample (about 10%) of the people who were assigned to take TRUVADA; these results should be interpreted with caution.

**Clinical Studies** 

#### STUDY 2

## Couples (male/female) where one partner has HIV and the other does not:

AMONG ALL PARTICIPANTS

ess chance of

IV infection

in people who took

**TRUVADA vs placebo** 

FURTHER ANALYSIS OF A SAMPLE OF PEOPLE ASSIGNED TO TAKE TRUVADA



in people who had TRUVADA in their body vs those who didn't\*

- Number of people who were assigned to take TRUVADA: 1.583
- Number of people who took a placebo (sugar pill): 1,586

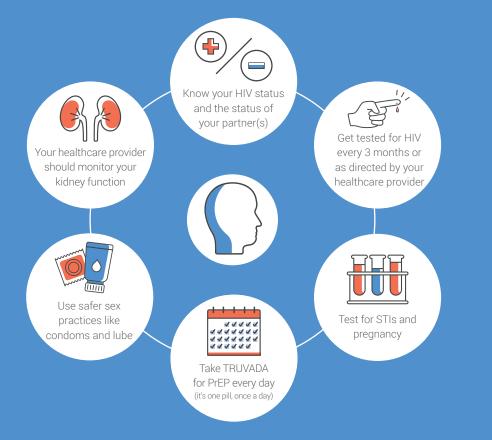
\*90% reduction was seen in a sample (about 10%) of the people who were assigned to take TRUVADA: these results should be interpreted with caution.



## Making TRUVADA for PrEP<sup>™</sup> part of an HIV prevention plan

TRUVADA for PrEP should be used as part of an overall prevention plan that can help you stay HIV-negative. While you're taking the medication, here are other steps you should take to stay healthy:

## While taking TRUVADA for PrEP



## You must stay HIV-negative to keep taking TRUVADA for PrEP

TRUVADA for PrEP is only for people who are HIV-negative. Tell your healthcare provider right away if you think you were exposed to HIV. He or she may want to do more tests to be sure you are still HIV-negative. You should get tested for HIV at least every 3 months while taking TRUVADA for PrEP.

TRUVADA for PrEP works best when you take it every day, not just when you think you've been exposed to HIV—it is less effective if you skip doses.

If you think you've been exposed to HIV, contact a healthcare provider right away.



## If you do become HIV-positive, you need more medicine than TRUVADA alone to treat HIV

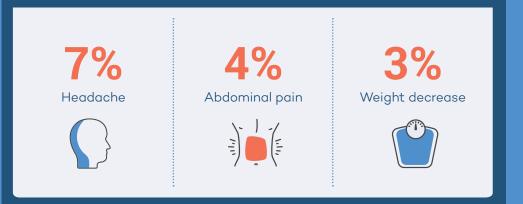
TRUVADA by itself is not a complete treatment for HIV. If you have HIV and take only TRUVADA, your HIV may become harder to treat now and in the future.



## **Possible Side Effects**

In clinical studies for TRUVADA for PrEP<sup>™</sup>, the most common side effects were headache, abdominal pain, and weight decrease.

Common side effects that were reported in more than 2% of study participants included:



You are encouraged to report negative side effects of prescription drugs to the FDA.Visit www.FDA.gov/medwatch, or call 1-800-FDA-1088.

## What are the other possible side effects of TRUVADA for PrEP™?

#### Serious side effects of TRUVADA may also include:

- Kidney problems, including kidney failure. Your healthcare provider may do blood tests to check your kidneys before and during treatment with TRUVADA. If you develop kidney problems, your healthcare provider may tell you to stop taking TRUVADA.
- Too much lactic acid in your blood (lactic acidosis), which 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, which in rare cases 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,** including bone pain, softening, or thinning, which may lead to fractures. Your healthcare provider may do tests to check your bones.

**Common side effects** in people taking TRUVADA for PrEP are stomach-area (abdomen) pain, headache, and decreased weight. Tell your healthcare provider if you have any side effects that bother you or do not go away.

Please see Important Facts about TRUVADA for PrEP, including **important warnings,** in brochure pocket.



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# What should I tell my healthcare provider before taking TRUVADA for PrEP<sup>™</sup>?

- All your health problems. Be sure to tell your healthcare provider if you have or have had any kidney, bone, or liver problems, including hepatitis.
- If you are pregnant or plan to become pregnant. It is not known if TRUVADA can harm your unborn baby. If you become pregnant while taking TRUVADA for PrEP, talk to your healthcare provider to decide if you should keep taking TRUVADA.
- If you are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed. If you become HIV-positive, HIV can be passed to the baby in breast milk.
- All the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. TRUVADA may interact with other medicines. Keep a list of all your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.
- If you take certain other medicines with TRUVADA, your healthcare provider may need to check you more often or change your dose. These medicines include certain medicines to treat hepatitis C (HCV) infection.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch, or call 1-800-FDA-1088.



## Questions for your healthcare provider

Do you have questions about HIV prevention or TRUVADA for PrEP? Write them down here and bring them up at your next appointment.



## Paying for TRUVADA for PrEP<sup>™</sup>

## **Financial Support**

If you need assistance paying for TRUVADA for PrEP, the Gilead Advancing Access® program may be able to help.

#### IF YOU HAVE COMMERCIAL INSURANCE

## The Gilead Advancing Access co-pay coupon card might help you save.

If you are eligible, the co-pay card covers up to \$3,600 in co-pays per year with no monthly limit for TRUVADA for PrEP. For full terms and conditions, visit **GileadAdvancingAccess.com**.

### IF YOU HAVE GOVERNMENT INSURANCE

If you are enrolled in government healthcare programs (such as Medicare Part D, Medicaid, TRICARE, or VA), you are not eligible for the Gilead Advancing Access program. However you may be eligible for alternate sources of funding through independent co-pay foundations.

### IF YOU DO NOT HAVE INSURANCE

The Medication Assistance Program may be able to determine if you are qualified to receive TRUVADA for PrEP free of charge.

## Get started with the Gilead Advancing Access program

Enroll at GileadAdvancingAccess.com



Call **1-800-226-2056** Monday–Friday | 9 am–8 pm ET

## **Insurance Support**

Navigating your insurance plan can be difficult. Gilead Advancing Access® program counselors may be able to help you:

- Research and assess your insurance coverage and benefits
- Work with your healthcare provider through the process of Prior Authorization, if requested
- Prior Authorization means your healthcare provider needs approval from your health insurance in order for TRUVADA for PrEP to be covered
- Understand what to do if your insurance claim has been denied
- Understand changes in your life or insurance that affect your coverage, such as:
  - Insurance changes
- If your insurance no longer covers TRUVADA for PrEP
- Denial of coverage
- A change in insurance because of a life event, such as loss of a job

Call Advancing Access to talk to a counselor about any financial or insurance support needs. You can also leave a confidential message any time.



## **Resources for you**

There are other organizations and resources that can help you:



Looking for a doctor who prescribes TRUVADA for PrEP<sup>™</sup>? Visit PrepLocator.org.



**Need help with other sexual health questions?** AIDS Service Organizations (ASOs) and Community-Based Organizations (CBOs) offer everything from STI testing to counseling services. There may be an organization in your area that can help you. Visit **locator.aids.gov** to find an ASO or CBO near you.



**Need condoms?** Condoms are a necessity. Paying for them doesn't have to be. ASOs and CBOs may provide condoms free of charge. Or you can visit **TRUVADA.com/Condoms** to receive free protection.



Want to get testing and medication reminders? Sign up for testing and medication reminders at TRUVADA.com/Reminders.







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