EMPOWER WOMEN TO HELP PROTECT THEMSELVES FROM HIV

Inform them of all their options, including TRUVADA FOR PrEP®

TRUVADA FOR PrEP should be used in combination with safer sex practices[1]

INDICATION

TRUVADA FOR PrEP (pre-exposure prophylaxis) is indicated to reduce the risk of sexually acquired HIV-1 in adults and adolescents (≥35 kg) who are at risk for HIV, when used in combination with safer sex practices. HIV-negative status must be confirmed immediately prior to initiation

- If clinical symptoms of acute HIV-1 infection are present and recent exposures (<1 month) are suspected, delay initiation for at least 1 month until HIV-negative status is reconfirmed. Alternatively, confirm HIV-negative status with a test cleared by the FDA to aid in the diagnosis of acute HIV-1 infection

Individuals at risk for sexually acquired HIV-1 may include those:

- With HIV-1 infected partner(s), **or**
- Who engage in sexual activity in a high prevalence area or social network **and** have additional risk factors, such as: inconsistent or no condom use, diagnosis of sexually transmitted infections (STIs), exchange of sex for commodities, use of illicit drugs or alcohol dependence, incarceration, or sexual partners of unknown HIV status with any of these risk factors

IMPORTANT SAFETY INFORMATION

BOXED WARNING: RISK OF DRUG RESISTANCE WITH USE OF TRUVADA FOR PrEP IN UNDIAGNOSED EARLY HIV-1 INFECTION and POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- **TRUVADA FOR PrEP must only be prescribed to individuals confirmed to be HIV-negative immediately prior to initiation and at least every 3 months during use. Drug-resistant HIV-1 variants have been identified with use of TRUVADA FOR PrEP following undetected acute HIV-1 infection. Do not initiate if signs or symptoms of acute HIV-1 infection are present unless HIV-negative status is confirmed**
- **Severe acute exacerbations of hepatitis B have been reported in HBV-infected patients who discontinued TRUVADA. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients with HBV after discontinuing TRUVADA. If appropriate, initiation of anti-hepatitis B therapy may be warranted**

Please click here for full Prescribing Information for **TRUVADA FOR PrEP**, including **BOXED WARNING**, and visit TRUVADAHCP.com for more information.

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PROACTIVE PREVENTION

MANY WOMEN UNDERESTIMATE THEIR RISK FOR HIV[2-4]

Did you know?

1 in 5 new HIV diagnoses is in a woman[5]

Most women at risk are not adequately protected from HIV[2,3,6,7]

- 9 out of 10 women at risk for HIV reported having vaginal sex without a condom in the previous year[6]
- Awareness and use of TRUVADA FOR PrEP® has been low among women who could benefit from it the most[2,3,7]

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindications

- TRUVADA FOR PrEP is contraindicated in individuals with unknown or positive HIV status

Warnings and precautions: Comprehensive risk reduction strategies

- **Reduce HIV-1 risk:** TRUVADA FOR PrEP is not always effective in preventing HIV-1. Use only as part of a comprehensive prevention strategy that includes safer sex practices, regular testing for HIV-1 and other STIs, and counseling on reducing sexual risk behaviors
- **Reduce potential for drug resistance:** TRUVADA FOR PrEP should only be used in individuals confirmed to be HIV-negative immediately prior to initiation, at least every 3 months while taking TRUVADA, and upon an STI diagnosis. HIV-1 resistance substitutions may emerge in individuals with undetected HIV-1 infection who are taking only TRUVADA. TRUVADA alone is not a complete regimen for treating HIV-1
  - HIV antibody tests may not detect acute HIV infection. If recent exposures are suspected or symptoms of acute HIV infection are present (e.g., fever, fatigue, myalgia, skin rash), delay initiating (≥1 month) or discontinue use and confirm HIV-negative status with a test approved by the FDA for the diagnosis of acute HIV infection
  - If a screening test indicates possible HIV-1 infection, convert the HIV-1 PrEP regimen to an HIV treatment regimen until HIV-negative status is confirmed
- **Counsel on adherence:** Counsel individuals to strictly adhere to their dosing schedule, as efficacy is strongly correlated with adherence. Some individuals, such as adolescents, may benefit from more frequent visits and counseling

Warnings and precautions

- **New onset or worsening renal impairment:** Cases of acute renal impairment and Fanconi syndrome have been reported with the use of tenofovir disoproxil fumarate (TDF). TRUVADA is not recommended in individuals with estimated creatinine clearance (CrCl) <60 mL/min. Avoid concurrent or recent use with a nephrotoxic agent. Acute renal failure has been reported after initiation of high dose or multiple NSAIDs in patients at risk for renal dysfunction; consider alternatives to NSAIDs in these patients. Monitor renal function in all patients – See Dosage and Administration section

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FOR WOMEN, SOME HIV RISK FACTORS ARE OUT OF THEIR CONTROL[8-11]

Where a woman lives—or her partner's HIV risk factors—can impact her risk for HIV[8-10]

HIV risk for many women can be associated with a steady male partner[11]

According to the CDC, only ~2% of women at risk for HIV are prescribed TRUVADA FOR PrEP[7]

You may have considered women who[1]

- Have an HIV-positive partner
- Are involved in commercial sex work*
- Have a high number of sex partners*

You should also consider all sexually active women who live in a high-prevalence area AND[1]

- Use condoms inconsistently or infrequently
- Have had an STI
- Have a partner of unknown HIV status with risk factors for HIV†

*In an area or social network with high HIV prevalence.

†For example, with a known or unknown concurrent sexual relationship or a history of illicit drug use, incarceration, or STI.

CDC=Centers for Disease Control and Prevention.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Bone effects:** Decreases in bone mineral density (BMD) and mineralization defects, including osteomalacia associated with proximal renal tubulopathy, have been reported with the use of TDF. Consider monitoring BMD in patients with a history of pathologic fracture or risk factors for bone loss
- **Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including TRUVADA. Discontinue use if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations
- **Drug interactions:** See Drug Interactions section. Consider the potential for drug interactions prior to and during use of TRUVADA and monitor for adverse reactions

Adverse reactions

- **Common adverse reactions** (>2% and more frequently than placebo) of TRUVADA FOR PrEP in clinical trials were headache, abdominal pain, and weight loss

Drug interactions

- **Prescribing information:** Consult the full Prescribing Information for TRUVADA for more information, warnings, and potentially significant drug interactions, including clinical comments
- **Hepatitis C antivirals:** Coadministration with ledipasvir/sofosbuvir, sofosbuvir/velpatasvir, or sofosbuvir/velpatasvir/voxilaprevir increases TDF exposure; monitor for adverse reactions
- **Drugs affecting renal function:** Coadministration of TRUVADA with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of emtricitabine and/or tenofovir

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PROACTIVE PREVENTION

YOU MAY ONLY HAVE ONE CHANCE TO HAVE AN OPEN CONVERSATION ABOUT HIV RISK

Investigate women's HIV risk

Some questions to consider:

- **Where does she live?**[8]
- **Is her partner's HIV status known?**[2,3]
- **Does she use condoms?**[9]
- **Has she had a recent STI?**[9]

Discuss HIV risk and prevention in an open manner

Help protect appropriate patients with TRUVADA FOR PrEP®, one tablet taken each day[1]

The only medication approved to significantly reduce the risk of sexually acquired HIV-1 in individuals at risk, in combination with safer sex practices[1,12]

For more information, visit **TRUVADAHCP.com**

IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy and lactation

- **Pregnancy:** An Antiretroviral Pregnancy Registry (APR) has been established. Available data from observational studies and the APR show no increase in the rate of major birth defects for TRUVADA compared with a US reference population. Consider HIV prevention methods, including TRUVADA FOR PrEP in women due to the potential increased risk of HIV-1 infection during pregnancy and mother to child transmission during acute HIV-1 infection
- **Lactation:** Emtricitabine and tenofovir have been detected in human milk. Evaluate the benefits and risks of TRUVADA FOR PrEP in breastfeeding women, including the risk of HIV-1 acquisition due to nonadherence, and subsequent mother to child transmission. Health benefits of breastfeeding should be considered along with potential adverse effects of TRUVADA on the child, which are unknown

Dosage and administration

- **Dosage:** One tablet once daily with or without food
- **HIV screening:** Test for HIV-1 infection prior to initiating and at least every 3 months during treatment
- **HBV screening:** Test for HBV infection prior to or when initiating treatment
- **Renal impairment and monitoring:** Not recommended in individuals with CrCl <60 mL/min. In all patients, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein on a clinically appropriate schedule. In patients with chronic kidney disease, also assess serum phosphorus

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TRUVADA FOR PrEP has a Risk Evaluation and Mitigation Strategy (REMS). For further information, click here

References: 1. TRUVADA [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2018. **2.** Bradley ELP, Hoover KW; Centers for Disease Control and Prevention Women and PrEP Discussion Series Team. Improving HIV preexposure prophylaxis implementation for women: summary of key findings from a discussion series with women's HIV prevention experts. *Womens Health Issues.* 2019;29(1):3-7. **3.** Collier KL, Colarossi LG, Sanders K. A PrEP information and self-screening tool for women. *AIDS Educ Prev.* 2018;30(1):13-25. **4.** Koren DE, Nichols JS, Simoncini GM. HIV pre-exposure prophylaxis and women: survey of the knowledge, attitudes, and beliefs in an urban obstetrics/gynecology clinic. *AIDS Patient Care STDS.* 2018;32(12):490-494. **5.** Centers for Disease Control and Prevention. *HIV Surveillance Report, 2017*; vol 29. https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdf. Published November 2018. Accessed January 25, 2019. **6.** Centers for Disease Control and Prevention. *HIV Infection, Risk, Prevention, and Testing Behaviors Among Heterosexuals at Increased Risk of HIV Infection–National HIV Behavioral Surveillance, 17 U.S. Cities, 2016.* HIV Surveillance Special Report 19. https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-number-19.pdf. Published April 2018. Accessed January 25, 2019. **7.** Huang YA, Zhu W, Smith DK, Harris N, Hoover KW. HIV preexposure prophylaxis, by race and ethnicity—United States, 2014–2016. *MMWR Morb Mortal Wkly Rep.* 2018;67(41):1147-1150. **8.** Centers for Disease Control and Prevention. HIV in the United States by region. https://www.cdc.gov/hiv/statistics/overview/geographicdistribution.html. Updated November 27, 2018. Accessed January 11, 2019. **9.** Centers for Disease Control and Prevention. *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2017 Update: A Clinical Practice Guideline.* http://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018. Accessed January 11, 2019. **10.** Chen YH, Raymond HF, McFarland W, Truong HM. HIV risk behaviors in heterosexual partnerships: female knowledge and male behavior. *AIDS Behav.* 2010;14(1):87-91. **11.** McMahon JM, Myers JE, Kurth AE, et al. Oral pre-exposure prophylaxis (PrEP) for prevention of HIV in serodiscordant heterosexual couples in the United States: opportunities and challenges. *AIDS Patient Care STDS.* 2014;28(9):462-474. **12.** Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med.* 2012;367(5):399-410.

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