Implementing TRUVADA FOR PrEP®

To help protect women from HIV

Once daily TRUVADA FOR PrEP is part of guideline-recommended care. Prescribe to appropriate patients as part of a comprehensive prevention strategy involving condoms, safer sex practices, and knowledge of partner(s)' HIV-1 status.[1,2]

HIV-1–negative status must be confirmed immediately prior to initiating TRUVADA FOR PrEP and at least every 3 months thereafter.

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 InformHer.com for more information.

Truvada®
emtricitabine 200 mg / tenofovir disoproxil fumarate 300 mg tablets
for PrEP pre-exposure prophylaxis

PROACTIVE PREVENTION

What to do prior to initiating TRUVADA FOR PrEP®

Some of these steps may already be a part of your routine practice

Screen for HIV and HBV[1]

- Confirm HIV-negative status with a test approved by the FDA to aid diagnosis of acute or primary HIV-1 infection
- Ensure no symptoms of acute HIV infection are present if recent exposures are suspected <1 month
- Test for hepatitis B; consider vaccination if HBV uninfected

Counsel on the importance of daily dosing[1]

- Stress the importance of adherence, since efficacy is strongly correlated with adherence, as well as using TRUVADA FOR PrEP as part of a comprehensive prevention plan

Assess renal function[1]

- Assess serum creatinine, estimated CrCl, urine glucose, and urine protein; TRUVADA FOR PrEP is not recommended in individuals with CrCl <60 mL/min
- In patients with chronic kidney disease, also assess serum phosphorus

Test for pregnancy[1]

- Counsel on the risks and benefits of using TRUVADA FOR PrEP during pregnancy, taking into account the increased risk of HIV-1 infection during pregnancy
- An Antiretroviral Pregnancy Registry is available; to enroll women taking TRUVADA FOR PrEP, call 1-800-258-4263

HBV=hepatitis B virus.

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

Warnings and precautions: Comprehensive risk reduction strategies (cont'd)

- **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

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

Truvada®
emtricitabine 200 mg / tenofovir disoproxil fumarate 300 mg tablets
for PrEP pre-exposure prophylaxis

What to do during follow-up visits

Screen for HIV and other STIs on a regular basis[1,2]

- Confirm HIV-negative status at least every 3 months and upon diagnosis of an STI
- Screen for STIs every 3 to 6 months per CDC recommendations

Reassess HIV risk[2]

Counsel individuals on the importance of adherence and safer sex practices[1]

Continue monitoring renal function on a clinically appropriate schedule[1]

- Reassess potential risks and benefits of using TRUVADA FOR PrEP® if a decrease in CrCl is observed during use

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

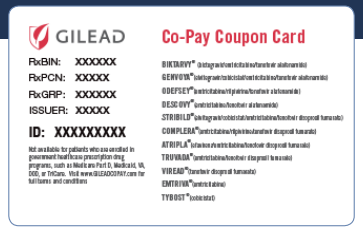
Please click here for full Prescribing Information for **TRUVADA FOR PrEP**, including **BOXED WARNING**, and visit InformHer.com for more information.

Truvada®
emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg tablets
for PrEP pre-exposure prophylaxis

TRUVADA FOR PrEP® patient support

Gilead Patient Assistance Program

Eligible patients may pay as little as a **$0 co-pay***



The co-pay coupon covers up to $7,200 per year with no monthly limit for eligible patients.

Enroll patients at:

GileadAdvancingAccess.com/hcp

OR

1-800-226-2056
Monday-Friday
9 AM to 8 PM ET

The Gilead Advancing Access® program is committed to helping eligible patients afford their Gilead medication whether they are insured, uninsured, or underinsured

ADVANCING ACCESS®

- **Insurance Support:** provides help with coverage and benefits investigations, as well as information regarding prior authorizations and alternative coverage options
- **Financial Support:** connects patients to appropriate financial assistance, including co-pay support, alternative funding information, and the Medication Assistance Program

*For eligible commercially insured patients only. See full terms and conditions at GileadAdvancingAccess.com/hcp/financial-assistance/copay-support.

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

References: 1. TRUVADA [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2018. **2.** 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 May 7, 2019.

GILEAD

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

Truvada®
emtricitabine 200 mg / tenofovir disoproxil fumarate 300 mg tablets
for PrEP pre-exposure prophylaxis