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

Sponsored by: GILEAD

You Are Invited to Attend...

Proactive HIV Prevention with TRUVADA for PrEP

In combination with safer sex practices to reduce the risk of sexually acquired HIV-1 in adults at high risk.

NOAH LEE, DO
Midland Medical Center

Thursday, May 10, 2018
6:00 PM EST (America/New_York)

Morton's The Steakhouse
777 South Flagler Drive
West Palm Beach, Florida
(561) 835-9664

Please ***RSVP*** *to* Ella Starikov at (650) 522-2473 or via e-mail at ella.starikov@gilead.com by«5/7/2018

IMPORTANT SAFETY INFORMATION

BOXED WARNING: RISK OF DRUG RESISTANCE WITH USE OF TRUVADA FOR PRE-EXPOSURE PROPHYLAXIS (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 initiating and periodically (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 TRUVADA for PrEP if signs or symptoms of acute HIV-1 infection are present unless negative infection status is confirmed.**

- **TRUVADA is not approved for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of TRUVADA have not been established in patients infected with HBV. Severe acute exacerbations of hepatitis B have been reported in patients coinfected with HBV and HIV-1 who have discontinued TRUVADA. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are infected with HBV and discontinue TRUVADA. If appropriate, initiation of anti-hepatitis B therapy may be warranted.**

To learn more about TRUVADA for PrEP, please see indication, prescribing considerations, and important safety information on the following pages and the accompanying full Prescribing Information, including **BOXED WARNING.**

Please be aware that if you are a licensed US physician, the meal associated with this program is reportable under the Federal Open Payments/Sunshine Act. Gilead policy and the PhRMA Code on Interactions with Healthcare Professionals limit attendance at this promotional educational program to healthcare professionals. Accordingly, attendance by guests is not appropriate and cannot be accommodated.

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INDICATION:

TRUVADA for PrEP (pre-exposure prophylaxis) is indicated in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 in adults at high risk.

- **Individuals at high risk for sexually acquired HIV-1 include:**
  - Individuals with HIV-1 infected partner(s).
  - Individuals who engage in sexual activity in a high prevalence area or social network **and** have one or more of the following: inconsistent or no condom use, diagnosis of sexually transmitted infections (STIs), exchange of sex for commodities (money, food, shelter, drugs), use of illicit drugs or alcohol dependence, incarceration, and/or sexual partners of unknown HIV status with any of the above risk factors.
- **Prescribing considerations:**
  - TRUVADA for PrEP must only be prescribed as part of a comprehensive prevention strategy because TRUVADA is not always effective in preventing the acquisition of HIV-1 infection.
  - Uninfected individuals must strictly adhere to their dosing schedule because the effectiveness of TRUVADA in reducing the risk of acquiring HIV-1 is strongly correlated with adherence.
  - HIV-1 negative status must be confirmed prior to initiating TRUVADA for PrEP and at least every 3 months thereafter.
    - If clinical symptoms of acute HIV-1 infection are present and recent exposures (<1 month) are suspected, delay initiating TRUVADA for PrEP for at least 1 month until negative HIV-1 status is reconfirmed.
    - Alternatively, negative HIV-1 status can be confirmed with a test approved by the FDA to aid diagnosis of acute or primary HIV-1 infection.

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CONTRAINDICATIONS:

- Do not use TRUVADA for PrEP in individuals with unknown or positive HIV status.

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 (DF). In all patients, assess estimated creatinine clearance (CrCl) prior to initiating and during therapy. In patients at risk for renal dysfunction, additionally monitor serum phosphorus, urine glucose, and urine protein. Avoid concurrent or recent use with a nephrotoxic agent. Cases of acute renal failure have been reported after initiation of high dose or multiple NSAIDs in patients at risk for renal dysfunction; consider alternatives to NSAIDs in these patients.
  - Do not use TRUVADA for PrEP in individuals with CrCl <60 mL/min. Reassess potential risks and benefits of using TRUVADA for PrEP if a decrease in CrCl is observed during use.
- **Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including TRUVADA. Discontinue TRUVADA for PrEP if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.
- **Use with other antiviral products:** Do not coadminister with products containing emtricitabine, tenofovir alafenamide, tenofovir DF, lamivudine, or adefovir dipivoxil
- **Bone effects:** Decreases in bone mineral density (BMD) and mineralization defects, including osteomalacia, have been seen in patients treated with tenofovir DF. In clinical trials conducted in pediatric subjects, the total body BMD gain was less in tenofovir DF treated subjects as compared to the control group. Consider monitoring BMD in patients with a history of pathologic fracture or risk factors for bone loss.

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IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS: RISK REDUCTION STRATEGIES:

- **Reduce exposure to HIV-1 infection:** TRUVADA for PrEP is not always effective in preventing the acquisition of HIV-1. Therefore, use only as part of a comprehensive prevention strategy that includes safer sex practices, regular testing for HIV-1 and other sexually transmitted infections, 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. 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.
  - Confirm HIV-negative status immediately prior to initiation.
  - Many HIV tests are antibody tests and may not detect acute HIV infection. Delay initiating (≥1 month) or discontinue TRUVADA for PrEP if current or recent symptoms of acute HIV infection are present (e.g., fever, fatigue, myalgia, skin rash) and recent exposures are suspected. Prior to initiating or continuing TRUVADA for PrEP, reconfirm HIV-negative status with a test approved by the FDA for the diagnosis of acute HIV infection.
- **Counsel on adherence:** Counsel individuals to strictly adhere to their dosing schedule. The effectiveness of TRUVADA for PrEP in reducing the risk of acquiring HIV-1 is strongly correlated with adherence.

ADVERSE REACTIONS:

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

DRUG INTERACTIONS:

- **Hepatitis C antivirals:** Coadministration with ledipasvir/sofosbuvir or velpatasvir/sofosbuvir increases tenofovir DF 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.

USE IN SPECIFIC POPULATIONS:

- **Pregnancy Category B:** There are no adequate and well-controlled trials in pregnant women. Use during pregnancy only if clearly needed. In uninfected women who become pregnant while taking TRUVADA for PrEP, careful consideration about continuing TRUVADA should be given, taking into account the potential increased risk of HIV-1 infection during pregnancy. An Antiretroviral Pregnancy Registry has been established; healthcare providers are encouraged to register patients by calling 1-800-258-4263.
- **Breastfeeding:** Emtricitabine and tenofovir have been detected in human milk. Mothers taking TRUVADA for PrEP should be instructed not to breastfeed because the potential for adverse reactions in nursing infants is not known and to avoid HIV-1 transmission to the infant if HIV-1 infection is acquired.
- **Pediatrics:** TRUVADA for PrEP is based on studies in adults.

DOSAGE AND ADMINISTRATION:

- **Adult dosage:** One tablet once daily with or without food.
- **Renal impairment:** Do not use in individuals with CrCl <60 mL/min.
- **Testing prior to initiation:** Test for HIV-1 and HBV infection.

For information about the TRUVADA for PrEP REMS program and access to REMS materials, please visit www.truvadaPrEPrems.com

Please see accompanying full Prescribing Information, including BOXED WARNING.

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