TRUVADA (emtricitabine/tenofovir disoproxil fumarate) is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk. This indication is based on clinical trials in men who have sex with men (MSM) at high risk for HIV-1 infection and in heterosexual serodiscordant couples.

**BOXED WARNING SPECIFIC FOR USING TRUVADA FOR A PrEP INDICATION:**

TRUVADA used for a PrEP indication must only be prescribed to individuals confirmed to be HIV-1 negative immediately prior to initiating and periodically (at least every 3 months) during use. Drug-resistant HIV-1 variants have been identified with the use of TRUVADA for a PrEP indication following undetected acute HIV-1 infection. Do not initiate TRUVADA for a PrEP indication if signs or symptoms of acute HIV infection are present unless negative infection status is confirmed.

1. **Risk of Development of Drug-Resistant HIV-1 Variants in Undiagnosed HIV-1–Infected Individuals**
   - HIV-1 variants with resistance have emerged in individuals taking TRUVADA for a PrEP indication with undetected acute HIV-1 infection
   - You must confirm a negative HIV-1 test immediately prior to initiating TRUVADA for a PrEP indication. If clinical signs or symptoms consistent with acute viral infection are present and recent (<1 month) exposures are suspected, delay starting PrEP for at least 1 month and reconfirm HIV-1 status or use a test approved by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection
   - Screen for HIV-1 infection at least once every 3 months while taking TRUVADA for PrEP. If symptoms consistent with acute HIV-1 infection develop following a potential exposure event, PrEP should be discontinued until negative infection status is confirmed using a test approved by the FDA as an aid in the diagnosis of HIV-1, including acute or primary HIV-1 infection
   - TRUVADA for a PrEP indication is contraindicated in individuals with unknown or HIV-1–positive status
   - Do not prescribe TRUVADA for a PrEP indication if signs or symptoms of acute HIV infection are present unless negative infection status is confirmed

- HIV-1–infected patients must take TRUVADA in combination with other antiretroviral agents to fully suppress virus replication and avoid the development of resistance

2. **Only use TRUVADA for a PrEP Indication as Part of a Comprehensive Prevention Strategy**
   - TRUVADA for a PrEP indication does not replace other HIV-1 prevention measures, including safer sex practices and correct and consistent condom use
   - Clinical trials included comprehensive prevention counseling, screening for and treatment of other sexually transmitted infections, and strong emphasis regarding consistent use of condoms and other safer sex practices

3. **The Importance of Strict Adherence to the Recommended Dosing Regimen**
   - The effectiveness of TRUVADA for a PrEP indication in reducing the risk of acquiring HIV-1 is strongly correlated with adherence and measurable drug levels
   - All uninfected individuals at high risk taking TRUVADA for a PrEP indication must be counseled to strictly adhere to the recommended daily dosing schedule to reduce the risk of acquiring HIV-1

For more information about TRUVADA and its indication for PrEP, please see the Full Prescribing Information and Medication Guide. For more information about the REMS program for TRUVADA for a PrEP indication, please log on to www.TRUVADApreamps.com. You may also obtain additional information and educational materials about the use of TRUVADA for a PrEP indication at 1-800-445-3235.