Safety Information Fact Sheet for Prescribers About Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg for HIV-1 Pre-exposure Prophylaxis (PrEP)

Emtricitabine/tenofovir disoproxil fumarate is indicated in combination with safer sex practices for HIV-1 pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and adolescents weighing at least 35 kg. Individuals must have a negative HIV-1 test immediately prior to initiating emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP.

**BOXED WARNING SPECIFIC FOR USING EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE FOR HIV-1 PrEP:**

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

**Key Safety Information to Communicate Regarding the Use of Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 PrEP:**

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 emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP with undetected acute HIV-1 infection
   - You must confirm a negative HIV-1 test immediately prior to initiating emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP. If clinical signs or symptoms consistent with acute viral infection are present and recent (<1 month) exposures are suspected, delay starting emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP for at least 1 month and reconfirm HIV-1 status or use a test approved or cleared 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 emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP. Some individuals, such as adolescents, may benefit from more frequent visits and counseling. If a screening test indicates possible infection, or symptoms consistent with acute HIV-1 infection develop following a potential exposure event, convert the HIV-1 PrEP regimen to an HIV treatment regimen until negative infection status is confirmed using a test approved by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection

   - Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP is contraindicated in individuals with unknown or HIV-1 positive status

   - Do not prescribe emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP if signs or symptoms of acute HIV infection are present unless negative infection status is confirmed

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

2. **Only Use Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 PrEP as Part of a Comprehensive Prevention Strategy**
   - Emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP does not replace other HIV-1 infection 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 emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP in reducing the risk of acquiring HIV-1 infection is strongly correlated with adherence, as demonstrated by measurable drug levels in clinical trials
   - All uninfected at-risk individuals taking emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP must be counseled to strictly adhere to the recommended daily dosing schedule to reduce the risk of acquiring HIV-1 infection
   - Some individuals, such as adolescents, may benefit from more frequent visits and counseling

For more information about emtricitabine/tenofovir disoproxil fumarate and its indication for HIV-1 PrEP, please see the Prescribing Information, including the BOXED WARNING, and the Medication Guide. For more information about the REMS program for emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP, please log on to www.ftc-tdf-preprems.com. You may also obtain additional information and educational materials about the use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP at 1-800-625-7471.

Reference ID: 4262803