

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.