Truvada® (emtricitabine/tenofovir disoproxil fumarate) – First-time Generic

- On June 8, 2017, the FDA approved Teva's AB-rated generic to Gilead's Truvada (emtricitabine/tenofovir disoproxil fumarate) 200 mg/300 mg oral tablet, in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients weighing at least 17 kg, and 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.

- When initiating therapy with emtricitabine/tenofovir disoproxil fumarate for the treatment of HIV-1 infection:

  - It is not recommended for use as a component of a triple nucleoside regimen.
  - It should not be coadministered with Atripla®, Complera®, Descovy®, Emtriva®, Genvoya®, Odefsey®, Stribild®, Vemlidy®, Viread®, or lamivudine-containing products.
  - In treatment experienced patients, the use of emtricitabine/tenofovir disoproxil fumarate should be guided by laboratory testing and treatment history.

- When prescribing emtricitabine/tenofovir disoproxil fumarate for PrEP, healthcare providers must:

  - Prescribe as part of a comprehensive prevention strategy because emtricitabine/tenofovir disoproxil fumarate is not always effective in preventing the acquisition of HIV-1 infection.
  - Counsel all uninfected individuals to strictly adhere to the recommended emtricitabine/tenofovir disoproxil fumarate dosing.
  - Schedule because the effectiveness of emtricitabine/tenofovir disoproxil fumarate in reducing the risk of acquiring HIV-1 was strongly correlated with adherence as demonstrated by measurable drug levels in clinical trials
  - Confirm a negative HIV-1 test immediately prior to initiating emtricitabine/tenofovir disoproxil fumarate for a PrEP indication. If clinical symptoms consistent with acute viral infection are present and recent (< 1 month) exposures are suspected, delay starting PrEP for at least one 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 emtricitabine/tenofovir disoproxil fumarate for PrEP.

- Emtricitabine/tenofovir disoproxil fumarate carries a boxed warning regarding the risk of post-treatment acute exacerbation of hepatitis B and risk of drug resistance with use of emtricitabine/tenofovir disoproxil fumarate for PrEP in undiagnosed early HIV-1 infection.