

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

- On June 8, 2017, the <u>FDA approved</u> Teva's AB-rated generic to Gilead's <u>Truvada</u>
 (<u>emtricitabine/tenofovir disoproxil fumarate</u>) 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 <u>Atripla</u>[®], <u>Complera</u>[®], <u>Descovy</u>[®], <u>Emtriva</u>[®], <u>Genvoya</u>[®], <u>Odefsey</u>[®], <u>Stribild</u>[®], <u>Vemlidy</u>[®], <u>Viread</u>[®], 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.</p>
 - 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 posttreatment 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.



optumrx.com

 $OptumRx^{@}\ specializes\ in\ the\ delivery,\ clinical\ management\ and\ affordability\ of\ prescription\ medications\ and\ consumer\ health\ products.$ We are an $Optum^{@}\ company\ --$ a leading provider of integrated health services. Learn more at optum.com.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.