U.S. FOOD & DRUG ADMINISTRATION

# TRUVADA: Important Updates to the REMS


July 1, 2019

The FDA announced the elimination of the REMS for Truvada and its four approved generics. With the removal of the REMS for emtricitabine/tenofovir disoproxil fumarate for PrEP, drug manufacturers are no longer required to provide educational materials; however, the approved labeling and Medication Guide explaining the risks and benefits of the product will continue to convey the important safety information and be widely available. Prescribers should continue to follow the labeled directions for the initiation and proper use of Truvada for the PrEP indication to minimize the risk of developing resistant HIV-1 variants when HIV-1 infection is present. The FDA continues to encourage at-risk individuals to have an ongoing dialogue with their health care professional about the benefits and risks of PrEP and other HIV prevention strategies when taking PrEP. Additionally, health care providers and at-risk individuals should access educational materials and treatment guidelines readily available from sources like the U.S. Centers for Disease Control and Prevention as well as local health departments.

https://www.fda.gov/news-events/fda-brief/fda-brief-fda-continues-encourage-ongoing-education-about-benefits-and-risks-associated-prep

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