

**FDA REQUIRED REMS
(Risk Evaluation
Mitigation Strategy)
SAFETY INFORMATION**

May 2018

UPDATE TO FDA-REQUIRED REMS SAFETY INFORMATION

Subject: New Information on FDA-Required Risk Evaluation Mitigation Strategy (REMS)

- Indication expanded to adolescents for emtricitabine/tenofovir disoproxil fumarate 200 mg/300 mg for HIV-1 pre-exposure prophylaxis (PrEP)
- Considerations for treating adolescents
- New adolescent brochure available at REMS website

Dear Healthcare Provider:

Emtricitabine/Tenofovir Disoproxil Fumarate REMS Sponsors would like to inform you of the recent update to add adolescents weighing at least 35 kg to the use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 infection.

Considerations for prescribing to adolescents:

- Ability of the individual to understand the importance of adherence to daily dosing
- The need for frequent HIV testing
- The need for frequent sexually transmitted infection testing
- The continued risk of pregnancy
- More frequent visits and counseling

In a clinical study in adolescents, the percentage of subjects with protective levels of drug declined markedly after subjects switched from monthly to quarterly visits. **This suggests that adolescents may benefit from more frequent visits and counseling.**

We would also like to remind you of the following important information from the REMS.

- Confirmation of a negative HIV-1 status immediately before prescribing
- Strict adherence to the recommended dosing regimen
- Regular monitoring of HIV-1 serostatus to avoid continuing to take emtricitabine/tenofovir disoproxil fumarate if seroconversion has occurred, to reduce the risk of development of resistant HIV-1 variants
- Other preventive measures should be used to reduce the risk of HIV-1 infection

Enclosed is the *Safety Information Factsheet for Prescribers* that provides more comprehensive information on the REMS program.

Visit the **REMS Website (www.ftc-tdf-preprems.com)** for training materials and educational materials for your patients, including a **new adolescent brochure**.

This letter is not intended as a comprehensive description of the risks associated with the use of emtricitabine/tenofovir disoproxil fumarate for HIV-1 PrEP. Please read the enclosed Prescribing Information, including the BOXED WARNING for more information.

Sincerely,

Emtricitabine/Tenofovir Disoproxil Fumarate REMS Team