UPDATE TO FDA-REQUIRED REMS SAFETY INFORMATION

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 <Name>:

The FDA has required this REMS update to the [Professional Organization]. We request that you distribute this information to your members about an expanded indication for emtricitabine/tenofovir disoproxil fumarate 200 mg/300 mg for HIV-1 PrEP to adolescents weighing at least 35 kg 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.

A new adolescent brochure is available for healthcare providers to provide to patients at the REMS website www.ftc-tdf-preprems.com. 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

The enclosed Safety Information Factsheet for Prescribers provides further information on the REMS program. Additional training materials for healthcare providers, along with educational materials for patients are available at the REMS Website www.ftc-tdf-preprems.com.

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

Reference ID: 4262803
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