From: Emtricitabine/Tenofovir Disoproxil Fumarate REMS Team
To: <Healthcare Provider Name>

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

View in Browser | Full Prescribing Information

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 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

Reference ID: 4262803
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

REMS-SSS-0027 05/18