# Truvada for PrEP Fact Sheet: Ensuring Safe and Proper Use

On July 16, 2012, the U.S. Food and Drug Administration approved Truvada (emtricitabine/tenofovir disoproxil fumarate) for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually acquired HIV-infection in adults at high risk. FDA has asked the manufacturer to put in place a variety of elements to ensure Truvada for PrEP is used safely and appropriately.

## What is Truvada?

A tablet taken orally once daily with or without food, Truvada is a drug used with other antiviral medicines to treat HIV infection in adults and children 12 years of age and older. It is a combination of two drugs, emtricitabine and tenofovir disoproxil fumarate, and is used to block the action of a protein that HIV needs to replicate in a person's body.

## What is PrEP?

PrEP is short for Pre-Exposure Prophylaxis and may be part of a comprehensive HIV prevention strategy that includes safer sex practices, such as consistent and correct condom use, regular HIV testing and risk reduction counseling. As part of PrEP, HIV-uninfected individuals who are at high risk of sexually acquired HIV infection take antiretroviral medication daily to try to lower their chances of becoming infected with HIV if they are exposed to the virus.

## What is a Risk Evaluation and Mitigation Strategy (REMS)?

A REMS is a risk management plan that FDA can require a drug company to develop and implement to manage serious risks associated with use of a drug. Under the Food and Drug Administration Amendments Act of 2007, FDA has the authority to require a manufacturer to develop a REMS when the agency finds a REMS is necessary to ensure that the benefits of a drug outweigh its risks.

A REMS goes beyond a drug's written prescribing information and can include a Medication Guide, communication plan, and other elements to ensure safe use of a drug. A REMS is required to mitigate a serious risk listed in the product label. Elements to ensure safe use must:

- be appropriate for the specific, serious risk(s) listed in the labeling;
- when possible, conform with REMS elements for other drugs with similar serious risks;
- when possible, be designed for compatibility with established drug distribution, procurement and dispensing systems; and
- cannot make it excessively difficult for patients to access the drug.

Every REMS is developed to address the unique risk-benefit profile of a specific drug or drug class.

## REMS for Truvada for the PrEP Indication

The central component of the REMS for Truvada for PrEP is a training and education program directed to prescribers and other health care professionals to help them educate uninfected individuals considering or taking Truvada for PrEP. This training and education program is not mandatory in order for prescribers to prescribe Truvada for the PrEP indication. The REMS for Truvada for PrEP includes:

- A Medication Guide to support the education of uninfected individuals taking Truvada for PrEP about the serious risk

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of becoming infected with HIV and the development of drug-resistant variants if they continue taking Truvada after becoming infected with HIV.

- Prescriber training and education targets likely prescribers of Truvada for PrEP. This program includes:
  - A training guide for health care professionals that emphasizes the importance of screening patients for sexually transmitted infections (STIs), the need for uninfected individuals to have a negative HIV-1 test result before taking Truvada for PrEP, the importance of patients strictly adhering to the recommended dosing regimen, and the use of Truvada for PrEP as part of a comprehensive prevention strategy that includes safe sex practices and regular HIV testing.
  - A safety brochure for prescribers outlining key serious risk information about Truvada for the PrEP indication, the importance of comprehensive management with regular monitoring of uninfected individuals' HIV-infection status and the importance of uninfected individuals adhering to the recommended dosing regimen.
  - A safety brochure for uninfected individuals outlining key serious risk information about Truvada for PrEP, recommended screening tests before starting Truvada for PrEP, the importance of regular testing for HIV status while taking Truvada for PrEP and key information to tell one's health care provider.
  - An education slide deck for face-to-face meetings between the drug maker and prescribers.
  - A checklist for prescribers indicating they have taken the necessary steps to ensure the drug will be used appropriately, to be placed in the uninfected individual's medical record.
  - An Agreement Form for Initiating Truvada for PrEP to be signed by both the prescriber and uninfected individual and placed in the individual's medical record.
- Assessment of the REMS annually to determine if the REMS is effective in informing and educating prescribers, health care professionals, and uninfected individuals about the risks of Truvada for a PrEP indication. If the FDA determines the REMS is not meeting its goals, the agency will re-evaluate the program and take appropriate action to ensure safe use of the drug.

## Additional actions to ensure safe use

FDA is also strengthening the language on Truvada's product label for the PrEP indication to ensure uninfected individuals and prescribers are fully aware of the risks and benefits of taking Truvada for PrEP.

This includes:

- Additional language to the BOXED WARNING alerting individuals and prescribers that a negative HIV test must be confirmed before prescribing the drug and at least every 3 months during use for PrEP.
- Detailed information in the INDICATIONS AND USAGE section outlining factors that may be considered to place uninfected individuals at high risk for becoming HIV infected.
- A new CONTRAINDICATION for use as PrEP in HIV-infected individuals or individuals with unknown HIV status.
- Added language to the WARNINGS AND PRECAUTIONS section describing how Truvada for PrEP should be used as part of a comprehensive management strategy, and the importance of strict adherence to the dosing regimen.

Furthermore, as a condition of approval, FDA is requiring Truvada's manufacturer to collect certain post-marketing data to help evaluate the drug's use for a PrEP indication in real-world practice.

*Created: July 2012*