

Prescriber Individual Agreement Form for Initiating PrTEVA-EMTRICITABINE/TENOFOVIR for Pre-exposure Prophylaxis (PrEP) in Adults at High Risk of HIV-1 Infection

This material was developed by Teva Canada Limited, as part of the risk minimization plan for Teva-Emtricitabine/Tenofovir. This material is not intended for promotional use.

Instructions:

Review form with an HIV-negative individual who is about to start or is taking TEVA-EMTRICITABINE/TENOFOVIR for a PrEP indication at each visit. File form in the individual's medical record.

TEVA-EMTRICITABINE/TENOFOVIR is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk.

When considering TEVA-EMTRICITABINE/TENOFOVIR for PrEP, the following factors may help to identify individuals at high risk:

- Has partner(s) known to be HIV-1 infected, or
- Engages in sexual activity within a high prevalence area or social network and one or more of the following:
 - Inconsistent or no condom use
 - Use of illicit drugs or alcohol dependence
 - Diagnosis of sexually transmitted infections
 - Incarceration
 - Exchange of sex for commodities (such as money, shelter, food, or drugs)
 - Partner(s) of unknown HIV-1 status with any of the factors listed above



Healthcare Provider Agreement

By signing below, I signify my understanding of the risks and benefits of TEVA-EMTRICITABINE/TENOFOVIR for a PrEP indication and my obligation as a prescriber to educate the HIV-negative person about these risks, counsel the person on risk reduction, monitor the person appropriately, and report adverse events. Specifically, I attest to having done the following:

- Confirmed the negative HIV-1 status of this person prior to starting TEVA-EMTRICITABINE/TENOFOVIR for a PrEP indication
- Read the Product Monograph, including BOXED WARNINGS
- Discussed with the HIV-negative person the known safety risks with use of TEVA-EMTRICITABINE/TENOFOVIR for a PrEP indication
- Reviewed the importance of adherence with a comprehensive prevention strategy, including practicing safer sex
- Discussed the importance of regular HIV-1 testing (at least every 3 months) while taking TEVA-EMTRICITABINE/TENOFOVIR for a PrEP indication
- Reviewed the TEVA-EMTRICITABINE/TENOFOVIR **Risk minimization tool for individuals before HIV-1 exposure and are at risk of infection – Important safety information** with the HIV-negative person at high risk prior to prescribing TEVA-EMTRICITABINE/TENOFOVIR for a PrEP indication
- Completed the items on the **Checklist for Prescribers: Initiation of TEVA-EMTRICITABINE/TENOFOVIR for Pre-Exposure Prophylaxis (PrEP)**



HIV-Negative Person Agreement

By signing below, I acknowledge that I have talked with my healthcare provider about the risks and benefits of TEVA-EMTRICITABINE/TENOFOVIR to reduce the risk of getting HIV-1 infection, and I understand them clearly.

- My healthcare provider talked with me about the importance of follow-up HIV-1 testing, and I agree to have repeat HIV-1 screening tests (at least every 3 months) as scheduled by my healthcare provider
- My healthcare provider talked with me about the safety risks involved with using TEVA-EMTRICITABINE/TENOFOVIR to reduce the risk of getting HIV-1 infection
- My healthcare provider talked with me about a complete prevention strategy and always practicing safer sex by using condoms correctly
- I will talk with my healthcare provider if I have any questions
- I have read the TEVA-EMTRICITABINE/TENOFOVIR **Risk minimization tool for individuals before HIV-1 exposure and are at risk of infection – Important safety information**

Please consult the Consumer Information section of the Product Monograph for information on warnings, precautions and side effects.

Healthcare Provider's Signature

Date

HIV-Negative Person's Signature

Date

TEVA-EMTRICITABINE/TENOFOVIR is indicated in combination with safer sex practices for PrEP to reduce the risk of sexually acquired HIV-1 infection in adults at high risk.

Consult the product monograph https://www.tevacanada.com/globalassets/canada-ph2/product-monographs/emtricitabine-tenofovir-tabs-200mg-300mg-teva-pm-apr11_2019-full-indication-wis-eng.pdf for contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The product monograph is also available by calling Teva Canada at 1-855-223-6838.

Reference: 1. TEVA-EMTRICITABINE/TENOFOVIR Product Monograph. Teva Canada Limited. April 11, 2019.



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