CATIE-News

CATIE’s bite-sized HIV and hepatitis C news bulletins.

Generic tenofovir + FTC coming to Canada

27 July 2017

There is a pill called Truvada that contains the two following medicines:

- tenofovir DF (disoproxil fumarate)
- FTC (emtricitabine)

For many years Truvada has been an important part of many combinations used in the treatment of HIV infection. However, that changed several years ago when clinical trials found that Truvada has an additional benefit. The use of daily oral Truvada significantly reduces the risk of HIV transmission for HIV-negative people when it is provided along with a comprehensive prevention package that includes regular testing and treatment of sexually transmitted infections, and ongoing adherence and risk-reduction counselling. This is called pre-exposure prophylaxis (PrEP).

Health Canada based its approval of Truvada to prevent HIV infection on data from clinical trials in men who have sex with men as well as in heterosexual couples where one partner was HIV positive. In these studies, Truvada was taken once daily every day and was highly effective in reducing the risk of HIV infection.

A drawback for many people who wish to use Truvada as part of lowering their risk for HIV infection is the price. This medicine costs about $CAN 1,000 monthly per person.

Enter the generics

Earlier this year, Health Canada approved the use and sale of generic fixed-dose formulations of tenofovir DF + FTC. This approval was based on data provided by generic companies showing two important things:

- that their versions of the drugs were absorbed as well as the branded version
- that levels of the generic drugs in the blood were within the range that is seen with the branded version

Showing that generic drugs have both similar absorption and blood concentrations to brand name drugs is called bio-equivalence. This is often the standard procedure for licensure of generic drugs in many therapeutic areas in Canada and other high-income countries.

In a study of 293 people in London, England, who purchased a generic combination of tenofovir DF + FTC, researchers found that most had levels of the drugs in their blood that were “similar to or slightly higher than” levels that were seen in a study of Truvada. No serious side effects occurred and no one developed HIV or hepatitis B virus infection.

Cost and access issues

In general, generic medicines are cheaper than the same medicines produced by brand name companies. In the case of the generic pill containing tenofovir DF + FTC, the wholesale price is expected to be around $400 monthly per patient (pharmacies will charge somewhat more). Although at least two generic companies will be offering a pill containing tenofovir DF + FTC, only such pills made by the generic company Teva are approved for use as HIV prevention and treatment.

This expected price will still be high for many people in need of PrEP. Ideally, Canada’s provinces and territories can begin the process of securing the generic formulation of tenofovir DF + FTC at greatly reduced prices and adding it
to the list of subsidized medicines that they offer for both HIV treatment and prevention.

As more companies enter the market and sell generic tenofovir DF + FTC, the price is expected to fall further.

The generic pill containing tenofovir DF + FTC will be available for pharmacies to order from wholesalers as of July 26.

Quebec already subsidizes Truvada for prevention and treatment. A major financial reason for subsidizing a pill containing generic tenofovir DF + FTC for prevention is that at least two studies in Canada have shown that the cost of preventing HIV is far cheaper than treating it.

As for the formal listing of a pill containing generic tenofovir + FTC for the prevention of HIV infection on provincial formularies, this is something that will take time and for which local advocacy is needed.

**CATIE resources**

- CATIE statement on the use of oral pre-exposure prophylaxis (PrEP) as a highly effective strategy to prevent the sexual transmission of HIV
- Pre-exposure prophylaxis (PrEP) resources
- Oral pre-exposure prophylaxis (PrEP) – fact sheet
- Toronto-led team explores different PrEP deployment scenarios – CATIE News

**REFERENCES:**


—Sean R. Hosein
Disclaimer

Decisions about particular medical treatments should always be made in consultation with a qualified medical practitioner knowledgeable about HIV- and hepatitis C-related illness and the treatments in question.

CATIE provides information resources to help people living with HIV and/or hepatitis C who wish to manage their own health care in partnership with their care providers. Information accessed through or published or provided by CATIE, however, is not to be considered medical advice. We do not recommend or advocate particular treatments and we urge users to consult as broad a range of sources as possible. We strongly urge users to consult with a qualified medical practitioner prior to undertaking any decision, use or action of a medical nature.

CATIE endeavours to provide the most up-to-date and accurate information at the time of publication. However, information changes and users are encouraged to ensure they have the most current information. Users relying solely on this information do so entirely at their own risk. Neither CATIE nor any of its partners or funders, nor any of their employees, directors, officers or volunteers may be held liable for damages of any kind that may result from the use or misuse of any such information. Any opinions expressed herein or in any article or publication accessed or published or provided by CATIE may not reflect the policies or opinions of CATIE or any partners or funders.

Information on safer drug use is presented as a public health service to help people make healthier choices to reduce the spread of HIV, viral hepatitis and other infections. It is not intended to encourage or promote the use or possession of illegal drugs.

Permission to Reproduce

This document is copyrighted. It may be reprinted and distributed in its entirety for non-commercial purposes without prior permission, but permission must be obtained to edit its content. The following credit must appear on any reprint: This information was provided by CATIE (the Canadian AIDS Treatment Information Exchange). For more information, contact CATIE at 1.800.263.1638.

© CATIE

Production of this content has been made possible through a financial contribution from the Public Health Agency of Canada.

Available online at: