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Generic tenofovir + FTC coming to Canada

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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

—Sean R. Hosein

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