CATIE Canada's source for HIV and hepatitis C information
La source canadienne de renseignements sur le VIH et l'hépatite C

CATIE-News

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

Symtuza approved in Canada for treatment of HIV

4 April 2018

- **Health Canada approves Symtuza, a new treatment option containing the drug darunavir.**
- **The new formulation offers darunavir in a once-daily treatment regimen.**
- **Symtuza has been shown to be generally safe and effective in clinical trials.**

In March 2018, Health Canada approved the use and sale of a fixed-dose combination of four HIV medicines sold under the brand name Symtuza. Manufactured by the pharmaceutical company Janssen, Symtuza should be available for ordering by wholesalers and pharmacies in mid-May.

Each tablet of Symtuza contains the following medications:

- darunavir – 800 mg
- cobicistat – 150 mg
- FTC (emtricitabine) – 200 mg
- TAF (tenofovir alafenamide) – 10 mg

The anti-HIV activity in Symtuza is provided by darunavir, a powerful protease inhibitor, together with the nucleoside analogues FTC + TAF. The purpose of cobicistat is to raise and maintain levels of darunavir in the blood so that once-daily dosing is possible. Cobicistat does not have anti-HIV activity.

Darunavir was approved in Canada in 2006 and sold under the brand name Prezista. It became a widely used part of many regimens. Darunavir has a good track record of general safety and effectiveness as part of combination HIV therapy. In 2014, Janssen received approval for the use and sale of Prezcobix: a fixed-dose combination of darunavir + cobicistat in one pill. Symtuza is another step forward in convenience, as it contains a complete regimen in one pill.

Symtuza will be available as yellow-brown film-coated tablets. Symtuza is taken once daily with food (the type of food does not matter).

Symtuza is approved for use in the following populations:

- HIV-positive adults
- adolescents aged 12 and older who weigh at least 40 kg (about 88 pounds)
- people with HIV that is not resistant to darunavir, TAF or FTC

Effectiveness and safety

Researchers recruited treatment-experienced participants who were taking a protease inhibitor–based regimen and whose viral loads were generally less than 50 copies/mL for a study called Emerald. Participants were not co-infected with hepatitis B virus and/or hepatitis C virus. Once in Emerald, participants were randomly assigned in a 2:1 ratio to receive Symtuza or to continue on their existing regimen.

After 48 weeks, 95% of participants on Symtuza and 94% of participants who continued on their existing regimen had an undetectable viral load. This shows that the two regimens have similar effectiveness. As participants were virologically suppressed and had on average about 630 CD4+ cells/mm^3 prior to entering Emerald, subsequent

increases in CD4+ counts were minimal, between 18 cells/mm^3 in Symtuza users and 4 cells/mm^3 in people who continued using their pre-study regimen. This difference was not statistically different.

As participants were treatment experienced and generally healthy with relatively high CD4+ cells when they entered Emerald, both Symtuza and their existing regimens were well tolerated. About 2% of Symtuza users developed diarrhea related to the study medication vs. 1% of people who used other protease inhibitor–based regimens. Levels of highly elevated "bad" cholesterol (LDL-C) in the blood occurred in 7% of Symtuza users and in 2% of people who used other protease inhibitor–based regimens. Also, highly elevated levels of total cholesterol in the blood occurred in 4% of Symtuza users vs. 2% of participants on other regimens.

Special populations

- Pregnant women: There are no data about the safety of Symtuza in pregnant women. Therefore, Janssen warns doctors that "Symtuza should not be used during pregnancy unless the potential benefit justifies the risk."
- Hepatitis B and/or hepatitis C co-infection and liver injury: Symtuza has not been specifically tested in people with these viruses. Also, it has not been tested in people with severe liver injury.

The Symtuza product monograph contains further details on other populations, precautions and warnings.

Access

After Health Canada licenses a drug, physicians can prescribe it but initially patients must pay for it themselves unless they have a private insurance plan that covers it. It may take months for such coverage to take effect after licensure.

If left untreated, HIV infection leads to catastrophic disease that can affect one's ability to work. HIV treatment is also expensive. Therefore, in Canada, provincial and territorial ministries of health heavily subsidize the cost of anti-HIV medications. Each ministry has a listing of drugs for which it is prepared to pay. These listings are called formularies.

In the months ahead, Janssen and provincial and territorial formularies will be negotiating the price of Symtuza. Check with a pharmacist to find out when Symtuza is listed on your region's formulary.

A CATIE factsheet on Symtuza is under development.

—Sean R. Hosein

REFERENCES:

1. Janssen. Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide). *Product monograph* . 7 March 2018. Available from : http://www.janssen.com/canada/sites/www_janssen_com_canada/files/prod_files/live/symtuza_cpm.pdf
2. Orkin C, Molina JM, Negredo E, et al. Efficacy and safety of switching from boosted protease inhibitors plus emtricitabine and tenofovir disoproxil fumarate regimens to single-tablet darunavir, cobicistat, emtricitabine and tenofovir alafenamide at 48 weeks in adults with virologically suppressed HIV-1 (EMERALD): a phase 3, randomised, non-inferiority trial. *Lancet HIV* . 2018 Jan;5(1):e23-e34.
3. Cevik M, Orkin C. Fixed-dose darunavir boosted with cobicistat combined with emtricitabine and tenofovir alafenamide fumarate. *Current Opinion in HIV/AIDS* . 2018; *in press* .
4. Health Canada. Darunavir/TMC 114. *Notice of Compliance* . 28 July 2006.
5. Janssen. Prezcobix now available for Canadians living with HIV. *Press release* . 17 September 2014.

Produced By:

555 Richmond Street West, Suite 505, Box 1104
Toronto, Ontario M5V 3B1 Canada
Phone: 416.203.7122
Toll-free: 1.800.263.1638
Fax: 416.203.8284
www.catie.ca
Charitable registration number: 13225 8740 RR

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

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

Available online at:
http://www.catie.ca/en/catienews/2018-04-04/symtuza-approved-canada-treatment-hiv