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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/mm³ prior to entering Emerald, subsequent

increases in CD4+ counts were minimal, between 18 cells/mm³ in Symtuza users and 4 cells/mm³ 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. Prezcofix now available for Canadians living with HIV. *Press release* . 17 September 2014.

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