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CATIE-News

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

Juluca approved in Canada for HIV treatment

29 May 2018

- **New anti-HIV medication combines dolutegravir and rilpivirine into a once-daily pill.**
- **Juluca is recommended for adults with a stable HIV viral load less than 50 copies per mL.**
- **Clinical trials showed 95% viral suppression with few side effects.**

In May 2018, Health Canada approved the use and sale of a fixed-dose combination of two medicines—dolutegravir + rilpivirine—sold under the brand name Juluca as maintenance therapy for HIV.

Manufactured by the pharmaceutical company Viiv Healthcare, Juluca should become available for ordering by wholesalers and pharmacies by mid-June 2018.

Juluca is meant to be used as a replacement for the current HIV regimen in the following patients:

- adults whose viral load has been stable and less than 50 copies/mL

Juluca is supplied as pink tablets and Viiv recommends that adults take one table once daily with a meal.

The drugs in Juluca have been available separately for several years in Canada and other high-income countries: rilpivirine was approved in Canada in 2011 and dolutegravir in 2013. However, putting both dolutegravir and rilpivirine into one pill offers the possibility of convenience.

Effectiveness

In pivotal clinical trials, Juluca has been tested in more than 1,000 HIV-positive volunteers whose viral loads were stable and less than 50 copies/mL on a different regimen of at least three anti-HIV drugs. Participants were randomly assigned to either continue taking their current regimen or switch their treatment to Juluca. After 48 weeks, 95% of participants who continued with their current regimen and 95% of participants who took Juluca maintained a suppressed viral load (less than 50 copies/mL). This study is ongoing and further information will be available in the future.

Safety

Overall, Juluca was well tolerated in clinical trials, with slightly more participants reporting headache and diarrhea compared to those continuing their current regimen. These side effects were generally of mild-to-moderate intensity.

Juluca contains dolutegravir and rilpivirine; both of these drugs can penetrate the brain. On the one hand, this is good because HIV-infected cells can travel to and reside in the brain, producing proteins that can impair this vital organ. On the other hand, penetration of the brain by these two drugs carries the two possibilities of suppressing the activity of HIV-infected cells in the brain and producing side effects that affect this organ. About one percent of participants left clinical trials of Juluca prematurely because of what the researchers called bothersome “neuropsychiatric” side effects, such as anxiety, sleeping problems, and depression. These side effects occurred often in people who had a history of such problems.

Special populations:

- Pregnant women: Viiv states that “Juluca has not been studied in pregnant women.” Additionally, in May 2018,

regulatory agencies in high-income countries and the World Health Organization (WHO) issued cautionary statements about the use of dolutegravir in pregnancy. Specifically, preliminary information from an ongoing clinical trial suggests that in women who took dolutegravir when they became pregnant, the drug was associated with an increased risk of a neural tube defect, which is a type of birth defect. Since Juluca contains dolutegravir, this information about the potential of birth defects is relevant.

- Older people: ViiV states that clinical trials of Juluca “did not include sufficient numbers of [participants] aged 65 and older to determine whether they respond differently from adult patients less than 65 years of age.”

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. Usually it takes between three and six months for such coverage to take effect.

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, ViiV and provincial and territorial ministries of health will be negotiating the price of Juluca. Check with a pharmacist to find out when Juluca is listed on your region’s formulary.

A CATIE factsheet on Juluca is under development.

Resources

[Agencies issue caution about use of dolutegravir by pregnant HIV-positive women](#) – *CATIE News*

[Dolutegravir + rilpivirine as maintenance therapy](#) – *TreatmentUpdate 224*

[The re-emergence of dual therapy](#) – *TreatmentUpdate 224*

—Sean R. Hosein

REFERENCES:

1. ViiV Healthcare. Juluca—dolutegravir and rilpivirine tablets. *Product Monograph* . 18 May, 2018.
2. Llibre JM, Hung CC, Brinson C, et al. Efficacy, safety, and tolerability of dolutegravir-rilpivirine for the maintenance of virological suppression in adults with HIV-1: phase 3, randomised, non-inferiority SWORD-1 and SWORD-2 studies. *Lancet*. 2018 Mar 3;391(10123):839-849.
3. Darcis G, Moutschen M. The effect of treatment simplification on HIV reservoirs. *Lancet HIV* . 2017 Aug;4(8):e328-e329.
4. Boswell R, Foisy MM, Hughes CA. Dolutegravir dual therapy as maintenance treatment in HIV-infected patients: A review. *Annals of Pharmacotherapy* . 2018; *in press* .
5. McComsey GA, Lupo S, Parks D, et al. Switch from tenofovir disoproxil fumarate combination to dolutegravir with rilpivirine improves parameters of bone health. *AIDS*. 2018 Feb 20;32(4):477-485.
6. Huang SH, Ren Y, Thomas AS, et al. Latent HIV reservoirs exhibit inherent resistance to elimination by CD8+ T cells. *Journal of Clinical Investigation* . 2018 Feb 1;128(2):876-889.
7. Barat C, Proust A, Deshiere A, et al. Astrocytes sustain long-term productive HIV-1 infection without establishment of reactivable viral latency. *Glia*. 2018; *in press* .
8. European Medicine Agency. New study suggests risk of birth defects in babies born to women on HIV medicine dolutegravir. *Press release* . 18 May, 2018.
9. World Health Organization. Potential safety issue related with dolutegravir in pregnant women with HIV. *Statement* . 18 May, 2018.
10. Food and Drug Administration. FDA to evaluate potential risk of neural tube birth defects with HIV medicine dolutegravir (in Juluca, Tivicay and Triumeq). *Drug Safety Communication* . 18 May, 2018.

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