DRUG REVIEW

September, 2022



Rukobia® - A Novel First-in-Class HIV-1 Treatment

Human Immunodeficiency Virus (HIV) targets the body's immune system by attacking white blood cells that fight infections. It can affect every part of the body as it slowly weakens a person's natural defenses against infection and disease. As of 2021, it is estimated that over 64,000 Canadians are living with HIV Type 1 (HIV-1) infection, including those with the most severe form known as Acquired Immunodeficiency Syndrome (AIDS).

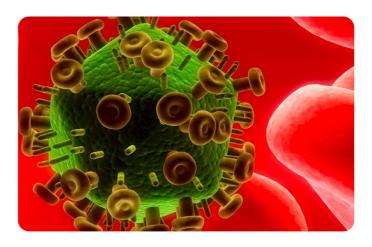
The goal of HIV treatment is to reduce a person's viral load to an undetectable level. Although there is no cure, antiretroviral therapies (ART) are the mainstay of treatment and have the potential to suppress active HIV infection, becoming a chronic, manageable disease.

Approximately 1% of patients with HIV in Canada are considered heavily treatment experienced (HTE) with multi-drug resistance (MDR) infection such that many drug classes are no longer effective at managing their condition. With no new antiretroviral classes introduced in the past decade and few options remaining, these individuals are at a higher risk of developing AIDS as well as potentially fatal infections and complications.

Rukobia® is the first and only attachment inhibitor that functions to prevent the virus from entering and infecting human cells. It is used in combination with other antiretrovirals in adults with MDR HIV-1 infection who have failed prior therapies due to resistance, intolerance, or safety considerations.

Clinical studies have demonstrated that Rukobia® is a safe and effective drug that allows the immune system to recover and regain the capacity to fight off infection. Importantly, Rukobia® offers another treatment option for patients with MDR HIV-1 due to its unique mechanism of action.

The annual cost of Rukobia® is \$45,200, which is more costly compared to other currently available ART. However, given that Rukobia® is an important lifesustaining alternative for a vulnerable subset of difficult-to-treat patients living with HIV, it is recommended that Rukobia® be placed under Special Authorization for ClaimSecure's managed formularies.



Drug Name	Rukobia®
Drug Ingredients	Fostemsavir
Annual Cost	\$45,200
Coverage Details	Special Authorization for Managed Formularies

ClaimSecure Inc. reserves the right to amend in part, or in its entirety, its Special Authorization guidelines.

References:

- 1. World Health Organization. Health topics: HIV/AIDS 2017.
- 2. Rukobia Product Monograph. ViiV Healthcare ULC. October 2021.

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