

ISENTRESS® (raltegravir) Fact Sheet

About ISENTRESS®

- ISENTRESS® is a medicine that helps control human immunodeficiency virus infection (HIV-1), in combination with other antiretroviral medications.
- ISENTRESS® has been shown to be effective at both reducing the amount of HIV in the blood (viral load) to undetectable levels and raising the number of white blood cells (CD4 cells) in patients starting HIV-1 therapy for the first time and in patients who were previously treated with other antiretroviral agents.

Indication and Mechanism of Action

- ISENTRESS® is approved by Health Canada for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in adult patients.
- ISENTRESS® belongs to a class of drugs known as HIV integrase inhibitors.
- ISENTRESS® blocks the action of integrase, an enzyme that the HIV virus needs to reproduce.
- By targeting the integrase enzyme, ISENTRESS® limits the ability of the virus to replicate and infect new cells.
- There are drugs in use that inhibit two other enzymes critical to the HIV-1 replication process – protease and reverse transcriptase – but ISENTRESS® is the only drug approved that inhibits the HIV integrase enzyme.
- ISENTRESS® does not cure HIV infection or AIDS or lower the chance of passing HIV to other people.

Dosage and Administration

- Treatment with ISENTRESS® is administered as a single 400 mg tablet taken orally twice daily with or without food with other HIV medications.
- ISENTRESS® does not require boosting with ritonavir, which can be associated with adverse side effects.

Efficacy

- The approval of ISENTRESS® for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients is based on the analysis of 48-week data from three ongoing, randomized, double-blind, placebo-controlled trials,

BENCHMRK 1 and BENCHMRK 2 (Protocols 018 and 019), in antiretroviral treatment-experienced HIV-1 infected adult patients and the analysis of 48-week data from an ongoing, randomized, double blind, active-control trial, STARTMRK (Protocol 021) in antiretroviral treatment-naïve HIV-1 infected adult patients.

- In the study of treatment-naïve patients (STARTMRK), ISENTRESS[®] was found to be as effective as efavirenz (one of the standard antiretrovirals prescribed for treatment-naïve patients) at suppressing viral load and restoring immune system function through 48 weeks in treatment-naïve patients. Both medicines were administered in combination with tenofovir and emtricitabine
- Through 48 weeks of therapy, ISENTRESS[®] demonstrated minimal effects on serum lipids compared to the group treatment with efavirenz, with small increases in total and LDL cholesterol and a decrease in serum triglycerides.
- There were also fewer central nervous system side effects with ISENTRESS[®] through 48 weeks.

Safety

- ISENTRESS[®] has gone through a rigorous clinical trial program and has been shown to be effective and well-tolerated.
- During clinical studies, side effects usually were mild and did not cause patients to stop taking ISENTRESS[®].
- The most common side effects reported in clinical trials with ISENTRESS[®] in treatment-experienced and treatment-naïve patients are diarrhea, nausea and headache.

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FOR MORE INFORMATION, PLEASE CONTACT:

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