

**AUTHORIZATION WITH
CONDITIONS OF ISENTRESS™
FACT SHEET**

**What is
ISENTRESS™?**

ISENTRESS™ is a human immunodeficiency virus integrase strand transfer inhibitor.

Health Canada has approved ISENTRESS™ with conditions, under the Notice of Compliance with Conditions policy. This authorization reflects the promising nature of the clinical evidence which must be verified and/or extended with further studies. Products approved under Health Canada's NOC/c policy, have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment.

**What is
ISENTRESS™ used
for?**

ISENTRESS™ is a medicine that helps control HIV infection, in combination with other antiretroviral medications. The term HIV stands for Human Immunodeficiency Virus. It is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

HIV is a disease that destroys the body's ability to protect itself from infection.

-It is caused by a virus (called HIV) that attacks certain white blood cells and weakens the immune system.

-HIV is spread by contact with blood of or sexual contact with an infected person.

Your physician has prescribed ISENTRESS™ to help control your HIV infection.

**How does
ISENTRESS™ work?**

ISENTRESS™ blocks an enzyme which the virus (HIV) needs in order to make more virus. The enzyme that ISENTRESS™ blocks is called HIV integrase.

ISENTRESS™ is used along with other HIV medicines. Anti-HIV medicines are also called “antiretroviral medicines” or (an-ti-re-tro-vi-ral medicines).

What other

HIV-infected patients are treated with antiretroviral (ARV) medicines.

medications can be used to treat HIV infection?

ARV's currently consist of four classes of medicines:

- Nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs)
- Protease Inhibitors (PIs)
- Non-nucleoside reverse transcriptase inhibitors (NNRTIs)
- Entry Inhibitors (EIs)

Most HIV-infected patients on therapy take a combination of three medicines from at least two classes of ARVs. This type of regimen is known as a highly active antiretroviral therapy (HAART). The focus of treatment is maximum durable suppression of HIV with the ideal objective of achieving undetectable viral load.

What are the potential benefits of ISENTRESS™?

When used with other anti-HIV medicines, ISENTRESS™ may do two things:

1. It may reduce the amount of HIV in your blood. This is called your "viral load".
 - Reducing the amount of HIV in the blood may keep your immune system healthy.
 - This in turn, can help your immune system to fight infection.
2. It may also increase the number of white blood cells that help fight the virus (HIV).
 - Physicians call them CD4 (T) cells.

ISENTRESS™ may not have these effects in all patients.

What do patients need to know about using ISENTRESS™?

ISENTRESS™ does not reduce the chance of passing HIV to others through sexual contact, sharing needles, or being exposed to your blood.

- ISENTRESS™ does not cure HIV infection or AIDS.
- The long-term effects of ISENTRESS™ are not known at this time.
- It is very important that you stay under the care of your physician during treatment with ISENTRESS™.

What are the side effects and how serious are they?

Like all prescription medicines, ISENTRESS™ can cause side effects, although not every body gets them. The following is **not** a complete list of side effects reported with ISENTRESS™. Do not rely on this fact sheet alone for information about side effects. Your doctor can discuss with you a more complete list of side effects.

In studies, side effects usually were mild and did not cause patients to stop taking ISENTRESS™. The side effects reported in patients were similar to side effects in patients treated with a tablet containing no

medication (a placebo).

The most common side effects include nausea, headache, diarrhea, fever, vomiting, fatigue, dizziness, difficulty sleeping, cough and rash.

In some patients with advanced HIV infection (AIDS), signs and symptoms of inflammation from opportunistic infections may occur when combination antiretroviral treatment is started. Tell your physician immediately if you notice any symptoms of infection.

What are the potential interactions with ISENTRESS™

Tell your physician about all the medicines you take. Include the following:

- prescription medicines, including rifampin, which may interact with ISENTRESS™
- non-prescription medicines
- vitamins
- herbal supplements

Know the medicines you take.

- Keep a list of your medicines. Show the list to your physician and pharmacist when you get a new medicine.

Who can be treated with ISENTRESS™?

ISENTRESS™ in combination with other antiretroviral agents is indicated for the treatment of HIV-1 infection in treatment-experienced adult patients who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents.

How is ISENTRESS™ taken?

Take ISENTRESS™ exactly as your physician has prescribed. The recommended dose is as follows:

- Take only one 400-mg tablet at a time
- Take it twice a day.
- Take it by mouth.
- Take it with or without food or drink.

If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do NOT take two tablets of ISENTRESS™ at the same time. In other words, do NOT take a double dose.

Where can I learn more about ISENTRESS™?

Contact your physician or pharmacist if you have any questions about ISENTRESS™. More information on ISENTRESS™ can be found at: <http://www.merckfrosst.com> or by contacting the Merck Frosst Medical Information Department at 1-800-567-2594.