

PART III: CONSUMER INFORMATION

PrISENTRESS®

raltegravir tablets (as raltegravir potassium)

This leaflet is part III of a three-part "Product Monograph" published when ISENTRESS® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ISENTRESS®. Contact your physician or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What is HIV?

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.

What the medication is used for:

- ISENTRESS® is a medicine that helps control HIV infection, in combination with other antiretroviral medications.
- Your physician has prescribed ISENTRESS® to help control your HIV infection.

ISENTRESS® has not been studied in children less than 16 years of age.

What it does:

ISENTRESS® is a medicine that helps to control HIV infection. The term HIV stands for Human Immunodeficiency Virus. It is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

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.

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.

When it should not be used:

- Do not take ISENTRESS® if you are hypersensitive to any of its ingredients (see What the non-medicinal ingredients are).

What the medicinal ingredient is:

Raltegravir potassium

What the non-medicinal ingredients are:

calcium phosphate dibasic anhydrous, hypromellose 2208, lactose monohydrate, magnesium stearate, microcrystalline cellulose, poloxamer 407 (contains 0.01% butylated hydroxytoluene as antioxidant), sodium stearyl fumarate.

In addition, the film coating contains the following inactive ingredients: black iron oxide, polyethylene glycol 3350, polyvinyl alcohol, talc, red iron oxide and titanium dioxide.

What dosage forms it comes in:

ISENTRESS® is available as pink, oval shaped, with 227 on one side, film-coated tablets containing 400 mg raltegravir (as raltegravir potassium), as the active ingredient.

WARNINGS AND PRECAUTIONS

Tell your physician about all the medicines you take (see INTERACTIONS WITH THIS MEDICATION)

BEFORE you use ISENTRESS[®] talk to your physician or pharmacist if:

- You have any allergies.
- You are pregnant or plan to become pregnant.
 - ISENTRESS[®] is not recommended for use during pregnancy. ISENTRESS[®] has not been studied in pregnant women.
- You are breast-feeding or plan to breast-feed.
 - It is recommended that HIV-infected women should not breast-feed their infants. This is because their babies could be infected with HIV through their breast milk.
 - Talk with your physician about the best way to feed your baby.

Other Warnings

Does ISENTRESS[®] lower the chance of passing HIV to other people?

No. ISENTRESS[®] does not reduce the chance of passing HIV to others through sexual contact, sharing needles, or being exposed to your blood.

- Continue to practice safer sex.
- Use latex or polyurethane condoms or other barrier methods to lower the chance of sexual contact with any body fluids. This includes semen from a man, vaginal secretions from a woman, or blood.
- Never re-use, or share needles.
- Ask your physician if you have any questions about safer sex or how to prevent passing HIV to other people.

What else is there to know?

- ISENTRESS[®] does not cure HIV infection or AIDS.
- It is very important that you stay under the care of your physician during treatment with ISENTRESS[®].

INTERACTIONS WITH THIS MEDICATION

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.

PROPER USE OF THIS MEDICATION

Usual adult dose:

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.

Do not change your dose or stop taking ISENTRESS[®] or your other anti-HIV medicines without first talking with your physician.

IMPORTANT: Take ISENTRESS[®] exactly as your physician prescribed and at the right times of day because if you don't:

- The amount of virus (HIV) in your blood may increase if the medicine is stopped for even a short period of time.
- The virus may develop resistance to ISENTRESS[®] and become harder to treat.
- Your medicines may stop working to fight HIV.
- The activity of ISENTRESS[®] may be reduced (due to resistance).

Overdose:

In case of drug overdose, contact a health care practitioner (e.g. doctor), hospital emergency department or the regional poison control centre, even if there are no symptoms.

Missed Dose:

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.

ISENTRESS[®] must be used with other anti-HIV medicines.

Be sure to keep a supply of your anti-HIV medicines.

- When your ISENTRESS[®] supply starts to run low, get more from your physician or pharmacy.
- Do not wait until your medicine runs out to get more.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, ISENTRESS[®] can cause side effects, although not everybody gets them. In studies, side effects usually were mild and did not cause patients to stop taking ISENTRESS[®]. The side effects reported in patients taking ISENTRESS[®] were similar to side effects in patients treated with a tablet containing no medication (a placebo).

The most common side effects of ISENTRESS[®] include:

- nausea
- headache
- diarrhea
- fever
- vomiting
- fatigue
- dizziness
- difficulty sleeping
- cough
- rash
- tiredness
- upper respiratory tract infection
- inflammation of the nasal passages and throat
- bronchitis

Additionally, while the medicine has been on the market, some further reactions have occurred:

- Depression and suicidal thoughts have been reported. If you develop these feelings, discuss this with your physician.
- Other side effects that have been reported include low blood platelet count, clumsiness and lack of coordination, rash with or without an increase in some white blood cells and severe skin reaction. If you develop any of these reactions, discuss with your physician.

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.

Contact your physician promptly if you experience unexplained muscle pain, tenderness, or weakness while taking ISENTRESS[®].

Contact your physician promptly if you develop a rash. Severe and life-threatening skin reactions and allergic reactions have been reported in some patients taking ISENTRESS[®].

Tell your physician if you develop any unusual side effect or if any known side effect does not go away or gets worse. For more information, ask your physician or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptoms / effects	Talk with your physician or pharmacist		Stop taking drug and call your physician or pharmacist
	Only if severe	In all cases	
Un-common			✓
<u>Severe skin reactions and allergic reactions:</u> occasionally life-threatening, with symptoms such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing			
persistent fatigue	✓		
<u>lack of white blood cells:</u> frequent infections such as fever, severe chills, sore throat or mouth ulcers	✓		
<u>lack of red blood cells:</u> tiredness, headaches, being short of breath when exercising, dizziness and looking pale	✓		
severe chest pain			✓
<u>stomach problems:</u> pain, nausea, vomiting, heartburn	✓		
<u>liver disease:</u> liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine		✓	
<u>kidney disease:</u> nausea, loss of appetite and weakness, pass little or no urine, breathlessness			✓
depression, suicidal thoughts and actions		✓	
shaking		✓	
speech disorders		✓	
disturbance in attention		✓	

This is not a complete list of side effects. For any unexpected effects while taking ISENTRESS[®], contact your physician or pharmacist.

HOW TO STORE IT

Store ISENTRESS® at room temperature (15°C–30°C).

Keep ISENTRESS® and all medicines out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect

or at Merck Canada Inc. by one of the following 2 ways:

- Call toll-free at 1-800-567-2594
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-800-369-3090, or
 - Mail to: Merck Canada Inc.
Pharmacovigilance
P.O. Box 1005
Pointe-Claire–Dorval, QC H9R 4P8

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program or Merck do not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.merck.ca> or by contacting the sponsor, Merck Canada Inc., at: 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

Last revised: February 10, 2012

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