

## PART III: CONSUMER INFORMATION

**ISENTRESS®**

\* Raltegravir tablets 400 mg

\* Raltegravir chewable tablets, 25 mg, 100 mg  
(\* as raltegravir potassium)**ISENTRESS HD®**Raltegravir tablets 600 mg  
(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® may be used to treat children and adolescents that are 2 years of age and older.

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 in combination with other HIV medicines to treat adults, adolescents, and children 2 years of age and older who are infected with HIV. 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:600 mg film-coated tablets:

croscarmellose sodium, hypromellose 2910, magnesium stearate, microcrystalline cellulose. In addition, the film coating contains the following inactive ingredients: black iron oxide, carnauba wax, hypromellose 2910, iron oxide yellow, lactose monohydrate, titanium dioxide, and triacetin.

400 mg raltegravir film-coated tablets

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, red iron oxide, talc and titanium dioxide.

25 mg and 100 mg raltegravir chewable tablets:

ammonium hydroxide, crospovidone, ethylcellulose 20 cP, fructose, hydroxypropyl cellulose, hypromellose 2910/6cP, macrogol/PEG 400, magnesium stearate, mannitol, medium chain triglycerides, monoammonium glycyrrhizinate, natural and artificial flavors (orange, banana, and masking), oleic acid, phenylalanine (as part of the artificial sweetener, aspartame), saccharin sodium, sodium citrate dihydrate, sodium stearyl fumarate, sorbitol, sucralose and yellow iron oxide.

ISENTRESS® 100 mg also contain red iron oxide

What dosage forms it comes in:

ISENTRESS HD® 600 mg film-coated tablets are yellow, oval shaped tablets debossed with Merck logo and “242” on one side.

ISENTRESS® 400 mg film-coated tablets are available as pink, oval shaped, with 227 on one side.

ISENTRESS<sup>®</sup> 100 mg orange-banana flavoured, chewable tablets are available as pale orange, oval shaped scored tablet, debossed with the Merck logo on one side of the score and 477 on the other, and scored on the other side of the tablet.

ISENTRESS<sup>®</sup> 25 mg orange-banana flavoured, chewable tablets are available as pale yellow, round, flat faced, beveled edge tablet debossed with the Merck logo on one side and 473 on the other side of the tablet.

## WARNINGS AND PRECAUTIONS

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

BEFORE you use ISENTRESS<sup>®</sup> talk to your physician or pharmacist if:

- You have any allergies.
- You take antacids. Certain antacids (those containing aluminum and/or magnesium) are not recommended with ISENTRESS<sup>®</sup>.
- You have phenylketonuria (PKU). ISENTRESS<sup>®</sup> Chewable Tablets contain phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with PKU.
- You are pregnant or plan to become pregnant.
  - If you take ISENTRESS<sup>®</sup> while you are pregnant, talk to your physician about how you can be included in the Antiretroviral Pregnancy Registry.
- 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<sup>®</sup> lower the chance of passing HIV to other people?**

No. ISENTRESS<sup>®</sup> 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<sup>®</sup> does not cure HIV infection or AIDS.
- It is very important that you stay under the care of your physician during treatment with ISENTRESS<sup>®</sup>.

## INTERACTIONS WITH THIS MEDICATION

Tell your physician about all the medicines you take including prescription and non-prescription medicines (including antacids), vitamins, and herbal supplements. Some medicines are not recommended with ISENTRESS<sup>®</sup>.

Tell your physician especially if you take:

- antacids containing aluminum, magnesium and calcium carbonate
- atazanavir
- rifampin
- tipranavir/ritonavir

Keep a list of all your medicines to show your physician and pharmacist.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with ISENTRESS<sup>®</sup>.
- Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take ISENTRESS<sup>®</sup> with other medicines.

## PROPER USE OF THIS MEDICATION

Take ISENTRESS<sup>®</sup> exactly as your physician has prescribed.

### Usual dose:

Take ISENTRESS<sup>®</sup> by mouth, with or without food.

ISENTRESS<sup>®</sup> must be used with other anti-HIV medicines.

Do not change your dose, or stop taking ISENTRESS<sup>®</sup> without first talking with your physician. Do not switch from the 400 mg tablet, 600 mg tablets, or the chewable tablets.

### Adult

Take one 400-mg tablet twice daily or two 600 mg tablets once daily as directed by your healthcare provider.

### Children and Adolescents

- Your child's healthcare provider will tell you the right dose and type of ISENTRESS<sup>®</sup> (tablet, chewable tablet) based on your child's weight.
- The 100 mg chewable tablet is scored and can be split into equal halves.
- Do not take more than 300 mg of the chewable tablet twice a day.

### Using different dosage forms/strengths:

The different dosage forms and strengths for ISENTRESS<sup>®</sup> are not interchangeable so:

- a) Use only the 600 mg tablet for the 1200 mg once daily dose.
- b) Use only the 400 mg tablet for the twice daily dose of 400 mg.

c) Use the 25 mg and 100 mg chewable tablets for only the children's dosages up to 300 mg twice daily.

**IMPORTANT: Take ISENTRESS<sup>®</sup> 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<sup>®</sup> and become harder to treat.
- Your medicines may stop working to fight HIV.
- The activity of ISENTRESS<sup>®</sup> may be reduced (due to resistance).

Overdose:

If you think you have taken too much ISENTRESS<sup>®</sup>, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, 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. Only take ISENTRESS<sup>®</sup> and ISENTRESS HD<sup>®</sup> as instructed.

ISENTRESS<sup>®</sup> must be used with other anti-HIV medicines.

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

- When your ISENTRESS<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>. The side effects reported in patients taking ISENTRESS<sup>®</sup> were similar to side effects in patients treated with a tablet containing no medication (a placebo).

The most common side effects of ISENTRESS<sup>®</sup> 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
- back pain
- depression

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, severe skin reaction, liver failure. 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.

Phenylketonuria (PKU). ISENTRESS<sup>®</sup> Chewable Tablets contain phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with PKU.

Contact your physician promptly if you experience unexplained muscle pain, tenderness, or weakness while taking ISENTRESS<sup>®</sup>.

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<sup>®</sup>.

Changes in your immune system (Immune Reconstitution Inflammatory Syndrome) can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time, or you could develop an autoimmune disease in which your immune system reacts against your own body (e.g. Grave's disease (which affects the thyroid gland), Guillain-Barre syndrome (which affects the nervous system) or polymyositis (which affects the muscles) and it may develop at any time, sometimes months later after the start of HIV therapy). Sometimes symptoms can be severe, so if you develop high temperature (fever), joint or muscle pain, redness, rash, swelling, or fatigue or any new symptoms contact your physician right away.

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.

Keep ISENTRESS<sup>®</sup> and all medicines out of the reach and sight of children.

**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	
<b>Uncommon</b>			
<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<sup>®</sup>, contact your physician or pharmacist.*

**HOW TO STORE IT**

Store ISENTRESS<sup>®</sup> and ISENTRESS HD<sup>®</sup> at room temperature (15°C–30°C).

400 mg tablets:  
Keep the desiccant in the bottle.

600 mg tablets, Chewable tablets 25 mg and 100 mg: Store in the original package with the bottle tightly closed. Keep the desiccant in the bottle to protect from moisture.

**Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

**3 ways to report:**

- Online at MedEffect (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 1908C  
Ottawa, ON  
K1A 0K9
 Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>).

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION****If you want more information about ISENTRESS<sup>®</sup>:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>) or Merck Canada website [www.merck.ca](http://www.merck.ca) or by calling Merck Canada at 1-800-567-2594.

To report an adverse event related to ISENTRESS<sup>®</sup>, please contact 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

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