

Patient Information

**ISENTRESS® (eye sen tris)
(raltegravir)
Film-Coated Tablets
ISENTRESS® (eye sen tris)
(raltegravir)
Chewable Tablets**

Read this Patient Information before you start taking ISENTRESS and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is ISENTRESS?

ISENTRESS is a prescription HIV medicine used with other HIV medicines to treat adults and children 2 years of age and older weighing at least 10 kg with human immunodeficiency virus (HIV-1) infection. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

When used with other HIV medicines, ISENTRESS may reduce the amount of HIV in your blood (called “viral load”). ISENTRESS may also help to increase the number of CD4 (T) cells in your blood which help fight off other infections. Reducing the amount of HIV and increasing the CD4 (T) cell count may improve your immune system. This may reduce your risk of death or infections that can happen when your immune system is weak (opportunistic infections).

It is not known if ISENTRESS is safe and effective in children under 2 years of age.

ISENTRESS does not cure HIV infection or AIDS. People taking ISENTRESS may still develop infections or other conditions associated with HIV infection. Some of these conditions are pneumonia, herpes virus infections, and Mycobacterium avium complex (MAC) infections.

Patients must stay on continuous HIV therapy to control infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others:

- **Do not share needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.**
- **Do not have any kind of sex without protection.** Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your doctor if you have any questions on how to prevent passing HIV to other people.

What should I tell my doctor before taking ISENTRESS?

Before taking ISENTRESS, tell your doctor if you:

- have liver problems.
- take antacids. Certain antacids (those containing aluminum and/or magnesium) are not recommended with ISENTRESS.
- have phenylketonuria (PKU). ISENTRESS Chewable Tablets contain phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with PKU.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if ISENTRESS can harm your unborn baby.

Pregnancy Registry: You and your doctor will need to decide if taking ISENTRESS is right for you. If you take ISENTRESS while you are pregnant, talk to your doctor about how you can be included in the Antiretroviral Pregnancy Registry. The purpose of the registry is to follow the health of you and your baby.

- are breastfeeding or plan to breastfeed.
 - Do not breastfeed if you are taking ISENTRESS. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby.
 - Talk with your doctor about the best way to feed your baby.

Tell your doctor about all the medicines you take, including: prescription and non-prescription medicines, vitamins, and herbal supplements. Taking ISENTRESS and certain other medicines may affect each other causing serious side effects. ISENTRESS may affect the way other medicines work and other medicines may affect how ISENTRESS works.

Especially tell your doctor if you take:

- antacids. It is not recommended to take ISENTRESS with certain antacids (those containing aluminum and/or magnesium). Talk to your doctor about other antacids you can take.
- rifampin (Rifadin, Rifamate, Rifater, Rimactane), a medicine commonly used to treat tuberculosis.

Ask your doctor or pharmacist if you are not sure whether any of your medicines are included in the list above.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine. Do not start any new medicines while you are taking ISENTRESS without first talking with your doctor.

How should I take ISENTRESS?

- **Take ISENTRESS exactly as prescribed by your doctor.**
- You should stay under the care of your doctor while taking ISENTRESS.
- Do not change your dose of ISENTRESS, switch between the film-coated tablet and the chewable tablet or stop your treatment without talking with your doctor first.
- Take ISENTRESS by mouth, with or without food.
- If your child is taking ISENTRESS, your child's doctor will decide the right dose based on your child's age and weight.
- ISENTRESS Chewable Tablets may be chewed or swallowed whole.
- ISENTRESS Film-Coated Tablets must be swallowed whole.
- 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 double your next dose or take more than your prescribed dose.
- If you take too much ISENTRESS, call your doctor or go to the nearest emergency room right away.
- Do not run out of ISENTRESS. Get your ISENTRESS refilled from your doctor or pharmacy before you run out.

What are the possible side effects of ISENTRESS?

ISENTRESS can cause serious side effects including:

- **Serious skin reactions and allergic reactions.** Severe, potentially life-threatening and fatal skin reactions and allergic reactions have been reported in some patients taking ISENTRESS. If you develop a rash with any of the following symptoms, stop using ISENTRESS and contact your doctor right away:

- fever
- generally ill feeling
- extreme tiredness
- muscle or joint aches
- blisters or sores in mouth
- blisters or peeling of the skin
- redness or swelling of the eyes
- swelling of the mouth or face
- problems breathing

Sometimes allergic reactions can affect body organs, like the liver. Contact your doctor right away if you have any of the following signs or symptoms of liver problems:

- yellowing of the skin or whites of the eyes
 - dark or tea colored urine
 - pale colored stools/bowel movements
 - nausea/vomiting
 - loss of appetite
 - pain, aching or tenderness on the right side below the ribs
- **Changes in your immune system (Immune Reconstitution 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. Tell your doctor right away if you start having new symptoms after starting your HIV medicine.
 - **Phenylketonuria (PKU). ISENTRESS Chewable Tablets** contain phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with PKU.

In clinical trials, the most common (≥2%) side effects of ISENTRESS include:

- dizziness
- headache
- nausea
- tiredness
- trouble sleeping

In clinical trials, less common (<2%) side effects include:

- allergic reaction
- depression
- hepatitis
- genital herpes
- herpes zoster including shingles
- kidney failure
- kidney stones
- stomach pain
- suicidal thoughts and actions
- vomiting
- weakness

Tell your doctor before beginning ISENTRESS if you have a history of muscle disorders (rhabdomyolysis or myopathy) or increased creatine kinase or if you are taking medications known to cause these conditions such as statins, fenofibrate, gemfibrozil or zidovudine.

Tell your doctor right away if you get unexplained muscle pain, tenderness, or weakness while taking ISENTRESS. This may be a sign of a rare but serious muscle problem that can lead to kidney problems.

Rash occurred more often in patients taking ISENTRESS and darunavir/ritonavir together than with either drug separately, but was generally mild.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ISENTRESS. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ISENTRESS?

Film-Coated Tablets:

- Store ISENTRESS Film-Coated Tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Chewable Tablets:

- Store ISENTRESS Chewable Tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Store ISENTRESS Chewable Tablets in the original package with the bottle tightly closed.
- Keep the drying agent (desiccant) in the bottle to protect from moisture.

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

General information about ISENTRESS

Medicines are sometimes prescribed for conditions that are not mentioned in Patient Information Leaflets. Do not use ISENTRESS for a condition for which it was not prescribed. Do not give ISENTRESS to other people, even if they have the same symptoms you have. It may harm them.

This leaflet gives you the most important information about ISENTRESS.

If you would like to know more, talk with your doctor. You can ask your doctor or pharmacist for information about ISENTRESS that is written for health professionals.

For more information go to www.ISENTRESS.com or call 1-800-622-4477.

What are the ingredients in ISENTRESS?

ISENTRESS Film-Coated Tablets:

Active ingredient: raltegravir

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

The film coating contains: polyvinyl alcohol, titanium dioxide, polyethylene glycol 3350, talc, red iron oxide and black iron oxide.

ISENTRESS Chewable Tablets:

Active ingredient: raltegravir

Inactive ingredients: hydroxypropyl cellulose, sucralose, saccharin sodium, sodium citrate dihydrate, mannitol, red iron oxide (100 mg tablet only), yellow iron oxide, monoammonium glycyrrhizinate, sorbitol, fructose, natural and artificial flavors (orange, banana, and masking that contains aspartame),

crospovidone, magnesium stearate, sodium stearyl fumarate, ethylcellulose 20 cP, ammonium hydroxide, medium chain triglycerides, oleic acid, hypromellose 2910/6cP, PEG 400.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Distributed by:
Merck Sharp & Dohme Corp., a subsidiary of **Merck & Co., Inc.**
Whitehouse Station, NJ 08889, USA

Revised 10/2013

usppi-0518-t-1310r024

Copyright © 2007, 2009, 2011 Merck Sharp & Dohme Corp., a subsidiary of **Merck & Co., Inc.**
All rights reserved

For patent information: www.merck.com/product/patent/home.html