Patient Information
ISENTRESS® (eye sen tris)
(raltegravir) Tablets

ISENTRESS
raltegravir tablets

Read the patient information that comes with ISENTRESS[1] before you start taking it and each time you get a refill. There may be new information. This leaflet is a summary of the information for patients. Your doctor or pharmacist can give you additional information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

What is ISENTRESS?

- ISENTRESS is an anti-HIV (antiretroviral) medicine used for the treatment of HIV. The term HIV stands for Human Immunodeficiency Virus. It is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). ISENTRESS is used along with other anti-HIV medicines. ISENTRESS will NOT cure HIV infection.
- People taking ISENTRESS may still develop infections, including opportunistic infections or other conditions that happen with HIV infection.
- Stay under the care of your doctor during treatment with ISENTRESS.
- The safety and effectiveness of ISENTRESS in children has not been studied.

ISENTRESS must be used with other anti-HIV medicines.

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.
- When used with other anti-HIV medicines, ISENTRESS may do two things:
  1. Reduce the amount of HIV in your blood. This is called your "viral load".
  2. Increase the number of white blood cells called CD4 (T) cells.
- ISENTRESS may not have these effects in all patients.

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 doctor if you have any questions about safer sex or how to prevent passing HIV to other people.

What should I tell my doctor before and during treatment with ISENTRESS?
Tell your doctor about all of your medical conditions. Include any of the following that applies to you:

- 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. If you take ISENTRESS while you are pregnant, talk to your doctor 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 doctor about the best way to feed your baby.

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

- prescription medicines, including rifampin (a medicine used to treat some infections such as tuberculosis)
- non-prescription medicines
- vitamins
- herbal supplements

Know the medicines you take.

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

How should I take ISENTRESS?

Take ISENTRESS exactly as your doctor 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.

Do not change your dose or stop taking ISENTRESS or your other anti-HIV medicines without first talking with your doctor.

IMPORTANT: Take ISENTRESS exactly as your doctor 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).

If you fail to take ISENTRESS the way you should, here's what to do:

- 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.
- If you take too much ISENTRESS, call your doctor or local Poison Control Center.

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

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

What are the possible side effects of ISENTRESS?

When ISENTRESS has been given with other anti-HIV drugs, side effects included:

- nausea
- headache
- tiredness
- weakness
- trouble sleeping
- stomach pain
- dizziness
- depression
- suicidal thoughts and actions

Other side effects include rash, severe skin reactions, feeling anxious, paranoia, low blood platelet count.

A condition called Immune Reconstitution Syndrome can happen in some patients with advanced HIV infection (AIDS) when combination antiretroviral treatment is started. Signs and symptoms of inflammation from opportunistic infections that a person has or had may occur as the medicines work to treat the HIV infection and help to strengthen the immune system. Call your doctor right away if you notice any signs or symptoms of an infection after starting ISENTRESS with other anti-HIV medicines.

Contact your doctor promptly if you experience unexplained muscle pain, tenderness, or weakness while taking ISENTRESS. This is because on rare occasions, muscle problems can be serious and can lead to kidney damage.

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

Tell your doctor if you have any side effects that bother you.

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

How should I store ISENTRESS?

- Store ISENTRESS at room temperature (68 to 77°F).
- **Keep ISENTRESS and all medicines out of the reach of children.**

General information about the use of 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 additional 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?
Active ingredient: Each film-coated tablet contains 400 mg of 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. In addition, the film coating contains the following inactive ingredients: polyvinyl alcohol, titanium dioxide, polyethylene glycol 3350, talc, red iron oxide and black iron oxide.

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