Patient Information

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 antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection in people 4 weeks of age and older. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

It is not known if ISENTRESS is safe and effective in babies under 4 weeks of age.

When used with other HIV medicines to treat HIV-1 infection, ISENTRESS may help:

- reduce the amount of HIV in your blood. This is called "viral load".
- increase the number of white blood cells called CD4+ (T) cells in your blood, which help fight off other infections.
- reduce the amount of HIV-1 and increase the CD4+ (T) cells in your blood, which may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

ISENTRESS does not cure HIV-1 infection or AIDS.

You must stay on continuous HIV therapy to control HIV-1 infection and decrease HIV-related illnesses.

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

- Do not share or re-use 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 any body fluids such as 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 you take ISENTRESS, tell your doctor if you:

- have liver problems
- have a history of a muscle disorder called rhabdomyolysis or myopathy
- have increased levels of creatine kinase in your blood
- 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: There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your doctor about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. Do not breastfeed if you take ISENTRESS.
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - o It is not known if ISENTRESS passes into your breast milk.
 - o Talk with your doctor about the best way to feed your baby.

Tell your doctor about all the medicines you take, including, prescription and over-the-counter medicines, vitamins, and herbal supplements. 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 any of these medicines:

- rifampin (Rifadin, Rifamate, Rifater, Rimactane)
- an antacid medicine that contains aluminum or magnesium
- a cholesterol lowering medicine (statin)
- a medicine that contains fenofibrate (Antara, Lipofen, Tricor, Trilipix)
- gemfibrozil (Lopid)
- a medicine that contains zidovudine (Combivir, Retrovir, Trizivir)

Ask your doctor or pharmacist if you are not sure if your medicine is one that is listed 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.
- Do not change your dose of ISENTRESS or stop your treatment without talking with your doctor first.
- Stay under the care of your doctor while taking ISENTRESS.
- ISENTRESS film-coated tablets must be swallowed whole.
- ISENTRESS chewable tablets may be chewed or swallowed whole.
- ISENTRESS for oral suspension should be given to your child within 30 minutes of mixing. See
 the detailed Instructions for Use that comes with ISENTRESS for oral suspension, for
 information about the correct way to mix and give a dose of ISENTRESS for oral suspension. If
 you have questions about how to mix or give ISENTRESS for oral suspension, talk to your doctor
 or pharmacist.
- Do not switch between the film-coated tablet, the chewable tablet, or the oral suspension without talking with your doctor first.
- **Do not** run out of ISENTRESS. Get a refill of your ISENTRESS from your doctor or pharmacy before you run out.
- 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 ISENTRESS than prescribed.
- If you take too much ISENTRESS, call your doctor or go to the nearest hospital emergency room right away.

What are the possible side effects of ISENTRESS?

ISENTRESS can cause serious side effects including:

- Serious skin reactions and allergic reactions. Some people who take ISENTRESS develop
 serious skin reactions and allergic reactions that can be severe, and may be life-threatening or lead
 to death. If you develop a rash with any of the following symptoms, stop using ISENTRESS and call
 your doctor right away:
 - o fever
 - o generally ill feeling
 - o extreme tiredness
 - o muscle or joint aches
 - o blisters or sores in mouth
 - o blisters or peeling of the skin
 - o redness or swelling of the eyes
 - o swelling of the mouth or face
 - o problems breathing

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

- o yellowing of your skin or whites of your eyes
- o dark or tea colored urine
- pale colored stools (bowel movements)
- o nausea or vomiting
- loss of appetite
- o pain, aching, or tenderness on the right side of your stomach area
- Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking HIV-1 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-1 medicine.

The most common side effects of ISENTRESS include:

- trouble sleeping
- headache
- dizziness
- nausea
- tiredness

Less common side effects of ISENTRESS include:

- depression
- hepatitis
- genital herpes
- herpes zoster including shingles
- kidney failure
- kidney stones
- indigestion or stomach area pain

- vomiting
- suicidal thoughts and actions
- weakness

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

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.

For Oral Suspension:

- Store ISENTRESS for oral suspension at room temperature between 68°F to 77°F (20°C to 25°C).
- Store in the original container. Do not open the foil packet until ready for use.

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

General information about ISENTRESS

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. 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.

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

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

ISENTRESS chewable tablets:

Active ingredient: raltegravir

Inactive ingredients: ammonium hydroxide, crospovidone, ethylcellulose 20 cP, fructose, hydroxypropyl cellulose, hypromellose 2910/6cP, magnesium stearate, mannitol, medium chain triglycerides, monoammonium glycyrrhizinate, natural and artificial flavors (orange, banana, and masking that contains aspartame), oleic acid, PEG 400, saccharin sodium, sodium citrate dihydrate, sodium stearyl fumarate, sorbitol, sucralose and yellow iron oxide. The 100 mg chewable tablet also contains red iron oxide.

ISENTRESS for oral suspension:

Active ingredient: raltegravir

Inactive ingredients: ammonium hydroxide, banana with other natural flavors, carboxymethylcellulose sodium, crospovidone, ethylcellulose 20 cP, fructose, hydroxypropyl cellulose, hypromellose 2910/6cP, macrogol/PEG 400, magnesium stearate, maltodextrin, mannitol, medium chain triglycerides, microcrystalline cellulose, monoammonium glycyrrhizinate, oleic acid, sorbitol, sucralose and sucrose.

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

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