

PATIENT INFORMATION

ISENTRESS® (eye **sen** tris)
(raltegravir)
film-coated tablets

ISENTRESS® HD (eye **sen** tris HD)
(raltegravir)
film-coated tablets

ISENTRESS® (eye **sen** tris)
(raltegravir)
chewable tablets

ISENTRESS® (eye **sen** tris)
(raltegravir)
for oral suspension

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

What are ISENTRESS and ISENTRESS HD?

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).

ISENTRESS HD is a prescription HIV medicine used with other antiretroviral medicines to treat HIV-1 infection in adults, and in children weighing at least 88 pounds (40 kg).

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

Before you take ISENTRESS or ISENTRESS HD, tell your healthcare provider about all of your medical conditions, including 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.
- receive kidney dialysis treatment
- are pregnant or plan to become pregnant. It is not known if ISENTRESS or ISENTRESS HD can harm your unborn baby.

Pregnancy Registry: There is a pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.

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

Tell your healthcare provider about all the medicines you take, including, prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with ISENTRESS and ISENTRESS HD.

- **Keep a list of your medicines to show your healthcare provider and pharmacist.**
- You can ask your healthcare provider or pharmacist for a list of medicines that interact with ISENTRESS and ISENTRESS HD.
- **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 or ISENTRESS HD with other medicines.

How should I take ISENTRESS or ISENTRESS HD?

- Take ISENTRESS or ISENTRESS HD exactly as prescribed by your healthcare provider.
- **Do not** change your dose of ISENTRESS or ISENTRESS HD or stop your treatment without talking with your healthcare provider first.
- Stay under the care of your healthcare provider during treatment with ISENTRESS or ISENTRESS HD.
- ISENTRESS film-coated tablets and ISENTRESS HD 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 healthcare provider or pharmacist.

- **Do not switch between the film-coated tablet, the chewable tablet, or the oral suspension without talking with your healthcare provider first.**
- **Do not** switch between the ISENTRESS 400 mg film-coated tablet and the ISENTRESS HD 600 mg film-coated tablet if your prescribed dose is 1200 mg.
- **Do not** run out of ISENTRESS or ISENTRESS HD. The virus in your blood may increase and the virus may become harder to treat. Get a refill of your ISENTRESS or ISENTRESS HD from your healthcare provider or pharmacy before you run out.
- Take ISENTRESS or ISENTRESS HD on a regular dosing schedule as instructed by your healthcare provider. Do not miss doses.
- If you take too much ISENTRESS or ISENTRESS HD, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of ISENTRESS or ISENTRESS HD?

ISENTRESS and ISENTRESS HD can cause serious side effects including:

- **Serious skin reactions and allergic reactions.** Some people who take ISENTRESS or ISENTRESS HD 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 or ISENTRESS HD and call your healthcare provider 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, lips, or face
 - problems breathing

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

- yellowing of your skin or whites of your eyes
- dark or tea colored urine
- pale colored stools (bowel movements)
- nausea or vomiting
- loss of appetite
- 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 healthcare provider right away if you start having new symptoms after starting your HIV-1 medicine.

The most common side effects of ISENTRESS and ISENTRESS HD include:

- trouble sleeping
- headache
- dizziness
- nausea
- tiredness

Less common side effects of ISENTRESS and ISENTRESS HD 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 healthcare provider right away if you get unexplained muscle pain, tenderness, or weakness during treatment ISENTRESS or ISENTRESS HD. These may be signs of a rare serious muscle problem that can lead to kidney problems.

Tell your healthcare provider 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 and ISENTRESS HD. For more information, ask your healthcare provider 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 and ISENTRESS HD?

ISENTRESS and ISENTRESS HD film-coated tablets:

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

ISENTRESS 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.

ISENTRESS 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 the safe and effective use of ISENTRESS and ISENTRESS HD

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use ISENTRESS or ISENTRESS HD for a condition for which it was not prescribed. Do not give ISENTRESS or ISENTRESS HD to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about ISENTRESS or ISENTRESS HD 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 and ISENTRESS HD?

ISENTRESS 400 mg 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 HD 600 mg film-coated tablets:

Active ingredient: raltegravir

Inactive ingredients: croscarmellose sodium, hypromellose 2910, magnesium stearate, microcrystalline cellulose.

The film coating contains: ferrousferic oxide, hypromellose 2910, iron oxide yellow, lactose monohydrate, triacetin and titanium dioxide.

The tablet may also contain trace amount of carnauba wax.

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.

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

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