

HIV-positive model.

When it comes
to taking care
of myself,

I'M ON IT

Learn more about ISENTRESS® (raltegravir)
or ISENTRESS® HD (raltegravir) as a treatment option

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 adults, and in children weighing at least 4.4 pounds (2 kg).
- 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). HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).
- ISENTRESS should not be used in children weighing less than 4.4 pounds (2 kg).

Discover ISENTRESS and a potential savings coupon offer at [isentress.com](https://www.isentress.com)

Please read the accompanying Patient Information and Instructions for Use for ISENTRESS and ISENTRESS HD and discuss them with your healthcare provider. The physician Prescribing Information also is available.



When it comes to taking care of your whole health, you're on it

Two important goals when you're living with HIV-1 are:

- Lowering your viral load to undetectable levels; and
- Raising your CD4 cell count (CD4 cells help fight off other infections)

You may have additional goals in mind for healthier living, such as



Eating a
balanced diet



Exercising
more



Managing other
health conditions

Use this brochure to better understand how **ISENTRESS®** (raltegravir) or **ISENTRESS® HD** (raltegravir) can fit into taking care of your whole health.



HIV-positive model.

Important Safety Information

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

Important Safety Information

- 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: 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.



ISENTRESS® (raltegravir) and ISENTRESS® HD (raltegravir) may help lower your viral load to undetectable

In a clinical study that lasted more than a year (96 weeks) with adults new to HIV-1 treatment, the percentage of patients reaching an undetectable viral load was:

At 48 weeks:

88%

when taking
ISENTRESS
+ another HIV-1 medication

At 96 weeks:

80%

when taking
ISENTRESS
+ another HIV-1 medication

89%

when taking
ISENTRESS HD
+ another HIV-1 medication

82%

when taking
ISENTRESS HD
+ another HIV-1 medication

ISENTRESS and ISENTRESS HD may not have these effects in all patients.

How it was studied

The 96-week trial compared the safety and effectiveness of ISENTRESS HD vs ISENTRESS in adults who were new to HIV-1 treatment.

- 266 adults took ISENTRESS + another HIV-1 medication
- 531 adults took ISENTRESS HD + another HIV-1 medication

Patients were assigned by chance to take one of the two treatment regimens, and neither the patients nor the doctors taking part in the study knew which regimen they were taking.

ISENTRESS may help control HIV-1 for over 4 years

A long-term clinical study lasting more than **4 years (240 weeks)** of adult patients being treated with HIV-1 medicine for the first time showed that ISENTRESS plus *Truvada*® may help lower viral load to undetectable and raise CD4 cell counts.

Important Safety Information

- 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.
- People taking ISENTRESS or ISENTRESS HD may still develop infections or other conditions associated with HIV-1 infections.
- The most common side effects of ISENTRESS or ISENTRESS HD include: trouble sleeping, headache, dizziness, nausea, and tiredness. Less common side effects include: depression, hepatitis, genital herpes, herpes zoster including shingles, kidney failure, kidney stones, indigestion or stomach area pain, vomiting, suicidal thoughts and actions, and weakness.
- Tell your doctor before you take ISENTRESS or ISENTRESS HD if you have a history of a muscle disorder called rhabdomyolysis or myopathy or increased levels of creatine kinase in your blood.

Talk to your doctor to see if once-daily ISENTRESS or ISENTRESS HD is right for you.



ISENTRESS® (raltegravir) and ISENTRESS® HD (raltegravir): Resistance

What does drug resistance mean?

In people living with HIV-1, as the virus multiplies in the body, it can change, and sometimes medicines that used to control the virus may not work anymore. This is known as drug resistance.

In a 96-week study of 531 adults who were new to HIV-1 treatment and were taking ISENTRESS HD, 4 were found to have developed drug resistance due to change in the virus.

less than 1% of people who took part in the study were found to have developed drug resistance

Important Safety Information

- Tell your doctor right away if you get unexplained muscle pain, tenderness, or weakness while taking ISENTRESS or ISENTRESS HD. These may be signs of a rare serious muscle problem that can lead to kidney problems.
- These are not all the possible side effects of ISENTRESS or ISENTRESS HD. For more information, ask your doctor or pharmacist. Tell your doctor if you have any side effect that bothers you or that does not go away.
- Tell your doctor provider about all your medical conditions, including if you have any allergies, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. **Do not breastfeed if you take ISENTRESS or ISENTRESS HD.** Women with HIV should not breastfeed because their babies could be infected with HIV through their breast milk.



How to take ISENTRESS® (raltegravir) and ISENTRESS® HD (raltegravir)

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ISENTRESS

HOW IT'S TAKEN

- 1 pill twice a day with water
- With or without food
- In combination with other antiretroviral agents

WHO CAN TAKE IT

Adults and children weighing at least 4.4 pounds

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ISENTRESS HD

HOW IT'S TAKEN

- 2 pills once a day with water
- With or without food
- In combination with other antiretroviral agents

WHO CAN TAKE IT

Adults and children weighing at least 88 pounds

Tablets not shown at actual size.

Taking ISENTRESS/ISENTRESS HD

- Take by mouth and swallow the film-coated tablets whole
- **Do not** change your dose or stop your treatment without talking with your doctor first. The viral load in your blood may increase and the virus may become harder to treat
- Take ISENTRESS on a regular dosing schedule as instructed by your doctor. Do not miss doses
- **Do not** run out of ISENTRESS
- Stay under the care of your doctor during treatment with ISENTRESS

Important Safety Information

- Tell your doctor about all the medicines you take, including, prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with ISENTRESS or ISENTRESS HD. Do not start taking a new medicine without telling your doctor. Your doctor can tell you if it is safe to take ISENTRESS or ISENTRESS HD with those other medicines.
- Take ISENTRESS or ISENTRESS HD exactly as prescribed by your doctor.
- Do not change your dose of ISENTRESS or ISENTRESS HD, do not switch between the film-coated tablet, the chewable tablet, or the oral suspension without talking to your doctor first or stop your treatment without talking with your doctor 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.
- If your child is taking ISENTRESS, your child's doctor will decide the right dose based on your child's age and weight.
- ISENTRESS or ISENTRESS HD film-coated tablets must be swallowed whole.
- Take ISENTRESS or ISENTRESS HD on a regular dosing schedule as instructed by your doctor. Do not miss doses.
- Get your ISENTRESS or ISENTRESS HD refilled from your doctor or pharmacy before you run out.



Taking ISENTRESS® (raltegravir) and ISENTRESS® HD (raltegravir) with other medications

Do you take medications for any of the following reasons?

ISENTRESS/ISENTRESS HD can be taken with a wide range of non-HIV-1 medicines



Cholesterol
statins



Pain
opioid analgesics



Birth Control
hormonal contraceptives



Fungal Infections
azole antifungals



Heartburn
proton pump inhibitors

Some medicines can interact with ISENTRESS and ISENTRESS HD. Tell your doctor if you take antacids containing aluminum, magnesium, or calcium; rifampin; tipranavir/ritonavir; etravirine; or other drugs such as carbamazepine, phenobarbital, and phenytoin. It is not recommended to take these medicines with ISENTRESS or ISENTRESS HD. Your doctor will tell you if it's safe to take ISENTRESS or ISENTRESS HD with other medicines.

Important Safety Information

- Some people who take ISENTRESS develop severe skin reactions and allergic reactions that can be serious, and may be life-threatening or lead to death. If you develop a rash, call your doctor right away. If you develop a rash with any of the following symptoms, stop using ISENTRESS and call your doctor or get medical help right away: fever; generally ill feeling; extreme tiredness; muscle or joint aches; blisters or sores in mouth; blisters or peeling of 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 doctor 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 doctor right away if you start having new symptoms after starting your HIV-1 medicine.
- People taking ISENTRESS or ISENTRESS HD may still develop infections or other conditions associated with HIV-1 infections.



Side effects

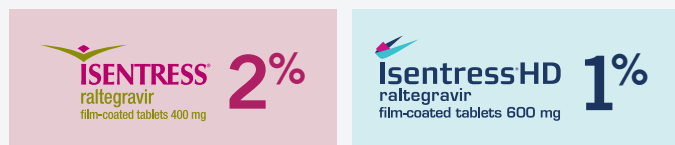
ISENTRESS® (raltegravir) and ISENTRESS® HD (raltegravir) have a low rate of side effects

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

- Trouble sleeping
- Dizziness
- Tiredness
- Headache
- Nausea

These are not all of the possible side effects of ISENTRESS HD and ISENTRESS.

In a 96-week study of adults who were being treated with HIV-1 medicines for the first time, some patients stopped taking the medicine because of side effects:



Both ISENTRESS and ISENTRESS HD were taken with Truvada (another HIV-1 medicine).

Continue to regularly see your doctor while taking ISENTRESS or ISENTRESS HD. Tell your healthcare team about any side effects you have. They may be able to help.

Important Safety Information

- These are not all the possible side effects of ISENTRESS or ISENTRESS HD. For more information, ask your doctor or pharmacist. Tell your doctor if you have any side effect that bothers you or that does not go away.

ISENTRESS can cause serious side effects, including:

- **Severe skin reactions and allergic reactions**
If you develop a rash, call your doctor right away. Stop using ISENTRESS and call your doctor or get medical help right away if you develop a rash with:
 - 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

Some of these reactions can be severe and may be life-threatening.

- **Liver problems**
Call your doctor right away if you have any of the following signs or symptoms:
 - Yellowing of your skin or the 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**
Tell your doctor right away if you start having new symptoms after starting your HIV-1 medicine.

Visit our website for information to help you start and manage your treatment



Doctor Discussion Guide

- A downloadable form to guide conversations with your doctor about your healthcare plan



Savings Coupon Information

- Eligible, privately insured patients may save on their out-of-pocket costs for ISENTRESS® (raltegravir)
- Not all patients are eligible. Certain restrictions apply. Please see Terms and Conditions

To explore all this and more, visit isentress.com



Please read the accompanying [Patient Information](#) and [Instructions for Use](#) for ISENTRESS and ISENTRESS HD and discuss them with your healthcare provider. The physician [Prescribing Information](#) also is available.

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