raltegravir (Isentress, Isentress HD)

WHAT IS RALTEGRAVIR?

Raltegravir, also known as raltegravir potassium and RAL (brand name Isentress, Isentress HD), is a drug used as part of antiretroviral therapy (ART). The FDA approved raltegravir in 2007 as an antiretroviral drug (ARV) for people with HIV infection. Raltegravir is manufactured by Merck & Co., Inc.

Raltegravir is a type of drug called an integrase inhibitor. Integrase inhibitors block integrase (an HIV enzyme). HIV uses integrase to insert (integrate) its viral DNA into the DNA of host CD4 cells. Blocking integrase prevents HIV from replicating.

When used in combination with other ARVs to treat HIV infection, raltegravir may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of CD4 cells in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting opportunistic infections (OIs) that can happen when your immune system is weak. Read more about viral suppression.

Raltegravir does not cure HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE RALTEGRAVIR?

Raltegravir comes in two forms: Isentress and Isentress HD.

Isentress is a prescription HIV medicine used in combination with other ARVs to treat HIV infection in adults and children who weigh at least 4.4 pounds (2 kg). The safety and effectiveness of Isentress has not been established in children who weigh less than 4.4 pounds (2 kg).

Isentress HD is a prescription HIV medicine used in combination with other ARVs to treat HIV infection in adults and children who weigh at least 88 pounds (40 kg) who have not taken ARVs before or whose virus has been suppressed on an initial regimen of Isentress. Isentress HD has not been studied in people who have taken ARVs in the past. The safety and effectiveness of Isentress HD has not been established in children who weigh less than 88 pounds (40 kg).

Raltegravir has not been carefully studied in the elderly (65 years of age and older).

All people living HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

WHO SHOULD NOT TAKE RALTEGRAVIR?

Do not take raltegravir if you are allergic to raltegravir or any of the ingredients in this drug.

Do not take Isentress if you take the following medications:

- Aluminum and/or magnesium-containing antacids
- Seizure medicines: carbamazepine, phenobarbital, phenytoin

Do not take Isentress HD if you take the following medications:

- Aluminum and/or magnesium-containing antacids
- Seizure medicines: carbamazepine, phenobarbital, phenytoin
- Tuberculosis (TB) medicines: rifampin, rifapentine
- Calcium carbonate-containing antacids
- Other ARVs: etravirine (Intelence), ritonavir (Norvir), tipranavir

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past four weeks, talk to your healthcare provider or pharmacist before starting treatment with raltegravir.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING RALTEGRAVIR?

Before you take raltegravir tell your healthcare provider about all of your medical conditions, and in particular 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). Raltegravir chewable tablets contain phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with PKU.
- Have kidney problems or receive kidney dialysis treatment

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with raltegravir. It is not known if raltegravir may harm your unborn baby. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with raltegravir. It is not known if raltegravir can pass to your baby in your breastmilk. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS RALTEGRAVIR TAKEN?

Raltegravir is taken by mouth as a film-coated tablet, chewable tablet, or oral suspension.

The recommended dosage of Isentress for adults who **HAVE OR HAVE NOT** taken ARVs previously is 800 mg daily taken as one 400 mg film-coated tablet twice daily, in combination with other ARVs.

The recommended dosage of Isentress HD for adults who **HAVE NOT** taken ARVs previously or who are virologically suppressed on an initial regimen of Isentress 400 mg twice daily is 1,200 mg daily taken as two 600 mg film-coated tablets once daily, in combination with other ARVs.

The recommended dosage of Isentress and Isentress HD for children varies based on the child's weight, age, and other medicines they are taking. Your healthcare provider will determine the correct dosage.

You should take dolutegravir at the same time each day with or without food. Film-coated tablets must be swallowed whole. Chewable tablets may be chewed or swallowed whole.

You need to take raltegravir in combination with other ARVs. Your healthcare provider will tell you what medicines to take and how to take them.

Isentress tablets are not the same as Isentress HD tablets for oral suspension and cannot be substituted for each other. Check to make sure you receive the correct form of raltegravir each time you or your child's prescription is filled to avoid using the wrong medicine.

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary side effects such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of raltegravir are trouble sleeping (insomnia), headaches, dizziness, nausea, and fatigue.

Less common side effects of raltegravir include:

- Depression
- Hepatitis
- Genital herpes
- Herpes zoster (shingles)
- Kidney failure
- Kidney stones

- Indigestion or stomach area pain
- Vomiting
- Suicidal thoughts and/or actions
- Weakness

Raltegravir can cause serious side effects including:

Severe skin reactions and allergic reactions. Some people who take raltegravir 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 healthcare provider right away. If you develop a rash with any of the following symptoms, stop using raltevravir and call your healthcare provider 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 the skin
- Redness or swelling of the eyes
- Swelling of the mouth, lips, or face
- Problems breathing

Liver problems. 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

Immune Reconstitution Inflammatory Syndrome (IRIS). IRIS is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting raltegravir.

Elevations in creatine kinase. Tell your healthcare provider right away if you get unexplained muscle pain, tenderness, or weakness during treatment with raltegravir. 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 raltegravir. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES RALTEGRAVIR REACT WITH OTHER DRUGS?

All ARVs can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take raltegravir with other medicines.

See above for a list of medicines that should not be taken with raltegravir.

MORE INFORMATION

Visit the Isentress website.

Download the full Prescribing Information.

Download the Patient Information leaflet.

Download the Isentress Patient Brochure

Download the Instructions for Use for babies and toddlers.

Download the Doctor Discussion Guide to bring to your next medical appointment.

Get a Merck coupon to help pay for your medication.

Reviewed March 2025