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Source : U.S. National Library of Medicine

URL of this page: <https://medlineplus.gov/druginfo/meds/a608004.html>

Raltegravir

pronounced as (ral teg' ra veer)

Why is this medication prescribed?

Raltegravir is used along with other medications to treat human immunodeficiency virus (HIV) infection in adults and children who weigh at least 4.5 lbs (2 kg). Raltegravir is in a class of medications called HIV integrase inhibitors. It works by decreasing the amount of HIV in the blood. Although raltegravir does not cure HIV, it may decrease your chance of developing acquired immunodeficiency syndrome (AIDS) and HIV-related illnesses such as serious infections or cancer. Taking these medications along with practicing safer sex and making other life-style changes may decrease the risk of transmitting (spreading) the HIV virus to other people.

How should this medicine be used?

Raltegravir comes as a tablet, a chewable tablet, and as granules for oral suspension to take by mouth. Raltegravir (Isentress[®]) tablets, chewable tablets, and oral suspension are usually taken with or without food twice a day. Raltegravir (Isentress[®] HD) tablets are usually taken with or without food once a day. Take raltegravir at the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take raltegravir exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the tablets whole; do not split, chew, or crush them. If you are taking the chewable tablets, you may chew or swallow them whole.

For children who have trouble chewing, the chewable tablets may be crushed and mixed with 1 teaspoon (5 mL) of liquid such as water, juice, or breast milk in a clean cup. The tablets will absorb the liquid and fall apart within 2 minutes. Using a spoon, crush any remaining pieces of the tablets. Drink the mixture right away. If any of the medication is left in the cup, add another teaspoonful (5 mL) of liquid, swirl and take it right away.

Before you take raltegravir oral suspension for the first time, read the written instructions that come with it that describe how to prepare the medication. Empty the contents of one granule packet into the mixing cup and add 2 teaspoons (10 mL) of water. Gently swirl the contents in the mixing cup for 45 seconds; do not shake. Use the dosing syringe provided to measure the amount of medication that your doctor has prescribed. Use the mixture within 30 minutes of preparation and discard any remaining suspension.

Continue to take raltegravir even if you feel well. Do not stop taking raltegravir or your other anti-HIV medications without talking to your doctor. If you stop taking raltegravir or skip doses, your condition may become worse and the virus may become resistant to treatment.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking raltegravir,

- tell your doctor and pharmacist if you are allergic to raltegravir, any other medications, or any of the ingredients in raltegravir products. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: antacids containing calcium, magnesium, or aluminum (Maalox, Mylanta, Tums, others); carbamazepine (Equetro, Tegretol, Teril); cholesterol-lowering medications (statins) such as atorvastatin (Lipitor, in Caduet), fluvastatin (Lescol), lovastatin (Altoprev), pravastatin (Pravachol), rosuvastatin (Crestor), and simvastatin (Zocor, in Vytorin); etravirine (Intelence); fenofibrate (Antara, Lipofen, Tricor, others); gemfibrozil (Lopid); phenobarbital; phenytoin (Dilantin, Phenytek); rifampin (Rifadin, Rimactane, in Rifamate, in Rifater), tipranavir (Aptivus) with ritonavir (Norvir); and zidovudine (Retrovir, others). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you are being treated with dialysis (medical treatment to clean the blood when the kidneys are not working properly), or if you have or have ever had hepatitis, high blood cholesterol or triglycerides (fatty substances in the blood), muscular disease or swelling of the muscles, or rhabdomyolysis (a skeletal muscle condition).
- tell your doctor if you are pregnant or plan to become pregnant. If you become pregnant while taking raltegravir, call your doctor. Tell your doctor if you are breast-feeding or plan to breastfeed. You should not breastfeed if you are infected with HIV or if you are taking raltegravir.
- if you have phenylketonuria (PKU, an inherited condition in which a special diet must be followed to prevent damage to your brain that can cause severe intellectual disability), you should know that the chewable tablets contain aspartame that forms phenylalanine.
- you should know that while you are taking medications to treat HIV infection, your immune system may get stronger and begin to fight other infections that were already in your body. This may cause you to develop symptoms of those infections. If you have new or worsening symptoms during your treatment with raltegravir.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take two tablets of raltegravir at the same time to make up for a missed dose.

What side effects can this medication cause?

Raltegravir may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- diarrhea
- gas
- stomach pain
- heartburn
- insomnia
- abnormal dreams
- depression
- headache

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:

- muscle pain or tenderness
- muscle weakness
- dark or cola-colored urine
- chest pain or pressure
- rash
- fever
- skin blisters or peeling
- hives
- itching
- swelling of the eyes, face, lips, tongue, throat, hands, feet, ankles, or arms
- difficulty breathing or swallowing
- extreme tiredness
- mouth lesions
- red, itchy, or swollen eyes
- pain in the upper right part of the stomach
- yellowing of the skin or eyes
- pale stools

- nausea
- vomiting
- loss of appetite
- fast heartbeat
- shortness of breath
- fever, sore throat, cough, chills, and other signs of infection
- lack of energy
- unexplained weight gain
- decrease in amount of urine
- swelling around the feet, ankles, or legs
- drowsiness

Raltegravir may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Do not remove the desiccant (small packet included with the tablets to absorb moisture) from your bottle.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

What other information should I know?

Keep all appointments with your doctor and the laboratory while taking raltegravir. Your doctor will order certain lab tests to check your body's response to raltegravir.

Do not let anyone else take your medication.

Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Isentress[®]
- Isentress[®] HD

Last Revised - 01/15/2022

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National Institutes of Health

Page last updated: 25 March 2022