PATIENT INFORMATION
Raltegravir (ral teg' ra vir) film-coated tablets

What are raltegravir tablets?

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

Before you take raltegravir tablets, tell your doctor 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
- receive kidney dialysis treatment
- are pregnant or plan to become pregnant. It is not known if raltegravir tablets can harm your unborn baby.

  Pregnancy Registry: There is a pregnancy registry for women who take raltegravir tablets 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 raltegravir.
  - 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 raltegravir can pass into your breast milk.
  - 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. Some medicines interact with raltegravir tablets.

- **Keep a list of your medicines to show your doctor and pharmacist.**
- You can ask your doctor or pharmacist for a list of medicines that interact with raltegravir tablets.
- **Do not start taking a new medicine without telling your doctor**. Your doctor can tell you if it is safe to take raltegravir tablets with other medicines.

How should I take raltegravir tablets?

- Take raltegravir tablets exactly as prescribed by your doctor.
- **Do not** change your dose of raltegravir 400 mg film-coated tablets or raltegravir 600 mg film-coated tablets or stop your treatment without talking with your doctor first.
- Stay under the care of your doctor during treatment with raltegravir tablets.
- Raltegravir 600 mg film-coated tablets **must be swallowed whole**.
- **Do not switch between the film-coated tablet, the chewable tablet, or the oral suspension without talking with your doctor first.**
- **Do not** switch between the raltegravir 400 mg film-coated tablets and raltegravir 600 mg film-coated tablets if your prescribed dose is 1200 mg.
- **Do not** run out of raltegravir tablets. The virus in your blood may increase and the virus may become harder to treat. Get a refill of your raltegravir tablets from your doctor or pharmacy before you run out.
- Take raltegravir tablets on a regular dosing schedule as instructed by your doctor. Do not miss doses.
- If you take too much raltegravir tablets, call your doctor or go to the nearest hospital

emergency room right away.

What are the possible side effects of raltegravir tablets?

Raltegravir tablets can cause serious side effects including:

- **Severe skin reactions and allergic reactions.** Some people who take raltegravir tablets 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 raltegravir tablets 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 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 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.

The most common side effects of raltegravir tablets include:

- trouble sleeping
- dizziness
- headache
- nausea
- tiredness

Less common side effects of raltegravir tablets:

- 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 during treatment with raltegravir tablets. 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 tablets.

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 raltegravir tablets?

Raltegravir 600 mg film-coated tablets:

- Store raltegravir tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Store raltegravir tablets in the original package with the bottle tightly closed.

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

General information about the safe and effective use of raltegravir tablets

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use raltegravir tablets for a condition for which it was not prescribed. Do not give raltegravir tablets to other people, even if they have the same symptoms that you have. It may harm them. You can ask your doctor or pharmacist for information about raltegravir tablets that is written for health professionals.

What are the ingredients in raltegravir tablets?

Active ingredient: Raltegravir

Inactive ingredients: croscarmellose sodium, magnesium stearate, microcrystalline cellulose, povidone K30 and tartaric acid.

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

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