**1.5.3 Patient Information Leaflet (PIL) or Package Insert****RALTEGRAVIR TABLETS 400 mg****PACKAGE LEAFLET: INFORMATION FOR THE USER**

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Raltegravir Tablet is and what it is used for
2. What you need to know before you take Raltegravir Tablet
3. How to take Raltegravir Tablet
4. Possible side effects
5. How to store Raltegravir Tablet
6. Contents of the pack and other information

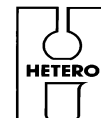
1. WHAT RALTEGRAVIR TABLET IS AND WHAT IT IS USED FOR

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).

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

When used with other HIV medicines to treat HIV-1 infection, RALTEGRAVIR may help:

- reduce the amount of HIV in your blood. This is called “viral load”.
- increase the number of white blood cells called CD4+ (T) cells in your blood, which help fight off other infections.
- reduce the amount of HIV-1 and increase the CD4+ (T) cells in your blood, which may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).



RALTEGRAVIR does not cure HIV-1 infection or AIDS.

You must stay on continuous HIV therapy to control HIV-1 infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others.

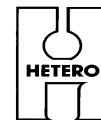
- Do not share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood.

Ask your doctor if you have any questions on how to prevent passing HIV to other people.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RALTEGRAVIR TABLET

Before you take RALTEGRAVIR, tell your doctor 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 any other medical conditions
- are pregnant or plan to become pregnant. It is not known if RALTEGRAVIR can harm your unborn baby. Pregnancy Registry: There is a pregnancy registry for women who take antiviral medicines 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.
 - o You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - o Talk with your doctor about the best way to feed your baby.

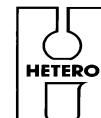


Tell your doctor about all the medicines you take, including, prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with RALTEGRAVIR. Keep a list of your medicines to show your doctor and pharmacist.

- You can ask your doctor or pharmacist for a list of medicines that interact with RALTEGRAVIR.
- Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take RALTEGRAVIR with other medicines.

3. HOW TO TAKE RALTEGRAVIR TABLET

- Take RALTEGRAVIR exactly as prescribed by your doctor.
- Do not change your dose of RALTEGRAVIR or stop your treatment without talking with your doctor first.
- Stay under the care of your doctor while taking RALTEGRAVIR.
- RALTEGRAVIR film-coated tablets must be swallowed whole.
- RALTEGRAVIR chewable tablets may be chewed or swallowed whole.
- RALTEGRAVIR for oral suspension should be given to your child within 30 minutes of mixing. See the detailed Instructions for Use that comes with RALTEGRAVIR for oral suspension, for information about the correct way to mix and give a dose of RALTEGRAVIR for oral suspension. If you have questions about how to mix or give RALTEGRAVIR for oral suspension, talk to your doctor or pharmacist.
- Do not switch between the film-coated tablet, the chewable tablet, or the oral suspension without talking with your doctor first.
- Do not run out of RALTEGRAVIR. Get a refill of your RALTEGRAVIR from your doctor or pharmacy before you run out.
- If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not double your next dose or take more RALTEGRAVIR than prescribed.
- If you take too much RALTEGRAVIR, call your doctor or go to the nearest hospital emergency room right away.



4. POSSIBLE SIDE EFFECTS

RALTEGRAVIR can cause serious side effects including:

- Serious skin reactions and allergic reactions. Some people who take RALTEGRAVIR 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 RALTEGRAVIR and call your doctor right away:

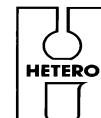
- o fever
- o generally ill feeling
- o extreme tiredness
- o muscle or joint aches
- o blisters or sores in mouth
- o blisters or peeling of the skin
- o redness or swelling of the eyes
- o swelling of the mouth or face
- o problems breathing

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:

- o yellowing of your skin or whites of your eyes
- o dark or tea colored urine
- o pale colored stools (bowel movements)
- o nausea or vomiting
- o loss of appetite
- o 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 include:



- trouble sleeping
- headache
- dizziness
- nausea
- tiredness

Less common side effects of RALTEGRAVIR 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 doctor right away if you get unexplained muscle pain, tenderness, or weakness while taking RALTEGRAVIR. These may be signs of a rare serious muscle problem that can lead to kidney problems.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of RALTEGRAVIR. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA1088.

5. HOW TO STORE RALTEGRAVIR TABLET

Film-Coated Tablets:

- Store RALTEGRAVIR film-coated tablets at room temperature between 68°F to 77°F (20°C to 25°C). Chewable Tablets:

- Store RALTEGRAVIR chewable tablets at room temperature between 68°F to 77°F (20°C to 25°C).



- Store RALTEGRAVIR chewable tablets in the original package with the bottle tightly closed.
- Keep the drying agent (desiccant) in the bottle to protect from moisture. For Oral Suspension:
- Store RALTEGRAVIR 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 RALTEGRAVIR and all medicines out of the reach of children.

General information about RALTEGRAVIR

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use RALTEGRAVIR for a condition for which it was not prescribed. Do not give RALTEGRAVIR to other people, even if they have the same symptoms you have. It may harm them.

You can ask your doctor or pharmacist for information about RALTEGRAVIR that is written for health professionals.

For more information go to www.RALTEGRAVIR.com or call 1-800-622-4477.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What RALTEGRAVIR Tablets 60 mg contains

The active substance is Raltegravir potassium.

Each film coated tablet contains Raltegravir Tablets 400mg.

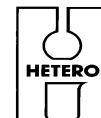
- The other ingredients are:
- Microcrystalline cellulose (Avicel PH 102), Lactose Monohydrate (Supertab 11 SD), Sodium stearyl fumarate, Magnesium stearate, Polyethylene oxide (Polyox WSR 301), Purified Water IHS/USP/Ph.Eur, Opadry II Pink 85F84416 IHS.

What RALTEGRAVIR Tablets 60 mg looks like and contents of the pack

Pink, oval, biconvex film coated tablets debossed with 'I' on one side and '46' on the other side.

Raltegravir Tablets 400mg are available in:

Container pack: 60's HDPE container



Marketing Authorization Holder and Manufacturer

Marketing Authorisation Holder:

Name: Hetero Labs Limited

Business Address: 7-2-A2, Hetero Corporate,
Industrial Estates,
Sanath Nagar,
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Country: INDIA

Manufacturer:

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