



### 1.5.3 Patient Information Leaflet (PIL) or Package Insert

Dolutegravir, Emtricitabine And Tenofovir Alafenamide Tablets 50 mg / 200 mg / 25 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 Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets is and what it is used for
2. What you need to know before you take Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets
3. How to take Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets
4. Possible side effects
5. How to store Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets
6. Contents of the pack and other information

## **1. WHAT DOLUTEGRAVIR, EMTRICITABINE AND TENOFOVIR ALAFENAMIDE TABLETS IS AND WHAT IT IS USED FOR**

### **Dolutegravir:**

Dolutegravir is a prescription medicine that is used to treat Human Immunodeficiency Virus-1 (HIV-1) infection together with:

- other antiretroviral medicines in adults and children who weigh at least 66 pounds (30 kg).



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- rilpivirine in adults to replace their current anti-HIV-1 medicines when their healthcare provider determines that they meet certain requirements.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

It is not known if Dolutegravir is safe and effective in children who weigh less than 66 pounds (30 kg) or in children who have received certain types of medicine for HIV-1 infection.

**Emtricitabine and Tenofovir Alafenamide**

Emtricitabine and Tenofovir Alafenamide is a prescription medicine that is used to treat Human Immunodeficiency Virus-1 (HIV-1):

- in adults and children who weigh at least 77 pounds (35 kg) together with other anti-HIV-1 medicines
- in children who weigh at least 55 pounds (25 kg) and less than 77 pounds (35 kg) together with certain other anti-HIV-1 medicines. Your healthcare provider will determine which other anti- HIV-1 medicines are used with Emtricitabine And Tenofovir Alafenamide .

HIV-1 is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

Emtricitabine And Tenofovir Alafenamide is not for use to help reduce the risk of getting HIV-1 infection by sexual contact in adults at high risk.

Emtricitabine And Tenofovir Alafenamide contains the prescription medicines emtricitabine (EMTRIVA) and tenofovir alafenamide.

It is not known if Emtricitabine And Tenofovir Alafenamide is safe and effective in children who weigh less than 55 pounds (25 kg).

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DOLUTEGRAVIR, EMTRICITABINE AND TENOFOVIR ALAFENAMIDE TABLETS**

**Dolutegravir:**

**Before you take Dolutegravir , tell your healthcare provider about all of your medical conditions , including if you:**

- have ever had an allergic reaction to dolutegravir.
- have or have had liver problems, including hepatitis B or C infection.



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- are pregnant or plan to become pregnant. Dolutegravir may harm your unborn baby.
- You should not take Dolutegravir at the time of becoming pregnant or during the first 12 weeks of pregnancy. Your healthcare provider may change your medicine during this time in your pregnancy.
- If you can become pregnant, your healthcare provider will perform a pregnancy test before you start treatment with Dolutegravir.
- If you can become pregnant, you should consistently use effective birth control (contraception) during treatment with Dolutegravir.
- Tell your healthcare provider right away if you are planning to become pregnant, you become pregnant, or think you may be pregnant during treatment with Dolutegravir .

Pregnancy Registry. There is a pregnancy registry for individuals who take antiretroviral medicines, including Dolutegravir , during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines interact with Dolutegravir . Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

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

**Emtricitabine and Tenofovir Alafenamide:**

**Before taking Emtricitabine and Tenofovir Alafenamide, tell your healthcare provider about all of your medical conditions , including if you:**

- have liver problems, including hepatitis B virus infection
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if Emtricitabine and Tenofovir Alafenamide can harm your unborn baby. Tell your healthcare provider if



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you become pregnant during treatment with Emtricitabine and Tenofovir Alafenamide.

Pregnancy Registry: There is a pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. Do not breastfeed if you take Emtricitabine and Tenofovir Alafenamide .
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - At least one of the medicines in Emtricitabine and Tenofovir Alafenamide can pass to your baby in your breast milk. It is not known if the other medicine in Emtricitabine and Tenofovir Alafenamide can pass into your breast milk.

Talk with your healthcare provider about the best way to feed your baby during treatment with Emtricitabine and Tenofovir Alafenamide .

Tell your healthcare provider about all the medicines you take, including prescription and over-the counter medicines, vitamins, and herbal supplements.

Some medicines may interact with Emtricitabine and Tenofovir Alafenamide . Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

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

### **3. HOW TO TAKE DOLUTEGRAVIR, EMTRICITABINE AND TENOFOVIR ALAFENAMIDE TABLETS**

#### **Dolutegravir**

- Take Dolutegravir exactly as your healthcare provider tells you to take it.



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- Take Dolutegravir with or without food.
- Do not change your dose or stop taking Dolutegravir without talking with your healthcare provider.
- If you take antacids, laxatives, or other medicines that contain aluminum, magnesium, or buffered medicines, Dolutegravir should be taken at least 2 hours before or 6 hours after you take these medicines.
- If you need to take iron or calcium supplements by mouth during treatment with Dolutegravir :
- If you take Dolutegravir with food, you may take these supplements at the same time that you take Dolutegravir .
- If you do not take Dolutegravir with food, take Dolutegravir at least 2 hours before or 6 hours after you take these supplements.

**Emtricitabine And Tenofovir Alafenamide**

Take Emtricitabine and Tenofovir Alafenamide exactly as your healthcare provider tells you to take it. Emtricitabine and Tenofovir Alafenamide must be taken together with other HIV-1 medicines to treat HIV-1 infection.

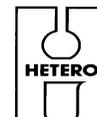
Take Emtricitabine and Tenofovir Alafenamide 1 time each day with or without food.

Do not change your dose or stop taking Emtricitabine and Tenofovir Alafenamide without first talking with your healthcare provider. Stay under a healthcare provider's care during treatment with Emtricitabine and Tenofovir Alafenamide.

Do not miss a dose of Emtricitabine and Tenofovir Alafenamide.

If you take too much Emtricitabine and Tenofovir Alafenamide, call your healthcare provider or go to the nearest hospital emergency room right away.

When your Emtricitabine and Tenofovir Alafenamide supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to Emtricitabine and Tenofovir Alafenamide and become harder to treat.



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**4. POSSIBLE SIDE EFFECTS**

**Dolutegravir can cause serious side effects including:**

Allergic reactions .Call your healthcare provider right away if you develop a rash with Dolutegravir .Stop taking Dolutegravir and get medical help right away if you develop a rash with any of the following signs or symptoms :

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

Liver problems . People with a history of hepatitis B or C virus may have an increased risk of developing new or worsening changes in certain liver tests during treatment with Dolutegravir .

Liver problems, including liver failure, have also happened in people without a history of liver disease or other risk factors. Your healthcare provider may do blood tests to check your liver. Call your healthcare provider right away if you develop any of the following signs or symptoms of liver problems :

<ul style="list-style-type: none"> <li>• your skin or the white part of your eyes turns yellow (jaundice)</li> </ul>	<ul style="list-style-type: none"> <li>• nausea or vomiting</li> </ul>
<ul style="list-style-type: none"> <li>• dark or “tea-colored” urine</li> </ul>	<ul style="list-style-type: none"> <li>• loss of appetite</li> </ul>
<ul style="list-style-type: none"> <li>• light-colored stools (bowel movements)</li> </ul>	<ul style="list-style-type: none"> <li>• pain, aching, or tenderness on the right side of your stomach area</li> </ul>

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 healthcare provider right away if you start having new symptoms after you start taking Dolutegravir .


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**The most common side effects of Dolutegravir include:**

- |                    |             |            |
|--------------------|-------------|------------|
| • trouble sleeping | • tiredness | • headache |
|--------------------|-------------|------------|

These are not all the possible side effects of Dolutegravir . Call your doctor for medical advice about side effects. You may report side effects to FDA at 1 800 FDA 1088.

Emtricitabine and Tenofovir Alafenamide may cause serious side effects , including:

**See "What is the most important information I should know about EMTRICITABINE AND TENOFOVIR ALAFENAMIDE ?"**

**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 healthcare provider right away if you start having any new symptoms after starting your HIV-1 medicine.

**New or worse kidney problems** , including kidney failure. Your healthcare provider should do blood and urine tests to check your kidneys before you start and during treatment with Emtricitabine and Tenofovir Alafenamide . Your healthcare provider may tell you to stop taking Emtricitabine and Tenofovir Alafenamide if you develop new or worse kidney problems.

**Too much lactic acid in your blood (lactic acidosis )**. Too much lactic acid is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.

**Severe liver problems**. In rare cases, severe liver problems can happen that can lead to death. Tell your healthcare provider right away if you get these symptoms: skin or the white part of your eyes turns yellow, dark "tea-colored" urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-area pain.

**The most common side effect of EMTRICITABINE AND TENOFOVIR ALAFENAMIDE is nausea.**

These are not all the possible side effects of Emtricitabine and Tenofovir Alafenamide .

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



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1-800-FDA-1088.

**5. HOW TO STORE DOLUTEGRAVIR, EMTRICITABINE AND TENOFOVIR ALAFENAMIDE TABLETS**

Store below 30°C and protect from moisture

**6. CONTENTS OF THE PACK AND OTHER INFORMATION**

**What Dolutegravir, Emtricitabine And Tenofovir Alafenamide Tablets 50 mg / 200 mg / 25 mg contains**

The active substance is Dolutegravir Sodium, Emtricitabine and Tenofovir alafenamide hemifumarate

Each film coated tablet contains Dolutegravir 50 mg equivalent to 52.60 mg of Dolutegravir sodium, Emtricitabine 200 mg and Tenofovir alafenamide 25 mg equivalent to 28.043 mg of Tenofovir alafenamide hemifumarate.

The other ingredients are:

- Microcrystalline cellulose (Avicel PH 112), Croscarmellose Sodium, USP/NF (Ac-di-sol), Magnesium stearate, Mannitol USP (Mannogem Powder), Sodium starch glycolate Type A, USP/NF (Primogel), Povidone, USP (Kollidon 30), Sodium stearyl fumarate, USP/NF, Purified Water IHS/USP/Ph.Eur, Opadry II white 85F18422, IHS

**What Dolutegravir, Emtricitabine And Tenofovir Alafenamide Tablets 50 mg / 200 mg / 25 mg looks like and contents of the pack**

White to off white, capsule shaped film coated tablets, debossed with "T47" on one side and "H" on other side.

**Dolutegravir, Emtricitabine And Tenofovir Alafenamide Tablets 50 mg / 200 mg / 25 mg are available in:**

Container pack: 30's HDPE container and 100's HDPE container

**Marketing Authorization Holder and Manufacturer**

**Marketing Authorisation Holder:**

**Name: Hetero Labs Limited**

**Hetero Labs Limited, India**



**Module 1 - Administrative Information and Product Information**

**Business Address:** 7-2-A2, Hetero Corporate,  
Industrial Estates,  
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Hyderabad-500 018  
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**Country:** INDIA

**Manufacturer:**

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Telangana.

**Country:** INDIA

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