

**PATIENT INFORMATION**

**Dolutegravir (doe loo TEG ra vir) and Lamivudine (la MI vyou deen) Tablets**

**What is the most important information I should know about Dolutegravir and Lamivudine Tablets?**

**If you have both human immunodeficiency virus-1 (HIV-1) and hepatitis B virus (HBV) infection, Dolutegravir and Lamivudine Tablets can cause serious side effects, including:**

- **Resistant HBV infection.** Your healthcare provider will test you for HBV infection before you start treatment with Dolutegravir and Lamivudine Tablets. If you have HIV-1 and hepatitis B, the hepatitis B virus can change (mutate) during your treatment with Dolutegravir and Lamivudine Tablets and become harder to treat (resistant). It is not known if Dolutegravir and Lamivudine Tablet is safe and effective in people who have HIV-1 and HBV infection.
- **Worsening of HBV infection.** If you have HIV-1 and HBV infection, your HBV may get worse (flare-up) if you stop taking Dolutegravir and Lamivudine Tablets. A “flare-up” is when your HBV infection suddenly returns in a worse way than before. Worsening liver disease can be serious and may lead to death.
  - Do not run out of Dolutegravir and Lamivudine Tablets. Refill your prescription or talk to your healthcare provider before your Dolutegravir and Lamivudine Tablet is all gone.
  - **Do not stop Dolutegravir and Lamivudine Tablets without first talking to your healthcare provider.** If you stop taking Dolutegravir and Lamivudine Tablets, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver.

**What is Dolutegravir and Lamivudine Tablets?**

Dolutegravir and Lamivudine Tablet is a prescription medicine that is used without other antiretroviral medicines to treat HIV-1 infection in adults:

- who have not received antiretroviral medicines in the past, **and**
- without known resistance to the medicines dolutegravir or lamivudine.

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

It is not known if Dolutegravir and Lamivudine Tablet is safe and effective in children.

**Do not take Dolutegravir and Lamivudine Tablets if you:**

- have ever had an allergic reaction to a medicine that contains dolutegravir or lamivudine.
- take dofetilide.

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

- have or have had liver problems, including hepatitis B or C infection.
- have kidney problems.
- are pregnant or plan to become pregnant. One of the medicines in Dolutegravir and Lamivudine Tablet (dolutegravir) may harm your unborn baby.
  - **You should not take Dolutegravir and Lamivudine Tablets if you are planning to become pregnant or during the first 12 weeks of pregnancy.** Your healthcare provider may prescribe a different medicine if you are planning to become pregnant or become pregnant during treatment with Dolutegravir and Lamivudine Tablets.
  - If you can become pregnant, your healthcare provider will perform a pregnancy test before you start treatment with Dolutegravir and Lamivudine Tablets.
  - If you can become pregnant, you should consistently use effective birth control (contraception) during treatment with Dolutegravir and Lamivudine Tablets.
  - 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 and Lamivudine Tablets. **Pregnancy Registry.** There is a pregnancy registry for people who take antiretroviral medicines, including Dolutegravir and Lamivudine Tablets, 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 Dolutegravir and Lamivudine Tablets.**
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - One of the medicines in Dolutegravir and Lamivudine Tablet (lamivudine) passes into your breast milk.
  - Talk with your healthcare provider about the best way to feed your baby.

**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 and Lamivudine Tablets. 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 and Lamivudine Tablets.
- **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 and Lamivudine Tablets with other medicines.

### **How should I take Dolutegravir and Lamivudine Tablets?**

- **Take Dolutegravir and Lamivudine Tablets 1 time a day exactly as your healthcare provider tells you.**
- Take Dolutegravir and Lamivudine Tablets with or without food.
- Do not change your dose or stop taking Dolutegravir and Lamivudine Tablets without talking with your healthcare provider.
- If you take antacids, laxatives, or other medicines that contain aluminum, magnesium, or buffered medicines, Dolutegravir and Lamivudine Tablets 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, including multivitamins that contain iron or calcium, by mouth during treatment with Dolutegravir and Lamivudine Tablets:
  - You may take these supplements at the same time that you take Dolutegravir and Lamivudine

Tablets with food.

- If you do not take these supplements with Dolutegravir and Lamivudine Tablets and food, take Dolutegravir and Lamivudine Tablets at least 2 hours before or 6 hours after you take these supplements.
- Do not miss a dose of Dolutegravir and Lamivudine Tablets. If you miss a dose of Dolutegravir and Lamivudine Tablets, take it as soon as you remember. Do not take 2 doses at the same time or take more than your prescribed dose.
- Stay under the care of a healthcare provider during treatment with Dolutegravir and Lamivudine Tablets.
- Do not run out of Dolutegravir and Lamivudine Tablets. The virus in your blood may increase and the virus may become harder to treat. When your supply starts to run low, get more from your healthcare provider or pharmacy.
- If you take too much Dolutegravir and Lamivudine Tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

### **What are the possible side effects of Dolutegravir and Lamivudine Tablets?**

**Dolutegravir and Lamivudine Tablets can cause serious side effects, including:**

- See “**What is the most important information I should know about Dolutegravir and Lamivudine Tablets?**”
- **Allergic reactions. Call your healthcare provider right away if you develop a rash with Dolutegravir and Lamivudine Tablets. Stop taking Dolutegravir and Lamivudine Tablets and get medical help right away if you develop a rash with any of the following signs or symptoms:**
  - fever
  - generally ill feeling
  - 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, face, lips, or tongue
  - 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 and Lamivudine Tablets. 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.

**Tell your healthcare provider right away if you get any of the following signs or symptoms of liver problems:**

  - your skin or the white part of your eyes turns yellow (jaundice)
  - dark or “tea-colored” urine
  - light-colored stools (bowel movements)
  - nausea or vomiting
  - loss of appetite
  - pain, aching, or tenderness on the right side of your stomach area
- **Too much lactic acid in your blood (lactic acidosis).** Lactic acidosis is a serious medical emergency that can lead to death.

**Tell your healthcare provider right away if you get any of the following symptoms that could be signs of lactic acidosis:**

  - feel very weak or tired
  - feel cold, especially in your arms and legs

- unusual (not normal) muscle pain
- trouble breathing
- stomach pain with nausea and vomiting
- feel dizzy or light-headed
- have a fast or irregular heartbeat

- **Lactic acidosis can also lead to severe liver problems**, which can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). **Tell your healthcare provider right away if you get any of the signs or symptoms of liver problems which are listed above under “Liver problems”.** You may be more likely to get lactic acidosis or severe liver problems if you are female or very overweight (obese).
- **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 and Lamivudine Tablets.
- **The most common side effects of Dolutegravir and Lamivudine Tablets include:**
  - headache
  - diarrhea
  - nausea
  - trouble sleeping
  - tiredness

These are not all the possible side effects of Dolutegravir and Lamivudine 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 Dolutegravir and Lamivudine Tablets?**

- Store Dolutegravir and Lamivudine Tablets below 86°F (30°C).
- Dolutegravir and Lamivudine Tablet comes in a non-child-resistant package.

**Keep Dolutegravir and Lamivudine Tablets and all medicines out of the reach of children.**

#### **General information about the safe and effective use of Dolutegravir and Lamivudine Tablets.**

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

#### **What are the ingredients in Dolutegravir and Lamivudine Tablets?**

**Active ingredients:** dolutegravir and lamivudine.

**Inactive ingredients:** colloidal silicon dioxide, mannitol, microcrystalline cellulose, povidone PVPK 30, purified water, sodium starch glycolate, sodium stearyl fumarate.

**The tablet film-coating contains:** ferrousferic oxide, hypromellose, macrogol, polysorbate 80, titanium dioxide.

**This product has been manufactured under license from the Medicines Patent Pool.**

**Any other use is not authorized.**

**Manufactured by:**

Cipla Limited  
Verna Industrial Estate,  
Goa 403722

For more information call 1-866-604-3268.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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**DOLUTEGRAVIR AND LAMIVUDINE TABLETS 50/300 mg**

**MODULE 1: ADMINISTRATIVE INFORMATION AND PRESCRIBED INFORMATION**

**1.6.2 Container labelling**

-Label artwork enclosed (Pack size of 30s)