

## Package leaflet: Information for the patient

### **Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets 50 mg/300 mg /300 mg**

**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, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets are and what it is used for
2. What you need to know before you take dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets
3. How to take dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets
4. Possible side effects
5. How to store dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets
6. Contents of the pack and other information

#### **1. What dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets are and what it is used for**

Dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets are a prescription medicine that is used alone as a complete regimen to treat Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and children who weigh 88 pounds (40 kg) or more.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). Dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets contain 3 prescription medicines, dolutegravir, lamivudine and tenofovir disoproxil fumarate.

- Dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets are not for use by themselves in people who have or have had resistance to dolutegravir, lamivudine, or tenofovir disoproxil fumarate.

Dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets may reduce the amount of HIV in your blood (called “viral load”). Dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets may also help to increase the number of CD4 (T) cells in your blood which help fight off other infections. Reducing the amount of HIV and increasing the CD4 (T) cell count may improve your immune system. This may reduce your risk of death or infections that can happen when your immune system is weak (opportunistic infections).

It is not known if dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets are safe and effective in children who weigh less than 88 pounds or in children who have received certain types of medicine for HIV-1 infection.

**Dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets do not cure HIV infection or AIDS.** You must keep taking HIV-1 medicines 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 safer 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 healthcare provider if you have any questions about how to prevent passing HIV to other people.

## **2. What you need to know before you take dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets**

### **Do not take dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets**

- if you take dofetilide. Taking dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets and dofetilide can cause side effects that may be serious or life-threatening.
- if you are allergic to dolutegravir or any of the ingredients in dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets. See the end of this Patient Information leaflet for a complete list of ingredients in dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets.

### **Take special care with dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets**

#### **Before you take dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets, tell your healthcare provider if you:**

- have had liver problems, including hepatitis B or C infection.
- have kidney problems.
- have bone problems.
- have any other medical condition.
- are pregnant or plan to become pregnant. It is not known if dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets will harm your unborn baby. Tell your healthcare provider if you become pregnant.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets.**
  - you should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby. Talk with your healthcare provider about the best way to feed your baby.

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

Some medicines interact with dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets. Keep a list of your medicines and show it to your healthcare provider and pharmacist. You can ask your healthcare provider or pharmacist for a list of medicines that interact with dolutegravir, lamivudine and tenofovir disoproxil fumarate 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, lamivudine and tenofovir disoproxil fumarate tablets with other medicines.

## Taking other medicines

**You should not take dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets if you also take:**

- abacavir
- lamivudine
- emtricitabine
- tenofovir
- adefovir

**Tell your healthcare provider if you take:**

- antacids, laxatives, or other medicines that contain aluminum, magnesium, sucralfate, or buffered medicines. Dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets should be taken at least 2 hours before or 6 hours after you take these medicines.
- anti-seizure medicines:
  - oxcarbazepine
  - phenytoin
  - phenobarbital
  - carbamazepine
- any other medicine to treat HIV-1
- iron or calcium supplements taken by mouth. Supplements containing calcium or iron may be taken at the same time with dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets if taken with food. Otherwise, dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets should be taken at least 2 hours before or 6 hours after you take these medicines.
- medicines used to treat hepatitis virus infections, such as interferon or ribavirin
- a medicine that contains metformin
- rifampin
- St. John's wort (*Hypericum perforatum*)
- didanosine
- atazanavir
- darunavir
- lopinavir with ritonavir
- ledipasvir with sofosbuvir

## Pregnancy

If you are pregnant, if you become pregnant, or if you are planning to have a baby:

- **Talk to your doctor** about the risks and benefits of taking dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets.

## Breast-feeding

**Women who are HIV-positive must not breast feed** because HIV infection can be passed on to the baby in breast milk.

**It is not known** whether the ingredients of dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets can pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding:

- **Talk to your doctor immediately.**

### **Driving and using machines**

Dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets can make you dizzy and have other side effects that make you less alert.

→ Don't drive or operate machinery unless you are sure you're not affected.

### **Important information about some of the ingredients of dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets**

This medicine contains lactose and mannitol. Tell your doctor before taking dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets if you cannot tolerate lactose or if you have an intolerance to any other sugars.

This medicine also contains. Mannitol may have a mild laxative effect.

### **3. How to take dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

For adults and children weighing 40 kg (88 lbs) or more, the usual dose of dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets is one tablet each day. An extra dose of dolutegravir only may be necessary for certain populations. Your healthcare provider will inform you if you need to take the extra dolutegravir dose.

Stay under the care of a healthcare provider during treatment with dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets.

Dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets may be taken with or without food.

### **Use in children**

Dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets should not be administered to pediatric patients weighing less than 40 kg (88 lbs).

### **If you take more dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets than you should**

If you take too many tablets of dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets, **contact your doctor or pharmacist for advice** or go to the nearest hospital emergency room right away.

### **If you forget to take dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets**

If you miss a dose of dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets, take it as soon as you remember. Do not take 2 doses at the same time or take more than what your healthcare provider tells you to take.

### **Don't stop taking dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets without advice from your doctor**

Take dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets for as long as your doctor recommends. Don't stop unless your doctor advises you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, but not everybody gets them.

**Dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets can cause serious side effects including:**

**Build-up of an acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets. Lactic acidosis is a serious medical emergency that can cause death. **Call 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
- unusual (not normal) muscle pain
- trouble breathing
- stomach pain with nausea and vomiting
- feel cold, especially in your arms and legs
- feel dizzy or light-headed
- have a fast or irregular heartbeat

**Serious liver problems** can happen in people who take dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets. In some cases these serious liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). **Call 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)
- loss of appetite for several days or longer
- nausea
- pain, aching, or tenderness on the right side of your stomach area

**You may be more likely to get lactic acidosis or serious liver problems if you are female, very overweight (obese), or have been taking nucleoside analog medicines for a long time.**

- **Worsening of hepatitis B virus in people who have HIV-1 infection.** If you have HIV-1 (Human Immunodeficiency Virus type 1) and hepatitis B virus (HBV) infection, your HBV may get worse (flare-up) if you stop taking dolutegravir, lamivudine and tenofovir disoproxil fumarate 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, lamivudine and tenofovir disoproxil fumarate tablets. Refill your prescription or talk to your healthcare provider before your dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets are all gone.
  - Do not stop dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets without first talking to your healthcare provider.
  - If you stop taking dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking

dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets.

- **Resistant Hepatitis B Virus (HBV).** If you have HIV-1 and hepatitis B, the hepatitis B virus can change (mutate) during your treatment with dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets and become harder to treat (resistant).
- **Allergic reactions.** Call your healthcare provider right away if you develop a rash with dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets. **Stop taking dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets and get medical help right away if you:**
  - **develop a rash with any of the following signs or symptoms:**
    - 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, face, lips, or tongue
    - problems breathing
- **Use with interferon and ribavirin-based regimens.** Worsening of liver disease that has caused death has happened in people infected with both HIV-1 and hepatitis C virus who are taking antiretroviral medicines and are also being treated for hepatitis C with interferon with or without ribavirin. If you are taking dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets and interferon with or without ribavirin, tell your healthcare provider if you have any new symptoms.
- **Changes in liver tests.** 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, lamivudine and tenofovir disoproxil fumarate tablets. Your healthcare provider may do tests to check your liver function before and during treatment with dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets.
- **Risk of inflammation of the pancreas (pancreatitis).** Children may be at risk for developing pancreatitis during treatment with lamivudine if they:
  - have taken nucleoside analogue medicines in the past
  - have a history of pancreatitis
  - have other risk factors for pancreatitis

**Call your healthcare provider right away if your child develops signs and symptoms of pancreatitis including severe upper stomach-area pain, with or without nausea and vomiting.** Your healthcare provider may tell you to stop giving dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets to your child if their symptoms and blood test results show that your child may have pancreatitis.

- **New or worse kidney problems, including kidney failure,** can happen in some people who take dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets. If you have had kidney problems in the past or need to take another medicine that can cause kidney problems, your healthcare provider may need to do blood tests to check your kidneys during your treatment with dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets.
- **Bone problems** can happen in some people who take dolutegravir, lamivudine and

tenofovir disoproxil fumarate tablets. Bone problems include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do additional tests to check your bones.

- **Changes in body fat can happen in people who take HIV-1 medicines.** These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these problems are not known.
- **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, lamivudine and tenofovir disoproxil fumarate tablets.

**The most common side effects of dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets include:**

- trouble sleeping
- nausea
- diarrhea
- pain
- depression
- tiredness
- generally not feeling well
- cough
- weakness
- headache
- nasal signs and symptoms
- rash

**The most common side effects of dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets in children include fever and cough.**

These are not all the possible side effects of dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets.

If you have any further questions on the use of this product, ask your health care provider.

## **5. How to store dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets**

Do not store above 30°C. Store in the original container.

Keep the bottle tightly closed. Do not remove desiccant.

Do not use this medicine after the expiry date which is stated after EXP on the carton and bottle.

Keep out the reach and sight of children.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets contains

- **The active substances are** dolutegravir, lamivudine and tenofovir disoproxil fumarate.  
Each film-coated tablet contains Dolutegravir sodium equivalent to Dolutegravir 50 mg, Lamivudine USP 300 mg, Tenofovir Disoproxil Fumarate 300 mg equivalent to tenofovir disoproxil 245 mg.
- **The other ingredients are** Mannitol, microcrystalline cellulose, sodium starch glycolate, povidone, lactose monohydrate, pregelatinized starch, croscarmellose sodium and sodium stearyl fumarate, polyvinyl alcohol, titanium dioxide, macrogol and talc.

### What dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets looks like and contents of the pack

Dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets are white colored, oval shaped, biconvex, film coated tablets, debossed with 'LA75' on one side and plain on the other side.

Dolutegravir, lamivudine and tenofovir disoproxil fumarate tablets are supplied in bottles containing 30 & 90 tablets.

**30's Count:** White opaque 100 cc HDPE bottles filled with 1gm silica gel canister closed with 38 mm child resistant closures.

**90's Count:** White opaque 250 cc HDPE bottles filled with 1gm silica gel canister closed with 53 mm child resistant closures.

### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Laurus Labs Limited,  
2<sup>nd</sup> Floor, Serene Chambers, Road No.-7,  
Banjara Hills, Hyderabad, Telangana – 500034.  
India.

### Manufacturer:

Laurus Labs Limited, (Unit-2),  
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Andhra Pradesh, India.

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