

Patient Information Leaflet
Dolutegravir 50 mg tablets
(Dolutegravir)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or nurse.
- 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- a) What Dolutegravir Tablets is and what it is used for**
- B) Before you take Dolutegravir Tablets**
- C) How to take Dolutegravir Tablets?**
- D) Possible side effects**
- E) How to store Dolutegravir Tablets?**
- F) Further information**

a) What Dolutegravir Tablets is and what it is used for

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

- other HIV-1 medicines in adults who have not received HIV-1 medicines in the past or to replace their current HIV-1 medicines.
- other HIV-1 medicines in children, weighing at least 14 kg, who have not received HIV-1 medicines in the past or to replace their current HIV-1 medicines when their healthcare provider determines that they meet certain requirements.

Dolutegravir is used together with rilpivirine as a complete regimen to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults to replace their current 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 tablets are safe and effective in children who weigh less than 31 pounds (14 kg) or in children who have received certain types of medicine for HIV-1 infection.

b) Before you take Dolutegravir Tablets?

Do not take dolutegravir tablets if you

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

Take special care with dolutegravir tablets

Before you take dolutegravir 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.

Taking other medicines

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 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 tablet with other medicines.

Taking dolutegravir tablets with food and drink

Take dolutegravir tablets with or without food.

Pregnancy and breast-feeding

- are pregnant or plan to become pregnant. Dolutegravir may harm your unborn baby.
 - Your healthcare provider may prescribe a different medicine than dolutegravir if you are planning to become pregnant or if pregnancy is confirmed during the first 12 weeks of pregnancy.
 - If you can become pregnant, your healthcare provider may perform a pregnancy test before you start treatment with dolutegravir.
 - If you can become pregnant, you and your healthcare provider should talk about the use of 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.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take dolutegravir tablets.**
 - 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 dolutegravir can pass to your baby in your breast milk.
 - Talk with your healthcare provider about the best way to feed your baby.

Driving and using machines

Dolutegravir 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.

c) How to take Dolutegravir Tablets

- **Take dolutegravir tablet exactly as your healthcare provider tells you to take it.**
- Take dolutegravir tablets with or without food.
- **Dolutegravir tablets are not the same as Tivicay PD tablets for oral suspension and cannot be substituted for each other. Check to make sure you receive the correct form of dolutegravir each time you or your child's prescription is filled to avoid using the wrong medicine.**
- Do not change your dose, switch medicines or stop taking dolutegravir tablets without talking with your healthcare provider first.

- If you take antacids, laxatives, or other medicines that contain aluminum, magnesium, or buffered medicines, dolutegravir 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 by mouth during treatment with dolutegravir tablets:
 - If you take dolutegravir tablets with food, you may take these supplements at the same time that you take dolutegravir tablets.
 - If you do not take dolutegravir tablets with food, take dolutegravir tablets at least 2 hours before or 6 hours after you take these supplements.

If you take more dolutegravir tablets than you should

- If you take too much dolutegravir tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

If you forget to take dolutegravir tablets

- Do not miss a dose of dolutegravir tablets.
- If you miss a dose of dolutegravir tablets, take it as soon as you remember. Do not take 2 doses at the same time or take more than your prescribed dose.

If you stop taking dolutegravir tablets

- Do not run out of dolutegravir 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.

d) Possible side effects

- **Dolutegravir tablet can cause serious side effects including:**
- **Allergic reactions.** Call your healthcare provider right away if you develop a rash with dolutegravir tablets. **Stop taking dolutegravir tablets and get medical help right away if you develop a rash with any of the following signs or symptoms:**

○ fever	○ blisters or peeling of the skin
○ generally ill feeling	○ redness or swelling of the eyes
○ tiredness	○ swelling of the mouth, face, lips, or tongue
○ muscle or joint aches	○ problems breathing
○ blisters or sores in mouth	
- **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 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. **Call your healthcare provider right away if you develop any of the following signs or symptoms of liver problems:**

○ your skin or the white part of your eyes turns yellow (jaundice)	○ nausea or vomiting
○ dark or “tea-colored” urine	○ loss of appetite
○ light-colored stools (bowel movements)	○ 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 healthcare provider right away if you start having new symptoms after you start taking dolutegravir tablets.

- **The most common side effects of dolutegravir tablet include:**
 - trouble sleeping
 - tiredness
 - headache

These are not all the possible side effects of dolutegravir tablet. Call your doctor for medical advice about side effects. You may report side effects to local reporting system.

e) How to store Dolutegravir Tablets

Do not store above 30°C.

Keep dolutegravir tablets and all medicines out of the reach of children.

General information about the safe and effective use of dolutegravir tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use dolutegravir tablets for a condition for which it was not prescribed. Do not give dolutegravir tablets to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about dolutegravir tablet that is written for health professionals. For more information, call 1-866-604-3268.

f) Further information

What dolutegravir tablets contains

Active ingredient: dolutegravir sodium.

Inactive ingredients: ‘, mannitol, microcrystalline cellulose, povidone, sodium starch glycolate, and sodium stearyl fumarate. The tablet film-coating contains the inactive ingredients iron oxide red, iron oxide yellow, macrogol/PEG, polyvinyl alcohol-part hydrolyzed, talc, and titanium dioxide.

What dolutegravir tablets looks like and contents of the pack

Brown coloured, round shaped biconvex film coated tablet debossed with “C 50” on one side and plain on other side.

Content: HDPE container of 30’s and 90’s tablets.

Name and full physical address of Marketing Authorization Holder and Manufacturing site:

Marketing Authorization Holder:

Cipla Ltd., Cipla House,
Peninsula Business Park, Ganpatrao Kadam Marg,
Lower Parel, Mumbai – 400013.India

Manufactured by:

Cipla Limited
Indore SEZ. Pithampur
Madhya Pradesh – 454775.
INDIA

This leaflet was last approved in 01/2024