Package leaflet: Information for the patient

Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate 50mg/300mg/300mg Tablets

Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4.

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 (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablet is and what it is used for

Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablet contains the active ingredient dolutegravir, lamivudine and tenofovir disoproxil fumarate. Dolutegravir belongs to a group of anti-retroviral medicines called *integrase inhibitors (INIs)*. Lamivudine belongs to the class of nucleoside reverse transcriptase inhibitor. Tenofovir disoproxil fumarate belongs to the class of nucleoside reverse transcriptase inhibitor.

Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablet is used to treat HIV-1 (human immunodeficiency virus type-1) infection in adults and paediatric patients weighing at least 40 kg.

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

Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets do not cure HIV-1 infection; it reduces the amount of virus in your blood, and keeps it at a low level. As a result of that, it also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

Not everyone responds to treatment with dolutegravir, lamivudine and tenofovir disoproxil fumarate in the same way. Your doctor will monitor the effectiveness of your treatment.

2. What you need to know before you take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets

Do not take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets:
- if you have ever had an allergic reaction to a medicine that contains dolutegravir, lamivudine or tenofovir disoproxil fumarate (ATRIPLA®, COMBIVIR, COMPLERA®, DESCOVY®, EPIVIR, EPIVIR-HBV, EPZICOM, GENVOYA®, ODEFSEY®, STRIBILD®, TIVICAY, TRIUMEQ®, TRUVADA®, VEMLIDY® or VIREAD).
- if you take adefovir (HEPSERA®)
- if you take dofetilide.

If you think any of these apply to you, tell your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before taking Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets, if you:

- have ever had an allergic reaction to Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets.
- have or had liver problems, including hepatitis B or C infection.
- have kidney problems.
- have bone problems.
- have any other medical condition.
- are breastfeeding or plan to breastfeed. 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.

Children
Do not give this medicine to children weighing less than 40 kg or with HIV-1 infection that is resistant to other medicines similar to Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets.

Other medicines and Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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. 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 (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets.

Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets may affect the way other medicines work, and other medicines may affect how dolutegravir, lamivudine and tenofovir disoproxil fumarate works.

Especially tell your healthcare provider if you take the following medications.
- didanosine (Videx, Videx EC)
- atazanavir (Reyataz)
- darunavir (Prezista)
- lopinavir with ritonavir (Kaletra)

- ledipasvir with sofosbuvir (HARVONI®)
- sofosbuvir with velpatasvir (EPCLUSA®)

- If you take antacids, laxatives, or other medicines that contain aluminum, magnesium, or buffered medicines, Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate 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 (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets:
  - If you take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets with food, you may take these supplements at the same time that you take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets.
  - If you do not take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets with food, take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets at least 2 hours before or 6 hours after you take these supplements.

Do not start taking a new medicine without telling your doctor or pharmacist. Your doctor or pharmacist can tell you if it is safe to take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets with other medicines.

Ask your doctor or pharmacist if you are not sure if your medicine is one that is listed above.

Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets with food
Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets can be taken with or without food.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not known if dolutegravir and tenofovir disoproxil fumarate will harm your unborn baby. Taking lamivudine during pregnancy has not been associated with an increased risk of birth defects.

You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby. Talk to your doctor or pharmacist about the best way to feed your baby.

Driving and using machines
Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets can make you dizzy and have other side effects that make you less alert.
- Do not drive or ride a bicycle or operate machinery unless you are sure you are not affected.

Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablet contains mannitol

Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets contains mannitol. Patients may have a mild laxative effect.

3. How to take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets

Always take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose in adults is one Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate 50 mg/300 mg/300 mg tablet once a day
- Stay under the care of a doctor or pharmacist while taking Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets.

Use in children and adolescents

Children and adolescents weighing at least 40 kg can take the adult dose of one Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate 50 mg/300 mg/300 mg tablet, once a day. Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets should not be used in children and adolescents with HIV-1 infection that is resistant to other medicines similar to Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets.

If you take more Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets than you should

If you take too much Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets, call your doctor or pharmacist or go to the nearest hospital emergency room right away.

If you forget to take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets

If you miss a dose of Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets, take it as soon as you remember. But if your next dose is due within 4 hours, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before. Do not take a double dose to make up for a forgotten dose.

Do not stop taking Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets without advice from your doctor or pharmacist.

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, although not everybody gets them.

When you are being treated for HIV-1, it can be hard to tell whether a symptom is a side effect of Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets or other medicines you are taking, or an effect of the HIV-1 disease itself. So it is very important to talk to your doctor about any changes in your health.

Some side effects may be serious. Tell your doctor straight away if you get any of the following:

- **Allergic reactions.** Call your healthcare provider right away if you develop a rash with Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets. **Stop taking Dolutegravir (as sodium)/Lamivudine/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

- **Build-up of an acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take Dolutegravir (as sodium)/Lamivudine/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
  - feel cold, especially in your arms and legs
  - feel dizzy or light-headed
  - have a fast or irregular heartbeat

- stomach pain with nausea and vomiting

- **Serious liver problems** can happen in people who take Dolutegravir (as sodium)/Lamivudine/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 (as sodium)/Lamivudine/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 (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets. Refill your prescription or talk to your healthcare provider before your Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets are all gone.
  - Do not stop Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets without first talking to your healthcare provider.
  - If you stop taking Dolutegravir (as sodium)/Lamivudine/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.
- **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 (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets and become harder to treat (resistant).
- **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 (as sodium)/Lamivudine/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 (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets. Your healthcare provider may do tests to check your liver function before and during treatment with Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets. In rare cases, severe liver problems can happen that can lead to death.
- **Risk of inflammation of the pancreas (pancreatitis).** Children may be at risk for developing pancreatitis during treatment with Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets if they:
  - have taken nucleoside analogue medicines in the past
  - have a history of pancreatitis
  - have other risk factors for pancreatitis

- **New or worse kidney problems, including kidney failure,** can happen in some people who take tenofovir disoproxil fumarate. Your healthcare provider should do blood tests to check your kidneys before you start treatment with Dolutegravir (as sodium)/Lamivudine/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 (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets.
- **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.
- **Bone problems** can happen in some people who take tenofovir disoproxil fumarate. 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.

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

The most common side effects of lamivudine in children include fever and cough.

Other side effects
- 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 doctor or pharmacist right away if you start having new symptoms after you start taking Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets.

Tell your doctor or pharmacist about any side effect that bothers you or that does not go away.

These are not all the possible side effects of Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets. For more information, ask your doctor or pharmacist.

Reporting of suspected adverse reactions

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the local reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

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

For 90's container: Discard 90 days after opening.

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 (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets contains

- The active substances are dolutegravir, lamivudine and tenofovir disoproxil fumarate. Each film-coated tablet contains 50 mg dolutegravir (as sodium), 300 mg lamivudine, 300 mg tenofovir disoproxil fumarate.
- The other ingredients are croscarmellose sodium, hydroxy propyl methyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, povidone, sodium starch glycolate. The tablet film-coating contains the inactive ingredients glycerol esters of fatty acids, FD&C blue #1 (E133), FD&C blue #2 (E132), polyvinyl alcohol-part hydrolysed (E1203), sodium lauryl sulfate, talc (E553b), titanium dioxide (E171).

What Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets looks like and contents of the pack

Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets are blue coloured, capsule shaped biconvex film coated tablet, debossed with 'C' on one side and plain on other side.

The film-coated tablets are provided in:

30's container: 85cc white HDPE bottle with 38 mm HDPE Non-CRC cap containing 30 tablets and two 2 gm Silica gel bags.

90's container: 200cc white HDPE bottle with 45 mm HDPE Non-CRC cap containing 90 tablets and two 2 gm Silica gel bags.

Not all pack sizes may be marketed.

Supplier

Cipla Ltd.
Cipla House,
Peninsula Business Park,
Ganapatrao Kadam Marg,
Lower Parel, Mumbai 400 013.
Maharashtra (INDIA).

Manufacturer

Cipla Limited
Goa Unit VII
Verna Industrial Estate
Verna Salcette
Goa- 403 722
India

This leaflet was last revised in 6/2018.