Package leaflet: Information for the patient

Dolutegravir, Lamivudine and Tenofovir Alafenamide Tablets 50 mg/300 mg/25 mg

Read all of this leaflet carefully before you start taking using 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 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your ask your doctor, health care provider or pharmacist.

In this leaflet:

a) What dolutegravir lamivudine and tenofovir alafenamide tablets are and what it is used for
b) Before you take dolutegravir lamivudine and tenofovir alafenamide tablets
c) How to take dolutegravir lamivudine and tenofovir alafenamide tablets
d) Possible side effects
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a) WHAT DOLUTEGRAVIR LAMIVUDINE AND TENOFOVIR ALAFENAMIDE TABLETS ARE AND WHAT IT IS USED FOR

Dolutegravir, lamivudine and tenofovir alafenamide tablets is a prescription medicine that is used as a complete regimen to treat human immunodeficiency virus (HIV-1) infection in adults and children who weigh at least 25 kg (55 pounds).
HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).
Dolutegravir, lamivudine and tenofovir alafenamide tablets contain 3 prescription medicines dolutegravir, lamivudine and tenofovir alafenamide.
Dolutegravir, lamivudine and tenofovir alafenamide tablets is not for use to help reduce the risk of getting HIV-1 infection by sexual contact in adults at high risk.

b) BEFORE YOU TAKE DOLUTEGRAVIR LAMIVUDINE AND TENOFOVIR ALAFENAMIDE TABLETS

Do not take dolutegravir lamivudine and tenofovir alafenamide tablets

· have ever had an allergic reaction to a medicine that contains dolutegravir, lamivudine, or tenofovir alafenamide
· take dofetilide
· have or have had liver problems, including hepatitis B or C infection
· have kidney problems
· are pregnant or plan to become pregnant. Dolutegravir, one of the medicines in dolutegravir, lamivudine and tenofovir alafenamide tablets, may harm your unborn baby.
  - Your healthcare provider may prescribe a different medicine than dolutegravir, lamivudine and tenofovir alafenamide tablets 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 will perform a pregnancy test before you start treatment with dolutegravir, lamivudine and tenofovir alafenamide tablets.
  - If you can become pregnant, you and your healthcare provider should talk about the use of effective birth control (contraception) during treatment with dolutegravir, lamivudine and tenofovir alafenamide 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, lamivudine and tenofovir alafenamide tablets.
· are breastfeeding or plan to breastfeed. **Do not breastfeed if you take dolutegravir, lamivudine and tenofovir alafenamide 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 all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
Some medicines may interact with dolutegravir, lamivudine and tenofovir alafenamide 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, lamivudine and tenofovir alafenamide tablets.
· **Do not start a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take dolutegravir, lamivudine and tenofovir alafenamide tablets with other medicines.

Important information about some of the ingredients of Dolutegravir lamivudine and tenofovir alafenamide Tablets

c) HOW TO TAKE DOLUTEGRAVIR LAMIVUDINE AND TENOFOVIR ALAFENAMIDE TABLETS

· Take dolutegravir, lamivudine and tenofovir alafenamide tablets 1 time a day exactly as your healthcare provider tells you.
· Take dolutegravir, lamivudine and tenofovir alafenamide tablets with or without food.
· Do not change your dose or stop taking dolutegravir, lamivudine and tenofovir alafenamide tablets without first talking with your healthcare provider. Stay under a healthcare provider’ s care when taking dolutegravir, lamivudine and tenofovir alafenamide tablets. Do not miss a dose of dolutegravir, lamivudine and tenofovir alafenamide tablets.
· If you miss a dose of dolutegravir, lamivudine and tenofovir alafenamide 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 take antacids, laxatives, or other medicines that contain aluminum, magnesium, or buffered medicines, dolutegravir, lamivudine and tenofovir alafenamide 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, lamivudine and tenofovir alafenamide tablets:
- If you take dolutegravir, lamivudine and tenofovir alafenamide tablets with food, you may take these supplements at the same time that you take dolutegravir, lamivudine and tenofovir Alafenamide tablets.
- If you do not take dolutegravir, lamivudine and tenofovir alafenamide tablets with food, take dolutegravir, lamivudine and tenofovir alafenamide tablets at least 2 hours before or 6 hours after you take these supplements.

· Do not run out of dolutegravir, lamivudine and tenofovir alafenamide 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, lamivudine and tenofovir alafenamide tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

d) POSSIBLE SIDE EFFECTS

· Dolutegravir, lamivudine and tenofovir alafenamide tablets can cause serious side effects, including:
· Worsening of hepatitis B virus infection (HBV). Your healthcare provider will test you for HBV infection before or when you start treatment with dolutegravir, lamivudine and tenofovir alafenamide tablets. If you have HBV infection and take dolutegravir, lamivudine and tenofovir alafenamide tablets, your HBV may get worse (flare-up) if you stop taking dolutegravir, lamivudine and tenofovir alafenamide tablets. A “flare-up” is when your HBV infection suddenly returns in a worse way than before.
- Do not run out of dolutegravir, lamivudine and tenofovir alafenamide tablets. Refill your prescription or talk to your healthcare provider before your dolutegravir, lamivudine and tenofovir alafenamide tablets is all gone.
- Do not stop taking dolutegravir, lamivudine and tenofovir alafenamide tablets without first talking to your healthcare provider.
- If you stop taking dolutegravir, lamivudine and tenofovir alafenamide tablets, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection, or give you a medicine to treat hepatitis B. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking dolutegravir, lamivudine and tenofovir alafenamide tablets.

· **Allergic reactions.** Call your healthcare provider right away if you develop a rash with dolutegravir, lamivudine and tenofovir alafenamide tablets. **Stop taking dolutegravir, lamivudine and tenofovir alafenamide 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, lamivudine and tenofovir alafenamide 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

· **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 while taking dolutegravir, lamivudine and tenofovir alafenamide tablets. Your healthcare provider may tell you to stop taking dolutegravir, lamivudine and tenofovir alafenamide tablets if you develop new or worse kidney problems.

· **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking medicines to treat HIV-1 infection. 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.

· **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.

· **Risk of inflammation of the pancreas (pancreatitis).** Children may be at risk for developing pancreatitis during treatment with dolutegravir, lamivudine and tenofovir alafenamide tablets if they:

o have taken nucleoside analogue medicines in the past

o have a history of pancreatitis

o have other risk factors for pancreatitis

The most common side effects of dolutegravir, lamivudine and tenofovir alafenamide tablets include:

- trouble sleeping
- nausea
- tiredness
- headache
- diarrhea

These are not all of the possible side effects of dolutegravir, lamivudine and tenofovir alafenamide tablets. Call your doctor for medical advice about side effects.

e) HOW TO STORE DOLUTEGRAVIR LAMIVUDINE AND TENOFOVIR ALAFENAMIDE TABLETS

· Store dolutegravir, lamivudine and tenofovir alafenamide tablets below 30° C (86° F).

· Keep and dispense dolutegravir, lamivudine and tenofovir alafenamide tablets in its original container.

· Keep the container tightly closed.

· The bottle of dolutegravir, lamivudine and tenofovir alafenamide tablets contains a desiccant packet to help keep your medicine dry (protect it from moisture). Do not remove the desiccant packet from the bottle.

Keep dolutegravir, lamivudine and tenofovir alafenamide tablets and all medicines out of reach of children.

General information about the safe and effective use of dolutegravir, lamivudine and tenofovir alafenamide tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information. Do not use

dolutegravir, lamivudine and tenofovir alafenamide tablets for a condition for which it was not prescribed. Do not give dolutegravir, lamivudine and tenofovir alafenamide 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, lamivudine and tenofovir alafenamide tablets that is written for health professionals.

f) FURTHER INFORMATION

What dolutegravir lamivudine and tenofovir alafenamide tablets contains

- Active ingredients: dolutegravir, lamivudine and tenofovir alafenamide.
Inactive ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate, mannitol, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, sodium starch glycolate, talc and titanium dioxide.
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What dolutegravir tablets looks like and contents of the pack

Dolutegravir, lamivudine and tenofovir alafenamide tablets are white to off-white coloured, oval shaped,biconvex, film-coated tablets, debossed with 'DL' on one side and plain on other side.

Dolutegravir, lamivudine and tenofovir alafenamide tablets are supplied in bottles containing 30, 90 & 180 tablets.

30's Count (Regular pack): White opaque 60 cc HDPE bottles filled with silica gel canister and closed with 33 mm- 400 ARGUS child resistant closures with TEKNIPLEX HS 123 induction sealing wad.

30's Count (Alternate pack): White opaque 60 cc HDPE bottles filled with silica gel canister and closed with 33 mm- 400 ARGUS child resistant closures with TEKNIPLEX HS 123 induction sealing wad.

90's Count: White opaque 150 cc HDPE bottles filled with silica gel canister and closed with 38 mm- 400 ARGUS child resistant closures with TEKNIPLEX HS 123 induction sealing wad.

180's Count: White opaque 250 cc HDPE bottles filled with silica gel canister and closed with 53 mm- 400 Screw closures with TEKNIPLEX HS 123 induction sealing wad.

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