

PACKAGE LEAFLET

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
2. What you need to know before you take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets
3. How to take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets
4. Possible side effects
5. How to store Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets
6. Contents of the pack and other information

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.