



Tenofovir Disoproxil Fumarate and Lamivudine Tablets 300mg/300 mg

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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 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 doctor or pharmacist.

What is in this leaflet:

- a) What Tenofovir Disoproxil Fumarate and Lamivudine Tablet is and what it is used for
- b) What you need to know before you take Tenofovir Disoproxil Fumarate and Lamivudine Tablet
- c) How to take Tenofovir Disoproxil Fumarate and Lamivudine Tablet
- d) Possible side effects Tenofovir Disoproxil Fumarate and Lamivudine Tablet
- e) How to store Tenofovir Disoproxil Fumarate and Lamivudine Tablet
- f) Further information

a) What Tenofovir Disoproxil Fumarate and Lamivudine Tablets is and what it is used for

Lamivudine and Tenofovir disoproxil fumarate tablets are a prescription medicine used:

- with other antiviral medicines to treat Human Immunodeficiency Virus (HIV) in adults and children older than 16 years of age or weighing at least 35 kg (77 pounds. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).
- When used with other HIV medicines, lamivudine and tenofovir disoproxil fumarate tablets may reduce the amount of HIV in your blood (called “viral load”). 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



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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).

- Lamivudine and tenofovir disoproxil fumarate do not cure HIV infection or AIDS. People taking lamivudine and tenofovir disoproxil fumarate tablets may still develop infections or other conditions associated with HIV infection.
- Patients must stay on continuous HIV therapy to control infection and decrease HIV-related illnesses.
- It is very important that you stay under the care of your healthcare provider.

It is not known if Lamivudine and Tenofovir disoproxil fumarate tablets are safe and effective in patients with HIV-1 infection who are 16 years of age or younger or who weigh less than 35 kg (77 pounds).

b) What you need to know before you take Lamivudine and tenofovir disoproxil fumarate tablets

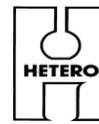
Lamivudine and tenofovir disoproxil fumarate tablets can cause serious side effects, including:

Build-up of an acid in your blood (lactic acidosis). Lactic acidosis can happen in some people who take lamivudine, tenofovir disoproxil fumarate, or similar (nucleoside analog) medicines. Lactic acidosis is a serious medical emergency that can lead to death.

Lactic acidosis can be hard to identify early, because the symptoms could seem like symptoms of other health problems. Call your healthcare provider right away if you get the following

symptoms which could be signs of lactic acidosis:

- feeling very weak or tired
- have unusual (not normal) muscle pain
- have trouble breathing
- have stomach pain with
- nausea (feel sick to your stomach)
- vomiting



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- feel cold, especially in your arms and legs
- feel dizzy or lightheaded
- have a fast or irregular heartbeat

Severe liver problems. Severe liver problems can happen in people who take lamivudine, tenofovir disoproxil fumarate, or similar medicines. In some cases these liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis) when you take lamivudine and tenofovir disoproxil fumarate tablets.

Call your healthcare provider right away if you have any of the following symptoms of liver problems:

- Your skin or the white part of your eyes turns yellow (jaundice).
- dark “tea-colored” urine
- light-colored bowel movements (stools)
- loss of appetite for several days or longer
- nausea
- stomach pain

You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight (obese), or have been taking lamivudine, tenofovir disoproxil fumarate, or similar medicines for a long time.

Worsening of your Hepatitis B infection. If you have hepatitis B Virus (HBV) infection it may become worse (flare-up) if you take lamivudine and tenofovir disoproxil fumarate tablets and then stop it. A “flare-up” is when your HBV infection suddenly returns in a worse way than before.

- Do not let your lamivudine and tenofovir disoproxil fumarate tablets run out.
Refill your prescription or talk to your healthcare provider before your lamivudine and tenofovir disoproxil fumarate tablets are all gone.
- Do not stop taking lamivudine and tenofovir disoproxil fumarate tablets without first talking to your healthcare provider.



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- If you stop taking lamivudine and tenofovir disoproxil fumarate tablets, your healthcare provider will need to check your health often and do regular blood tests to check your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking lamivudine and tenofovir disoproxil fumarate tablets.

c) How to take lamivudine and tenofovir disoproxil fumarate Tablet

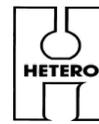
Before you take lamivudine and tenofovir disoproxil fumarate tablets, tell your healthcare provider if you:

- have liver problems, including hepatitis B (HBV) infection
- have kidney problems
- have bone problems
- have any other medical conditions, including HIV infection
- are pregnant or plan to become pregnant. It is not known if lamivudine and tenofovir disoproxil fumarate tablets will harm your unborn baby.
- **are breast-feeding or plan to breastfeed.** You should not breastfeed if you have HIV infection or AIDS. The virus that causes HIV can pass through your breast milk to your baby. Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Lamivudine and Tenofovir disoproxil fumarate tablets may affect the way other medicines work, and other medicines may affect how lamivudine and tenofovir disoproxil fumarate tablets work.

Do not take lamivudine and tenofovir disoproxil fumarate tablets if you also take:

- other medicines that contain tenofovir disoproxil fumarate such as:
 - tenofovir disoproxil fumarate (VIREAD)
 - efavirenz, emtricitabine, and tenofovir disoproxil fumarate (ATRIPLA)
 - rilpivirine, emtricitabine, and tenofovir disoproxil fumarate (COMPLERA)
 - emtricitabine and tenofovir disoproxil fumarate (TRUVADA)
 - cobicistat, elvitegravir, emtricitabine, tenofovir disoproxil fumarate (STRIBILD)
- other medicines that contain lamivudine or emtricitabine such as:



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- lamivudine (EPIVIR, EPIVIR-HBV)
- lamivudine and zidovudine (COMBIVIR)
- abacavir sulfate and lamivudine (EPZICOM)
- abacavir sulfate, lamivudine, and zidovudine (TRIZIVIR)
- emtricitabine (EMTRIVA)
- adefovir (HEPSERA)

Especially tell your healthcare provider if you take the following medications, as the dose of these other medications may need to be changed:

- didanosine (VIDEX, VIDEX EC)
- atazanavir (REYATAZ)
- lopinavir with ritonavir (KALETRA)
- interferon alfa and ribavirin

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

d) Possible side effects

Lamivudine and Tenofovir disoproxil fumarate tablets may cause serious side effects, including:

- **“What is the most important information I should know about Lamivudine and Tenofovir disoproxil fumarate tablets”?**
- **New or worse kidney problems** can happen in some people who take 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 lamivudine and tenofovir disoproxil fumarate tablets.
- **Bone problems** can happen in some people who take 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.



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- **Changes in body fat** can happen in some people who take antiviral medicines. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these conditions are not known.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV 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 if you start having new symptoms after starting your HIV medicine.

The most common side effects of lamivudine and tenofovir disoproxil fumarate tablets are:

- nausea
- rash
- diarrhea
- headache
- fatigue
- nasal signs and symptoms
- cough
- pain
- depression
- weakness

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of lamivudine and tenofovir disoproxil fumarate tablets. For more information, ask your healthcare provider or pharmacist.

e) How to store Tenofovir Disoproxil Fumarate and Lamivudine 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 carton.

Do not store above 30°C

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 to protect the environment.



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f) Further information

What Tenofovir Disoproxil Fumarate and Lamivudine Tablets contains

The active substances are Tenofovir Disoproxil Fumarate and Lamivudine.

Inactive Ingredients are

Lactose monohydrate, corn starch, croscarmellose sodium, povidone, isopropyl alcohol, microcrystalline cellulose, crospovidone, colloidal silicon dioxide, FD&C Blue #2/ indigo carmine AL, magnesium stearate Opadry Light blue (Y-30-10671-A).

What Tenofovir Disoproxil Fumarate and Lamivudine Tablets looks like and contents of the pack

Tenofovir Disoproxil Fumarate and Lamivudine film-coated tablets are provided in cartons bottles with a child resistant-closure. Each pack type contains 30 film-coated tablets.

Light blue to blue, capsule shaped, biconvex film coated tablets, debossed with '129' on one side and 'H' on other side.



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

Marketing Authorization Holder

Name: Hetero Labs Limited
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