

MEDICATION GUIDE
Lamivudine and Tenofovir Disoproxil Fumarate Tablets, 300 mg/300 mg
Co-packaged with Nevirapine Tablets USP, 200 mg

Read this Medication Guide before you start taking lamivudine and tenofovir disoproxil fumarate tablets, co-packaged with nevirapine tablets and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or treatment.

What is the Most Important Information I Should Know About Lamivudine and Tenofovir Disoproxil Fumarate Tablets Co-packaged with Nevirapine Tablets?

Nevirapine, one component of Lamivudine and Tenofovir Disoproxil Fumarate Tablets Co-packaged with Nevirapine Tablets, can cause serious side effects. These include severe liver and skin problems that can cause death. These problems can happen at any time during treatment, but your risk is higher during the first 18 weeks of treatment.

1. Severe liver problems: Anyone who takes nevirapine may get severe liver problems. In some cases these liver problems can lead to liver failure and the need for a liver transplant, or death.

People who have a higher CD4⁺ cell count when they begin nevirapine treatment have a higher risk of liver problems, especially:

- Women with CD4⁺ counts higher than 250 cells/mm³. This group has the highest risk.
- Men with CD4⁺ counts higher than 400 cells/mm³.

If you are a woman with CD4⁺ counts higher than 250 cells/mm³ or a man with CD4⁺ counts higher than 400 cells/mm³, you and your doctor will decide whether starting nevirapine is right for you.

In general, women have a higher risk of liver problems compared to men.

People who have abnormal liver test results before starting nevirapine treatment and people with hepatitis B or C also have a greater chance of getting liver problems.

You may get a rash if you have liver problems.

Stop taking nevirapine and call your doctor right away if you have any of the following symptoms of liver problems:

- dark (tea colored) urine
- yellowing of your skin or whites of your eyes
- light-colored bowel movements (stools)
- fever
- nausea (feeling sick to your stomach)
- feel unwell or like you have the flu
- pain or tenderness on your right side below your ribs
- tiredness
- loss of appetite

Your doctor should see you and do blood tests often to check your liver function during the first 18 weeks of treatment with nevirapine. You should continue to have your liver checked regularly during your treatment with nevirapine. It is important for you to keep all of your doctor appointments.

2. Severe rash and skin reactions: Skin rash is the most common side effect of nevirapine. Most rashes happen in the first 6 weeks of taking nevirapine. **Rashes and skin reactions may be severe, life-threatening, and in some people, may lead to death. Stop using nevirapine and call your doctor right away if you get a rash with any of the following symptoms:**

- blisters
- mouth sores
- red or inflamed eyes, like "pink eye" (conjunctivitis)
- liver problems (see symptoms of liver problems above)
- swelling of your face
- fever
- feel unwell or like you have the flu
- tiredness
- muscle or joint aches

If your doctor tells you to stop treatment with nevirapine because you have had any of the serious liver or skin problems described above, you should never take nevirapine again.

See the section "**What are the possible side effects of Lamivudine and Tenofovir Disoproxil Fumarate Tablets Co-packaged with Nevirapine Tablets?**" for more information.

Patients taking lamivudine and tenofovir disoproxil fumarate, two components of lamivudine and tenofovir disoproxil fumarate tablets co-packaged with nevirapine tablets, may develop:

3. 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
- feel cold, especially in your arms and legs
- feel dizzy or lightheaded
- have a fast or irregular heartbeat

4. 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, two components of lamivudine and tenofovir disoproxil fumarate tablets co-packaged with nevirapine tablets, and then stop them. 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 co-packaged with nevirapine run out.

Refill your prescription or talk to your healthcare provider before your lamivudine and tenofovir disoproxil fumarate tablets co-packaged with nevirapine are all gone.

Do not stop taking lamivudine and tenofovir disoproxil fumarate tablets co-packaged with nevirapine without first talking to your doctor.

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

What are Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets?

Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets can be used alone or in combination with other antiviral medicines to treat Human Immunodeficiency Virus (HIV) in patients 16 years of age and older with a body weight of at least 35 kg (77 pounds). HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets are prescription antiviral medicines. Lamivudine and tenofovir disoproxil fumarate are a type of medicines called nucleoside analog reverse transcriptase inhibitors (NRTIs) and nevirapine is a non-nucleoside analog reverse transcriptase inhibitor (NNRTI).

When used with alone or in combination with other HIV medicines, Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets may:

1. Reduce the amount of HIV in your blood (called "viral load")
2. Help increase the number of CD4 (T) cells in your blood which help fight off other infections.

Reducing the amount of HIV and increasing the 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 Tablets, Co-packaged with Nevirapine Tablets do not cure HIV-1 infection or AIDS and you may continue to experience illnesses associated with HIV-1 infection, including opportunistic infections. You should remain under the care of a doctor **while taking lamivudine and tenofovir disoproxil fumarate tablets, co-packaged with nevirapine tablets.**

You must stay on continuous HIV therapy to control HIV infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others:

- **Do not share needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.**
- **Do not have any kind of sex without protection.** Always practice safer sex by using a latex or polyurethane condom or other barrier to reduce the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your doctor if you have any questions on how to prevent passing HIV to other people.

Who Should Not Take Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets?

Tell your doctor if you have or have had liver or kidney problems. Your doctor may tell you not to take nevirapine, one component of Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets, if you have certain liver problems.

Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets are only for people diagnosed with HIV. If you have not been diagnosed as HIV positive, then do not take Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets.

What Should I Tell My Doctor Before Taking Lamivudine And Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets?

Before you take Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets, tell your doctor if you:

- Have or have had hepatitis (inflammation of your liver) or problems with your liver. See "**What is the most important information I should know about Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets?**" and "**Who should not take Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets?**"
- Receive dialysis
- Have skin problems, such as rash
- Have any medical conditions
- Are pregnant or planning to become pregnant. It is not known if Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets will harm your unborn baby.
- Are breastfeeding or plan to breast-feed. Lamivudine and tenofovir disoproxil fumarate tablets, co-packaged with nevirapine tablets can pass into your breast milk and may harm your baby. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. Do not breast-feed during treatment with Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets. Talk to your doctor about the best way to feed your baby.

Tell your doctor and pharmacist about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets may affect the way other medicines work, and other medicines may affect how Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets work.

You should not take Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets if you also take:

- St. John's Wort. St. John's Wort can lower the amount of Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets in your body.
- efavirenz (Sustiva[®]), etravirine (Intenceo[®]), rilpivirine (Edurant[®]), or delamanvir (Rescriptor[®]).
- atazanavir (Reyataz[®])
- boceprevir (Victrelis[®])
- telaprevir (Incivek[®])
- tipranavir (Aptivus[®])
- darunavir (Prezista[®])
- lopinavir and ritonavir (Kaletra[®]) once daily
- fosamprenavir calcium (Lexiva[®]) without ritonavir (Norvir[®])

- itraconazole (Sporanox[®])
- ketoconazole (Nizora[®])
- rifampin (Rifadin[®], Rifamate[®], Rifater[®])
- Birth control pills. Birth control pills taken by mouth (oral contraceptives) and other hormone types of birth control may not work to prevent pregnancy. Talk with your doctor about other types of birth control that you can use to prevent pregnancy during treatment with Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets.
- 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:
 - lamivudine (EPIVIR, EPIVIR-HBV)
 - lamivudine and zidovudine (COMBIVIR)
 - abacavir sulfate and lamivudine (EPZICOM)
 - abacavir sulfate, lamivudine, and zidovudine (TRIZIVIR)
 - emtricitabine (EMTRIVA)
 - adefovir (HEPSERA)
 - didanosine (VIDEC, VIDEX EC)
 - interferon alfa and ribavirin

Also tell your doctor if you take:

- clarithromycin (Biaxin[®])
- fluconazole (Diflucan[®])
- indinavir sulfate (Crixivan[®])
- methadone
- nelfinavir mesylate (Viracept[®])
- rifabutin (Mycobutin[®])
- warfarin (Coumadin[®], Jantoven[®])
- saquinavir mesylate (Invirase[®])
- amiodarone, disopyramide (Norpace[®]), lidocaine
- carbamazepine, clonazepam (Klonopin[®]), ethosuximide (Zarontin[®])
- diltiazem, nifedipine, verapamil
- cyclophosphamide
- ergotamine
- cyclosporine, tacrolimus, sirolimus (Rapamune[®])
- cisapride (Propulsid[®])
- fentanyl

If you are not sure if you take a medicine above, ask your doctor or pharmacist.

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

How Should I Take Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged With Nevirapine Tablets?

- Take the medicines in this co-packaged exactly as directed by your doctor. If you do not understand these directions, ask your pharmacist, nurse, or doctor to explain them to you

Adults and Adolescents 16 years of age and older with a body weight of at least 35 kg (77 pounds)

- The usual dose of the Lamivudine and Tenofovir Disoproxil Fumarate Tablets (both the medications are present in one single tablet) for adult and adolescents is one tablet taken once a day. The usual dose of the co-packaged nevirapine tablets for adults is one tablet daily for the first 14 days followed by one tablet twice daily thereafter. Starting with one Nevirapine Tablet a day for the first 14 days lowers the chance of rash, which could be serious. Therefore, it is important to strictly follow the once daily dose of nevirapine tablets for the first 14 days. Follow your doctor's instructions.
- Take each dose with a full glass of water. These medications are taken with or without food.
- Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged With Nevirapine Tablets are not recommended in patients less than 16 years of age with a body weight less than 35 kg (77 pounds).
- Do not let your Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets run out.
- If you stop taking nevirapine tablets for more than 7 days, ask your doctor before you start taking them again. You may need to begin taking nevirapine starting dose again, which is taken 1 time each day for 14 days.

Starting nevirapine tablets:

1. Your doctor should start you with 1 dose each day to lower your chance of getting a serious rash. **It is important that you only take 1 dose of nevirapine each day for the first 14 days.**
 - **Call your doctor right away if you get a skin rash during the first 14 days of nevirapine treatment.**
 - **Do not increase your dose to 2 times a day if you have a rash.**
 - You should never take your starting dose for longer than 28 days. If after 28 days you are still receiving this starting dose because you have a rash, you and your doctor should talk about prescribing another HIV medicine for you instead of nevirapine.
2. Day 15, you will take 1 nevirapine tablet two times a day.
 - Treatment of HIV/AIDS almost always requires the use of all the three drugs. If you need to stop taking one of the medicines you are taking for HIV, you should stop all of them until you can talk to your doctor.
 - Your doctor may want you to have blood tests or other medical evaluations during treatment with this medication to monitor progress and side effects.

What are the Possible Side Effects of Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged With Nevirapine Tablets?

(Also see "What is the most important information I should know about Lamivudine and Tenofovir Disoproxil Fumarate Tablets Co-packaged with Nevirapine Tablets?" at the beginning of this Medication Guide).

Lamivudine and Tenofovir Disoproxil Fumarate, two components of lamivudine and tenofovir disoproxil fumarate tablets co-packaged with nevirapine tablets, may cause other serious side effects, including:

New or worse kidney problems can happen in some people who take lamivudine and tenofovir disoproxil fumarate. 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. 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.

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

Lamivudine and Tenofovir Disoproxil Fumarate Tablets Co-packaged with Nevirapine Tablets may cause other serious side effects, including:

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 effect of nevirapine, one component of lamivudine and tenofovir disoproxil fumarate tablets co-packaged with nevirapine tablets, is rash.

Tell your doctor if you have any side effects that bothers you or that does not go away while taking lamivudine and tenofovir disoproxil fumarate tablets, co-packaged with nevirapine tablets.

These are not all the possible side effects of Lamivudine and Tenofovir Disoproxil Fumarate Tablets Co-packaged with Nevirapine Tablets. For more information ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may also report side effects to Hetero Labs Limited at 866-495-1995 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

How Do I Store Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged with Nevirapine Tablets?

- **Keep lamivudine and tenofovir disoproxil fumarate tablets, co-packaged with nevirapine tablets and all other medicines out of reach of children.**
- Store lamivudine and tenofovir disoproxil fumarate tablets, co-packaged with nevirapine tablets at room temperature below 30°C (86°F).
- Keep lamivudine and tenofovir disoproxil fumarate tablets, co-packaged with nevirapine tablets in the original blister cards.
- Do not keep medicine that is out of date or that you no longer need. If you throw any medicines away make sure that children will not find them.

General Information about Lamivudine and Tenofovir Disoproxil Fumarate Tablets, co-packaged with Nevirapine Tablets:

- Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use lamivudine and tenofovir disoproxil fumarate tablets, co-packaged with nevirapine tablets for a condition for which it was not prescribed. Do not give lamivudine and tenofovir disoproxil fumarate tablets, co-packaged with nevirapine tablets to other people, even if they have the same symptoms you have. It may harm them.
- This Medication Guide summarizes the most important information about lamivudine and tenofovir disoproxil fumarate tablets, co-packaged with nevirapine tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about lamivudine and tenofovir disoproxil fumarate tablets, co-packaged with nevirapine tablets that are written for health professionals.
- Do not use lamivudine and tenofovir disoproxil fumarate tablets, co-packaged with nevirapine tablets if the seal over bottle opening is broken or missing.

What are the Ingredients of Lamivudine and Tenofovir Disoproxil Fumarate Tablets, Co-packaged With Nevirapine Tablets?

Lamivudine and tenofovir Disoproxil Fumarate Tablets

Active Ingredient: lamivudine, USP and tenofovir disoproxil fumarate
Inactive Ingredients: colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, FD & C Blue #2/ indigo carmine aluminum lake, lactose monohydrate, magnesium stearate, microcrystalline cellulose and povidone. The tablets are coated with opadry II light blue which contains FD&C Blue #2/ indigo carmine aluminum lake, hypromellose, lactose monohydrate, titanium dioxide and triacetin.

Nevirapine Tablets, USP

Active Ingredient: nevirapine, USP

Inactive Ingredients: colloidal silicon dioxide, corn starch, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, povidone and sodium starch glycolate.

Rx only

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