• iraconazole (Sporanox®)
• ketoconazole (Nizoral®)
• ritampin (Ritam®), Rifamata®, Ritam®

Birth control pills. Birth control pills taken by mouth (oral contraceptives) and other hormonal types of birth control that 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®), emtricitabine, and tenofovir disoproxil fumarate (ATRIPLE)
• nitroprusside, entecavir, and tenofovir disoproxil fumarate (COMPLERA)

• emtricitabine and tenofovir disoproxil fumarate (TRUVADA)
• ceftriaxone, etravirine, entecavir, and tenofovir disoproxil fumarate (STELLBRID)
• other medicines that contain lamivudine or emtricitabine such as: lamivudine (Epivir, Epivir-HBV)
• lamivudine and cidofovir (COMBIVIR)
• abacavir sulfate and lamivudine (EPZICON)
• abacavir sulfates, lamivudine, and cidofovir (TRUVIR)
• emtricitabine (EMTRIVA)
• adenosine (HEPESERA)
• didanosine (VIDEX, VIDEX EC)
• etravirine and etravirine

Also tell your doctor if you take:
• clarithromycin (Biaxin®)
• fluconazole (Diflucan®)
• indinavir sulfates (Crixivan®)
• methadone
• nefuvir meylate (Vireaze®)
• ritabutin (Mycobut®)
• warfarin (Coumadin®, Jantoven®)
• saquinavir meylate (Invirase®)
• amiodarone, desipramine (Norpramin®, lidocaine
• carisoprodine, clonazepam (Klonopin®), ethosuximide (Zentron®)
• dihydrostreptomycin, rifampin, or pyrazinamid (Rifaximin)

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 30 kg (77 pounds)
• The usual dose of the Lamivudine and Tenofovir Disoproxil Fumarate Tablets (both the medicines 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 incidence rate of rash, which is the most common serious side effect. 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 use 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 may 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.
2. Call your doctor right away if you get a skin rash during the first 14 days of nevirapine treatment.
3. 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.
4. Day 15, you will take 1 nevirapine tablet two times a day.
5. 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.
6. 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
• 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 antiretroviral 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, is rash.

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

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 800-456-1995 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. 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, crossmethylcellulose sodium, 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, 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 titanium dioxide with Nevirapine Tablets.

Lamivudine Tablets, USP Active ingredient: lamivudine, USP
Inactive ingredients: colloidal silicon dioxide, corn starch, crossmethylcellulose sodium, magnesium stearate, microcrystalline cellulose, povidone and sodium starch glycolate.

Nevirapine Tablets, USP Active ingredient: nevirapine, USP
Inactive ingredients: colloidal silicon dioxide, corn starch, crossmethylcellulose sodium, magnesium stearate, microcrystalline cellulose and povidone.

Rx only

All brand names listed are the registered trademarks of their respective owners and are not trademarks of Hetero Labs Limited.