

# LAMIVUDINE, NEVIRAPINE AND ZIDOVUDINE TABLETS

Lamivudine/Nevirapine/Zidovudine (150mg/200mg/300mg)

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## What Lamivudine, Nevirapine and Zidovudine Tablets are used for

Lamivudine, Nevirapine and Zidovudine Tablets contains lamivudine, zidovudine and nevirapine. These medicines are antiviral medicines, also known as antiretrovirals, belonging to the following two groups: nucleoside analogues (NRTIs, lamivudine and zidovudine) and non-nucleoside reverse transcriptase inhibitors (NNRTIs, nevirapine). They are used to treat Human Immunodeficiency Virus (HIV) infection.

Lamivudine, Nevirapine and Zidovudine Tablet is used as antiretroviral combination therapy for the treatment of HIV infection. The three medicines contained in this product can be used separately with other medicines for combination treatment of HIV infection or can be used together. The dose of each active ingredient in Lamivudine/Nevirapine/Zidovudine Tablets is the same as that recommended for the medicines when used separately. Treatment with Lamivudine/Nevirapine/Zidovudine Tablets will only be

instituted by your doctor when you have been shown to be stable on the three individual compounds.

## How Lamivudine, Nevirapine and Zidovudine Tablets work

Lamivudine/Nevirapine/Zidovudine Tablets reduces the amount of HIV in your body, and keeps it at a low level. It also increases CD4 cell counts. CD4 cells are a type of white blood cells that plays an important role in maintaining a healthy immune system to help fight infections. Response to treatment with Lamivudine/Nevirapine/Zidovudine Tablets varies between patients. Your doctor will be monitoring the effectiveness of your treatment.

Lamivudine, Nevirapine and Zidovudine Tablets may improve your condition, but it is not a cure for your HIV infection. HIV infection is a disease spread by contact with blood or sexual contact with an infected individual. Treatment with Lamivudine/Nevirapine/Zidovudine Tablets has not been shown to eliminate the risk of passing HIV infection on to others by sexual contact or by blood transfer. Therefore, you must continue to take appropriate precautions to avoid giving the virus to others.

## Before you use Lamivudine, Nevirapine and Zidovudine Tablets

### -When you must not use it

Do not take Lamivudine, Nevirapine and Zidovudine Tablets if:

- if you are hypersensitive (allergic) to lamivudine, zidovudine, nevirapine or any of the other ingredients of in the tablet
- if you have permanent liver disease or marked changes in liver function
- if you previously experienced liver inflammation, severe skin rash or liver injury while on treatment with nevirapine-containing products.

-Patients taking Lamivudine/Nevirapine/Zidovudine Tablets must not take products containing St. John's wort (*Hypericum perforatum*) as this may stop Lamivudine/Nevirapine/Zidovudine Tablets from working properly.

### -Before you start to use it

You should have told your doctor:

- if you have ever had or still have a liver disease (such as hepatitis),
- if you are suffering from or have ever suffered from kidney disease.
- if you have low red blood cell count (anemia) as well as low white blood cell count (neutropenia/leucopenia).

Regular blood tests will be arranged to check whether this product is suitable for you.

It is important that your doctor knows about all your symptoms even when you think they are not related to HIV infection. Your doctor may decide to prescribe lamivudine, zidovudine and/or nevirapine as separate medicines instead of Lamivudine/Nevirapine/Zidovudine Tablets.

### Pregnancy and breast-feeding

If you become pregnant, or are planning to become pregnant, you must contact your doctor to discuss the potential benefits and risks of your antiretroviral therapy to you and your child.

If you have taken Lamivudine/Nevirapine/Zidovudine Tablets during your pregnancy, your doctor may request regular visits to monitor the development of your child. Such visits may include blood tests and other diagnostic tests.

Your doctor will discuss with you the risk and benefit of taking this medicine while you are pregnant.

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Generally it is recommended that HIV-infected women should not breast-feed their infants because of the possibility that the baby may be infected with HIV through the breast milk.

### Driving and using machines

Lamivudine/Nevirapine/Zidovudine Tablets may cause side effects such as drowsiness or headache, that can impair your ability to drive and to use machines.

### -Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. These may affect the action of Lamivudine/Nevirapine/Zidovudine Tablets.

Lamivudine/Nevirapine/Zidovudine Tablets must not be taken with -herbal preparations containing St. John's Wort.

-stavudine, emtricitabine, efavirenz, ribavirin (antiviral agents), -ketoconazole, an antifungals

Lamivudine/Nevirapine/Zidovudine Tablets may also interact with the following medicines and may make any side effects worse or may impact on the either agent's efficacy:

- oral contraceptives ("the pill"). Therefore, you should employ an alternative contraceptive method such as barrier contraception (e.g. condoms), if you are taking Lamivudine/Nevirapine/Zidovudine Tablets
- fluconazole (antifungal medicine),
- clarithromycin, rifabutin (antibiotics),
- warfarin (medicine for prophylaxis of blot clots),
- doxorubicin (anti-cancer medicine).

This is not a complete list of medicines that may interact with this product. Talk to your doctor

or pharmacist as they will have a more detail and complete list.

### **How to use it**

#### -How much to take

The initial 14 days of dosing is one Lamivudine, Nevirapine, and Zidovudine Tablet taken once per day on an empty stomach followed by a daily oral dose of lamivudine 150 mg and zidovudine 300 mg 12 hours later.

The recommended maintenance oral dose is one Lamivudine, Nevirapine, and Zidovudine Tablet taken twice daily on an empty stomach, in adults and children with a body weight of 30 kg or more.

#### Children:

Lamivudine/Nevirapine/Zidovudine Tablets is not indicated for children weighing less than 30 kg, since appropriate dose reductions cannot be made.

#### Elderly:

No specific dose adjustment required.

#### Dose adjustments:

If your dose of Lamivudine/Nevirapine/Zidovudine Tablets needs to be reduced, for example if you have kidney problems or discontinuation of therapy with one of the active substances of Lamivudine/Nevirapine/Zidovudine Tablets is necessary, then your medicine may be changed to separate preparations of lamivudine, zidovudine and nevirapine.

#### -When to take it

Always take Lamivudine/Nevirapine/Zidovudine Tablets exactly as your doctor told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be taken on an empty stomach.

#### -How long to take it

Take this medicine as long as the doctor tells you to. Always take the exact dose as your doctor or pharmacist has told you. Check with them if you are not sure.

#### -If you forget to take it

If you accidentally miss a dose, take it as soon as you remember. If you notice later, then simply take your normal dose when the next one is due. Do not take a double dose to make up for forgotten individual doses.

#### -If you take too much (overdose)

If you have taken too many tablets or if someone accidentally swallows some, you should contact your doctor, health care provider or the nearest hospital emergency department for further advice.

### **While you are using**

#### -Things you must do

Patients treated with Lamivudine/Zidovudine or any other antiretroviral therapy may continue to develop opportunistic infections and other complications of HIV infections. If you notice any symptoms of infection, please inform your doctor immediately.

#### Liver disease

During the first 10 to 12 weeks of treatment with Lamivudine/Nevirapine/Zidovudine Tablets your doctor will closely monitor you for the occurrence of severe and life-threatening skin reactions and serious hepatic injuries.

As Lamivudine/Nevirapine/Zidovudine Tablets may cause changes in liver function, your doctor will monitor the function of your liver by blood tests before and at regular intervals during treatment with Lamivudine/Nevirapine/Zidovudine Tablets. Patients with chronic hepatitis B or C and treated with antiretroviral agents are at increased risk for severe and potentially fatal liver adverse

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events and may require additional blood tests for control of liver function.

If you develop clinical symptoms suggesting an injury of the liver, such as loss of appetite, nausea, jaundice (yellowing of the skin and eye white), dark urine, discoloured stools, pain and tenderness in the upper right abdomen, you should discontinue taking

Lamivudine/Nevirapine/Zidovudine Tablets and must contact your doctor immediately.

If you have a chronic hepatitis B infection, you should not stop your treatment without instructions from your doctor, as you may have a recurrence of your hepatitis. This recurrence may be more severe if you have serious liver disease.

## Skin reactions

Lamivudine/Nevirapine/Zidovudine Tablets may cause skin reactions and allergic reactions, which in the worst case can be serious and life-threatening. Fatalities have been reported. Such reactions may appear in form of rash accompanied by other side effects such as fever, blistering, mouth sores, eye inflammation, facial swelling, general swelling, muscle or joint aches, a reduction in white blood cells (granulocytopenia), general feelings of illness or severe problems with liver or kidneys. If you experience a severe rash or any rash associated with other side effects of a hypersensitivity reaction, you should discontinue taking

Lamivudine/Nevirapine/Zidovudine Tablets right away and must contact your doctor immediately.

If you develop severe liver, skin or allergic reactions while taking Lamivudine/Nevirapine/Zidovudine Tablets, never take Lamivudine/Nevirapine/Zidovudine Tablets or any other nevirapine-containing product again without asking your doctor.

## -Things you must not do

Because your medicine controls and does not cure your condition, you will normally need to take it continuously. You should not stop treatment unless your doctor tells you to.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## -Things to be careful of

Combination antiretroviral therapy may cause changes in body shape due to changes in fat distribution. These may include loss of fat from legs, arms and face, increased fat in the abdomen (belly) and other internal organs, breast enlargement and fatty lumps on the back of the neck ('buffalo hump'). The cause and long-term health effects of these conditions are not known at this time.

## Immune reactivation syndrome

In some patients with advanced HIV infection (AIDS) and a history of opportunistic infections, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started.

If you notice any symptoms of infection, inform your doctor immediately.

## **Side Effects**

Like all medicines, Lamivudine/Nevirapine/Zidovudine Tablets can cause side effects, although not everybody gets them. When treating HIV infection, it is not always possible to differentiate between unwanted effects caused by Lamivudine/Nevirapine/Zidovudine Tablets, and those caused by any other medicines you may be taking at the same time, and by the HIV disease. For this reason, it is important that you inform your doctor of any change in your health.

The major side effects of Lamivudine/Nevirapine/Zidovudine Tablets are severe and life-

threatening cutaneous reactions and serious hepatic injuries.

The reported side effects are:

- fatigue
- headache
- nausea, vomiting
- fever
- rash (red, raised or itchy)
- increase in certain liver enzymes
- joint pain, muscle pain and other muscle disorders
- hair loss
- anaemia (low red blood cell count) and neutropenia (low white blood cell count).

If the number of red blood cells is reduced, you may have symptoms of tiredness or breathlessness and a reduction in your white blood cell count can make you more prone to infections.

## Lactic acidosis

Females, particularly if very overweight, and patients with liver disease may be more at risk of getting a rare, but serious side effect called lactic acidosis, a build-up of lactic acid in the body. If lactic acidosis occurs, it usually develops after a few months of treatment. Deep rapid breathing, drowsiness, and non-specific symptoms such as nausea, vomiting and stomach pain, might indicate the development of this condition. While you are being treated with Lamivudine/Nevirapine/Zidovudine Tablets your doctor will monitor you for any signs that you may be developing lactic acidosis.

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 as soon as possible

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website

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[portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers  
→ Reporting).

**Date of Revision**  
21-09-2015

**Storage and Disposal of  
Lamivudine/ Nevirapine/  
Zidovudine Tablets**

**Serial Number**  
BPFK(R4/1)210915/00318

-Storage

Store below 30°C.

-Disposal

Do not use after the expiry date stated on the label.

Return any unused tablets to your pharmacist to be disposed of. Only keep the tablets if your doctor tells you to. Do not throw them away in your normal household drainage or waste. This will help to protect the environment.

**Product Description**

-What it looks like

Lamivudine/Nevirapine/Zidovudine Tablets are white colored, capsules shaped, film coated tablet engraved ZLN on one side and plain on other side.

-Ingredients

Active ingredient:

Each tablet contains Lamivudine 150 mg, Nevirapine 200mg and Zidovudine 300mg.

Inactive ingredients:

Microcrystalline cellulose, Talc, Colloidal silicon dioxide, croscarmellose sodium, Povidone (K-30), Magnesium Stearate, Opadry white (Y-1-7000) and Purified water.

-MAL Number

MAL11060028A

**Manufacturer**

Strides Arcolab Limited  
36/7, Suragajakkanahalli,  
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Bangalore-562 106, INDIA.

**Product Registration Holder**

Actavis Sdn Bhd  
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