

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER**Lamivudine tablets 150 mg**

Lamivudine

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, health care provider 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.

In this leaflet:

1. What Lamivudine tablets 150 mg is and what it is used for
2. Before you take Lamivudine tablets 150 mg
3. How to take Lamivudine tablets 150 mg
4. Possible side effects
5. How to store Lamivudine tablets 150 mg
6. Further information

1. WHAT LAMIVUDINE TABLETS 150 MG IS AND WHAT IT IS USED FOR

Lamivudine tablets 150 mg belongs to a group of antiviral medicines, also known as antiretrovirals, called nucleoside analogue reverse transcriptase inhibitors (NRTIs). These are used to treat Human Immunodeficiency Virus (HIV) infection.

Lamivudine tablets 150 mg is used in antiretroviral combination therapy for the treatment of HIV infection. Lamivudine tablets 150 mg reduces the amount of HIV virus in your body, and keeps it at a low level. It also increases CD4 cell counts. CD4 cells are a type of white blood cell that plays an important role in maintaining a healthy immune system to help fight infection. Response to treatment with Lamivudine tablets 150 mg varies between patients. Your doctor or health care provider will be monitoring the effectiveness of your treatment.

Lamivudine tablets 150 mg 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 tablets 150 mg has not been shown to reduce 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.

During your treatment, other infections linked to your weakened immunity (opportunistic infections) may arise. These will require specific and sometimes preventive treatment.

2. BEFORE YOU TAKE LAMIVUDINE TABLETS 150 MG**Do not take Lamivudine tablets 150 mg if:**

You are allergic (hypersensitive) to lamivudine or any of the other ingredients of Lamivudine tablets 150 mg (see section 6, What Lamivudine tablets 150 mg contains).

Take special care with Lamivudine tablets 150 mg

Discuss the use of Lamivudine tablets 150 mg with your doctor or health care provider if you have kidney disease. The standard recommended dose of Lamivudine tablets 150 mg may have to be reduced.

Please speak with your doctor or health care provider if you have a history of liver disease. Patients with chronic hepatitis B or C and treated with antiretroviral agents are at increased risk for severe and potentially fatal liver adverse events and may require blood tests for control of liver function.

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

In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please inform your doctor or health care provider immediately.

You will need to take Lamivudine tablets 150 mg every day. This medicine helps to control your condition, but it is not a cure for HIV infection. You may continue to develop other infections and other illnesses associated with HIV disease. You should keep in regular contact with your doctor or health care provider. Do not stop taking your medicine without first talking to your doctor or health care provider.

Taking other medicines

Please tell your doctor, health care provider 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 tablets 150 mg, or Lamivudine tablets 150 mg may affect their action.

Taking Lamivudine tablets 150 mg with food and drink

Lamivudine tablets 150 mg may be taken with or without food.

Pregnancy

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

If you have taken Lamivudine tablets 150 mg during your pregnancy, your doctor or health care provider may request regular visits to monitor the development of your child. Such visits may include blood tests and other diagnostic tests.

In children whose mother took nucleoside and nucleotide analogues during pregnancy, the benefit from the reduced chance of being infected with HIV is greater than the risk of suffering from side effects.

Breast-feeding

Since lamivudine and the virus pass into breast milk it is recommended that HIV infected woman taking Lamivudine tablets 150 mg do not breast-feed their infants under any circumstances in order to avoid transmission of HIV.

Driving and using machines

No information on the effects of lamivudine on the ability to drive and use machines is available.

3. HOW TO TAKE LAMIVUDINE TABLETS 150 MG

Always take Lamivudine tablets 150 mg exactly as your doctor or health care provider told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

The usual daily dose for adults and adolescents over 12 years of age is 300 mg. This can be taken either as 1 x 150 mg tablet twice a day approximately 12 hours apart or 300 mg once a day (2 x 150

mg tablet). Swallow Lamivudine tablets 150 mg with water or another drink. The tablets can be taken with or without food.

If you have a kidney problem, your dose may be altered. Please follow the instructions of your doctor or health care provider.

Lamivudine tablets 150 mg will always be taken in combination with other antiretroviral medication; please make sure to follow the instructions within the supplied package leaflets.

If you take more Lamivudine tablets 150 mg than you should

If you have taken too many tablets or if someone accidentally swallows some, there is no immediate danger. However, you should contact your doctor, health care provider or the nearest hospital emergency department for further advice.

If you forget to take Lamivudine tablets 150 mg

If you accidentally miss a dose, 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 have any further questions on the use of this product, ask your doctor or health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lamivudine tablets 150 mg 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 tablets 150 mg, or those caused by any other medicines you may be taking at the same time, or by the HIV disease. For this reason, it is important that you inform your doctor or health care provider of any change in your health.

Short-term adverse reactions to combination antiretroviral therapy are common. After you start taking Lamivudine tablets 150 mg headache, nausea and vomiting, abdominal pain, diarrhoea and fatigue may occur: these reactions are usually mild and disappear within a few weeks even if treatment is continued.

Commonly reported (greater than 1 in every 100 patients treated) side effects are fatigue, headache, insomnia, nausea, abdominal pain, diarrhoea and hair loss.

The following side effects are *uncommon* (between 1 in 1,000 and 1 in 100 patients treated): decrease of white blood cells.

Combination antiretroviral therapy may cause a condition called lactic acidosis, which is a build up of lactic acid in the body, that can cause dehydration and coma. These reactions have been reported on rare occasions in patients taking NRTIs. Deep, rapid breathing, drowsiness, and non specific symptoms such as nausea, vomiting and stomach pain, may indicate the development of lactic acidosis.

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.

Combination antiretroviral therapy may also cause raised lactic acid and sugar in the blood, hyperlipaemia (increased fats in the blood) and resistance to insulin.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist as soon as possible.

5. HOW TO STORE LAMIVUDINE TABLETS 150 MG

Keep out of the reach and sight of children.

Store below 25°C in the original container, protected from moisture.

Do not use Lamivudine tablets 150 mg after the expiry date which is stated on the labelling. The expiry date refers to the last day of that month.

Do not use Lamivudine tablets 150 mg if you notice any change in the physical description of the tablets than what is mentioned below (see “What Lamivudine tablets 150 mg looks like and contents of the pack”):

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Lamivudine tablets 150 mg contains

- The active ingredient is lamivudine.
- The other ingredients are microcrystalline cellulose, sodium starch glycolate, magnesium stearate and Opadry 03H58900 White (film coating material).

What Lamivudine tablets 150 mg looks like and contents of the pack

Lamivudine tablets 150 mg are white to off-white, capsule shaped, biconvex, film coated tablets with ‘RX919’ debossed on one side and plain on the other side, available as a pack of 60’s in white opaque HDPE bottles and in clear PVC blister strips..

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This leaflet was last approved in 02/2007.

Detailed information on this medicine is available on the World Health Organization (WHO) web site:
<http://mednet3.who.int/prequal/> .