

# LAMIVUDINE TABLETS 150MG/300MG

Lamivudine 150mg/300mg

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## What Lamivudine Tablets are used for and how they work

Lamivudine tablets 150 mg /300 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 (AIDS).

## How Lamivudine Tablets work

Lamivudine tablets 150 mg / 300 mg is used in antiretroviral combination therapy for the treatment of HIV infection (AIDS). Lamivudine tablets 150 mg/ 300 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/ 300 mg varies between patients. Your doctor or health care provider will be monitoring the effectiveness of your treatment. Lamivudine tablets 150 mg/ 300 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/ 300 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.

Lamivudine tablets 150 mg/ 300 mg is an antiviral medication that prevents human immunodeficiency virus (HIV) cells from multiplying in your body. Its main mode of action is as a chain terminator of viral reverse transcription.

## Before you use Lamivudine Tablets

### When you must not take it

#### If you are allergic

Do not take Lamivudine tablets 150 mg/ 300 mg if you're allergic (hypersensitive) to lamivudine or any of the other ingredients of Lamivudine tablets 150 mg/ 300 mg.

Check with your doctor if you think this applies to you.

### Before you start to take it

Inform your doctor if you have any of the following conditions:

#### If you have kidney disease

Discuss the use of Lamivudine tablets 150 mg/ 300 mg with your doctor or health care provider if you have kidney disease. The standard recommended dose of Lamivudine tablets 150 mg/ 300 mg may have to be reduced.

#### If you have liver disease

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.

#### Pregnancy

If you are pregnant, if you become pregnant, or are planning to become pregnant, talk to your doctor about the risks and benefits to you and your baby of taking Lamivudine tablets 150 mg /300 mg.

Lamivudine tablets 150 mg/ 300 mg and similar medicines may cause side effects in unborn babies.

#### 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 /300 mg, or Lamivudine tablets 150 mg/ 300 mg may affect their action.

The following medicines should not be used with Lamivudine tablets 150 mg/300 mg:-

- Trimethoprim 160mg/ Sulfamethoxazole 800mg
- Lamivudine and zidovudine in combination with zalcitabine

## How to take Lamivudine Tablets

### How much to take

Swallow Lamivudine tablets 150 mg /300 mg, with some water; it can be taken with or without food.

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If you cannot swallow the tablets whole, you may crush and combine them with a small amount of food or drink, and take the entire dose immediately.

Take this medication exactly as it was prescribed for you. Do not take the medication in larger amounts, or take it for longer than recommended by your doctor.

The usual daily dose to be taken is provided below:

## Adults and Adolescents >16 years of age

The recommended oral dose of lamivudine in HIV-1 infected adults and adolescents >16 years of age is 300 mg daily, administered as either 150 mg twice daily or 300 mg once daily, in combination with other antiretroviral agents.

## If you have Kidney Problems

Your doctor will adjust your dose according to your kidney function.

## If you have Liver Problems

No dose adjustment is necessary in patients with moderate or severe liver problems unless accompanied by kidney problems.

## Elderly

Follow your doctor's advice on the dose that you should take.

## **When to take it**

Always take Lamivudine tablets 150 mg/300 mg exactly as your doctor has told you.

Check with your doctor or pharmacist if you're not sure.

## **How long to take it**

You need to keep taking Lamivudine tablets 150 mg/ 300 mg every day to stop your illness getting worse. You may still develop other infections and illnesses linked to HIV infection.

Keep in touch with your doctor, and don't stop taking Lamivudine without your doctor's advice.

## **If you forget to take it**

If you forget to take a dose, take it as soon as you remember. Then

continue your treatment as before.

Don't take a double dose to make up for a missed dose.

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

Accidentally taking too much Lamivudine tablets 150 mg /300 mg is unlikely to cause any serious problems. If you take too much, tell your doctor or your pharmacist, or contact your nearest hospital emergency department for further advice.

## **While you are taking Lamivudine Tablets 150mg/300mg**

### **Things you must do**

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

### **Things you must not do**

#### Do not breast-feed under any circumstances.

Since lamivudine and the virus pass into breast milk it is recommended that HIV infected woman taking Lamivudine tablets 150 mg /300 mg do not breast-feed their infants under any circumstances in order to avoid transmission of HIV.

#### You should not have unprotected sex/ sexual contact

Treatment with Lamivudine tablets 150 mg/ 300 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.

#### Do not share needles.

Sharing drug or medicine needles is never safe, even for a healthy person.

#### Avoid drinking alcohol

Avoid drinking alcohol while taking Lamivudine tablets 150 mg /300 mg. Alcohol may increase the risk of damage to the pancreas and/or liver.

## **Things to be careful of**

No information on the effects of Lamivudine tablets 150 mg/300 mg on the ability to drive and use machines is available.

If you are feeling abnormal or unusual problems call your doctor.

## **Side Effects**

Like all medicines, Lamivudine tablets 150 mg /300 mg can cause side effects, but not everyone gets them.

When you're being treated for HIV, it can be hard to tell whether a symptom is a side effect of Lamivudine tablets 150 mg/ 300 mg or other medicines you are taking, or an effect of the HIV disease itself. So it is very important to talk to your doctor about any changes in your health.

As well as the side effects listed below for Lamivudine tablets 150 mg/ 300 mg, other conditions can develop during combination therapy for HIV. It is important to read the information later in this section under 'Other possible side effects of combination therapy for HIV'.

### Common side effects

- headache
- feeling sick (*nausea*)
- being sick (*vomiting*)
- diarrhoea
- stomach pains
- tiredness, lack of energy
- fever (high temperature)
- general feeling of being unwell
- muscle pain and discomfort
- joint pain
- difficulty in sleeping (*insomnia*)
- cough
- irritated or runny nose
- rash
- hair loss (*alopecia*).

### If you get side effects

Tell your doctor or pharmacist if any of the side effects gets severe or troublesome, or if you notice any side effects not listed in this leaflet.

Other possible side effects of combination therapy for HIV Combination therapy including Lamivudine may cause other conditions to develop during HIV treatment.

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Old infections may flare up. People with advanced HIV infection (AIDS) have weak immune systems, and are more likely to develop serious infections (opportunistic infections). When these people start treatment, they may find that old, hidden infections flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.

If you get any symptoms of infection while you're taking Lamivudine tablets 150 mg/ 300 mg:

Tell your doctor immediately. Don't take other medicines for the infection without your doctor's advice.

## Your body shape may change

People taking combination therapy for HIV may find that their body shape changes, because of changes in fat distribution:

- Fat may be lost from the legs, arms or face.
- Extra fat may build up around the tummy (abdomen), or on the breasts or internal organs.
- Fatty lumps (sometimes called buffalo hump) may appear on the back of the neck.

It is not yet known what causes these changes, or whether they have any long-term effects on your health. If you notice changes in your body shape:

Tell your doctor.

## Lactic acidosis is a rare but serious side effect

Some people taking Lamivudine, or other medicines like it (NRTIs), develop a condition called lactic acidosis, together with an enlarged liver.

Lactic acidosis is caused by a build-up of lactic acid in the body. It is rare; if it happens, it usually develops after a few months of treatment. It can be life-threatening, causing failure of internal organs.

Lactic acidosis is more likely to develop in people who have liver disease, or in obese (very

overweight) people, especially women.

Signs of lactic acidosis include:

- deep, rapid, difficult breathing
- drowsiness
- numbness or weakness in the limbs
- feeling sick (nausea), being sick (vomiting)
- stomach pain.

During your treatment, your doctor will monitor you for signs of lactic acidosis. If you have any of the symptoms listed above or any other symptoms that worry you:

See your doctor as soon as possible.

You may have problems with your bones

Some people taking combination therapy for HIV develop a condition called osteonecrosis. With this condition, parts of the bone tissue die because of reduced blood supply to the bone. People may be more likely to get this condition:

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight.

Signs of osteonecrosis include:

- stiffness in the joints
- aches and pains (especially in the hip, knee or shoulder)
- difficulty moving.

If you notice any of these symptoms:

Tell your doctor.

## Other effects may show up in blood tests

Combination therapy for HIV can also cause:

increased levels of lactic acid in the blood, which on rare occasions can lead to lactic acidosis  
increased levels of sugar and fats (triglycerides and cholesterol) in the blood

resistance to insulin (so if you're diabetic, you may have to change your insulin dose to control your blood sugar).

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 portal.bpfk.gov.my (Consumers → Reporting).

## **Storage and Disposal of Lamivudine Tablets 150mg/300mg**

### Storage

Store below 30°C, in the original carton to protect the medication.

### 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 Tablets 150 mg are white, circular, biconvex film coated tablets TMT engraved on one side and break line on other side.

Lamivudine Tablets 300 mg white, circular, biconvex, film coated tablets L300 engraved on one side and plain on other side.

### Ingredients

The active substance is lamivudine.

The tablets also contain the following other ingredients:

Microcrystalline cellulose, sodium starch glycollate, Colloidal silicon dioxide, Povidone (K-30), Magnesium Stearate, Opadry White (Hydroxy Propyl methylcellulose 2910/ Hypromellose 5cP USP, Titanium dioxide USP, Polyethylene glycol 400 (Macrogol) NF) and Purified water.

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**Product Registration No.**

Lamivudine Tablets 300 mg –

MAL11030100A

Lamivudine Tablets 150 mg –

MAL12045010A

**Manufacturer**

**Strides Arcolab Limited**

36/7, Suragajakkanahalli,

Indlavadi Cross, Anekal Taluk,

Bangalore-562 106, INDIA.

**Marketing Authorization Holder**

**Ascent Pharmahealth Malaysia Sdn Bhd**

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Uptown, 47400 Petaling Jaya,

Selangor Darul Ehsan, Malaysia

**Date of Revision**

30-04-2013