

**PACKAGE LEAFLET**

## Package leaflet: Information for the user

### Lamivudine 300 mg Film-coated tablets

lamivudine

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet:

1. What Lamivudine 300 mg is and what it is used for
2. What you need to know before you take Lamivudine 300 mg
3. How to take Lamivudine 300 mg
4. Possible side effects
5. How to store Lamivudine 300 mg
6. Contents of the pack and other information

#### 1. What Lamivudine 300 mg is and what it is used for

**Lamivudine 300 mg is used to treat HIV (human immunodeficiency virus) infection in adults and children.**

The active ingredient in Lamivudine 300 mg is lamivudine. Lamivudine 300 mg is a type of medicine known as an anti-retroviral. It belongs to a group of medicines called *nucleoside analogue reverse transcriptase inhibitors (NRTIs)*.

Lamivudine 300 mg does not completely cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. It also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

Not everyone responds to treatment with Lamivudine 300 mg in the same way. Your doctor will monitor the effectiveness of your treatment.

#### 2. What you need to know before you take Lamivudine 300 mg

##### Do not take Lamivudine 300 mg:

- if you are **allergic** to lamivudine or to any of the other ingredients of this medicine (listed in section 6).

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

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Lamivudine 300 mg.

### **Take special care with Lamivudine 300mg**

Some people taking Lamivudine 300 mg or other combination treatments for HIV are more at risk of serious side effects. You need to be aware of the extra risks:

- if you have ever had **liver disease**, including hepatitis B or C (if you have hepatitis B infection, do not stop Lamivudine 300 mg without your doctor's advice, as your hepatitis may come back)
- if you are seriously **overweight** (especially if you are a woman)
- **if you have a kidney problem**, your dose may be altered.

**Talk to your doctor if any of these apply to you.** You may need extra check-ups, including blood tests, while you are taking your medicine. **See Section 4 for more information.**

### **Look out for important symptoms**

Some people taking medicines for HIV infection develop other conditions, which can be serious. You need to know about important signs and symptoms to look out for while you are taking Lamivudine 300 mg.

**Read the information 'Other possible side effects of combination therapy for HIV' in Section 4 of this leaflet.**

### **Protect other people**

HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). You can still pass on HIV when taking this medicine, although the risk is lowered by the effective antiretroviral therapy.

Discuss with your doctor the precautions needed to avoid infecting other people.

### **Other medicines and Lamivudine 300 mg**

STell your doctor or pharmacist if you are taking or have recently taken any other medicines, or if you have taken any recently, including herbal medicines or other medicines you bought without a prescription.

Remember to tell your doctor or pharmacist if you begin taking a new medicine while you are taking Lamivudine 300 mg.

### **These medicines should not be used with Lamivudine 300 mg:**

- medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly
- other medicines containing lamivudine, (used to treat **HIV infection** or **hepatitis B infection**)
- emtricitabine (used to treat **HIV infection**)
- high doses of **co-trimoxazole**, an antibiotic
- cladribine (used to treat **hairy cell leukaemia**)

**Tell your doctor** if you're being treated with any of these.

### **Pregnancy and breast-feeding**

#### *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 300 mg.

Lamivudine 300 mg and similar medicines may cause side effects in unborn babies. If you have taken Lamivudine 300 mg during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child.

In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

#### *Breast-feeding*

**Women who are HIV-positive must not breast-feed**, because HIV infection can be passed on to the baby in breast milk.

A small amount of the ingredients in Lamivudine Hetero can also pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding:

**Talk to your doctor immediately.**

### **Driving and using machines**

Lamivudine 300 mg is unlikely to affect your ability to drive or use machines.

## **3. How to take Lamivudine 300 mg**

**Always take this medicine exactly as your doctor has told you.** Check with your doctor or pharmacist if you are not sure.

Swallow the tablet, with some water. Lamivudine 300 mg can be taken with or without food.

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

### **Stay in regular contact with your doctor**

Lamivudine 300 mg helps to control your condition. You need to keep taking it 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 300 mg** without your doctor's advice.

### **How much to take**

**Adults, adolescents and children who weigh at least 25 kg:**

The usual dose is **one 300 mg tablet once a day**.

A 150 mg strength Lamivudine Hetero tablet is also available for the treatment of children from 3 months of age who weigh less than 25 kg.

An oral solution is also available for the treatment of children over 3 months of age, or for people who need a lower dose than usual, or who cannot take tablets.

**If you have a kidney problem**, your dose may be altered.  
**Talk to your doctor** if this applies to you.

**If you take more Lamivudine 300 mg than you should**

Accidentally taking too much Lamivudine 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.

**If you forget to take Lamivudine 300 mg**

If you forget to take a dose, take it as soon as you remember. Then continue your treatment as before. Do not take a double dose to make up for a forgotten dose.

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

**4. Possible side effects**

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Like all medicines, this medicine can cause side effects, but not everybody gets them.

When you are being treated for HIV, it can be hard to tell whether a symptom is a side effect of Lamivudine 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 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**

These may affect **up to 1 in 10** people

- 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).

### **Uncommon side effects**

These may affect **up to 1 in 100** people:

Uncommon side effects that may show up in blood tests are:

- a decrease in the number of cells involved in blood clotting (thrombocytopenia)
- a low red blood cell count (anaemia) or low white blood cell count (neutropenia)
- an increase in the level of liver enzymes.

### **Rare side effects**

These may affect **up to 1 in 1000** people:

- serious allergic reaction causing swelling of the face, tongue or throat which may cause difficulty in swallowing or breathing
- inflammation of the pancreas (*pancreatitis*)
- breakdown of muscle tissue
- liver disorders, such as jaundice, enlarged liver or fatty liver, inflammation (*hepatitis*).

A rare side effect that may show up in blood tests is:

- increase in an enzyme called amylase.

### **Very rare side effects**

These may affect **up to 1 in 10,000** people:

- Lactic acidosis (excess lactic acid in the blood)
- tingling or numbness of the arms, legs, hands or feet.

A very rare side effect that may show up in blood tests is:

- a failure of the bone marrow to produce new red blood cells (*pure red cell aplasia*).

### **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 300 mg may cause other conditions to develop during HIV treatment.

### **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.

In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

If you get any symptoms of infection while you are taking Lamivudine 300 mg:

**Tell your doctor immediately.** Do not take other medicines for the infection without your doctor's advice.

### **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.**

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Lamivudine 300 mg**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. Do not use this medicine after three months of first opening the HDPE container.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Lamivudine 300 mg contains**

The active substance is lamivudine. Each film-coated tablet contains 300 mg of lamivudine.

The other ingredients are: isomalt (E953), crospovidone A, magnesium stearate (E572), hypromellose (E464), titanium dioxide (E171), macrogol 400, polysorbate 80 (E433).

### **What Lamivudine 300 mg looks like and contents of the pack**

Lamivudine 300 mg film-coated tablets are supplied in Alu/PVC-Alu-OPA blister pack containing 30 tablets and in HDPE container with child resistant polypropylene cap containing 30 tablets.

The tablets are white capsule shaped, biconvex film coated tablets with a dimension of 19.10 x 8.90 mm, debossed with 17 on one side and J on the other side.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Accord Healthcare Limited  
Sage House, 319 Pinner Road,  
North Harrow, Middlesex,  
HA1 4HF, United Kingdom

### **Manufacturer**

Pharmadox Healthcare Ltd.  
KW 20A - Kordin Industrial Park  
PLA 3000 Paola  
Malta

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Hungary: Lamivudine HSPT 300 mg tableta  
Italy: Lamivudina Accord  
Netherlands: Lamivudine Accord 300 mg, filmomhulde tabletten  
Spain: Lamivudina Accord 300 mg, comprimidos recubiertos con película EFG  
United Kingdom :Lamivudine 300 mg Film-coated tablets

**This leaflet was last revised in 03/2018.**



