

Lamivudine/Zidovudine
150 mg/300 mg Tablets
(Strides Pharma Science Ltd.)
HA291

WHOPAR part 3

Section 6 updated:
October 2018

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Lamivudine 150 mg and Zidovudine 300 mg tablets *

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 health care provider
- 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 health care provider. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

1. What Lamivudine 150 mg and Zidovudine 300 mg tablets is and what it is used for
2. What you need to know before you take Lamivudine 150 mg and Zidovudine 300 mg tablets
3. How to take Lamivudine 150 mg and Zidovudine 300 mg tablets
4. Possible side effects
5. How to store Lamivudine 150 mg and Zidovudine 300 mg tablets
6. Contents of the pack and other information

1. WHAT LAMIVUDINE 150 MG AND ZIDOVUDINE 300 MG TABLETS IS AND WHAT IT IS USED FOR

Lamivudine 150 mg and Zidovudine 300 mg tablets is used for the treatment of human immunodeficiency virus (HIV-1) in infected patients weighing 25 kg or more.

Lamivudine 150 mg and Zidovudine 300 mg tablets contains the active substances *lamivudine* and *zidovudine*. Both are *antiviral* medicines also known as antiretrovirals, called nucleoside analogue reverse transcriptase inhibitors (NRTIs). Both substances interfere with enzymes used by HIV for making copies of itself and thereby block the reproduction of the virus.

Lamivudine 150 mg and Zidovudine 300 mg tablets reduces the amount of HIV 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 for a healthy immune system and for helping your body to fight infection.

To prevent the virus from becoming resistant, Lamivudine and Zidovudine Tablets 150 mg/300 mg should always be given in combination with another antiretroviral medicine.

Lamivudine 150 mg and Zidovudine 300 mg tablets may improve your condition, but it is not a cure for HIV infection.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LAMIVUDINE 150 MG AND ZIDOVUDINE 300 MG TABLETS

Do not take Lamivudine 150 mg and Zidovudine 300 mg tablets:

- if you are allergic (hypersensitive) to lamivudine, zidovudine or to any of the other ingredients of Lamivudine 150 mg and Zidovudine 300 mg tablets (listed in section 6, below).
- if you have a very low red blood cell count (severe anaemia) or a very low white blood cell count (neutropenia or leucopenia).

Check with your health care provider if you think any of these apply to you.

Take special care with Lamivudine 150 mg and Zidovudine 300 mg tablets

Some people taking Lamivudine 150 mg and Zidovudine 300 mg tablets 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 and Zidovudine Tablets 150 mg/300 mg without your health care provider's advice, as your hepatitis may come back)
- if you have **kidney disease**
- if you are seriously **overweight** (especially if you are a woman)

Talk to your health care provider if any of these apply to you. Your health care provider will decide if the active substances are suitable for you. You may need extra check-ups,

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 150 mg and Zidovudine 300 mg tablets.

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 effective antiretroviral therapy.

Discuss with your health care provider the precautions needed to avoid infecting other people.

Other medicines and Lamivudine 150 mg and Zidovudine 300 mg tablets

Tell your health care provider if you are taking 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 health care provider if you begin taking a new medicine while you are taking Lamivudine 150 mg and Zidovudine 300 mg tablets.

These medicines should not be used with Lamivudine 150 mg and Zidovudine 300 mg tablets:

- other medicinal products containing lamivudine, to treat **HIV infection or hepatitis B infection**
- emtricitabine, to treat **HIV infection**
- stavudine, to treat **HIV infection**

- ribavirin or injections of ganciclovir to treat **viral infections**
- high doses of **co-trimoxazole**, an antibiotic
- cladribine, used to treat **hairy cell leukaemia**

Tell your health care provider if you are being treated with any of these.

Some medicines can make it more likely that you'll have side effects, or make side effects worse.

These include:

- sodium valproate, to treat **epilepsy**
- interferon, to treat **viral infections**
- pyrimethamine, to treat **malaria** and other parasitic infections
- dapsons, to prevent **pneumonia** and treat skin infections
- fluconazole or flucytosine, to treat **fungal infections** such as **candida**
- pentamidine or atovaquone to treat parasitic infections such as **PCP**
- amphotericin or co-trimoxazole, to treat **fungal and bacterial infections**
- probenecid, to treat **gout** and similar conditions, and given with some antibiotics to make them more effective
- **methadone**, used as a **heroin substitute**
- vincristine, vinblastine or doxorubicin, to treat **cancer**.

Tell your health care provider if you are taking any of these.

Some medicines interact with Lamivudine 150 mg and Zidovudine 300 mg tablets

These include:

- **clarithromycin**, an antibiotic
if you are taking clarithromycin, take your dose at least 2 hours before or after you take your Lamivudine 150 mg and Zidovudine 300 mg tablets.
- **phenytoin**, for treating **epilepsy**.

Tell your health care provider if you are taking phenytoin. Your health care provider may need to monitor you while you are taking **Lamivudine 150 mg and Zidovudine 300 mg tablets**.

- medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly.

Pregnancy

Ask your health care provider for advice before taking any medicine. Be sure to tell your health care provider immediately if you are or may be pregnant.

In babies born to mothers who have taken antiretroviral medicines comprising nucleoside and nucleotide analogues, the benefit of reduced risk of becoming infected with HIV outweighs the risk of side effects of these medicines.

Breastfeeding

If you want to breast-feed your baby, you should discuss the risks and benefits with your health care provider.

Driving and using machines

Lamivudine 150 mg and Zidovudine 300 mg tablets may cause side effects such as dizziness, fatigue or headache, which can affect your ability to drive and to use machines. Therefore, don't drive or operate machines unless you are feeling well.

3. HOW TO TAKE LAMIVUDINE 150 MG AND ZIDOVUDINE 300 MG TABLETS

Always take **Lamivudine 150 mg and Zidovudine 300 mg tablets** exactly as your health care provider has told you. This is to make sure that your medicine is fully effective, and to reduce the risk of developing resistance to the treatment. You should check with your health care provider if you are not sure. Always take the dose recommended by your health care provider. Do not change the dose unless your health care provider tells you to.

Taking Lamivudine 150 mg and Zidovudine 300 mg tablets

Lamivudine 150 mg and Zidovudine 300 mg tablets may be taken with food or between meals, swallowed with some water or another drink. If you cannot swallow the tablets, you may crush and take them immediately with a small amount of semi-solid food or drink. You must make sure that you take the whole dose.

How much to take

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

The usual dose is one tablet Lamivudine 150 mg and Zidovudine 300 mg tablets twice a day, leaving approximately 12 hours between each dose.

Children weighing less than 25 kg:

This product should not be used in children weighing less than 25 kg since appropriate dose adjustments cannot be made. For these patients other formulations should be used, e.g. a tablet which can be used to give smaller doses of lamivudine and zidovudine.

If you have a kidney problem, your dose may need to be altered. Talk to your health care provider if this applies to you.

If you take more Lamivudine 150 mg and Zidovudine 300 mg tablets than you should

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

If you forget to take Lamivudine 150 mg and Zidovudine 300 mg tablets

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 have any further questions on the use of this product, ask your health care provider.

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 health care provider will test for these changes.

Treatment with Lamivudine 150 mg and Zidovudine 300 mg tablets often causes a loss of fat from legs, arms and face (lipoatrophy). This loss of body fat has been shown to be not fully reversible after discontinuation of zidovudine. Your health care provider should monitor for signs of lipoatrophy. Tell your health care provider if you notice any loss of fat from your legs, arms, and face. When these signs occur, Lamivudine 150 mg and Zidovudine 300 mg tablets should be stopped and your HIV treatment changed.

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

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

As well as the side effects listed below for Lamivudine 150 mg and Zidovudine 300 mg tablets, 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’.

Very common side effects

These may affect **more than than 1 in 10** people:

- headache
- feeling sick (*nausea*).

Common side effects

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

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

Common side effects that might show up in blood tests are:

- a low red blood cell count (*anaemia*) or low white blood cell count (*neutropenia* or *leucopenia*)
- an increase in the level of liver enzymes
- an increased amount in the blood of *bilirubin* (a substance produced in the liver) which may make your skin appear yellow.

Uncommon side effects

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

- feeling breathless
- wind (*flatulence*)
- itching
- muscle weakness.

An uncommon side effect that may show up in blood test is:

- a decrease in the number of cells involved in blood clotting (*thrombocytopenia*) or in all kinds of blood cells (*pancytopenia*).

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
- liver disorders, such as jaundice, enlarged liver or fatty liver, inflammation (*hepatitis*)
- lactic acidosis (excess lactic acid in the blood; see the next section, 'Other possible side effects of combination therapy for HIV')
- inflammation of the pancreas (*pancreatitis*)
- chest pain; disease of the heart muscle (*cardiomyopathy*)
- fits (*convulsions*)
- feeling depressed or anxious, not being able to concentrate, feeling drowsy
- indigestion, taste disturbance
- changes in the colour of your nails, your skin or the skin inside your mouth
- a flu-like feeling – chills and sweating
- tingly feelings in the skin (pins and needles)
- sensation of weakness in the limbs
- breakdown of muscle tissue
- numbness
- passing urine more often
- enlarged breasts in men.

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

- an increase in an enzyme called amylase
- a failure of the bone marrow to produce new red blood cells (*pure red cell aplasia*).

Very rare side effects

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

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

- a failure of the bone marrow to produce new red and white blood cells (*aplastic anaemia*).

If you get side effects

Tell your health care provider if any of the side effects get 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 such as Lamivudine 150 mg and Zidovudine 300 mg tablets 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 (conditions 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 health care provider immediately to seek necessary treatment.

If you get any symptoms of infection while you are taking Lamivudine 150 mg and Zidovudine 300 mg tablets:

Tell your health care provider immediately. Do not take other medicines for the infection without your health care provider's advice.

Lactic acidosis is a rare but serious side effect

Some people taking Lamivudine 150 mg and Zidovudine 300 mg tablets 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 health care provider 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 health care provider 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 health care provider.

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.

Reporting of side effects

If you get any side effects, talk to health care provider. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE LAMIVUDINE 150 MG AND ZIDOVUDINE 300 MG TABLETS

Keep out of the reach and sight of children.

Do not store above 30°C. Protect from light and moisture.

Do not use Lamivudine 150 mg and Zidovudine 300 mg tablets after the expiry date, which is stated on the container label. The expiry date refers to the last day of that month.

Do not use Lamivudine 150 mg and Zidovudine 300 mg tablets if the tablet looks different from the description below, under 'Further Information'.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lamivudine 150 mg and Zidovudine 300 mg tablets contains

The active ingredients are lamivudine and zidovudine. The other ingredients are:

- *core tablet*: microcrystalline cellulose, sodium starch glycolate, colloidal anhydrous silica, purified talc, magnesium stearate
- *tablet film coating*: hypromellose, titanium dioxide and polyethylene glycol 400

What Lamivudine 150 mg and Zidovudine 300 mg tablets looks like and contents of the pack

White to-off white, oval shaped film-coated tablets, with LZ debossed on one side and break-line on the other side.

Tablets are available in white opaque HDPE container with LDPE cap containing 60 tablets.

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For any information about this medicinal product, please contact the local representative of the supplier:

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Section 6 updated:
October 2018

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Section 6 updated:
October 2018

This leaflet was first approved in August 2007

Section 6 was updated in May 2016

All sections were updated in August 2018

Section 6 was updated in October 2018

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