



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

1. What Lamivudine is and what it is used for

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

The active ingredient in Lamivudine is lamivudine. Lamivudine 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 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 in the same way. Your doctor will monitor the effectiveness of your treatment.

2. What you need to know before you take Lamivudine

Do not take Lamivudine:

- if you are **allergic** to lamivudine or 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

Some people taking Lamivudine 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, don't stop Lamivudine without your doctor's advice, as your hepatitis may come back)
- if you're seriously overweight (especially if you're 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're 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're taking Lamivudine.

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 doctor the precautions needed to avoid infecting other people.

Other medicines and Lamivudine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, 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're taking Lamivudine.

These medicines should not be used with Lamivudine:

- 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, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

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.

Lamivudine and similar medicines may cause side effects in unborn babies. If you have taken Lamivudine 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 can also pass into your breast milk.

If you're breast-feeding, or thinking about breast-feeding:

Talk to your doctor immediately.

Driving and using machines

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

Lamivudine contains Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take Lamivudine

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

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

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

Stay in regular contact with your doctor

Lamivudine 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 without your doctor's advice.

How much to take

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

The recommended dose of Lamivudine is 300 mg once a day.

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

An oral solution may also be available for the treatment of children over 3 months of age, or for people who need a lower dose than usual, or who can't 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 than you should

Accidentally taking too much Lamivudine 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

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.

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

When you're being treated for HIV, it can be hard to tell whether a symptom is a side effect of Lamivudine 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, 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 1,000** 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 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're taking Lamivudine:

Tell your doctor immediately. Don't 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 possible side effects not listed in this leaflet. You can also report side effects directly via

The United Kingdom

Yellow Card Scheme

Website: 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

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 label and carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C

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 protect the environment.

6. Contents of the pack and other information

What Lamivudine contains

- The active substance is lamivudine. Each film-coated tablet contains 300 mg of lamivudine.
- The other ingredients are:
Tablet core: Microcrystalline cellulose (E460), sodium starch glycolate (Type A), magnesium stearate (E572)
Film-coat: Hypromellose (E464), macrogol 400, titanium dioxide (E171), polysorbate 80 (E433) and iron oxide black (E172).

What Lamivudine looks like and contents of the pack

Film-coated tablet

Grey, film coated, diamond shaped tablets, debossed with 'Z26' on one side and plain on the other side.

Lamivudine film-coated tablets are available in blister packs and HDPE bottle.

Pack sizes:

Blister pack: 1, 14, 30, 60, 120 and 500 tablets

Bottle pack: 30 and 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Milpharm Limited
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Manufacturer

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