



Lamivudine and Zidovudine Tablets USP 150mg/ 300mg

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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 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.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

- a) What Lamivudine and Zidovudine Tablet is and what it is used for
- b) What you need to know before you take Lamivudine and Zidovudine Tablet
- c) How to take Lamivudine and Zidovudine Tablet
- d) Possible side effects
- e) How to store Lamivudine and Zidovudine Tablet
- f) Further information

a) What Lamivudine and Zidovudine Tablet is and what it is used for

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

Lamivudine and Zidovudine Tablet contains two active ingredients that are used to treat HIV infection: lamivudine and zidovudine. Both of these belong to a group of antiretroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs)..



Lamivudine and Zidovudine Tablets USP 150mg/ 300mg

Lamivudine and Zidovudine Tablet 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 and Zidovudine Tablet in the same way. Your doctor will monitor the effectiveness of your treatment.

b) What you need to know before you take Lamivudine and Zidovudine Tablet

Do not take Lamivudine and Zidovudine Tablet

- If you are allergic to lamivudine or zidovudine, or any of the other ingredients of this medicine (listed in section 6).
- If you have a very low red blood cell count (*anaemia*) or a very low white blood cell count (neutropenia).

Check with your doctor if you think any of these apply to you.

Warnings and precautions

- Some people taking Lamivudine and Zidovudine Tablet 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 Tablet without your doctor'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 doctor if any of these apply to you. Your doctor will decide if the active substances are suitable for 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 and Zidovudine Tablet. 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



Lamivudine and Zidovudine Tablets USP 150mg/ 300mg

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 and zidovudine

Tell your doctor or pharmacist 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 doctor or pharmacist if you begin taking a new medicine while you are taking Lamivudine and Zidovudine Tablet

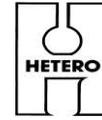
These medicines should not be used with Lamivudine and Zidovudine Tablet :

- Other medicinal products containing lamivudine, to treat HIV infection or hepatitis B infection Elevated potassium levels in your blood.
- 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 doctor 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
- Dapsone, 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.



Lamivudine and Zidovudine Tablets USP 150mg/ 300mg

Tell your doctor if you are taking any of these.

Some medicines interact with Lamivudine and Zidovudine Tablet

These include:

- clarithromycin, an antibiotic

If you are taking clarithromycin, take your dose at least 2 hours before or after you take your Lamivudine and Zidovudine Tablet

- Phenytoin, for treating epilepsy.

Tell your doctor if you are taking phenytoin. Your doctor may need to monitor you while you are taking Lamivudine and Zidovudine Tablet .

Pregnancy and Breast-feeding

Pregnancy

If you are pregnant, if you become pregnant or if you are planning to become pregnant talk to your doctor about the risks and benefits to you and your baby of taking Lamivudine and Zidovudine Tablet .

Lamivudine and Zidovudine Tablet and similar medicines may cause side effects in unborn babies. If you have taken Lamivudine and Zidovudine Tablet 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.

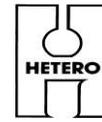
Breast-feeding

Women who are HIV-positive must not breastfeed, because HIV infection can be passed on to the baby in breast milk. A small amount of the ingredients in Lamivudine and Zidovudine Tablet can also pass into your breast-milk.

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

Driving and using machines

Lamivudine and Zidovudine Tablet can make you dizzy and have other side effects that make you less alert. Do not drive or operate machines unless you are feeling well.



Lamivudine and Zidovudine Tablets USP 150mg/ 300mg

c) How to take Lamivudine and Zidovudine Tablet

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 Lamivudine and Zidovudine Tablet tablets, with some water. Lamivudine and Zidovudine Tablet 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 and Zidovudine Tablet 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 do not stop taking Lamivudine and Zidovudine Tablet without your doctor's advice.

How much to take

Adults and adolescents 30 kg or more

The usual dose of Lamivudine and Zidovudine Tablet is one tablet twice a day.

Take the tablets at regular times, leaving approximately 12 hours between each tablet.

Children who weigh between 21 and 30 kg

The usual starting dose of Lamivudine and Zidovudine Tablet is one half tablet ($\frac{1}{2}$) taken in the morning and one whole tablet taken in the evening.

Children who weigh between 14 and 21 kg

The usual starting dose of Lamivudine and Zidovudine Tablet is one half tablet ($\frac{1}{2}$) taken in the morning and one half tablet ($\frac{1}{2}$) taken in the evening. For children who weigh less than 14 kg lamivudine and zidovudine (the ingredients of Lamivudine and Zidovudine Tablet) should be taken separately.

If you take more Lamivudine and Zidovudine Tablet than you should

If you accidentally take too much Lamivudine and Zidovudine Tablet, tell your doctor or your pharmacist, or contact your nearest hospital emergency department for further advice.



Lamivudine and Zidovudine Tablets USP 150mg/ 300mg

If you forget to take Lamivudine and Zidovudine Tablet

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.

d) 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. Treatment with Lamivudine and Zidovudine Tablet 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 doctor should monitor for signs of lipoatrophy. Tell your doctor if you notice any loss of fat from your legs, arms, and face. When these signs occur, Lamivudine and Zidovudine Tablet 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 and Zidovudine Tablet 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 and Zidovudine Tablet 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

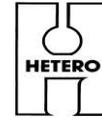
These may affect more than 1 in 10 people:

- Headache
- Feeling sick (*nausea*).

Common side effects

These may affect up to 1 in 10 people:

- Being sick (*vomiting*)
- Diarrhoea



Lamivudine and Zidovudine Tablets USP 150mg/ 300mg

- 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.

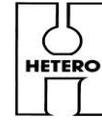
Uncommon side effects

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*).



Lamivudine and Zidovudine Tablets USP 150mg/ 300mg

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’)
- Inflammations 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:

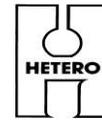
- An increase in an enzyme called amylase
- A failure of the bone marrow to produce new red blood cells (*pure red cell aplasia*).

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 or white blood cells (*aplastic anaemia*).



Lamivudine and Zidovudine Tablets USP 150mg/ 300mg

If you get side effects

Tell your doctor or pharmacist 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 and Zidovudine Tablet 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 and Zidovudine Tablet : Tell your doctor immediately. Do not take other medicines for the infection without your doctor's advice.

Lactic acidosis is a rare but serious side effect

Some people taking Lamivudine and Zidovudine Tablet 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



Lamivudine and Zidovudine Tablets USP 150mg/ 300mg

- 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.

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- 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.

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

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 (see details below).



Lamivudine and Zidovudine Tablets USP 150mg/ 300mg

By reporting side effects you can help provide more information on the safety of this medicine

e) How to store Lamivudine and Zidovudine Tablet

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.

Store Below 30°C, Protect from moisture

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.

f) Further information

What Lamivudine and Zidovudine contains

The active substances are Lamivudine USP and Zidovudine USP.

The other ingredients are

- **Core Tablet:**

Microcrystalline cellulose, sodium starch glycolate, magnesium stearate, colloidal silicon dioxide

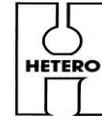
- **Film coat Tablet;**

Opadry White (YS-1-7003)

What Lamivudine and zidovudine looks like and contents of the pack

Lamivudine and zidovudine film-coated tablets are provided in cartons bottles with a child resistant-closure. Each pack type contains 60 film-coated tablets.

White, film coated, Capsule shaped tablets debossed with 'H' and score line on one side and '2' on other side.



Hetero

Lamivudine and Zidovudine Tablets USP 150mg/ 300mg

Name and full physical address of Marketing Authorization Holder and Manufacturing site

Marketing Authorization Holder

Name: Hetero Labs Limited
Business Address: 7-2-A2, Hetero Corporate,
Industrial Estates, Sanath
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Telangana. India
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Manufacturing site

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