

PATIENT INFORMATION LEAFLET
Lamivudine and Zidovudine tablets for oral suspension 30 mg/60 mg
(Lamivudine and Zidovudine)

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, health care provider or nurse.
- 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.

In this leaflet:

- a. What Lamivudine and Zidovudine Tablets for Oral Suspension is and what it is used for
- b. Before you take Lamivudine and Zidovudine Tablets for Oral Suspension
- c. How to take Lamivudine and Zidovudine Tablets for Oral Suspension
- d. Possible side effects
- e. How to store Lamivudine and Zidovudine Tablets for Oral Suspension
- f. Further information

a) WHAT LAMIVUDINE AND ZIDOVUDINE TABLETS FOR ORAL SUSPENSION IS AND WHAT IT IS USED FOR

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

Lamivudine and Zidovudine tablets for oral suspension 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 for oral suspension 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 tablets for oral suspension in the same way. Your doctor will monitor the effectiveness of your treatment.

b) BEFORE YOU Take LAMIVUDINE AND ZIDOVUDINE TABLETS FOR ORAL SUSPENSION

Do not take Lamivudine and Zidovudine Tablets For Oral Suspension

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

- 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.

Take special care With Lamivudine And Zidovudine Tablets For Oral Suspension

Some people taking Lamivudine and Zidovudine tablets for oral suspension 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 for oral suspension 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 d 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 tablets for oral suspension.

Read the information ‘Other possible side effects of combination therapy for HIV’ in Section ‘d’ of this leaflet.

Taking other medicines

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 tablets for oral suspension.

These medicines should not be used with Lamivudine and Zidovudine tablets for oral suspension:

- 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 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 *Pneumocystis jirovecii pneumonia* (often referred to 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 doctor if you are taking any of these.

Some medicines interact with Lamivudine and Zidovudine tablets for oral suspension

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 tablets for oral suspension.

- **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 tablets for oral suspension.

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

Tell your doctor or pharmacist if you are being treated with any of these.

Lamivudine And Zidovudine Tablets For Oral Suspension can be taken with or without food.

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 tablets for oral suspension.

Lamivudine and Zidovudine tablets for oral suspension and similar medicines may cause side effects in unborn babies. If you have taken Lamivudine and Zidovudine tablets for oral suspension 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

Breast-feeding is **not recommended** in women living with HIV because HIV infection can be passed on to the baby in breast milk.

A small amount of the ingredients in Lamivudine and Zidovudine tablets for oral suspension can also pass into your breast-milk.

If you're breast-feeding, or thinking about breast-feeding, you should **discuss it with your doctor as soon as possible**.

Driving and using machines

Lamivudine and Zidovudine tablets for oral suspension 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.

c) HOW TO TAKE LAMIVUDINE AND ZIDOVUDINE TABLETS FOR ORAL SUSPENSION

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

For children unable to swallow tablets, the following procedure can be used.

1. Place the tablet(s) in a container and add two teaspoonfuls (10 mL) of drinking water per tablet.
2. Swirl the container until the tablet(s) breaks up into pieces small enough for the child to swallow. A spoon can be used to crush the pieces, if needed.
3. Drink the mixture within 1 hour.
4. Rinse the container with an additional small amount of water and drink the contents to assure that the entire dosage is taken.

DO NOT MIX THE LAMIVUDINE AND ZIDOVUDINE TABLETS FOR ORAL SUSPENSION WITH ANY LIQUID OTHER THAN WATER. SPLIT TABLETS WHEN NEEDED. STORE UNUSED HALF TABLETS IN A SEPARATE BAG OR BOTTLE AND USE AS SOON AS PRACTICAL.

How much to take

The recommended oral dosage of scored Lamivudine and Zidovudine twice daily in HIV-1- infected pediatric patients at least 3 months of age and weighing greater than or equal to 5 kg is shown in Table 1. Lamivudine and Zidovudine Tablets for Oral Suspension must be administered on an empty stomach, without food.

Table 1: Recommended Pediatric Dosage of Lamivudine and Zidovudine Tablets

| Body Weight Range (kg) | Dosage Regimen Using Scored Lamivudine and Zidovudine Tablets, 30 mg/60 mg | | Total Daily Dose (mg) |
|------------------------|--|--|-----------------------|
| | AM Dose (mg) | PM Dose (mg) | |
| 5 to less than 6 | 1 tablet (30 mg L/60 mg Z) | 1 tablet (30 mg L/60 mg Z) | 60L/120Z |
| 6 to less than 11 | 1.5 tablet (45 mg L/90 mg Z) | 1.5 tablet (45 mg L/90 mg Z) | 90L/180Z |
| 11 to less than 14 | 2 tablets (60 mg L/120 mg Z) | 2 tablets (60 mg L/120 mg Z) | 120L/240Z |
| 14 to less than 18 | 2.5 tablets (75 mg L/150 mg Z) | 2.5 tablets (75 mg L/150 mg Z) | 150L/300Z |
| 18 to less than 22 | 3 tablets (90 mg L/180 mg Z) | 3 tablets (90 mg L/180 mg Z) | 180L/360Z |
| 22 to less than 25 | 3.5 tablets (105 mg L/210 mg Z) | 3.5 tablets (105 mg L/210 mg Z) | 210L/420Z |
| 25 to less than 28 | 4 tablets (120 mg L/240 mg Z) | 4 tablets (120 mg L/240 mg Z) | 240L/480Z |
| 28 to less than 30 | 4.5 tablets (135 mg L/270 mg Z) | 4.5 tablets (135 mg L/270 mg Z) | 270L/540Z |
| 30 and greater | 5 tablets (150 mg L/300 mg Z) ^a | 5 tablets (150 mg L/300 mg Z) ^a | 300L/600Z |

L = lamivudine; Z = zidovudine

a = For recommended doses of lamivudine 150 mg twice daily and zidovudine 300 mg twice daily (adult maximum daily dose), the adult formulations (lamivudine 150 mg tablet and zidovudine 300 mg tablet) can be used.

Safety and efficacy have not been established in patients who are less than 3 months of age.

If you take more Lamivudine And Zidovudine Tablets For Oral Suspension than you should

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

If you forget to take LAMIVUDINE AND ZIDOVUDINE TABLETS FOR ORAL SUSPENSION

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.

Keep in touch with your doctor, and do not stop taking Lamivudine And Zidovudine Tablets For Oral Suspension without your doctor's advice.

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

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 tablets for oral suspension 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 tablets for oral suspension 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 tablets for oral suspension 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 tablets for oral suspension, 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
- 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 leukopenia)
- 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 or white blood cells (aplastic anaemia).

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 tablets for oral suspension 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 tablets for oral suspension:

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 tablets for oral suspension 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

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

e) HOW TO STORE LAMIVUDINE AND ZIDOVUDINE TABLETS FOR ORAL SUSPENSION

Do not store above 30°C.

f) FURTHER INFORMATION

What Lamivudine And Zidovudine Tablets For Oral Suspension contains

The active substances are lamivudine and zidovudine.

The other ingredients are aspartame, colloidal silicon dioxide, flavor orange permaseal PHS-131987, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, and starch.

What Lamivudine And Zidovudine Tablets For Oral Suspension looks like and contents of the pack

Lamivudine and Zidovudine Tablets for oral suspension, containing 30 mg lamivudine and 60 mg zidovudine, are scored, white, circular, biconvex uncoated tablets with a deep score on one side and debossed “DR” on other side. They are available as follows:

60 Tablets per bottle with silica gel dessicant 1000 Tablets per bottle with silica gel dessicant Unit Dose Pack of 60 in PVC/PE/PVDC/Aluminum blisters

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

Marketing Authorization Holder

CIPLA LTD

Cipla House,

Peninsula Business Park,

Ganpatrao Kadam Marg,

Lower Parel, Mumbai-400013

Country: India

Manufacturing Site

Cipla Limited, Goa Unit VII,

Plot No. S- 103 to S -105, S-107 to S-112 & L-147 to L-147-1,

Verna Industrial Estate, Verna, Salcette, Goa 403722, India

This leaflet is prepared in January 2024