

Patient Information Leaflet

ZOVILAM Tablets 150mg/300mg Lamivudine / Zidovudine Tablets 150mg/300mg

Read this entire 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 personally. 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?

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1. What ZOVILAM is used for
ZOVILAM is used to treat HIV (human immunodeficiency virus) infection in adults and children.

2. How ZOVILAM works

ZOVILAM contains two active ingredients that are used to treat HIV infection: lamivudine and zidovudine. Both of these belong to a group of anti-retroviral medicines called *nucleoside analogue reverse transcriptase inhibitors (NRTI's)*.

ZOVILAM 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 ZOVILAM in the same way. Your doctor will monitor the effectiveness of your treatment.

3. Before you take ZOVILAM_ When you must not take it

- If you're **allergic** (hypersensitive) to lamivudine or zidovudine, or any of the other ingredients of ZOVILAM (listed in section 8)
- 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.

Before you start to take it

Some people taking ZOVILAM 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 ZOVILAM without your doctor's advice, as your hepatitis may come back)
- If you have **kidney disease**
- If you are seriously **overweight** (especially if you're a woman)
- If you're **diabetic** and using insulin.

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're taking your medicine. See section 6 for more information.

Taking other medicines

Tell your doctor or pharmacist if you're taking any other medicines, or if you've 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're taking ZOVILAM.

These medicines should not be used with ZOVILAM:

- Other medicinal products containing lamivudine, to treat **HIV infection or hepatitis B infection**
- Emtricitabine, to treat **HIV infection**

- Stavudine or zalcitabine, to treat **HIV infection**

- Ribavirin, or injections of ganciclovir to treat **viral infections**

- High doses of **co-trimoxazole**, an antibiotic.

Tell your doctor if you're 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**.

Tell your doctor if you're taking any of these.

Some medicines interact with ZOVILAM these include:

- **Clarithromycin**, an antibiotic; if you're taking clarithromycin, take your dose at least 2 hours before or after you take your ZOVILAM
- **Phenytoin**, for treating **epilepsy**. *Tell your doctor if you're taking phenytoin. Your doctor may need to monitor you while you're taking ZOVILAM.*

4. How to take ZOVILAM
Always take ZOVILAM exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

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Swallow ZOVILAM tablets, with some water. ZOVILAM 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 the entire dose immediately.

How much to take

Adults and adolescents over 12 years of age

The usual dose of ZOVILAM is one tablet twice a day.

When to take it

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

How long to take it

ZOVILAM 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 ZOVILAM without your doctor's advice.

If you forget to take it

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 take too much (overdose)

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

5. While you are using ZOVILAM

Things you must do

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 ZOVILAM. Read the information 'other possible side effects of combination therapy for HIV' in section 6 of this leaflet.

Things you must not do

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).

ZOVILAM will not stop you passing HIV infection on to other people. To protect other people from becoming infected with HIV:

- **Use a condom** when you have oral or penetrative sex
- **Don't risk blood transfer** – for example, don't share needles

Thing to be careful of

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 ZOVILAM. ZOVILAM and similar medicines may cause side effects in unborn babies. If you become pregnant while you're taking ZOVILAM, your baby may be given extra check-ups (including blood tests) to make sure it is developing normally.

Children whose mothers took NRTI's (medicines like ZOVILAM) during pregnancy had a reduced risk of being infected with HIV. This benefit is greater than the risk of having 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. If you're breast-feeding or thinking about breast-feeding:

Talk to your doctor immediately.

Driving and using machines

ZOVILAM can make you dizzy and have other side effects that make you less alert.

Don't drive or operate machines unless you're feeling well.

6. Side effects

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

When you're being treated for HIV, it can be hard to tell whether

a symptom is a side effect of ZOVILAM or other medicines you're 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 ZOVILAM, 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. You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Consumers -> Reporting -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Very common side effects

- Headache
- Feeling sick (*nausea*)
- Common side effects**
- 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.

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Other possible side effects of combination therapy for HIV

Combination therapy such as ZOVILAM 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.

If you get any symptoms of infection while you're taking ZOVILAM:

Tell your doctor immediately.

Don't take other medicines for the infection without your doctor's advice.

Your body shape may change

People taking combination therapy for HIV may find that their body shape changes, because of changes in fat distribution:

- Fat may be lost from the legs, arms or face
- Extra fat may build up around the tummy (abdomen), or on the breasts or internal organs
- Fatty lumps (sometimes called buffalo hump) may appear on the back of the neck.

It is not yet known what causes these changes, or whether they have any long-term effects on your health. If you notice changes in your body shape:

➤ **Tell your doctor.**

Lactic acidosis is a rare but serious side effect

Some people taking ZOVILAM, or other medicines like it (NRTI's), 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
- Increased levels of sugar and fats (triglycerides and cholesterol) in the blood Resistance to insulin (so if you're diabetic, you may have to change your insulin dose to control your blood sugar)

7. Storage and disposal of ZOVILAM

- Keep ZOVILAM out of the reach and sight of children.
- Do not store above 30°C.
- Store it in its original container.
- Do not take ZOVILAM after the expiry date shown on the carton.
- If you have any unwanted ZOVILAM tablets, don't dispose of them in your waste water or your household rubbish. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product description

What it looks like ZOVILAM Tablets

150mg/300mg: White to off white, capsule shaped, biconvex film coated tablet, debossed with "M103" on one side and plain on the other.

Ingredients: Microcrystalline cellulose, Colloidal anhydrous silica, Sodium starch glycolate, Magnesium stearate, Opadry white, Propylene glycol.

MAL12065068A

9. Manufacturer

Mfd. by:

Mylan Laboratories Limited
F-4 & F-12, MIDC, Malegaon,
Sinnar,
Nashik - 422 113, Maharashtra,
INDIA

Marketed by:

Matrix
(A division of Mylan Laboratories Limited)

Marketing Authorization Holder

Pahang Pharmacy Sdn. Bhd. Lot
5979, Jalan Teratai,
5 ½ Miles off Jalan Meru,
Klang, Selangor, MALAYSIA

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