

LAMIVUDINE 150MG AND ZIDOVUDINE 300MG TABLETS

Lamivudine/Zidovudine (150mg/300mg)

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What Lamivudine 150mg and Zidovudine 300mg Tablets are used for and how they work

Lamivudine/Zidovudine tablets are used to treat HIV (human immunodeficiency virus) infection in adults and children above 12 years old.

Lamivudine/Zidovudine tablets 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 (NRTIs).

How Lamivudine 150mg and Zidovudine 300mg Tablets work

Lamivudine/Zidovudine tablets do 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/Zidovudine tablets in the same way. Your doctor will monitor the effectiveness of your treatment.

Before you use Lamivudine 150mg and Zidovudine 300mg Tablets

-When you must not take it

Do not take Lamivudine/Zidovudine Tablets if:

- you are allergic to lamivudine or zidovudine, or any of the other ingredients of this medicine
- 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

Tell your doctor:

- if you have ever had liver disease, including hepatitis B or C (if you have hepatitis B infection, do not stop Lamivudine/Zidovudine tablets without your doctor's advice, as your hepatitis may come back)
 - if you have kidney disease
- 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 this medicine.

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/Zidovudine tablets. Lamivudine/Zidovudine tablets and similar medicines may cause side effects in unborn babies. If you become pregnant while you are taking Lamivudine/Zidovudine tablets,

your baby may be given extra check-ups (including blood tests) to make sure it is developing normally.

Your doctor will discuss with you the risk and benefit of taking this medicine while you are pregnant.

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 are breast-feeding or thinking about breast-feeding:

Talk to your doctor immediately.

Driving and using machines

Lamivudine/Zidovudine tablets 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.

-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/Zidovudine tablets.

These medicines should not be used with Lamivudine/Zidovudine tablets:

- other medicinal products containing lamivudine, to treat HIV infection or hepatitis B infection
- stavudine or zalcitabine, to treat HIV infection
- ribavirin to treat viral infections

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

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

- interferon, to treat viral infections
- pyrimethamine, to treat malaria and other parasitic infections
- dapsone, to prevent pneumonia and treat leprosy
- flucytosine, to treat fungal infections such as candida
- pentamidine to treat opportunistic infections such as Pneumocystis Pneumonia (PCP)
- amphotericin or co-trimoxazole, to treat fungal and bacterial infections
- methadone, used as a heroin substitute
- vincristine, vinblastine or doxorubicin, to treat cancer.
- phenytoin, for treating epilepsy.

Tell your doctor if you are taking any of these.

Your doctor may need to monitor you while you are taking Lamivudine/Zidovudine tablets.

This is not a complete list of medicines that may interact with this product. Talk to your doctor or pharmacist as they will have a more detail and complete list.

How to take it

-How much to take

Adults and adolescents (>12 years old)

The usual dose of Lamivudine/Zidovudine tablets is one tablet twice a day.

Dose Adjustment

Because it is a fixed-dose combination, Lamivudine/Zidovudine tablets should not be prescribed for patients requiring dosage adjustment such as those with reduced kidney function, mild to moderate impaired liver function or liver cirrhosis

Children (<12 years old)

Lamivudine/Zidovudine tablets are not recommended for children below 12 years old.

-When to take it

Swallow Lamivudine/Zidovudine tablets, with some water.

-How long to take it

Take this medicine as long as the doctor tells you to. Always take the exact dose as your doctor or pharmacist has told you. Check with them if you are not sure.

-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. Do not take a double dose to make up for a forgotten dose.

-If you take too much (overdose)

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

While you are using it

-Things you must do

Stay in regular contact with your doctor

Lamivudine/Zidovudine tablets 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.

-Things you must not do

Do not stop taking Lamivudine/Zidovudine tablets without your doctor's advice.

-Things to be careful of

Patients treated with Lamivudine/Zidovudine or any other antiretroviral therapy may continue to develop

opportunistic infections and other complications of HIV infections. If you notice any symptoms of infection, please inform your doctor immediately.

Lamivudine/Zidovudine may improve your condition but it is not a cure for your HIV infection. Treatment with this product has not been shown to reduce the risk of passing HIV infection on to others by sexual contact or by blood transfer. Therefore, you must continue to take appropriate precaution to avoid giving the virus to others.

Changes of body fat may occur in patients receiving combination antiretroviral therapy. Contact your doctor if you notice changes in body fat.

Side Effects

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/Zidovudine tablets 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.

Very common

- headache

Common

- being sick (vomiting)
- diarrhoea
- stomach pains
- feeling dizzy
- tiredness, lack of energy
- muscle pain and discomfort
- joint pain
- skin rash
- hair loss (alopecia)
- feeling sick (nausea)

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Rare

- inflammation of the pancreas (*pancreatitis*)
- Lactic acidosis; build-up of lactic acid in the body.
- Hepatomegaly with steatosis; abnormal enlargement of the liver and accumulation of fat in the liver.

This is not a complete list of side effects for this product. Inform your doctor or pharmacist if you encounter any other side effects or the side effect in this list is unbearable or prolonged.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Lamivudine 150mg and Zidovudine 300mg Tablets

-Storage

Store below 30°C. Protect from light.

-Disposal

Do not use after the expiry date stated on the label.

Return any unused tablets to your pharmacist to be disposed of. Only keep the tablets if your doctor tells you to. Do not throw them away in your normal household drainage or waste. This will help to protect the environment.

Product Description

-What it looks like

Lamivudine 150mg and Zidovudine 300mg Tablets are white to off-white colored oval shaped film coated tablet with 'LZ' engraved on one side and break line on other side.

-Ingredients

Active ingredient:

Each tablet contains Lamivudine 150 mg and Zidovudine 300mg.

Inactive ingredients:

Microcrystalline cellulose, Talc, Sodium starch glycolate, Colloidal silicon dioxide, Povidone (K-30), Magnesium Stearate, Opadry white (Y-1-7000), Isopropyl Alcohol and Purified water.

-MAL Number

MAL10100011AZ

Manufacturer

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Product Registration Holder

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Date of Revision

21-09-2015

Serial Number

BPFK(R4/1)210915/00317