

# ZIDOVUDINE TABLETS

Zidovudine (100 mg, 300mg)

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## What *Zidovudine Tablets* is used for

*Zidovudine tablets* is used to treat HIV (human immunodeficiency virus) infection.

If you're pregnant, your doctor may want you to take *Zidovudine tablets* to help you prevent passing on HIV to your unborn baby.

## How *Zidovudine Tablets* works

The active ingredient in *Zidovudine tablets* is zidovudine. *Zidovudine tablets* is a type of medicine known as an anti-retroviral. It belongs to a group of medicines called nucleoside analogue reverse transcriptase inhibitors (NRTI's).

*Zidovudine tablets* does not get rid of HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. *Zidovudine tablets* 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.

## Before you use *Zidovudine Tablets*

### When you must not use it

- If you're allergic (hypersensitive) to zidovudine or any other ingredients of

*Zidovudine tablets* (listed in section 8).

- If you have a very low white blood cell count (neutropenia) or a very low red blood cell count (anaemia).

### Before you start to use it

Inform your doctor or pharmacist if you have the below problems. They will consider the risk and benefit of taking *Zidovudine Tablets* before giving it to you.

- If you have ever had liver disease (including hepatitis B or C)
- If you're seriously overweight (especially if you're a woman)
- If you're diabetic and using insulin.
- If you have bone marrow compromise problem or are taking bone marrow suppressive medicines
- If you have kidney problem.

If any of the above applies to you and you are given *Zidovudine Tablets*, you may need extra check-ups, including blood tests, while you're taking your medication. 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 *Zidovudine tablets*.

Don't take these medicines with *Zidovudine tablets*

- Stavudine, used to treat HIV infection.
- Ribavirin to treat viral infections.
- Rifampicin, which is an antibiotic.

Some medicines can make it more likely that you'll have side effects, or make side effects worse, these includes

- Sodium valproate, used to treat epilepsy.
- Aciclovir, ganciclovir or interferon, used to treat virus infections.
- Pyrimethamine, used to treat malaria and other parasitic infections.
- Dapsone, used to prevent pneumonia and treat skin infections.
- Fluconazole or flucytosine, used to treat fungal infections such as candida.
- Pentamidine or atovaquone, used to treat pneumocystis carinii pneumonia (PCP).
- Amphotericin or co-trimoxazole, used to treat fungal and bacterial infections.
- Probenecid, used to treat gout.
- Methadone, used as a heroin substitute.
- Vincristine, vinblastine or doxorubicin, used to treat cancer.

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

Other medicines that have shown to interact with zidovudine.

- Clarithromycin, which is an antibiotic
- Phenytoin, used for treating epilepsy.

If you are not sure, please talk to your doctor or pharmacist as they will have a more detail and complete list of medicines that might not go well with zidovudine.

## How to use *Zidovudine Tablets*

Always take *Zidovudine tablets* exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure. Swallow the tablets whole, with some water.

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## How much to use

Adults and adolescents

- The usual dose of *Zidovudine tablets* is 500-600mg/day in 2-3 divided doses in combination with other antiretroviral medicines.

Pregnant women

- You should not normally take *Zidovudine tablets* during the first 14 weeks of your pregnancy. After week 14, the usual dose is 100mg 5 times per day until you start to go into labour.

People with kidney or liver problems

- If you have severe kidney or liver problems, you may be given a lower dose of *Zidovudine tablets*, depending on how well your kidneys or liver are working. Follow your doctor's advice.

## When to use it

*Zidovudine* may be taken with or without food.

## How long to use it

*Zidovudine tablets* is used in combination with other anti-retroviral medicines, to treat HIV. To control your HIV infection, and to stop your illness getting worse, you must keep taking all your medicines.

Do not stop taking *Zidovudine tablets* without advice from doctor or pharmacist.

Take *zidovudine tablets* for as long as your doctor recommends.

## If you forget to use it

If you forget to take a dose, don't worry. You can take your next dose as soon as you remember but if it is too near your next dose, just skip the dose you missed and take your next dose at the usual time. Then continue your treatment as before.

Do not take a double dose to make up for a missed dose.

## If you use too much (overdose)

The most common effects of taking too much *Zidovudine tablets* are tiredness, headaches and being sick (vomiting). If you or anyone accidentally taken too many *Zidovudine Tablets*, please go to the Emergency Department of your nearest hospital as you may need medical attention.

## **While you are using it**

### Things you must do

Please attend all the appointments given to you as your doctor might need to do regular blood tests on you to monitor the treatment progress and detect any side effects encountered.

Stay in regular contact with your doctor

- *Zidovudine tablets* helps to control your condition, but it is not a cure for HIV infection. 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 *Zidovudine tablets* without your doctor's advice.

### Things you must not do

HIV infection is spread by sexual contact with someone who's got the infection, or by transfer of infected blood (for example, by sharing injection needles).

*Zidovudine tablets* will not stop you from passing HIV infection on to other people, by having sex or by blood transfer. Do not have unprotected sex or share needles.

## Things to be careful of

If you are taking *Zidovudine Tablet* and you are planning to get pregnant, please discuss with your doctor about the risks and benefits.

*Zidovudine tablets* and similar medicines may cause side effects in unborn babies; if it does, these effects won't show up until after the baby has been born. Even so, the benefit of protecting your baby from getting HIV is greater than the risk of your baby getting side effects.

If you've taken *zidovudine tablets* while you were pregnant, your baby may be given extra check-ups (which may include blood tests), to make sure it's developing normally.

## Breast feeding

Women who are HIV-positive must not breast feed, because HIV infection can be passed on to the baby through breast milk. If you're breast feeding, or thinking about breast feeding: Talk to your doctor immediately.

## Driving and using machines

*Zidovudine tablets* can make you dizzy and have other side effects that make you less alert. Do not drive or operate machinery unless you are feeling well.

## **Side Effects**

Like all medicines, *Zidovudine tablets* can cause side effects, but not everyone gets them. Some side effects may show up in your blood tests, and may not appear until 4 to 6 weeks after you start taking *Zidovudine tablets*. If you get any of these effects, and if they are severe, your doctor may advise you to stop taking *Zidovudine tablets*.

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Some of the recorded side effects are:

- Headaches.
- Feeling sick (nausea).
- Being sick (vomiting).
- Stomach pains.
- Aching muscles.
- 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.
- Feeling breathless.
- General aches and pains.
- Weakness.
- A decrease in the number of all kinds of blood cells (pancytopenia).
- Joint aches and pain, joint stiffness or difficulty in movement (osteonecrosis)
- Fat redistribution (redistribution of body fat causing buffalo hump, facial wasting and central obesity.)
- Lactic acidosis - (a medical emergency that can cause death and must be treated in the hospital. It is caused by build-up of lactic acid in your blood.)
- Severe hepatomegaly with steatosis (liver enlargement with abnormal retention of fat in the liver cells)

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects.

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](http://portal.bpfk.gov.my) (Consumers →Reporting)

## Storage and Disposal of Zidovudine Tablets

### Storage

- Keep *Zidovudine tablets* out of the sight and reach of children.
- Don't store *Zidovudine tablets* above 30 °c.
- Store in the original container
- Don't take *Zidovudine tablets* after the expiry date shown on the carton. .

### Disposal

If you have any unwanted *Zidovudine tablets*, do not dispose any of them in your water waste or your household rubbish. Take them back to your pharmacist, who will dispose of them in a way that won't harm the environment

## Product Description

### What it looks like

Zidovudine Tablets 100 mg:  
White to off-white round biconvex tablet, debossed with "M55" on one side and plain on the other side.

Zidovudine Tablets 300 mg:  
White to off-white round, biconvex tablet, debossed with "M106" on one side and plain on the other.

### Ingredients

Active Ingredient  
Zidovudine

Inactive Ingredients  
Microcrystalline cellulose,  
Sodium starch glycolate,  
Magnesium stearate, Opadry  
White 03B28772 (Hyromellose,  
Titanium dioxide, Polyethylene glycol 400) Polyethylene glycol 400

### MAL numbers:

Zidovudine Tablets 100 mg:  
MAL12070002AZ  
Zidovudine Tablets 300 mg:  
MAL12070004AZ

## Manufacturer

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

Marketed by:

Matrix  
(A division of Mylan Laboratories Limited)

## Product Registration Holder

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

## Date of Revision

24/11/2015

## Serial Number

BPFK(R4/1)161115/00426