PATIENT INFORMATION LEAFLET
Zidovudine Tablets 300 mg*
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 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, pharmacist or health care provider.

In this leaflet:
1. What Zidovudine Tablets 300 mg is and what it is used for
2. Before you take Zidovudine Tablets 300 mg
3. How to take Zidovudine Tablets 300 mg
4. Possible side effects
5. Storing Zidovudine Tablets 300 mg
6. Further information

1. WHAT ZIDOVUDINE TABLETS 300 mg IS AND WHAT IT IS USED FOR
Zidovudine Tablets 300 mg contains zidovudine which belongs to a group of antiviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs). Medicines used to treat human immunodeficiency virus (HIV) infection are called antiretrovirals.
Zidovudine Tablets 300 mg is used in combination with other antiretroviral medicines for the treatment of HIV infection. It is also used for preventing mother-to-child transmission of HIV during childbirth. Zidovudine Tablets 300 mg reduces the amount of virus in your body, and keeps it at a low level. It also increases CD4 cell count. CD4 cells are a type of white blood cells that are important for maintaining a healthy immune system to help fight infection. How well treatment with Zidovudine Tablets 300 mg works varies between patients. Your doctor or health care provider will be monitoring the effectiveness of your treatment.
Zidovudine Tablets 300 mg may improve your condition, but it is not a cure for HIV infection. HIV infection is a disease spread by contact with blood or by sexual contact with someone who has HIV infection. Treatment with Zidovudine Tablets 300 mg has not been shown to eliminate the risk of passing HIV infection on to others by sexual contact or by blood transfer. Therefore, you must continue to take appropriate precautions to avoid giving the virus to others.

2. BEFORE YOU TAKE ZIDOVUDINE TABLETS 300 mg
Do not take Zidovudine Tablets 300 mg if:
• you are allergic (hypersensitive) to zidovudine or to any of the other ingredients of Zidovudine Tablets 300 mg (see section 6, What Zidovudine Tablets 300 mg contains);

* Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.
• you have very low red blood cell count (severe anaemia) or very low white blood cell count (neutropenia).

Newborn babies must not be given Zidovudine Tablets 300 mg if the baby has some types of liver problems including some cases of excessive bilirubin in the blood (hyperbilirubinaemia), which makes the skin look yellow.

**Take special care with Zidovudine Tablets 300 mg**

Some people taking medicines for HIV infection may develop other possibly serious conditions (see section 4, Possible Side Effects) and you need to look out for any signs and symptoms of these conditions.

Before using this medicine, you should tell your doctor or health care provider if:

• you suffer from liver disease (such as hepatitis),
• you have diabetes and you are using insulin

You need to take Zidovudine Tablets 300 mg every day. You should keep in regular contact with your doctor or health care provider. Do not stop taking your medicine without first talking to your doctor or health care provider.

**Taking other medicines**

Tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including herbal medicines or medicines obtained without a prescription. These may affect the action of Zidovudine Tablets 300 mg or Zidovudine Tablets 300 mg may affect their action.

You should not be take Zidovudine Tablets 300 mg in combination with stavudine or ribavirin. Zidovudine Tablets 300 mg may also interact with valproic acid (or sodium valproate), fluconazole and probenecid making side effects worse; their use should be carefully considered.

Taking Zidovudine Tablets 300 mg at the same time as other medicines that can injure the kidneys or bone marrow may increase the risk of side effects to Zidovudine Tablets 300 mg. Such medicines include pentamidine, dapsone, pyrimethamine, sulfamethoxazole + trimethoprim, amphotericin, flucytosine, ganciclovir, valganciclovir, interferon, vincristine, vinblastine and doxorubicin. If you have to take any of these medications with Zidovudine Tablets 300 mg then your doctor may need to monitor more closely your kidney function and blood parameters and, if required, the dosage of one or more of the medicines may be reduced.

Tell your doctor or health care provider if you are taking phenytoin (for epilepsy) or clarithromycin (an antibiotic) because they may interact with zidovudine.

**Taking Zidovudine Tablets 300 mg with food and drink**

Zidovudine Tablets 300 mg may be taken with food or between meals. Swallow the tablet whole with water or another drink.

**Pregnancy**

If you become pregnant, or are planning to become pregnant, you must contact your doctor or health care provider to discuss the potential adverse effects and the benefits and risks of your antiretroviral therapy to you and your child.

Be sure to tell your doctor immediately if you are, or may be, pregnant.

**Breastfeeding**

Zidovudine, the active ingredient in this medicine, appears in breast milk.

If you are thinking of breastfeeding your baby, you should discuss the risks and benefits with
your doctor or health care provider.

**Driving and using machines**
Zidovudine Tablets 300 mg can make you dizzy and have other side effects that make you less alert. You should not drive or operate machines unless you are feeling well and alert.

### 3. HOW TO TAKE ZIDOVUDINE TABLETS 300 mg
Always take Zidovudine Tablets 300 mg exactly as your doctor or health care provider has instructed you. You should check with your doctor, health care provider or pharmacist if you are unsure.

The usual dose of Zidovudine Tablets 300 mg for patients weighing 25 kg or more is one tablet of 300 mg zidovudine twice a day. Take each dose of Zidovudine Tablets 300 mg about 12 hours apart.

Other formulations containing less zidovudine are available for children weighing less than 25 kg.
Zidovudine Tablets 300 mg should always be taken with other antiretroviral medicines; please make sure you follow the instructions in the supplied package leaflets.

**Kidney or liver problems**
If you have severe kidney or liver problems, your doctor or health care provider might ask you to take a lower dose of zidovudine.

**If you take more Zidovudine Tablets 300 mg than you should**
If you have taken too many tablets or if someone accidentally swallows some, there is no immediate danger. However, you should contact your doctor or health care provider, or the nearest hospital emergency department for further advice.

**If you forget to take Zidovudine Tablets 300 mg**
If you forget to take a dose of your medicine, take it as soon as you remember, and then continue as before. If your next dose is due in less than 6 hours, do not take the missed dose, but take the next regular dose when it is due. Do not take a double dose to make up for missed individual doses.

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

### 4. POSSIBLE SIDE EFFECTS
Like all medicines, Zidovudine Tablets 300 mg can cause side effects, but not everybody gets them. It is important that you tell your doctor or health care provider of any change in your health.

The most serious adverse reactions include anaemia (low red blood cell count), and low white blood cell count. These are more common in patients with advanced HIV infection. Furthermore, zidovudine may cause loss of body fat, particularly in the arms, legs and face.

*Very common side effects* (may affect more than 1 in 10 patients treated): headache and nausea (feeling sick).

*Common side effects* (may affect up to 1 in 10 patients treated): vomiting, muscle aches, diarrhoea, stomach pains, feeling dizzy, decreased red blood cells (anaemia), decreased white blood cells (leucopenia, neutropenia) and increase of liver enzymes and of bilirubin in the blood (which may make your skin look yellow).
Uncommon side effects (may affect between 1 in 1000 and 1 in 100 patients treated): skin rash, feeling breathless, fever, general aches and pains, wind (flatulence), weakness, decreased blood platelets (thrombocytopenia) or decrease of all blood cells (pancytopenia).

Rare side effects (may affect between 1 in 10 000 to 1 in 1000 patients treated): indigestion, loss of appetite, taste disturbance, anxiety, depression, sleeplessness (insomnia), difficulty in concentrating, feeling drowsy, changes in the colour of nails, of skin and of skin inside the mouth, tingling of the skin ('pins and needles'), chest pain and heart muscle disorder, fits (convulsions), flu-like feeling (chills, sweating and cough), passing urine more often, enlarged breasts in men, inflammation of the pancreas, liver disorders including jaundice, enlarged liver and fat accumulation in the liver, and decrease in a type of red blood cells (pure red cell aplasia).

Very rare side effects (fewer than 1 in 10 000 patients treated): inability to produce new blood cells (aplastic anaemia).

The following side effects occur at a frequency that is not known:

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 (immune reconstitution syndrome), so that the body starts to fight these infections.

If you get any symptoms of infection while you are taking Zidovudine Tablets 300 mg tell your doctor or health care provider immediately.

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 if these changes have any long-term effects on your health. If you notice changes in your body shape, tell your doctor or health care provider.

Lactic acidosis
People taking zidovudine, or other medicines like it (NRTIs), develop a serious 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, and can cause internal organs to fail.

Lactic acidosis is more likely in people who have liver disease, or in 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 treatment, your doctor or health care provider 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.

**Bone problems**

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
- are also taking anti-inflammatory medicines called corticosteroids
- drink alcohol
- have very weak immune system
- 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 or health care provider.

5. **STORING ZIDOVUDINE TABLETS 300 mg**

Keep out of the reach and sight of children.

Do not store above 30° C. Store in the original container.

Do not use Zidovudine Tablets 300 mg after the expiry date (exp) stated on the carton. The expiry date refers to the last day of that month.

Do not use Zidovudine Tablets 300 mg if the tablets are discoloured.

Medicines should not be disposed of in wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. **FURTHER INFORMATION**

**What Zidovudine Tablets 300 mg contains**

The active ingredient is 300 mg zidovudine.

The other ingredients are:

*Tablet core:* Magnesium stearate, microcrystalline cellulose, povidone, and sodium starch glycolate.

*Coating:* Hypromellose (hydroxypropyl methylcellulose), polyethylene glycol 400 and titanium dioxide.

**What Zidovudine Tablets 300 mg looks like and contents of the pack**

Round, white, film-coated, biconvex tablet debossed “ML8” on the periphery of one side and plain on the other side.

The tablets should not be divided.
The primary packs are:

- White HDPE bottles with child-resistant cap.
  Pack size: 60 tablets
- PVDC-coated PVC/aluminium blister cards
  Pack size: 10 × 10 tablets

Supplier

Macleods Pharmaceuticals Limited
304 Atlanta Arcade
Marol Church Road
Andheri (East)
Mumbai 400 059
India
Telephone: + 91 22 66762800
Fax: + 91 22 28216599
Email: vijay@macleodspharma.com

Manufacturer

Macleods Pharmaceuticals Limited
Unit II, Plot No. 25–27
Survey No. 366
Premier Industrial Estate
Kachigam
Daman 396 210
India
Telephone: + 91 0260 2244227
Fax: + 91 0260 2241565
E-mail: rakeshchaurasia@macleodspharma.com
vijay@macleodspharma.com

For any information about this medicinal product, please contact the supplier.

This leaflet was last approved in July 2012.

Detailed information on this medicine is available on the World Health Organization (WHO) web site: http://who.int/prequal/.