1.3 PRESCRIBING INFORMATION

1.3.2 Patient Information leaflet

Enclosed overleaf.

PATIENT INFORMATION LEAFLET
Zidovudine Tablets USP 300 mg
$R_{X\ Only}$

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, please 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:

Zidovudine Tablets USP 300 mg

Zidovudine Tablets USP 300 mg, each contain 300 mg of active pharmaceutical ingredient Zidovudine, used in the treatment of HIV infection.
The other ingredients are microcrystalline cellulose, hypromellose, sodium starch glycolate, magnesium stearate, titanium dioxide and polyethylene glycol.
Zidovudine Tablets are Zidovudine Tablets are White coloured, biconvex, round film coated tabletsdebossed with ‘D’ on one side and ‘11’ on other side.

The Marketing Authorisation Holder for Zidovudine Tablets is:

M/s Aurobindo Pharma Ltd
Plot No.: 2, Maitrivihar,
Ameerpet, Hyderabad-500 038
India.

Zidovudine Tablets are manufactured by:

Aurobindo Pharma Limited
Unit III, Sy. No. 313 & 314,
Bachupally, Bachupally Mandal,
Medchal-Malkajgiri District,
Telangana State, India.

1. What are zidovudine tablets USP and what are they used for?

Zidovudine Tablets USP 300 mg belongs to a group of antiviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs). These are used to treat Human Immunodeficiency Virus (HIV) infection.

Zidovudine Tablets USP 300 mg is used in antiretroviral combination therapy for the treatment of HIV infection, and for the prevention of mother-to-child transmission of HIV during childbirth. Zidovudine Tablets USP 300 mg reduces the amount of virus in your body, and keeps it at a low level. It also increases CD4 cell counts. CD4 cells are a type of white blood cells that plays an important role in maintaining a healthy immune system to help fight infection. Response to treatment with Zidovudine Tablets USP 300 mg varies between patients. Your doctor or health care provider will be monitoring the effectiveness of your treatment.

Zidovudine Tablets USP 300 mg may improve your condition, but it is not a cure for your HIV infection. HIV infection is a disease spread by contact with blood or sexual contact with an infected individual. Treatment with Zidovudine Tablets USP 300 mg 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 precautions to avoid giving the virus to others.

During treatment, other infections linked to weakened immunity (opportunistic infections) may arise. These may require specific and sometimes preventive treatment.

2. BEFORE YOU TAKE ZIDOVUDINE TABLETS USP 300 mg

Do not take Zidovudine Tablets USP 300 mg if:

- You are allergic (hypersensitive) to zidovudine or any of the other ingredients of Zidovudine Tablets USP 300 mg (see section 6, What Zidovudine Tablets USP 300 mg contains);
- You have very low red blood cell count (severe anaemia) or very low white blood cell count (neutropenia).

Take special care with Zidovudine Tablets USP 300 mg

Before using this medicine, you should have told your doctor or health care provider:

- if you suffer from kidney disease or liver disease (such as hepatitis),
- if you have had peripheral neuropathy (persistent tingling or numbness or pain in the feet and/or hands),
- if you have suffered from pancreatitis (inflammation of the pancreas).

Anaemia (low red blood cell count) and neutropenia / leucopenia (low white blood cell count) may occur within 4-6 weeks after starting treatment with Zidovudine Tablets USP 300 mg. If severe, your physician may stop treatment with Zidovudine Tablets USP 300 mg. This occurs more commonly in patients with advanced HIV disease and with higher doses of zidovudine. Regular blood tests will be arranged to check whether there is a problem. This adverse reaction is infrequent in patients with early HIV disease and blood tests may be performed less frequently.

The class of medicines to which Zidovudine Tablets USP 300 mg belongs (NRTIs) can cause a condition called lactic acidosis, together with an enlarged liver. Lactic acidosis, if it occurs, usually develops after a few months of treatment. Lactic acidosis is a buildup of lactic acid in the body, which can cause dehydration and coma. Deep, rapid breathing, drowsiness, and non specific symptoms such as nausea,

vomiting and stomach pain, may indicate the development of lactic acidosis. In addition lactic acidosis may lead to rare cases of liver failure, renal failure or fatal hepatitis. This rare, but serious side effect occurs more often in women, particularly if very overweight. If you have liver disease you may also be more at risk of getting this condition. While you are taking Zidovudine Tablets USP 300 mg, your doctor or health care provider will monitor you closely for any signs that you may be developing lactic acidosis.

Please speak with your doctor or health care provider if you have a history of liver disease. Patients with chronic hepatitis B or C and treated with antiretroviral agents are at increased risk for severe and potentially fatal liver adverse events and may require blood tests for monitoring of liver function.
If you have a chronic hepatitis B infection, you should not stop your treatment without instructions from your doctor or health care provider, as you may have a recurrence of your hepatitis. This recurrence may be more severe if you have serious liver disease.

In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is called immune reconstitution syndrome and it is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please inform your doctor or health care provider immediately.

Loss of body fat may occur in patients receiving zidovudine. Contact your doctor or health care provider if you notice changes in body fat.

Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue). The risk of developing this disease may be higher if your immune system is severely weakened, or if you drinking alcohol regularly. If you notice joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement, inform your doctor or health care provider.

You will need to take Zidovudine Tablets USP 300 mg every day. This medicine helps to control your condition, but it is not a cure for HIV infection. You may continue to develop other infections and other illnesses associated with HIV disease. 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
Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. These may affect the action of Zidovudine Tablets USP 300 mg, or Zidovudine Tablets USP 300 mg may affect their action.

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

Taking Zidovudine Tablets USP 300 mg at the same time as other medicines that are potentially toxic to the kidneys or bone marrow may increase the risk of adverse reactions to Zidovudine Tablets USP 300 mg. Such medicines include, for instance, pentamidine, dapsone, pyrimethamine, cotrimoxazole, amphotericin, flucytosine, ganciclovir, valganciclovir, interferon, vincristine, vinblastine and doxorubicin. If you require any of these medications with Zidovudine Tablets USP 300 mg then your doctor may need to monitor your kidney function and blood parameters more closely and, if required, the dosage of one or more of the drugs may be reduced.

Taking Zidovudine Tablets USP 300 mg with food and drink
Zidovudine Tablets USP 300 mg may be taken with or without food.

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 may be pregnant.

Breastfeeding
Zidovudine, the active agent in this medicine, is found in human breast milk.
If you are interested in breastfeeding your baby, you should discuss the risks and benefits with your doctor or healthcare provider.

Driving and using machines
No studies on the effects of zidovudine on the ability to drive and use machines have been performed. However, you should take into account the state of your health and the possible side effects of zidovudine before considering driving or using machines.

3. How To Take Zidovudine Tablets USP 300 mg

Always take Zidovudine Tablets USP 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 USP 300 mg for patients weighing 25 kg or more is one tablet of 300 mg zidovudine twice a day. Each dose of Zidovudine Tablets USP 300 mg should be taken approximately 12 hours apart. Swallow Zidovudine Tablets USP 300 mg whole with water or another drink. They can be taken with or without food.

Other formulations containing less zidovudine are available for dosing in children weighing less than 25kg.

Zidovudine Tablets USP 300 mg will always be taken in combination with other antiretroviral medication; please make sure to follow the instructions within the supplied package leaflets.

If you take more Zidovudine Tablets USP 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 USP 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 forgotten dose, but take the next regular dose when it is due. Do not take a double dose to make up for forgotten 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 USP 300 mg can cause side effects, although not everybody gets them. When treating HIV infection, it is not always possible to differentiate between unwanted effects caused by Zidovudine Tablets USP 300 mg, or those caused by any other medicines you may be taking at the same time, or by the HIV disease. For this reason, it is important that you inform 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 commonly reported (greater than 1 in every 10 patients treated) side effects are headache and nausea.

Commonly reported (greater than 1 in every 100 patients treated) side effects are vomiting, muscle aches, decreased red blood cells (anaemia), decreased white blood cells (leucopenia, neutropenia) and transient increase of liver enzymes and bilirubin in the blood.

The following side effects are *uncommon* (between 1 in 1,000 and 1 in 100 patients treated): decreased blood platelets (thrombocytopenia) and muscle tissue disorders (myopathy).

There are *rare* reports (between 1 in 10,000 to 1 in 1,000 patients treated) of anxiety, depression, sleeplessness (insomnia), nail and skin pigmentation, hives, sweating, fat accumulation in the liver and increased urinary frequency.

Also, a condition called lactic acidosis, which is a build up of lactic acid in the body that can cause dehydration and coma and has been reported on rare occasions in patients taking zidovudine. Deep, rapid breathing, drowsiness, and nonspecific symptoms such as nausea, vomiting and stomach pain, may indicate the development of lactic acidosis.

There are *very rare* reports (less than 1 in 10,000 patients treated) of disruption of production of red blood cells (aplastic anaemia).

The following side effects occur at a frequency that is not known:
Zidovudine and other antiretroviral agents may cause changes in body shape due to changes in fat distribution. These may include loss of fat from legs, arms and face, increased fat in the abdomen (belly) and other internal organs, breast enlargement and fatty lumps on the back of the neck ('buffalo hump').

The cause and long-term health effects of these conditions are not known at this time.

Combination antiretroviral therapy may also cause hyperlipidaemia (increased fats in the blood), increased blood sugar and resistance to insulin.
Also, osteonecrosis (death of bone tissue) and immune reconstitution syndrome have been reported in patients taking combination antiretroviral therapy (see section 2).
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist as soon as possible.

5. Storing Zidovudine Tablets USP 300 mg

Keep out of the reach and sight of children.

Do not store above 30°C. Protect from high humidity.

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

Do not use Zidovudine Tablets USP 300 mg if you notice the tablets are discoloured, spotted or brittle. Medicines should not be disposed of via 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

If you notice any side effect (s) with the use of this drug, please report it immediately vial internet to the following e-mail address: **Pharmacovigilance@aurobindo.com**

If you have questions or concerns, or want more information about zidovudine oral solution, consult your doctor. This medicine was prescribed for your particular condition. Do not use zidovudine oral solution for another condition.