PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking ADCO LAMIVUDINE & ZIDOVUDINE 150/300

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

ADCO LAMIVUDINE & ZIDOVUDINE 150/300 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1.SCHEDULING STATUS: **S4**

2.PROPRIETARY NAME AND DOSAGE FORM:

ADCO LAMIVUDINE & ZIDOVUDINE 150/300 (film-coated tablets)

3. COMPOSITION:

What ADCO LAMIVUDINE & ZIDOVUDINE 150/300 contains

- The active substances are lamivudine 150 mg and zidovudine 300 mg.
- The other ingredients are:
  - colloidal anhydrous silica
  - microcrystalline cellulose
  - magnesium stearate
  - sodium starch glycollate
  - the coating contains Colour Opadry White,(Polyvinyl chloride, titanium dioxide, macrogol/PEG 3350, talc).

4. WHAT ADCO LAMIVUDINE & ZIDOVUDINE 150/300 IS USED FOR:

ADCO LAMIVUDINE & ZIDOVUDINE 150/300 belongs to a group of antiviral medicines, also known as antiretrovirals, called nucleoside analogue reverse transcriptase inhibitors (NRTIs). These are used to treat Human Immunodeficiency Virus (HIV) infection.

DATE OF APPROVAL: 22 SEPTEMBER 2010

ADCO LAMIVUDINE & ZIDOVUDINE 150/300 is used as part of anti-retroviral combination therapy for the treatment of HIV infected adults and children over 12 years of age.

ADCO LAMIVUDINE & ZIDOVUDINE 150/300 reduces the amount of HIV in your body, and keeps it at a low level. It also increases CD4 cell counts.

CD4 cells are a type of white blood cell, that play an important role in maintaining a healthy immune system to help fight infection.

ADCO LAMIVUDINE & ZIDOVUDINE 150/300 is also used for Prevention in Adults after being exposed to HIV due to a work-related incident:

The best prevention against work-related exposure to HIV, is adherence to universal precautions including, amongst others, careful disposal of sharp objects e.g. needles and scalpels and the use of protective barriers (e.g. gloves, eyeglasses, etc).

ADCO LAMIVUDINE & ZIDOVUDINE 150/300 is indicated for the initial preventative treatment (until blood test results are available) in HIV negative adults whenever there has been exposure to material known to be, or strongly suspected to be, infected with HIV. This includes:

- injury through the skin resulting from needles, instruments, bone fragments, etc)
- exposure to broken skin (abrasions, cuts, eczema, etc)
- exposure of moist linings of the digestive, urinary, reproductive (genital) or respiratory tract (lining of the nose) including the eye.

Response to treatment with **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** varies between patients. Your doctor will be monitoring the effectiveness of your treatment.

5. BEFORE TAKING ADCO LAMIVUDINE & ZIDOVUDINE 150/300:

Do not take ADCO LAMIVUDINE & ZIDOVUDINE 150/300:

- If you are hypersensitive (allergic) to lamivudine or zidovudine or any of the other ingredients of **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** tablets.

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

- Children below the age of 12 years.

You should not take either zalcitabine or stavudine with **ADCO LAMIVUDINE & ZIDOVUDINE 150/300**.

If you are not sure please ask your doctor.

Take special care with ADCO LAMIVUDINE & ZIDOVUDINE 150/300:

Treatment with **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** has not been shown to reduce the risk of passing HIV infection on to others by unprotected sexual contact or by blood transfer (for example, blood transfusions or sharing needles). You should continue to use appropriate precautions to prevent this.

- **Effects on the blood**: Anaemia (low red blood cell count) and neutropenia/leucopenia (low white blood cell count) may occur within 4-6 weeks due to treatment with zidovudine, one of the active substances in **ADCO LAMIVUDINE & ZIDOVUDINE 150/300.** If severe, your physician may stop treatment with **ADCO LAMIVUDINE & ZIDOVUDINE 150/300.** This has occurred more commonly in patients with advanced HIV disease and with higher doses of zidovudine than the dose in **ADCO LAMIVUDINE & ZIDOVUDINE 150/300.** Regular blood tests will be arranged to check whether there is a problem with your white and red blood cell count. This adverse reaction is infrequent in patients with early HIV disease and blood tests may be performed less frequently.

  If you take ribavirin and zidovudine together it may cause or worsen anaemia. Please contact your doctor if you notice symptoms of anaemia (such as tiredness and shortness of breath). Your doctor will advise you whether you should stop taking **ADCO LAMIVUDINE & ZIDOVUDINE 150/300.**
- **Inflammation (swelling/irritation) of the pancreas:** Rare cases of inflammation of the pancreas have been reported for patients treated with lamivudine and zidovudine. Inflammation of the pancreas must be considered whenever a patient develops abdominal pain, nausea, vomiting or elevated biochemical markers. Discontinue use of **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** until diagnosis of inflammation of the pancreas is excluded.
- **Infections**: Opportunistic infections (infections that occur due to a weakened immune system as in the HIV patient) and other complications of HIV infection may continue to develop in patients receiving **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** or any other anti-HIV medicines therapy.

Lactic acidosis/severe hepatomegaly with steatosis: Lactic acidosis (too much acid in your blood) or severe hepatomegaly (enlarged liver) including fatal cases, have been reported with the use of **ADCO LAMIVUDINE & ZIDOVUDINE 150/300**.

Symptoms may include generalised weakness, lack of appetite, and sudden unexplained weight loss, digestive tract symptoms and respiratory symptoms (difficulty in breathing and increased rate of breathing).

- **Fat redistribution:** Redistribution, accumulation or loss of body fat may occur in patients receiving combination antiretroviral therapy. Contact your doctor if you notice changes in body fat (e.g. fat on your back resulting in a lump of unusual size, increased fat on the face, breast enlargement.)

During treatment with **ADCO LAMIVUDINE & ZIDOVUDINE 150/300,** you should take care with the concomitant use of self-administered medications due to the possibility of interactions.

Please speak with your doctor if you have a history of liver disease. Patients with chronic hepatitis who are treated with anti-HIV medicines are at increased risk of severe and potentially fatal liver side-effects 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, as you may have a recurrence of your hepatitis. This recurrence may be more severe if you have serious liver disease.

Effects on the ability to drive and operate machinery:
No studies to investigate the effect of lamivudine or zidovudine on driving performance or the ability to drive machinery have been performed.

Taking other medicines with ADCO LAMIVUDINE & ZIDOVUDINE 150/300:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ADCO LAMIVUDINE & ZIDOVUDINE 150/300 with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

It is important that you tell your doctor about all the medicines you are taking including those you have bought yourself. These may affect the action of **ADCO LAMIVUDINE & ZIDOVUDINE 150/300**, or **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** may affect their action. **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** should not be taken with high doses of co-trimoxazole, or injections of ganciclovir or foscarnet, as lamivudine, one of the active substances in **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** may interact with these. **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** should also not be taken with stavudine, as zidovudine the other active substance in **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** may reduce the action of this medicinal product.

Zidovudine may interact with the following medicines:

- Phenytoin – zidovudine may decrease the concentration of phenytion in the blood and therefore phenytoin levels must be monitored.
- Probenecid- the amount of zidovudine in the blood may increase
- Ribavirin – use of this medicine with **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** should be avoided.
- The following medicines may alter the way in which zidovudine is metabolised in the body: Aspirin,codeine, morphine, indomethacin, ketoprofen, naproxen, oxazepam, lorazepam, cimetidine, clofibrate, dapsone, isoprinosine and methadone.
- Some patient receiving **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** may continue to experience opportunistic infections, therefore prophylactic antimicrobial therapy such as pyrimethamine, co-trimoxazole and acyclovir must be considered.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby while taking ADCO LAMIVUDINE & ZIDOVUDINE 150/300, please consult your doctor, pharmacist or other health care professional for advice.

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

If you are breast-feeding please inform your doctor before taking any medicines. Do not take **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** if you are breastfeeding. HIV infected women must not breastfeed their infants under any circumstances in order to avoid transmission of HIV.

6. HOW TO TAKE ADCO LAMIVUDINE & ZIDOVUDINE 150/300

Always take ADCO LAMIVUDINE & ZIDOVUDINE 150/300 as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Always take **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Swallow **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** tablets with water. The tablets can be taken with or without food.

If you cannot swallow the tablet(s), you may crush and combine them with a small amount of food or drink, and take the entire dose immediately.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children over the age of 12 years:

The recommended dose: One tablet twice daily.

Prevention in Adults after being exposed to the HIV virus due to a work-related incident:

The course of medication should be started as soon as possible (preferably within 1-2 hours) after the exposure has occurred and continued until confirmation of HIV-status of source material.

In cases where the source material is confirmed to be infected with HIV, it is recommended that the preventative course be continued for a period of 4 weeks.

The following dosing guideline should be followed: 1 tablet taken twice daily.

Kidney or liver impairment:

If you suffer from kidney or liver impairment, your doctor will determine if you need a lower dosage.

If dosage adjustments are required your doctor may decide to change your medicine to lamivudine and zidovudine as separate medicines.

Dosage in the elderly:

Special care is advised in elderly patients due to age-associated changes such as the decrease in kidney function and alteration of blood (haematological) parameters.

Do not share medicines prescribed for you with others.

IF YOU TAKE MORE ADCO LAMIVUDINE & ZIDOVUDINE 150/300 THAN YOU SHOULD:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

If you have accidentally taken too much **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** you should tell your doctor or your pharmacist, or contact your nearest hospital emergency department for further advice.

IF YOU FORGET TO TAKE ADCO LAMIVUDINE & ZIDOVUDINE 150/300:

If you forget to take a dose of **ADCO LAMIVUDINE & ZIDOVUDINE 150/300**, take it as soon as you remember and then continue as before. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of **ADCO LAMIVUDINE & ZIDOVUDINE 150/300**, ask your doctor or pharmacist.

7. POSSIBLE SIDE EFFECTS

Not all side effects reported for ADCO LAMIVUDINE & ZIDOVUDINE 150/300 are included in this leaflet. Should your general health worsen while taking ADCO LAMIVUDINE &

ZIDOVUDINE 150/300, please consult your doctor, pharmacist or other healthcare professional for advice.

ADCO LAMIVUDINE & ZIDOVUDINE 150/300 can cause side effects. When treating HIV infection, it is not always possible to tell whether some of the undesirable effects that occur are caused by **ADCO LAMIVUDINE & ZIDOVUDINE 150/300**, by other medicines you are taking at the same time or by the HIV disease. For this reason it is very important that you inform your doctor about any changes in your health.

ADCO LAMIVUDINE & ZIDOVUDINE 150/300 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 raised lactic acid and sugar in the blood, hyperlipidaemia (increased fats in the blood) and resistance to insulin.

Frequent side effects:

Headache and nausea, vomiting, stomach pain, diarrhoea, increase in certain liver enzymes, joint pain, muscle pain and other muscle disorders, dizziness, tiredness, difficulty sleeping, hair loss, anaemia (low red blood cell count) and neutropenia (low white blood cell count). If the number of red blood cells is reduced you may have symptoms of tiredness or breathlessness and a reduction in your white blood cell count can make you more prone to infection.

Less Frequent side effects:

Flatulence, breathlessness, rash (red, raised or itchy), fever, general aches and pains and reduction in platelets (blood cells important for blood clotting). If you have a low platelet count you may notice that you bruise more easily. Cough, nasal symptoms, patchy colour changes inside the mouth, heartburn, chest pain (possibly indicating a heart muscle disease called cardiomyopathy),

breakdown of muscle tissue, liver disorders such as enlarged liver, fatty liver, inflammation of the liver (hepatitis), inflammation of the pancreas, nail and skin colour changes, sweating, flu-like feeling, drowsiness, passing urine more frequently, breast enlargement in male patients, chest pain, chills, loss of appetite, taste changes, tingling in the limbs, seizures, inability to concentrate, depression and feeling anxious, increase of lactic acid in the body known as lactic acidosis.

Your doctor may decide that you need to stop taking **ADCO LAMIVUDINE & ZIDOVUDINE 150/300** and take lamivudine and zidovudine separately.

This will allow your doctor to vary the dose or stop one of the active substances if it is considered that this will help manage some side effects.

If any of the side effects become serious or persist, please tell your doctor or pharmacist.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

8. STORING AND DISPOSING OF ADCO LAMIVUDINE & ZIDOVUDINE 150/300:

Store at or below 25 °C in tightly closed containers.

Protect from moisture and light.

KEEP OUT OF REACH OF CHILDREN.

Store in original package.

Do not use after the expiry date stated on the carton. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (E.g. toilets).

9. IDENTIFICATION OF ADCO LAMIVUDINE & ZIDOVUDINE 150/300

A white, film-coated tablet, embossed with “ZLM” on one side.

10. PRESENTATION OF ADCO LAMIVUDINE & ZIDOVUDINE 150/300

56 and 60’s tablets are packed into a white cylindrical HDPE container with a white ribbed HDPE closure. The closure contains an aluminium induction sealing wad. Purified cotton and a silica gel bag are placed in the container.

HDPE securitainers with polypropylene closure in packs of 56’s and 60’s.

11. REFERENCE NUMBER:

44/20.2.8/0106

12. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69

Bryanston, 2021

www.adcock.co.za

13. DATE OF PUBLICATION:

22/09/2010