Scheduling Status:
S4

ZIDOCOMB 150/300
150 mg/ 300 mg film-coated tablets
Lamivudine/ Zidovudine
Sugar free

Read all of this leaflet carefully before you start taking ZIDOCOMB 150/300

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

What is in this leaflet

WARNING:

THE CLASS OF MEDICINES TO WHICH ZIDOCOMB 150/300 BELONGS (NRTIS), CAN CAUSE A CONDITION CALLED LACTIC ACIDOSIS, TOGETHER WITH AN ENLARGED LIVER AND FATTY LIVER DISEASE. IT CAN BE LIFE-THREATENING. LACTIC ACIDOSIS IS CAUSED BY A BUILD-UP OF LACTIC ACID IN THE BODY.

DEEP, RAPID BREATHING, DROWSINESS, AND NON-SPECIFIC SYMPTOMS SUCH AS NAUSEA, VOMITING AND STOMACH PAIN MIGHT INDICATE THE DEVELOPMENT OF LACTIC ACIDOSIS.

LACTIC ACIDOSIS CAN BE LIFE-THREATENING AND MAY CAUSE INFLAMMATION OF THE PANCREAS, LIVER FAILURE OR KIDNEY FAILURE.

LACTIC ACIDOSIS, IF IT OCCURS, USUALLY DEVELOPS AFTER A FEW OR SEVERAL MONTHS OF TREATMENT.

YOUR DOCTOR WILL DISCONTINUE YOUR TREATMENT WITH ZIDOCOMB 150/300 SHOULD THE ABOVE OCCUR.

ZIDOCOMB 150/300 WILL BE ADMINISTERED WITH CAUTION TO ANY PATIENT WHO HAS LIVER DISEASE, OR OTHER KNOWN RISK FACTORS FOR LIVER DISEASE AND FATTY LIVER DISEASE, AS WELL AS IN OBESE (VERY OVERWEIGHT) PATIENTS, ESPECIALLY WOMEN.

IF YOU ARE INFECTED WITH HIV AS WELL AS HEPATITIS C AND YOU ARE BEING TREATED WITH MEDICINES CALLED ALPHA-INTERFERON AND RIBAVIRIN, YOU MAY CONSTITUTE A SPECIAL RISK.

IF YOU ARE AT INCREASED RISK YOUR HEALTH CARE PROVIDER WILL MONITOR YOUR CONDITION CLOSELY.

ZIDOCOMB 150/300 IS NOT USED FOR THE TREATMENT OF CHRONIC HEPATITIS B VIRUS (HBV) INFECTION AND THE SAFETY AND EFFICACY OF ZIDOCOMB 150/300 HAS NOT BEEN ESTABLISHED IN PATIENTS CO-INFECTED WITH HBV AND HIV.

IF YOU HAVE HEPATITIS B AS WELL AS HIV, YOUR HEPATITIS B MAY WORSEN IF YOU STOP TREATMENT WITH ZIDOCOMB 150/300. YOUR LIVER FUNCTION WILL BE CLOSELY MONITORED BY YOUR HEALTH CARE PROVIDER FOR AT LEAST SEVERAL MONTHS AFTER STOPPING TREATMENT WITH ZIDOCOMB 150/300.

IF APPROPRIATE, YOUR DOCTOR MAY INITIATE ANTI-HEPATITIS B THERAPY.

1. What ZIDOCOMB 150/300 is and what it is used for

ZIDOCOMB 150/300 belongs to a group of antiviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs), also known as antiretrovirals.

ZIDOCOMB 150/300 is used to treat Human Immunodeficiency Virus (HIV) infection.

ZIDOCOMB 150/300 is used as prevention treatment (until results of the source material are available) in HIV negative adults after exposure to material known to be, or strongly suspected to be, infected with HIV.

2. What you need to know before you take ZIDOCOMB 150/300

Do not take ZIDOCOMB 150/300:

- If you are hypersensitive (allergic) to lamivudine, zidovudine or to any of the other ingredients of ZIDOCOMB 150/300 (listed in section 6).
- if you have a very low red blood cell count (anaemia) or a very low white blood cell count (neutropenia).
- if you are a child younger than 12 years.
- if you are taking other medicine for HIV infection such as stavudine.

- if you are taking a medicine called zalcitabine.

Warnings and precautions

Take special care with ZIDOCOMB 150/300:

- if you experience deep, rapid breathing, drowsiness, and nonspecific symptoms such as nausea, vomiting and stomach pain, it might indicate the development of lactic acidosis, which is a rare, but serious side effect (see Possible side effects)
- if you develop stomach pain, nausea and vomiting, it may be inflammation of the pancreas and you should contact your doctor
- if you are taking ZIDOCOMB 150/300 and/or other combination treatments for HIV, you may develop other infections and complications of HIV infection (see below – Infections)
- if you have kidney disease
- if you have ever had liver disease, including hepatitis B or C (if you have hepatitis B infection, do not stop ZIDOCOMB 150/300 without your doctor's advice, as your hepatitis may come back)
- if you notice changes in body fat (redistribution, accumulation or loss of body fat may occur in patients receiving combination antiretroviral therapy)
- if you are co-infected with hepatitis C receiving interferon alfa and ribavirin, you may be at special risk. It may cause or worsen anaemia. Please contact your doctor if you notice symptoms of anaemia (such as tiredness and shortness of breath).

Protect other people

Treatment with ZIDOCOMB 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.

Blood reactions

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 ZIDOCOMB 150/300. If severe, your doctor may stop treatment with ZIDOCOMB 150/300. This has occurred more frequently in patients with advanced HIV disease and with higher doses of zidovudine than the dose in ZIDOCOMB 150/300. Regular blood tests will be arranged to check whether there is a problem with your white and red blood cell count. This side effect is infrequent in patient with early HIV disease and blood tests may be performed less frequently.

Infections

If you have 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 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.

In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking ZIDOCOMB 150/300. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

If you notice any symptoms of infection, please inform your doctor immediately.

Bone problems

Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms, please inform your doctor.

Children and adolescents

Zidocomb 150/300 must not be given to children younger than 12 years.

Oher medicines and ZIDOCOMB 150/300:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

These medicines should not be used with ZIDOCOMB 150/300:

- other medicines containing lamivudine, to treat HIV infection or hepatitis B infection
- high doses of co-trimoxazole, an antibiotic
- emtricitabine, to treat HIV infection
- zalcitabine, to treat HIV infection
- ribavirin or injections of ganciclovir to treat viral infections
- cladribine, used to treat hairy cell leukaemia
- medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly
- stavudine, to treat HIV infection.

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

- rifampicin, to treat tuberculosis

- valproic acid, to treat epilepsy
- probenecid, to treat gout and similar conditions, and given with some antibiotics to make them more effective
- paracetamol, to treat pain
- atovaquone
- interferon, to treat viral infections
- pyrimethamine, to treat malaria and other parasitic infections
- dapsone, to prevent pneumonia and treat skin infections
- fluconazole or flucytosine, to treat fungal infections such as candida
- pentamidine or atovaquone to treat parasitic infections such as Pneumocystis jirovecii pneumonia (often referred to as PCP)
- amphotericin, to treat fungal and bacterial infections
- methadone, used as a heroin substitute
- vincristine, vinblastine or doxorubicin, to treat cancer.

Some medicines interact with ZIDOCOMB 150/300:

- clarithromycin, an antibiotic. If you are taking clarithromycin, take your dose at least 2 hours before or after you take your ZIDOCOMB 150/300.
- phenytoin, to treat epilepsy.

ZIDOCOMB 150/300 with food and drink

See section 3.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not take ZIDOCOMB 150/300 if you are pregnant or breastfeeding your infant.

Driving and using machines

It is not always possible to predict to what extent ZIDOCOMB 150/300 may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZIDOCOMB 150/300 affects them.

ZIDOCOMB 150/300 can make you dizzy and have other side effects that make you less alert. Do not drive or use machines until you are feeling well. No studies on the effects on the ability to drive and use machines have been performed.

3. How to take ZIDOCOMB 150/300

Only doctors experienced in treatment of HIV infection should prescribe treatment with ZIDOCOMB 150/300 for you.

Do not share medicines prescribed for you with any other person.

Always take ZIDOCOMB 150/300 exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is one ZIDOCOMB 150/300 tablet twice a day.

ZIDOCOMB 150/300 can be taken with or without food.

Your doctor will tell you how long your treatment with ZIDOCOMB 150/300 will last. Do not stop treatment early. If you have the impression that the effect of ZIDOCOMB 150/300 is too strong or too weak, tell your doctor or pharmacist.

If your doctor wishes to reduce your dose of ZIDOCOMB 150/300, for example if you have kidney problems, then your medicine may be changed to lamivudine and zidovudine taken as separate medicines.

Post Exposure prevention treatment:

You should start taking ZIDOCOMB 150/300 as soon as possible (1-2 hours) after the exposure has occurred.

The usual dose is one ZIDOCOMB 150/300 tablet twice a day to be taken for 28 days if the source material is confirmed to be infected with HIV.

Treatment will be stopped immediately by your doctor if the source material is not infected with HIV.

Your doctor will tell you how long your treatment with ZIDOCOMB 150/300 will last. Do not stop treatment early because you are feeling better. Your infection may become resistant against the treatment.

If you have the impression that the effect of ZIDOCOMB 150/300 is too strong or too weak, tell your doctor or pharmacist.

If you take more ZIDOCOMB 150/300 than you should

No specific signs or symptoms have been identified following such overdosage.

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

If you forget to take ZIDOCOMB 150/300

If you forget to take a dose of ZIDOCOMB 150/300 take it as soon as you remember and then continue as before but you should not take more than your total daily dose in any 24-hour period.

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

If you stop taking ZIDOCOMB 150/300

ZIDOCOMB 150/300 should be used every day to work properly. If you stop using ZIDOCOMB 150/300 your infection will get worse and you will cultivate resistance against the medicine.

4. Possible side effects

ZIDOCOMB 150/300 can have side effects.

Not all side effects reported for ZIDOCOMB 150/300 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZIDOCOMB 150/300, please consult your health care provider for advice.

If any of the following happens, stop taking ZIDOCOMB 150/300 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious reaction to ZIDOCOMB 150/300. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital of you notice any of the following:

Less frequently:

- signs of recurrent infections such as fever and sore throat
- fits (convulsions)
- chest pain; disease of the heart muscle
- difficulty breathing.

Lactic acidosis is a serious side effect

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, causing failure of internal organs. Lactic acidosis is more likely to develop in people who have liver disease, or in obese (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.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequently reported side effects

- headache
- difficulty in sleeping
- cough
- irritated, runny nose
- feeling sick (nausea)
- being sick (vomiting)
- stomach pains
- diarrhoea
- hair loss
- an area of swelling of the lower layer of skin and tissue just under the skin or mucous membranes
- muscle pain and discomfort
- joint pain
- tiredness, lack of energy
- fever (high temperature)
- a low red blood cell count (anaemia) or low white blood cell count (neutropenia or leukopenia)
- 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
- general feeling of being unwell
- inflammation caused by over-active immune system.

Less frequently reported side effects

- a decrease in the number of cells involved in blood clotting (*thrombocytopenia*)
- a failure of the bone marrow to produce new red blood cells (*pure red cell aplasia*)
- tingly feelings in the skin (pins and needles)
- weakness, numbness, pain
- an increase in an enzyme called amylase

- breakdown of muscle tissue
- a decrease in the number of all kinds of blood cells (*pancytopenia*)
- a failure of the bone marrow to produce new red or white blood cells (*aplastic anaemia*)
- feeling depressed or anxious, not being able to concentrate, feeling drowsy
- feeling bloated
- indigestion, taste disturbance
- changes in the colour of nails, your skin or the skin inside your mouth
- inflammation of the pancreas
- hives
- passing urine more often
- enlarged breasts in men.
- a flu-like feeling – chills and sweating
- physical weakness
- neurological effects that starts later.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Zidocomb 150/300.

5. How to store ZIDOCOMB 150/300

Store all medicines out of reach of children.

Store at or below 30 °C.

Protect from light and moisture.

Keep the container tightly closed. Store in the original container.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Content of the pack and other information

What ZIDOCOMB 150/300 contains

The active substances are lamivudine 150 mg and zidovudine 300 mg per tablet.

The other ingredients are colloidal silicon dioxide (HDK®N20 Pharma), magnesium stearate, microcrystalline cellulose (Avicel PH102), sodium starch glycolate as the core of the tablet and Opadry White 13B58802 consisting of HPMC2910/ hypromellose, macrogol/PEG, polysorbate 80, titanium dioxide as the tablet coating.

The tablets are sugar free.

What ZIDOCOMB 150/300 looks like and contents of the pack

ZIDOCOMB 150/300: White, scored on both tablet faces, film-coated, modified capsule-shaped tablets, debossed with "D 02" on both tablet faces.

ZIDOCOMB 150/300 is packed into 75 ml HDPE opaque white bottles with 38 mm child-resistant heat induction seal cap.

Holder of the Certificate of Registration

iPharma (Pty) Ltd

124 Elevation Avenue, Randjesfontein

Midrand, 1683, SOUTH AFRICA

Tel. no.: (011) 314 2366

This leaflet was last revised in:

28 May 2026

Registration number:

53/20.2.8/0184

Access to the corresponding Professional Information

The Full Professional Information Leaflet is available from iPharma (Pty) Ltd, please email info@ipharma.co.za to request a digital copy.

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