PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ADCO-ZIDOVUDINE SYRUP, 50 mg/5 ml syrup
Zidovudine

Contains sweeteners:
Sugar invert 2750,00 mg and glycerol 400,00 mg per 5 ml syrup.

Read all of this leaflet carefully before you start taking ADCO-ZIDOVUDINE SYRUP

- 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.
- ADCO-ZIDOVUDINE SYRUP 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

1. What ADCO-ZIDOVUDINE SYRUP is and what it is used for

Zidovudine is an anti-virus medicine used in the treatment of the infection caused by the Human Immunodeficiency Virus (HIV). HIV grows and multiplies through DNA chain formation. Zidovudine becomes incorporated into the DNA chain and causes chain termination. This helps keep HIV from reproducing.
This medicine is used in combination with other antiretroviral medicines in the treatment of HIV infection in adults, children and mothers who are not breastfeeding. It is used to slow the progression of the disease.

2. What you need to know before you take ADCO-ZIDOVUDINE SYRUP

Do not take ADCO-ZIDOVUDINE SYRUP:

- If you are hypersensitive (allergic) to zidovudine or any of the other ingredients of ADCO-ZIDOVUDINE SYRUP (listed in section 6).
- If you have anaemia or other blood problems.
- If you are taking other medicines containing these active ingredients: stavudine and ribavirin.

- If you are breastfeeding.
- Pregnancy: this medicine has not been shown to be safe during the first trimester (3 months) of pregnancy for the mother and unborn baby.
- ADCO-ZIDOVUDINE SYRUP should not be given to new born babies with liver problems or that has increased amounts of bilirubin (a compound that is formed when red blood cells break down) in the blood.

Warnings and precautions

Take special care with ADCO-ZIDOVUDINE SYRUP:

- The use of ADCO-ZIDOVUDINE SYRUP with rifampicin or stavudine should be avoided.
- ADCO-ZIDOVUDINE SYRUP is not a cure for HIV infection or acquired immunodeficiency syndrome (AIDS). People taking ADCO-ZIDOVUDINE SYRUP (or combination therapy) may still develop opportunistic infections or other illnesses associated with HIV disease and AIDS. It is therefore important that you remain under the supervision of your doctor while taking ADCO-ZIDOVUDINE SYRUP.
- ADCO-ZIDOVUDINE SYRUP does not reduce the risk of passing HIV to others through sexual contact or blood contamination. You should use appropriate precautions.
- Pregnant women using this medicine to prevent infection of their infants must be aware that HIV may still pass to the infant.
- This medicine may cause blood problems such as anaemia (lacking of enough healthy red blood cells to carry adequate oxygen to your body’s tissues), neutropenia (decreased number of neutrophils, a type of white blood cell) and leucopenia (decreased amount of disease fighting cells (leukocytes) in your blood). Be sure to go for regular check-ups to your doctor.
- It may result in a condition called lactic acidosis. Symptoms include nausea, vomiting, stomach pain, difficulty in breathing, tiredness and weight loss. If you are feeling unwell, consult your doctor.
- If you pick up weight or feel your fat is being redistributed in your body (central obesity, buffalo hump, breast enlargement). These patients should have a thorough cardiovascular risk assessment.
- If you lose weight (in your face, limbs and buttocks).
- Treatment with ADCO-ZIDOVUDINE SYRUP may also lead to an increase of the amount of fat and sugar in your blood. Patients should be regularly assessed.
- If you experience joint aches and pain, joint stiffness or difficulty in movement. You may have a condition known as osteonecrosis.
- You may develop a syndrome known as immune reconstitution inflammatory syndrome (IRIS). This describes a collection of inflammatory disorders associated with contradictory worsening of pre-existing opportunistic infections (such as tuberculosis, cytomegalovirus retinitis and cryptococcal meningitis) following the initiation of combination antiretroviral therapy (usually within 3 months) and occurs in patients with low CD4 counts. You should start or continue your treatment for the specific opportunistic infections and also continue your antiretroviral therapy.
- If you are also taking other medicine (prescription and non-prescription).
- If you have any of the following symptoms: stomach pain, nausea, vomiting. You may

have pancreatitis (inflammation of the pancreas) and should stop your ADCO-ZIDOVUDINE SYRUP and contact your doctor immediately.
- If you have kidney problems. Your doctor will adjust your dose of ADCO-ZIDOVUDINE SYRUP accordingly.
- Liver disease has been known to occur. Treatment should be temporarily or permanently stopped if there is evidence of worsening of liver disease.
- If you have chronic hepatitis B or C, and you are treated with antiretroviral therapy, you have a higher risk of severe and potentially fatal liver complications. If you are infected with HIV and hepatitis B virus your doctor will carefully consider the best treatment for you. If you have a history of liver disease or chronic hepatitis B infection, your doctor may conduct blood tests to monitor your liver function.
- The use of ADCO-ZIDOVUDINE SYRUP with ribavirin (used to treat hepatitis C) should be avoided as it may increase the risk for you to develop anaemia.
- If you are breastfeeding. Transmission of HIV to your infant can occur.

Children
Special medical care (clinical and laboratory follow up) should be taken in infants, babies and children that were exposed to antiretroviral medicines that belong in the classes of medicines called nucleoside and nucleotide analogues during pregnancy. Your doctor may want to do tests to check your child for any signs of anaemia (low red blood cell count); neutropenia (decrease in the main type of the white blood cells); peripheral neuropathy (weakness and numbness associated with nerve damage in the hands and feet) and neurological disorders (disease that affect the nervous system) such as seizures and hypertonia (medical condition associated with muscle stiffness and uncontrolled muscle movement).

Low haemoglobin (a protein in your red blood cells that carries oxygen to your body's organs and tissues and transports carbon dioxide from your organs and tissues back to your lungs) concentrations have been reported in infants that were exposed to ADCO-ZIDOVUDINE SYRUP when the mother used ADCO-ZIDOVUDINE SYRUP to prevent mother-to-foetus transmission. The anaemia resolved within 6 weeks after completion of zidovudine therapy.

Other medicines and ADCO-ZIDOVUDINE SYRUP
Always tell your health care provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.)

There may be an interaction with the following types of medicines when taken with ADCO-ZIDOVUDINE SYRUP:
- Caution should be exercised when used together with self-administered medicines.
- Blood levels of phenytoin may be increased or decreased when taken together with ADCO-ZIDOVUDINE SYRUP.
- Medicines that affect the metabolism of zidovudine include aspirin, codeine, morphine, indomethacin, ketoprofen, naproxen, oxazepam, lorazepam, cimetidine, clofibrate, dapsone, isoprinosine and atovaquone.

- Medicines that are toxic to the kidney or suppress the bone marrow from producing blood cells such as systemic pentamidine, dapsone, pyrimethamine, co-trimoxazole, amphotericin, flucytosine, ganciclovir, interferon, vincristine, vinblastine and doxorubicin. These medicines may increase the risk of toxicity of ADCO-ZIDOVUDINE SYRUP when taken together.
- Ribavirin or stavudine.
- Probenecid, a drug used in the treatment of gout.
- Do not use ADCO-ZIDOVUDINE SYRUP with rifampicin as it may lead to partial or total loss of effectiveness of zidovudine.
- Valproic acid, fluconazole or methadone. These medicines may increase the risk of toxicity of ADCO-ZIDOVUDINE SYRUP when taken together.
- Clarithromycin tablets reduce the absorption of zidovudine. This can be avoided by taking your ADCO-ZIDOVUDINE SYRUP and clarithromycin at least two hours apart.

Pregnancy, breastfeeding and fertility

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.

The safety of ADCO-ZIDOVUDINE SYRUP whilst pregnant and breastfeeding is not known. There are no data on the effect of zidovudine on female fertility. In men, zidovudine has not shown to affect sperm count, morphology or motility.

Driving and using machines

There have been no studies to investigate the effect of ADCO-ZIDOVUDINE SYRUP on driving performance or the ability to use machines.
It is not always possible to predict to what extent ADCO-ZIDOVUDINE SYRUP 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 ADCO-ZIDOVUDINE SYRUP affects them.

ADCO-ZIDOVUDINE SYRUP contains sodium benzoate

This medicine contains 10,00 mg sodium benzoate in each 5 ml of syrup (0,20 % m/v). Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

ADCO-ZIDOVUDINE SYRUP contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dosage unit (5 ml), that is to say essentially' sodium-free'.

ADCO-ZIDOVUDINE SYRUP contains glycerol

May cause headache, stomach upset and diarrhoea.

ADCO-ZIDOVUDINE SYRUP contains sugar invert
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine contains 2750,00 mg of invert sugar per 5 ml. This should be taken into account in patients with diabetes mellitus. May be harmful to the teeth.

3. How to take ADCO-ZIDOVUDINE SYRUP
Do not share medicines prescribed for you with any other person.
Always take ADCO-ZIDOVUDINE SYRUP exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Even if you feel better, do not stop taking ADCO-ZIDOVUDINE SYRUP without talking to your doctor. Using ADCO-ZIDOVUDINE SYRUP as directed should give you the best chance to delay the development of drug resistance.

Dosage in adults when used in combination with other antiretroviral medicines:
The usual dose is 25 ml (250 mg) or 30 ml (300 mg) twice a day or 16,67 ml (166,67 mg) or 20 ml (200 mg) three times a day. This gives a maximum dose of 500 mg or 600 mg zidovudine per day. More than 1000 mg daily in divided doses has been used.
When you are also using other antiretroviral medicines, please refer to their individual package inserts for instructions on how to use them.

Dosage in children 3 months to 12 years of age when used in combination with other antiretroviral medicines:
If you are a child or you are giving ADCO-ZIDOVUDINE SYRUP to a child, your doctor will decide on the right dose based on the child's height and weight.
You should not give your child more than 20 ml (200 mg) every six hours.

Dosage in the prevention of mother-to-foetus transmission:
Pregnant women when they are over 14 weeks pregnant:
The usual dose is 10 ml (100 mg) five times a day. This gives a maximum dose of 500 mg zidovudine per day.
Your doctor will decide on the right dose (via injection) to be given when you are in labour, during birth and also until the umbilical cord is clamped.

Newborn infants – starting within 12 hours after birth until 6 weeks of age:
The usual dose is 0,2 ml/kg (2 mg/kg) every six hours. Your doctor will decide the on right dose (via injection) if the infant is unable to receive zidovudine via the mouth.

Dosage adjustments in patients that have blood problems:
Your dose of ADCO-ZIDOVUDINE SYRUP can be reduced or completely stopped if you have low levels of haemoglobin or neutrophils in your blood. Your doctor will decide on the correct dose to use.

Dosage adjustments when using other antiretroviral medicines:
Your doctor will advise you on how to adjust the dose of your antiretroviral medicines.

Dosage in patients over 65 years of age:
No specific data are available for patients over 65 years of age. Special care should be taken and your doctor must monitor you before and during the use of ADCO-ZIDOVUDINE SYRUP.

Dosage in patients with kidney problems:
If you have advanced kidney failure, you may be given a lower dose.
The usual dose in patients with severe kidney problems on haemodialysis is 10 ml (100 mg) or 13,33 ml (133,33 mg) three times a day or 7,5 ml (75 mg) or 10 ml (100 mg) four times a day. This gives a maximum dose of 300 mg or 400 mg zidovudine per day.

Dosage in patients with liver problems:
Your doctor will advise you on how to adjust the dose of your ADCO-ZIDOVUDINE SYRUP if you have liver problems

Your doctor will tell you how long your treatment with ADCO-ZIDOVUDINE SYRUP will last. Do not stop treatment early. If you have the impression that the effect of ADCO-ZIDOVUDINE SYRUP is too strong or too weak, tell your doctor or pharmacist.

Shake the bottle before use.

If you take more ADCO-ZIDOVUDINE SYRUP than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
You may experience the following symptoms if you take more ADCO-ZIDOVUDINE SYRUP than you should:

- A feeling of constant tiredness and weakness
- Headache
- Vomiting
- Blood abnormalities such as anaemia (lacking of enough healthy red blood cells to carry adequate oxygen to your body’s tissues), neutropenia (decreased number of neutrophils, a type of white blood cell) and leucopenia (decreased amount of disease fighting cells (leukocytes) in your blood)

The treatment of overdose should be symptomatic and supportive.

If you forget to take ADCO-ZIDOVUDINE SYRUP
Do not take a double dose to make up for forgotten individual doses.

If you stop taking ADCO-ZIDOVUDINE SYRUP
Do not stop taking ADCO-ZIDOVUDINE SYRUP unless your doctor tells you to, even if you are feeling better.

4. Possible side effects
ADCO-ZIDOVUDINE SYRUP can have side effects.
Not all side effects reported for ADCO-ZIDOVUDINE SYRUP are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking ADCO-ZIDOVUDINE SYRUP, please consult your health care provider for advice.
If any of the following happens, stop taking ADCO-ZIDOVUDINE SYRUP and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

These are all very serious side effects. If you have them, you may have had a serious reaction to ADCO-ZIDOVUDINE SYRUP. You may need urgent medical attention or hospitalisation.

Check with your doctor immediately if any of the following side effects occur:
Frequent side effects:

- lacking of enough healthy red blood cells to carry adequate oxygen to your body's tissues
- decreased number of neutrophils, a type of white blood cell
- decreased amount of disease fighting cells in your blood
- headache, dizziness
- nausea, vomiting, diarrhoea, stomach pain
- elevated liver enzymes and bilirubin
- muscle aches and pain
- feeling unwell

Less frequent side effects:

- decrease of the number of platelets in your blood
- lower-than-normal number of red and white blood cells and platelets in the blooda rare disorder of blood production in which the bone marrow fails to function in an adequate manner resulting in anaemia
- a rare condition in which the body stops producing enough new blood cells
- lactic acidosis (symptoms include nausea, vomiting, stomach pain, difficulty in
- breathing, tiredness and weight loss)
- an eating disorder known as anorexia where people obsess about their weight and
- what they eat
- anxiety, depression
- sleeplessness

- a sensation of “pins and needles” felt in the arms hands, legs and feet
- convulsions
- drowsiness
- forget important things, lack the focus to perform specific tasks, and struggle to concentrate
- a disease of the heart muscle that makes it harder for the heart to pump blood to the rest of the body
- cough, difficult to breath
- colour changes of the inside of the mouth
- passing of wind
- inflammation of the pancreas
- taste disturbances
- indigestion
- an enlarged liver with an increased build-up of fat in the liver
- colour changes of the nails and skin, rash, itching, formation of hives, sweating
- muscle weakness
- the need to urinate more often than normal
- enlarged breasts in men
- fever, general pain, chills, chest pain, feeling like you have the flu, abnormal physical weakness or lack of energy

Some other conditions that might occur during treatment with ADCO-ZIDOVUDINE SYRUP:
Treatment with zidovudine has been associated with loss of subcutaneous fat which is most evident in the face, limbs and buttocks. Patients receiving ADCO-ZIDOVUDINE SYRUP should be frequently examined and questioned for signs of lipoatrophy. When such development is found, treatment with ADCO-ZIDOVUDINE SYRUP should not be stopped.
Weight and levels of blood lipids and glucose may increase during antiretroviral therapy.
In HIV-infected patients with severe immune deficiency at the time of initiation of combination antiretroviral therapy, an inflammatory reaction to asymptomatic or residual opportunistic infections may arise. Autoimmune disorders (such as Graves' disease and autoimmune hepatitis) have also been reported; however, the reported time to onset is more variable and these events can occur many months after initiation of treatment.
Cases of osteonecrosis (joint aches and pain, joint stiffness or difficulty in movement.) have been reported, particularly in patients with generally acknowledged risk factors, advanced HIV disease or long-term exposure to combination antiretroviral therapy. The frequency of this is unknown.

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 or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ADCO-ZIDOVUDINE SYRUP.

5. How to store ADCO-ZIDOVUDINE SYRUP

Store all medicines out of reach of children.
Store at or below 25 °C in tightly closed containers. Protect from moisture and light.
Store in the original package or container.
Do not store in the bathroom.
Do not use after the expiry date on the label/carton/bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems.

6. Contents of the pack and other information

What ADCO-ZIDOVUDINE SYRUP contains
The active substance is zidovudine.
Every 5 ml of syrup contains 50 mg zidovudine.
Contains a preservative: 10,00 mg sodium benzoate (0,20 % m/v).
The other ingredients are acid citric monohydrate, sugar invert, sodium hydroxide, glycerol, flavour kiwi QL40609, banana flavour 75420-33 and purified water.

What ADCO-ZIDOVUDINE SYRUP looks like and contents of the pack
Syrup.
A clear, colourless to pale yellow liquid with smell and taste of kiwi and banana.

ADCO-ZIDOVUDINE SYRUP may be packed in one of the following containers:
White HDPE 250 ml Boston round bottle, containing 240 ml of syrup, fitted with a 24/410 screw on closure, placed into a 450 micron Thermo Mechanical Pulp (TMP) board 149 mm (H) x 60 mm (W) x 60 mm (L) plain carton with an approved package insert.

2,5 L Amber HDPE container, containing 2,5 L of syrup, fitted with a white, polypropylene, 38 mm, screw on closure.
Amber glass 200 ml Medropp generic bottle, containing 200 ml of syrup, fitted with a white, 28 mm, EXPE generic screw on closure.

Not all pack sizes may be marketed.

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