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.

Holder of Certificate of Registration

Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand, 1685
Customer Care: 0860 ADCOCK / 232625

The leaflet was last revised in

31 July 2023

Registration number

41/20.2.8/0511

Solely for use in South Africa and in the Sub-Saharan African countries stated below:
Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Comoros, Congo, Cote d' Ivoire, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, Seychelles, Sierra Leone, Somalia, Swaziland, Tanzania, Togo, Uganda, DR Congo (Zaire), Zambia, Zimbabwe.

SKEDULERINGSTATUS

S4

ADCO-ZIDOVUDINE STROOP, 50 mg/5 ml stroop
Zidovudien

Bevat versoeters:
Omgekeerde suiker 2750,00 mg en gliserol 400,00 mg per 5 ml stroop.

Lees die hele voubiljet voordat u ADCO-ZIDOVUDINE STROOP begin gebruik
- Hou hierdie voubiljet. U mag dit weer moet lees.
- Vra asseblief u dokter, apteker, verpleegster of ander gesondheidsorgverskaffer as u enige verder vrae het.
- ADCO-ZIDOVUDINE STROOP is vir u persoonlik voorgeskryf en u moenie u medisyne met enige ander persone deel nie. Dit kan hulle skaad, selfs al het hulle dieselfde simptome as u.

Wat in hierdie voubiljet is

1. Wat ADCO-ZIDOVUDINE STROOP is en waarvoor dit gebruik word
Zidovudien is ’n antiretrovirale medisyne wat vir die behandeling van die infeksie wat deur die Menslike Immuniteitsgebreksvirus (MIV) veroorsaak word. MIV groei en vermeerder deur DNS-kettingvorming. Zidovudien word in die DNS-ketting opgeneem en veroorsaak ketting-beëindiging. Dit help om te verhoed dat MIV reproduseer.
Hierdie medisyne word saam met ander antiretrovirale medisynes gebruik by die behandeling van MIV-infeksies vir volwassenes, kinders en moeders wat nie borsvoed nie. Dit word gebruik om die vordering van die siekte te vertraag.

2. Wat u moet weet voordat u ADCO-ZIDOVUDINE STROOP gebruik
Moenie ADCO-ZIDOVUDINE STROOP gebruik nie:
- As u hipersensitief (allergies) is vir zidovudien of enige van die ander bestanddele van ADCO-ZIDOVUDINE STROOP (in afdeling 6 gelys).
- As u bloedarmoede of ander bloedprobleme het.
- As u enige ander medisyne gebruik wat hierdie aktiewe bestanddele bevat: stavudien en ribavirien.
- As u borsvoed.

- Hierdie medisyne is nie aangedui om veilig vir die moeder as u swanger is en die ongebore baba te wees tydens die eerste trimester (die eerste 3 maande) van swangerskap nie.
- ADCO-ZIDOVUDINE STROOP moet nie aan pasgebore babas met lewerprobleme of verhoogde hoeveelhede van bllirubien in die bloed ('n samestelling wat gevorm word wanneer rooi bloedselle afbreek) gegee word nie.

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg wanneer u ADCO-ZIDOVUDINE STROOP gebruik:

- Die gebruik van ADCO-ZIDOVUDINE STROOP saam met rifampisien of stavudien moet vermy word.
- ADCO-ZIDOVUDINE STROOP is nie 'n geneesmiddel vir MIV-infeksie of verworwe immuniteitsgebreksindroom (VIGS) nie. Mense wat ADCO-ZIDOVUDINE STROOP (of kombinasieterapie) gebruik mag steeds opportunistiese infeksies of ander siektes wat met MIV of VIGS geassosieer word, kry. Daarom is dit belangrik dat u onder die toesig van u dokter bly wanneer u ADCO-ZIDOVUDINE STROOP gebruik.
- ADCO-ZIDOVUDINE STROOP verminder nie die risiko van oordrag van MIV na ander mense deur seksuele kontak of bloedbesmetting nie. U moet gepaste voorsorg tref.
- Swanger vroue wat hierdie medisyne gebruik om infeksie van hulle babas te voorkom moet bewus wees daarvan dat MIV steeds na die baba oorgedra kan word.
- Hierdie medisyne mag bloedprobleme soos bloedarmoede (gebrek aan genoeg gesonde rooi bloedselle om genoeg suurstof na die liggaamsweefsels te dra nie), neutropenie (verminderde getal neutrofiele, 'n soort wit bloedsel) en leukopenie (verminderde aantal siektebevegtende selle (leukosiete) in u bloed) veroorsaak. Maak seker dat u gereeld vir ondersoeke na u dokter gaan.
- Dit kan tot 'n toestand wat melkasidose genoem word lei. Simptome sluit naarheid, braking, maagpyn, asemnood, moegheid en gewigsverlies in. Raadpleeg u dokter as u siek voel.
- As u gewig optel of voel u vet hervers prei in u liggaam (sentrale vetsug, buffelboggel, borsvergroting). Hierdie pasiënte moet 'n deeglike kardiovaskulêre risikobepaling ondergaan.
- As u gewig verloor (in u gesig, ledemate en boude).
- Behandeling met ADCO-ZIDOVUDINE STROOP mag ook tot 'n toename van die hoeveelheid vet en suiker in u bloed lei. Pasiënte moet gereeld ondersoek word.
- As u gewrigspyne, -styfheid of moeilike beweging ervaar. U mag 'n toestand wat as osteonekrose bekend staan hê.
- U mag 'n toestand wat as immuunrekonstitusie inflammatoriese sindroom (IRIS) bekend staan. Dit beskryf 'n versameling van inflammatoriese versteurings wat met teenstrydige verergering van reeds bestaande opportunistiese infeksie geassosieer word (soos tuberkulose, sitomegalovirus retinitis en kriptokokkale meningitis) na die aanvang van kombinasie antiretrovirale terapie (gewoonlik binne 3 maande) en kom by pasiënte met lae CD4-tellings voor. U moet u behandeling vir die spesifieke opportunistiese infeksies begin of daarmee voortgaan asook aanhou met u antiretrovirale terapie.
- As u ook ander medisyne gebruik (met of sonder voorskrif).
- As u enige van die volgende simptome ervaar: maagseer, naarheid, braking. U kan pankreatitis hê (inflammasie van die pankreas) en moet die gebruik van ADCO-ZIDOVUDINE STROOP onmiddellik staak en u dokter dadelik kontak.

- As u nierprobleme het. U dokter sal u dosis van ADCO-ZIDOVUDINE STROOP ooreenstemmend aanpas.
- Dit is bekend dat lewersiekte mag voorkom. Behandeling moet tydelik of permanent gestaak word as daar bewyse is dat lewersiekte vererger.
- As u chroniese hepatitis B of C het en u word behandel met antiretrovirale terapie, het u 'n hoër risiko van erge of potensiële dodelike lewerkomplikasies. As u met MIV-hepatitis B-virus besmet is, sal u dokter die beste behandeling vir u noukeuring oorweeg. As u 'n geskiedenis van lewersiekte of chroniese hepatitis B-infeksie het, mag u dokter bloedtoetse doen om u lewerfunksie te monitor.
- Die gebruik van ADCO-ZIDOVUDINE STROOP saam met ribavirien (gebruik vir die behandeling van hepatitis C) moet vermy word aangesien dit die risiko dat u bloedarmoede kan ontwikkel verhoog.
- As u bosrvoed. Oordrag van MIV na u baba kan voorkom

Kinders
Spesiale mediese sorg (kliniese- en laboratorium-opvolging) moet met babas en kinders wat aan antiretrovirale medisynes wat tot die klasse van medisynes wat nukleosied- en nekleutiedanaloë tydens swangerskap blootgestel is, geneem word. U dokter mag toetse wil doen om u kind te ondersoek vir enige tekens van bloedarmoede (lae rooi bloedseltelling); neutropenie (vermindering in die hooftipe wit bloedselle); perifiraleneuropatie (swakheid en gevoelloosheid wat met senuweeskade in die hande en voete gepaard gaan) en neurologiese steurnisse (siektes wat die senuweestelsel aantas) soos stuipe en hipertonie (mediese toestand wat met spierstyfheid en onbeheerde spierbeweging geassosieer word).

Lae hemoglobien ('n proteïen in u rooi bloedselle wat suurstof na u liggaamsorgane dra en koolstofdioksied van u organe en weefsels terug na die longe vervoer) konsentrasies is in babas wat aan ADCO-ZIDOVUDINE STROOP blootgestel is toe die moeder ADCO-ZIDOVUDINE STROOP gebruik het om moeder-na-fetus oordrag te voorkom, aangemeld. Die bloedarmoede het binne 6 weke na voltooiïng van zidovudienterapie opgeklaar.

Ander medisyne en ADCO-ZIDOVUDINE STROOP
Vertel altyd u gesondheidsorgverskaffer as u enige ander medisyne gebruik.
(Dit sluit all aanvullende en transionele medisynes in.)

Daar mag 'n interaksie met die volgende tipes medisyne wees wanneer dit saam met ADCO-ZIDOVUDINE STROOP geneem word:
- Versigtigheid moet aan die dag gelê word wanneer dit saam met enige selftoegediende medisyne gebruik word.
- Vlakke van fenitoïen in die bloed mag verhoog of verlaag wanneer dit saam met ADCO-ZIDOVUDINE STROOP gebruik word.
- Medisyne wat die metabolisme van zidovudien beïnvloed sluit aspirien, kodeïen, morfien, indometasien, ketoprofen, naproxen, oksasepam, lorasepam, simetidien, klofibraat, dapsone, isoprinosien en atovakoon in.

- Medisyne wat giftig is vir die niere of wat keer dat beenmurg bloedselle produseer, soos sistiese pentamidien, dapsoon, pirimetamien, ko-trimoksasool, amfioterisien, flusitosien, gansiklovir, interferon, vinkristien, vinblastien en doksorubisien.

Hierdie medisynes mag die risiko van giftigheid van ADCO-ZIDOVUDINE STROOP verhoog wanneer dit gelyktydig gebruik word.

- Ribaviren of stavudien.
- Probenecid, 'n medisyne wat vir die behandeling van jig gebruik word.
- Moenie ADCO-ZIDOVUDINE STROOP saam met rifampisien gebruik nie aangesien dit tot gedeeltelike of algehele verlies van die doeltreffendheid van zidovudien kan lei.
- Valproïensuur, flukonasool of metadoon. Hierdie medisynes mag die risiko van giftigheid van ADCO-ZIDOVUDINE STROOP verhoog wanneer dit gelyktydig gebruik word.
- Klaritromisien tablette verlaag die opname van zidovudien. Dit kan verhoed word deur ADCO-ZIDOVUDINE STROOP en klaritromisien ten minste twee ure van mekaar te neem.

Swangerskap, borsvoeding en vrugbaarheid

Raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer as u swanger is of borsvoed, dink u mag dalk swanger wees of beplan om 'n baba te hê voordat u hierdie medisyne gebruik.

Die veiligheid van ADCO-ZIDOVUDINE STROOP tydens swangerskap en borsvoeding is onbekend.
Daar is geen data oor die invloed van zidovudien op vroulike vrugbaarheid nie. Zidovudien het nie getoon dat dit spermtelling, -morfologie of -beweeglikheid in mans beïnvloed nie.

Bestuur en bedryf van masjinerie

Daar was geen studies om die invloed van ADCO-ZIDOVUDINE STROOP op bestuursvermoë of die vermoë om masjinerie te bedryf nie.
Dit is nie altyd moontlike om te voorspel tot watter mate ADCO-ZIDOVUDINE STROOP mag inmeng met die daaglikse aktiwiteite van 'n pasiënt nie. Pasiënte moet seker maak dat hulle nie aan die bogenoemde aktiwiteite deelneem tot hulle bewus is van die mate waartoe ADCO-ZIDOVUDINE STROOP hulle beïnvloed nie.

ADCO-ZIDOVUDINE STROOP bevat natriumbensoaat

Hierdie medisyne bevat 10,00 mg natriumbensoaat in elke 5 ml stroop (0,20 % m/v).
Natriumbensoaat kan geelsug (vergeling van die vel en oë) in pasgebore babas (tot 4 weke oud) verhoog.

ADCO-ZIDOVUDINE STROOP bevat natrium

Hierdie medisinale produk bevat minder as 1 mmol natrium (23 mg) per dosiseenheid (5 ml), dit wil sê dis in wese 'natriumvry'.

ADCO-ZIDOVUDINE STROOP bevat gliserol

Mag hoofpyn, omgekrapte maag en diarree veroorsaak.

ADCO-ZIDOVUDINE STROOP bevat omgekeerde suiker
As u dokter vir u gesê het dat u onverdraagsaamheid vir sekere suikers het, kontak u dokter voordat u hierdie medisinale produk gebruik. Hierdie medisyne bevat 2750,00 mg omgekeerde suiker per 5 ml. Dit moet in berekening geneem word vir pasiënte met diabetes mellitus. Dit mag skadelik vir tande wees.

3. Hoe om ADCO-ZIDOVUDINE STROOP te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie.
Gebruik ADCO-ZIDOVUDINE STROOP altyd presies soos u dokter of apteker aan u voorgeskryf het. Bevestig met u dokter of apteker as u nie seker is nie. Moenie ophou om ADCO-ZIDOVUDINE STROOP te gebruik sonder om met u dokter te praat nie, selfs al voel u beter. Deur ADCO-ZIDOVUDINE STROOP soos aangedui te gebruik sal u die beste kans bied om die ontwikkeling van weerstandigheid vir medisynes te vertraag.

Dosering vir volwassenes wanneer tesame met ander antiretrovirale medisynes gebruik word:
Die gewone dosis is 25 ml (250 mg) of 30 ml (300 mg) twee keer per dag of 16,67 ml (166,67 mg) of 20 ml (200 mg) drie keer per dag. Dit gee ’n maksimum dosis van 500 mg of 600 mg zidovudien per dag. Meer as 1000 mg daagliks in verdeelde dosisse is al gebruik.
Verwys asseblief na hulle individuele voubiljette vir instruksies oor hoe om hulle te gebruik wanneer u ook ander antiretrovirale medisynes gebruik.

Dosering vir kinders van 3 maande tot 12 iaar oud wanneer dit tesame met ander antiretrovirale medisynes gebruik word:
As u ’n kind is of u gee ADCO-ZIDOVUDINE STROOP vir ’n kind gee, sal u dokter besluit wat die regte dosis is, gebasseer op die kind se lengte en gewig.
U moet nie meer as 20 ml (200 mg) elke 6 ure vir u kind gee nie.

Dosering vir die voorkoming van moeder-na-fetus oordraging:
Swanger vroue wanneer hulle meer as 14 weke swanger is:
Die gewone dosis is 10 ml (100 mg) vyf keer per dag. Dit gee ’n maksimum dosis van 500 mg zidovudien per dag.
U dokter sal besluit wat die regte dosis (per inspuiting) is wat geneem moet word tydens kraam, gedurende geboorte en ook totdat die naelstring afgebind is.

Pasgebore babas – neem aanvang binne 12 ure na geboorte tot 6 weke oud:
Die gewone dosis is 0,2 ml/kg (2 mg/kg) elke ses ure. U dokter sal besluit oor die regte dosis (per inspuiting) as die baba nie in staat is om zidovudien mondeliks te ontvang nie.

Dosisaanpassings vir pasiënte wat bloedprobleme het:
U dosis van ADCO-ZIDOVUDINE STROOP kan verminder word of heeltemal gestaak word as u lae vlakke hemoglobien of neutrofiele in u bloed het. U dokter sal oor die regte dosis om te gebruik besluit.

Dosisaanpassings as u ander antiretrovirale medisynes gebruik:
U dokter sal u inlig oor hoe om die dosis van u antiretrovirale medisynes aan te pas.

Dosis vir pasiënte wat ouer as 65 jaar is:
Geen spesifieke data is beskikbaar vir pasiënte wat ouer as 65 jaar is nie. Spesiale sorg moet geneem word en u dokter moet u monitor voor en tydens die gebruik van ADCO-ZIDOVUDINE STROOP.

Dosis vir pasiënte met nierprobleme:
As u gevorderde nierversaking het kan u ’n laer dosis gegee word.
Die gewone dosis vir pasiënte met erge nierprobleme wat op hemodialise is, is 10 ml (100 mg) of 13,33 ml (133,33 mg) drie keer per dag of 7,5 ml (75 mg) of 10 ml (100 mg) vier keer per dag. Dit gee ’n maksimum dosis van 300 mg of 400 mg zidovudien per dag.

Dosis vir pasiënte met lewerprobleme:
U dokter sal u inlig hoe om die dosis van u ADCO-ZIDOVUDINE STROOP aan te pas as u lewerprobleme het.

U dokter sal u inlig oor hoe lank u behandeling met ADCO-ZIDOVUDINE STROOP sal duur. Moenie die behandeling vroeg staak nie. As u die indruk kry dat die uitwerking van ADCO-ZIDOVUDINE STROOP te sterk of te swak is, lig u dokter of apteker in.

Skud die bottel goed voor gebruik.

As u meer ADCO-ZIDOVUDINE STROOP gebruik as wat u moet
Raadpleeg u dokter of apteker in die geval van oordosering. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.
U mag die volgende simptome ervaar as u meer ADCO-ZIDOVUDINE STROOP gebruik as wat u moet:

- ’n Gevoel van voortdurende moegheid en swakheid
- Hoofpyn
- Braking
- Bloedabnormaliteite soos bloedarmoede (tekort aan genoeg rooi bloedselle om genoeg suurstof na u liggaamsweefsels te vervoer), neutropenie (verminderde aantal neutrofiele, ’n soort wit bloedselle) en leukopenie (verminderde aantal siektebevegtende selle (leukosiete) in u bloed)

Die behandeling van oordosering moet simptomaties en ondersteunend wees.

As u vergeet om ADCO-ZIDOVUDINE STROOP te gebruik
Moenie ’n dubbeldosis gebruik om op te maak vir vergete individuele dosisse nie.

As u gebruik van ADCO-ZIDOVUDINE STROOP staak
Moenie gebruik van ADCO-ZIDOVUDINE STROOP staak nie behalwe as u dokter sê u moet, selfs al voel u beter.

4. Moontlike newe-effekte
ADCO-ZIDOVUDINE STROOP kan newe-effekte hê.
Nie alle newe-effekte wat aangemeld is vir ADCO-ZIDOVUDINE STROOP word in hierdie voubiljet ingesltuit nie. Indien u algemene gesondheid versleg of as u enige nadelige gevolge ervaar tydens gebruik van ADCO-ZIDOVUDINE STROOP, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.
Staak gebruik van ADCO-ZIDOVUDINE STROOP en lig u dokter onmiddellik in of gaan na die ongevalle afdeling van u naaste hospitaal as enige van die volgende gebeur:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal,
- uitslag of jeuking,
- floute

Hierdie is almal baie ernstige newe-effekte. As u hulle ervaar, mag u ’n ernstige reaksie op ADCO-ZIDOVUDINE STROOP gehad het. U mag dringende mediese aandag of hospitalisasie benodig.

Raadpleeg u dokter onmiddelik as u enige van die volgende newe-effekte ervaar:
Gereelde newe-effekte:

- tekort aan genoeg gesonde rooi bloedselle om genoeg suurstof na die liggaamsweefsels te vervoer
- afname van die getal neutrofiele, ’n soort wit bloedsel
- verminderde aantal van siektebevegtende selle in u bloed
- hoofpyn, duiseligheid
- naarheid, braking, diarree, maagpyn
- verhoogde lewerensieme en bilirubien
- spierpyne
- siek gevoel

Minder gereelde newe-effekte:

- afname van die getal plaatjies in u bloed
- laer as normale getal rooi en wit bloedselle, ’n seldsame versteuring van bloedproduksie waar die beenmurg nie die funksie op ’n voldoende manier kan volhou nie wat bloedarmoede veroorsaak
- ’n seldsame toestand waar die liggaam ophou om genoeg nuwe bloedselle te produseer
- melkasidose (simptome sluit naarheid, braking, maagpyn, asemnood, moegheid en gewigsverlies in)
- ’n eetversteuring bekend as anoreksie waar mense behep is met hulle gewig en wat hulle eet
- angstigheid, depressie

- slapeloosheid
- ’n sensasie van “naalde en spelde” in die arms, hande, bene en voete gevoel
- stuipe
- lomerigheid
- vergeet belangrike dinge, gebrek aan fokus om spesifieke take te verrig, en sukkel om te konsentreer
- ’n siekte van die hartspier wat dit moeiliker maak vir die hart om bloed na die res van die liggaam te pomp
- hoes, moeite om asem te haal
- verandering van kleur in die binnekant van die mond
- passering van wind
- inflammasie van die pankreas
- versteuring van smaak
- slegte spysvertering
- ’n vergrote lewer met ’n toename in die opbou van vet in die lewer
- verandering van kleur van die naels en vel, uitslag, jeuking, vorming van galbulte, sweet
- swakheid van spiere
- die nood om meer dikwels as gewoonlik te urineer
- vergroting van borste in mans
- koors, algemene pyn, koue rillings, borspyn, voel of u griep het, abnormale fisiese swakheid of tekort aan energie

Sommige ander toestande wat mag voorkom tydens benadeling met ADCO-ZIDOVUDINE STROOP:
Behandeling met zidovudien is verbind aan verlies van onderhuidse vet wat mees opmerklik is in die gesig, ledemate en boude. Pasiënte wat ADCO-ZIDOVUDINE STROOP ontvang moet gereeld ondersoek en uitgevra word oor tekens van lipoatrofie. Wanneer sulke ontwikkelings gevind word moet behandeling met ADCO-ZIDOVUDINE STROOP nie gestaak word nie.
Gewig en vlakke van bloedlipiede en glukose mag tydens antiretrovirale behanceling toeneem.
By MIV-besmette pasiënte met erge immuniteisversteuring ten tye van aanvang van kombinasie antiretrovirale terapie, kan inflammatoriese reaksie tot asimptomatiese of oorblywende opportunistiese infeksies opduik. Outoimmuunversteurings (soos Graves se siekte en outoimmuun-hepatitis) is ook aangemeld; die aangemelde tyd tot aanvang is egter meer wisselvallig en hierdie gevalle kan baie maande na die aanvang van behandeling voorkom.
Gevalle van osteonekrose (gewrigspyne, gewrigstyfheid of moeilikheid om te beweeg) is aangemeld, gedeeltelik in pasiënte met algemene erkende risikofaktore, gevorderde MIV-siekte of langtermyn blootstelling aan kombinasie antiretrovirale terapie. Die gereeldheid hiervan is onbekend.

As u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte
As u newe-effekte kry, praat met u dokter of apteker. U kan newe-effekte ook by SAHPRA aanmeld via die **"6.04 Adverse Drug Reaction Reporting Form"**, aanlyn gevind onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld kan u help om meer inligting te verskaf oor die veiligheid van ADCO-ZIDOVUDINE STROOP.

5. Hoe om ADCO-ZIDOVUDINE STROOP te bêre

Bêre alle medisyne buite bereik van kinders.
Bêre teen of laer as 25 °C in diggeseëlde houers.
Beskerm teen vog en lig.
Bêre in die oorspronklike verpakking of houer.
Moenie in die badkamer bêre nie.
Moenie na die vervaldatum op die etiket/dosie/bottel gebruik nie.
Gee alle ongebruikte medisyne aan u apteker terug
Moenie ongebruikte medisyne in dreine of rioolstelsels afspoel nie.

6. Inhoud van die pak en ander inligting

Wat ADCO-ZIDOVUDINE STROOP bevat
Die aktiewe bestanddeel is zidovudien.
Elke 5 ml stroop bevat 50 mg zidovudien.
Bevat 'n preserveermiddel: 10,00 mg natriumbensoaat (0,20 % *m/v*).
Die ander bestanddele is suur sitroenmonohidraat, omgekeerde suiker, natriumhidroksied, gliserol, kiwigeursel QL40609, piesanggeursel 75420-33 en gesuiwerde water.

Hoe ADCO-ZIDOVUDINE STROOP lyk en inhoud van die pak
STROOP.
'n Helder, kleurlose tot ligte geel vloeistof wat na kiwi en piesang ruik en proe.

ADCO-ZIDOVUDINE STROOP mag in een van die volgende houers verpak wees:
Wit HDPE 250 ml Boston ronde bottel, wat 240 ml stroop bevat, met 'n 24/410 aanskroefproppie, in 'n 450 mikron Thermomeganiespulp (TMP) karton 149 mm (H) x 60 mm (W) x 60 mm (L) gewone kartondosie met 'n goedgekeurde voubiljet verpak.

2,5 L Amber HDPE houer, wat 2,5 L stroop bevat, toegerus met 'n wit, polipropileen, 38 mm, aanskroefproppie.
Amber glas 200 ml Medropp generiese bottel, wat 200 ml stroop bevat, toegerus met 'n wit, 28 mm, EXPE generiese aanskroefproppie.

Nie alle verpakkings word noodwendig bemark nie.

Houer van Registrasiesertifikaat
Adcock Ingram Beperk
New Road 1
Erand Gardens
Midrand, 1685
Klantediens: 0860 ADCOCK / 232625

Laaste hersiening van voubiljet
31 Julie 2023

Registrasienommer
41/20.2.8/0511

Slegs vir gebruik in Suid-Afrika en in Sub-Sahare Afrikalande hieronder genoem: Angola, Benin, Botswana, Burkina Faso, Burundi, Kameroen, Sentraal-Afrikaanse Republiek, Tsjad, Comore, Kongo, Ivoorkus, Djiboeti, Ekwatoriale-Guinee, Eritrea, Ethiopië, Gaboen, Gambië, Ghana, Guinee, Guinee-Bissau, Kenia, Lesotho, Liberië, Madagaskar, Malawi, Mali, Mauritanië, Mosambiek, Namibië, Niger, Nigerië, Rwanda, Senegal, Seychelles, Sierra Leone, Somalië, Eswatini, Tanzanië, Togo, Uganda, DR Kongo (Zaire), Zambië, Zimbabwe.

adcock ingram

31794 05/2024