PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ADCO LAMIVUDINE SOLUTION, 10 mg/mL, solution

Lamivudine

Contains sugar: Sucrose 200 mg/mL

Read all of this leaflet carefully before you start taking ADCO LAMIVUDINE SOLUTION

- 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 LAMIVUDINE SOLUTION 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 LAMIVUDINE SOLUTION is and what it is used for
2. What you need to know before you take ADCO LAMIVUDINE SOLUTION
3. How to take ADCO LAMIVUDINE SOLUTION
4. Possible side effects
5. How to store ADCO LAMIVUDINE SOLUTION
6. Contents of the pack and other information

1. What ADCO LAMIVUDINE SOLUTION is and what it is used for

Lamivudine 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. Lamivudine helps control HIV infection by inhibiting or interfering with the reverse transcriptase enzyme that HIV needs to multiply. This helps keep HIV from reproducing.

ADCO LAMIVUDINE SOLUTION is used in combination with other antiviral medicines in the treatment of HIV infection in adults and children. It has been shown to work particularly well in combination with zidovudine-containing medicines.

2. What you need to know before you take ADCO LAMIVUDINE SOLUTION

If you are taking medicines on a regular basis, using ADCO LAMIVUDINE SOLUTION at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care provider for advice. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before taking ADCO LAMIVUDINE SOLUTION.

ADCO LAMIVUDINE SOLUTION is not a cure for HIV infection or AIDS. People taking ADCO LAMIVUDINE SOLUTION may still develop 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 LAMIVUDINE SOLUTION. ADCO LAMIVUDINE SOLUTION does not reduce the risk of passing HIV to others through sexual contact or blood contamination. You should use appropriate precautions.

A condition called lactic acidosis and severe liver disease has occurred with the use of ADCO LAMIVUDINE SOLUTION. These conditions may result in death.

Do not take ADCO LAMIVUDINE SOLUTION

- If you are hypersensitive (allergic) to lamivudine or any of the other ingredients in ADCO LAMIVUDINE SOLUTION (listed in section 6).

Warnings and precautions

Take special care with ADCO LAMIVUDINE SOLUTION:

- If you have, or previously had, a hepatitis B or C infection of the liver. ADCO LAMIVUDINE SOLUTION may make the infection worse.
- If you develop stomach pain, nausea or vomiting. Check with your doctor, as these could be signs of an inflamed pancreas.
- It may result in a condition called lactic acidosis. If you are feeling unwell, consult your doctor.
- Liver disease has been known to occur.
- If you have kidney disease.
- If you have lipodystrophy (a problem with the way your body uses and stores fat). This condition is characterised by being overweight (obesity), build-up of fat on the back of the neck between the shoulders (buffalo hump), loss of fat under the skin (making the face look thin), breast enlargement and high levels of fat and glucose (sugar) in the blood. If you have any of these signs, you should be thoroughly examined by your doctor.
- If you have advanced HIV infection, your immune system is weak, and you are more likely to develop serious infections (opportunistic infections). Such infections may have been “silent” and not detected by the weakened immune system before treatment was started. After starting treatment, the immune system becomes stronger, and may attack the infections, which can cause symptoms of infection or inflammation. Symptoms usually include fever, plus some of the following: headache, stomach ache or difficulty breathing.
- In rare cases, as your immune system becomes stronger, it can also attack healthy body tissue (autoimmune disorders). The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection.

- If you notice any of these symptoms of osteonecrosis (where parts of the bone tissue die, because of reduced blood supply to the bone): joint aches and pain, joint stiffness or difficulty in movement, tell your doctor.

Other medicines and ADCO LAMIVUDINE SOLUTION

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:

- Co-trimoxazole, which is an antibiotic used for urinary tract and other infections.
- Zalcitabine an anti-retroviral agent.
- Emtricitabine (used to treat HIV infection).
- Cladribine (used to treat a certain type of cancer).
- Medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly.

ADCO LAMIVUDINE SOLUTION with food and drink

ADCO LAMIVUDINE SOLUTION can be taken with or without food.

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 ADCO LAMIVUDINE SOLUTION.

Driving and using machines

It is not always possible to predict to what extent ADCO LAMIVUDINE SOLUTION may interfere with your daily activities. You should ensure that you do not engage in the above

activities until you are aware of the measure to which ADCO LAMIVUDINE SOLUTION affects you.

ADCO LAMIVUDINE SOLUTION contains sucrose

ADCO LAMIVUDINE SOLUTION contains sucrose. This may have an effect on the control of your blood sugar if you have diabetes mellitus. Sucrose may be harmful to teeth. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ADCO LAMIVUDINE SOLUTION.

3. How to take ADCO LAMIVUDINE SOLUTION

Do not share medicines prescribed for you with other persons.

It is important that you take this medicine exactly as directed by your doctor. Check with your doctor if you are not sure. Even if you feel better, do not stop taking ADCO LAMIVUDINE SOLUTION without talking to your doctor. Using ADCO LAMIVUDINE SOLUTION as directed should give you the best chance to delay the development of drug resistance.

Shake the bottle well before use. Use a measuring spoon or cup, which you can obtain from your doctor or pharmacist.

The usual dose for adults and adolescents more than 12 years of age is 6 medicine measures (300 mg of lamivudine) once daily or 3 medicine measures (150 mg of lamivudine) twice daily in combination with other anti-HIV medicines. This gives a daily maximum of 300 mg.

If you weigh less than 50 kg, the recommended dose is 2 mg/kg twice daily. Your doctor will calculate the right dose based on your weight.

If you are a child or you are giving ADCO LAMIVUDINE SOLUTION to a child, the recommended dose is 4 mg/kg twice daily. Do not take or give more than 300 mg in a day. Your doctor will calculate the right dose based on the child's weight.

For children younger than 3 months of age, your doctor will calculate the right dose.

If you take more ADCO LAMIVUDINE SOLUTION than you should

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

If you forget to take a dose of ADCO LAMIVUDINE SOLUTION

Take the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ADCO LAMIVUDINE SOLUTION can have side effects.

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

If any of the following happens, stop taking ADCO LAMIVUDINE SOLUTION 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 LAMIVUDINE SOLUTION. You may need urgent medical attention or hospitalisation.

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

- A breakdown of muscle tissue that releases a damaging protein into the blood (rhabdomyolysis); symptoms include: dark, reddish urine, a decreased amount of urine, weakness and muscle aches.
- Excess lactic acid in the blood (lactic acidosis); symptoms include: rapid breathing, excessive sweating, cool and clammy skin, sweet-smelling breath, stomach pain, nausea or vomiting, confusion and tiredness.
- Inflammation of the pancreas (pancreatitis); symptoms include severe stomach pain with nausea, vomiting and fever.
- Inflammation of the liver (hepatitis); symptoms include: yellow skin or eyes (jaundice), nausea, fatigue and fever.

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

Tell your doctor if you notice any of the following side effects:

Frequent side effects:

- Nausea, vomiting, stomach pain or cramps, diarrhoea
- Unusual weakness or tiredness
- Fever, general feeling of illness
- Difficulty in sleeping

- Headache, sensation of pins and needles, tingling, burning, numbness
- Muscle pain or cramping
- Joint pain
- Cough, irritated or runny nose

Side effects with frequency unknown:

- Loss of hair

Side effects that may show up in your blood tests:

- A reduction in the number of white blood cells (neutropenia)
- A reduction in the number of platelets (cells that make the blood clot) (thrombocytopenia)
- A reduction in the number of red blood cells (anaemia)
- A failure of the bone marrow to produce new red blood cells (pure red cell aplasia)
- An increase in liver enzymes
- An increase in the level of an enzyme called amylase in the blood

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 "**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 LAMIVUDINE SOLUTION.

5. How to store ADCO LAMIVUDINE SOLUTION

- Store all medicines out of reach of children.
- Store at or below 25 °C in tightly closed containers.
- Protect from moisture and light.
- Do not store in a bathroom.
- 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. Contents of the pack and other information

What ADCO LAMIVUDINE SOLUTION contains

Every 1 mL contains 10 mg lamivudine as the active ingredient.

Contains preservatives:

1,80 mg methylparaben (0,18 % *m/v*)

0,20 mg propylparaben (0,02 % *m/v*)

The other ingredients are:

Acid citric monohydrate, methylparaben, passionfruit flavour 10851-33, propylene glycol, propylparaben, purified water, sodium citrate, sucrose

What ADCO LAMIVUDINE SOLUTION looks like and contents of the pack

A clear, colourless to pale yellow liquid with a passionfruit flavour.

White HDPE round bottles or amber glass bottles containing 240 mL of solution. Amber HDPE container containing 2,5 L of solution.

Not all packs and pack sizes may be marketed.

Holder of certificate of registration

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