Patient Information Leaflet for ADCO-LAMIVUDINE TABLETS

SCHEDULING STATUS

S4

ADCO-LAMIVUDINE TABLETS, 150 mg, film-coated tablets

Lamivudine

Sugar free

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

- 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 TABLETS 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 TABLETS 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 TABLETS 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 TABLETS

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

Two conditions called lactic acidosis and severe liver disease have occurred with the use of this medicine. These conditions may result in death.

Do not take ADCO-LAMIVUDINE TABLETS

- If you are hypersensitive (allergic) to lamivudine or any of the other ingredients in ADCO-LAMIVUDINE TABLETS (listed in section 6.1).

Warnings and precautions

Take special care with ADCO-LAMIVUDINE TABLETS:

- If you have, or previously had, a hepatitis B infection of the liver. ADCO-LAMIVUDINE TABLETS 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 TABLETS

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 TABLETS with food and drink

ADCO-LAMIVUDINE TABLETS 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 healthcare provider for advice before taking ADCO-LAMIVUDINE TABLETS.

Driving and using machines

It is not always possible to predict to what extent ADCO-LAMIVUDINE TABLETS 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 TABLETS affects you.

3. How to take ADCO-LAMIVUDINE TABLETS

Do not share medicines prescribed for you with other persons.

Always take ADCO-LAMIVUDINE TABLETS exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

Using ADCO-LAMIVUDINE TABLETS as directed should give you the best chance to delay the development of drug resistance.

The usual adult dose is 2 tablets (300 mg of lamivudine) once daily or one tablet (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 TABLETS 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 TABLETS 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 TABLETS

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 TABLETS can have side effects.

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

If any of the following happens, stop taking ADCO-LAMIVUDINE TABLETS 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 TABLETS. 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 and 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 TABLETS.

5. How to store ADCO-LAMIVUDINE TABLETS

- Store all medicines out of reach of children.
- Keep well closed, store in a dry place and at or below 25 °C in the original package.
- Store away from heat and direct light. Do not store in any damp places as moisture may break it down.
- 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 TABLETS contains

Each film-coated tablet contains 150 mg lamivudine as an active ingredient.

The other ingredients are:

Tablet core: magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate

Film coating: macrogol, polyvinyl alcohol-part, talc, titanium dioxide

What ADCO-LAMIVUDINE TABLETS looks like and contents of the pack

A white film-coated, oval, biconvex tablet with a breakline on one side.

56 and 60 tablets are packed in a white polypropylene securitainer fitted with a low density polyethylene lid.

56 and 60 tablets are packed in a white, high density polyethylene (HOPE) securitainer fitted with a white polypropylene child resistant with heat induction liner closure.

A white polypropylene capsule containing silica gel desiccant is included in the container.

Blister packs:

60 tablets are packed in blister strips composed of white PVC/PE/PVDC-Al or PVC/PVDC-Al.

Blister strips are packed in an outer cardboard carton.

Amber glass bottles:

60 tablets are packed in 50 ml amber glass bottle with wadding and a silica gel, fitted with a white EXPE screw generic closure.

Not all packs and sizes may be marketed.

Holder of certificate of registration

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