Patient Information Leaflet for ADCO-LAMIVUDINE 300 mg TABLETS

SCHEDULING STATUS

S4

ADCO-LAMIVUDINE 300 mg TABLETS, film-coated tablets

Lamivudine

Sugar free

Read all of this leaflet carefully before you start taking ADCO-LAMIVUDINE 300 mg 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 300 mg 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 300 mg TABLETS is and what it is used for
2. What you need to know before you take ADCO-LAMIVUDINE 300 mg TABLETS
3. How to take ADCO-LAMIVUDINE 300 mg TABLETS
4. Possible side effects
5. How to store ADCO-LAMIVUDINE 300 mg TABLETS
6. Contents of the pack and other information

1. What ADCO-LAMIVUDINE 300 mg TABLETS is and what it is used for

ADCO-LAMIVUDINE 300 mg TABLETS belongs to a group of antiviral medicines, also known as antiretrovirals, called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

ADCO-LAMIVUDINE 300 mg TABLETS is indicated for use in combination with other antiviral medicines in the treatment of HIV infection in adults and children over 12 years of age and weighing over 50 kg.

2. What you need to know before you take ADCO-LAMIVUDINE 300 mg TABLETS

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking ADCO-LAMIVUDINE 300 mg TABLETS.

ADCO-LAMIVUDINE 300 mg TABLETS is not a cure for HIV infection or AIDS. People taking ADCO-LAMIVUDINE 300 mg 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 300 mg TABLETS. ADCO-LAMIVUDINE 300 mg TABLETS does not reduce the risk of passing HIV to others through sexual contact or blood contamination. You should use appropriate precautions.

ADCO-LAMIVUDINE 300 mg TABLETS may lead to serious problems with your liver or cause too much acid in your blood. If left untreated, this may cause death. The safety and efficacy of ADCO-LAMIVUDINE 300 mg TABLETS in patients who are infected with both human immunodeficiency virus (HIV) and hepatitis B virus (HBV) have not been established. ADCO-LAMIVUDINE 300 mg TABLETS should not be used for the treatment of chronic HBV infection. You should be closely monitored by your doctor for several months if you are infected with HBV and discontinue the use of ADCO-LAMIVUDINE 300 mg TABLETS.

Do not take ADCO-LAMIVUDINE 300 mg TABLETS

- If you are hypersensitive (allergic) to lamivudine or any of the other ingredients in ADCO-LAMIVUDINE 300 mg TABLETS (listed in section 6.1).

Warnings and precautions

Take special care with ADCO-LAMIVUDINE 300 mg TABLETS:

- If you are pregnant or breastfeeding.
- If you have, or previously have had, a hepatitis B infection of the liver. ADCO-LAMIVUDINE 300 mg 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 300 mg 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 300 mg TABLETS with food and drink

ADCO-LAMIVUDINE 300 mg 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 300 mg TABLETS.

Driving and using machines

It is not always possible to predict to what extent ADCO-LAMIVUDINE 300 mg 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 300 mg TABLEST affects you.

3. How to take ADCO-LAMIVUDINE 300 mg TABLETS

Do not share medicines prescribed for you with other person.

Always take ADCO-LAMIVUDINE 300 mg TABLETS 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-LAMIVUDINE 300 mg TABLETS without talking to your doctor.

The usual adult dose is 1 tablet (300 mg of lamivudine) once daily.

If you use more ADCO-LAMIVUDINE 300 mg 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 ADCO-LAMIVUDINE 300 mg TABLETS

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

4. Possible side effects

ADCO-LAMIVUDINE 300 mg TABLETS can have side effects.

Not all side effects reported for ADCO-LAMIVUDINE 300 mg TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO-LAMIVUDINE 300 mg TABLETS, please consult your healthcare provider for advice.

If any of the following happens, stop taking ADCO-LAMIVUDINE 300 mg 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 300 mg 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 300 mg TABLETS.

5. How to store ADCO-LAMIVUDINE 300 mg 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 this medicine 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 300 mg TABLETS contains

Each film-coated tablet contains 300 mg lamivudine as an active ingredient.

The other ingredients are:

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

Film coating: hypromellose, macrogol, polysorbate 80, titanium dioxide.

What ADCO-LAMIVUDINE 300 mg TABLETS looks like and contents of the pack

A white film-coated, oval shaped tablet debossed with 'H' on one side and '31' on the other side.

ADCO-LAMIVUDINE 300 mg TABLETS is packed in sizes of 28's, 30’s and 600's in a white HDPE container with a white polypropylene cap or white child resistant plastic cap that has a pulp lining.

Not all pack sizes may be marketed.

Holder of certificate of registration

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