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APPROVED PATIENT INFORMATION LEAFLET JULY 2026

SCHEDULING STATUS: S4

LAMILEOD 10 mg/mL (oral solution)

Lamivudine

Contains sugar (200 mg of sucrose), Preservative (1,50 mg of methyl hydroxybenzoate), (0,18 mg of propyl hydroxybenzoate) and solvent (20 mg of propylene glycol).

Each ml of oral solution contains 200 mg of sucrose, 1,50 mg of Methyl hydroxybenzoate, 0,18 mg of Propyl hydroxybenzoate and 20 mg of Propylene Glycol

Read all of this leaflet carefully before you start taking LAMILEOD 10 mg/mL

- 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.
- **LAMILEOD 10 mg/mL** 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 **LAMILEOD 10 mg/mL** is and what it is used for
2. What you need to know before you take **LAMILEOD 10 mg/mL**
3. How to take **LAMILEOD 10 mg/mL**
4. Possible side effects
5. How to store **LAMILEOD 10 mg/mL**
6. Contents of the pack and other information

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1. What LAMILEOD 10 mg/mL is and what it is used for.

LAMILEOD 10 mg/mL contains lamivudine which belongs to a group of antiviral medicines, also known as antiretrovirals, called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

These are used to treat human immunodeficiency virus (HIV) infection, which can lead to acquired immunodeficiency syndrome (AIDS).

LAMILEOD 10 mg/mL is used in antiretroviral combination therapy for the treatment of HIV infection in children and adults.

LAMILEOD 10 mg/mL does not cure AIDS or kill HIV but helps to prevent further damage to the immune system by slowing production of new viruses.

2. What you need to know before you take LAMILEOD 10 mg/mL

Do not take LAMILEOD 10 mg/mL:

- If you are allergic (hypersensitive) to lamivudine or any of the other ingredients of this medicine, (listed in section 6 below).

Warnings and precautions

Take special care with **LAMILEOD 10 mg/mL**:

if you have ever had liver disease, including hepatitis B or C

if you have ever had kidney disease

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.

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 LAMILEOD 10 mg/mL

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

These medicines should not be used with **LAMILEOD 10 mg/mL**:

- Zalcitabine or emtricitabine, used to treat HIV infection.

Some medicines may affect how **LAMILEOD 10 mg/mL** works or make it more likely that you’ll have side effects. These medicines include:

- Trimethoprim-sulphamethoxazole (also known as co-trimoxazole), an antibiotic used to treat *Pneumocystis carinii* pneumonia or toxoplasmosis.
- Cladribine (used to treat a certain type of cancer).

Pregnancy, breastfeeding and fertility

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If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **LAMILEOD 10 mg/mL**.

Do not take **LAMILEOD 10 mg/mL** if you are pregnant, are considering becoming pregnant or are breastfeeding.

Driving and using machines

It is not always possible to predict to what extent **LAMILEOD 10 mg/mL** 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 **LAMILEOD 10 mg/mL** affects them.

It is not always possible to predict to what extent **LAMILEOD 10 mg/mL** 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 **LAMILEOD 10 mg/mL** affects them.

LAMILEOD 10 mg/mL contains sugar/sodium

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

LAMILEOD 10 mg/mL may have an effect on the control of your blood sugar if you have diabetes mellitus. Please note that each 150 mg dose (or 15 ml) contains 3 g of sucrose.

If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

3. How to take LAMILEOD 10 mg/mL

Do not share medicines prescribed for you with any other person.

Always take **LAMILEOD 10 mg/mL** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

LAMILEOD 10 mg/mL is always taken with zidovudine.

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LAMILEOD 10 mg/mL may be taken with or without food.

Adults and children more than 12 years of age:

The usual dose is:

Either
- 15 ml to be taken twice daily, or
- 30 ml to be taken once daily.

Children older than three months to 12 years of age:

Your doctor will decide on the correct dose of **LAMILEOD 10 mg/mL** for your child, depending on their weight.

The usual dose of **LAMILEOD 10 mg/mL** is:

- 4 mg/kg body weight twice daily up to a maximum of 30 ml daily, or

If you have the impression that the effect of **LAMILEOD 10 mg/mL** is too strong or too weak, talk to your doctor or pharmacist.

If you take more LAMILEOD 10 mg/mL than you should

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

If you forget to take LAMILEOD 10 mg/mL

If you forget to take a dose, take it as soon as you remember. **Do not take a double dose** to make up for forgotten individual doses.

If **LAMILEOD 10 mg/mL** is stopped earlier than your doctor has prescribed, your symptoms of may return or worsen. Always take **LAMILEOD 10 mg/mL** for as long as your doctor has prescribed.

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4. Possible side effects

LAMILEOD 10 mg/mL can have side effects.

Not all side effects reported for **LAMILEOD 10 mg/mL** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **LAMILEOD 10 mg/mL**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **LAMILEOD 10 mg/mL** 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 **LAMILEOD 10 mg/mL**. 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. VR

Tell your doctor if you notice any of the following:

Frequent

- headache
- Nausea (feeling sick), vomiting (being sick), pain in the stomach, diarrhoea
- Rash, loss of hair
- Joint stiffness, muscle pain
- Extremely tired, lacking energy, having a high temperature
- inflammation of the pancreas (pancreatitis)
- tingling or numbness of the hands and feet (paraesthesia)
- numbness, tingling or weakness of the arms and legs (peripheral neuropathy)
- cough, irritated or runny nose

Less frequent:

Less frequent side effects that may show up in blood tests are:

- a low red blood cell count (anaemia) or low white blood cell count (neutropenia)
- a decrease in the number of cells involved in blood clotting (thrombocytopenia)
- an increase in the level of liver enzymes
- increase in an enzyme called amylase
- failure of the bone marrow to produce new red blood cells (pure red cell aplasia).

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 or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and reporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com By reporting side effects, you can help provide more information on

the safety of **LAMILEOD 10 mg/mL.**

5. How to store LAMILEOD 10 mg/mL

Store at or below 30 °C.

Keep the bottles tightly closed.

Discard oral solution one month after first opening.

KEEP OUT OF THE REACH OF CHILDREN.

Store in the original package / container.

Do not store in a bathroom.

Do not use after the expiry date stated on the blister / label / carton 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 pack and other information

What LAMILEOD 10 mg/mL contains

The active ingredient is lamivudine.

The other ingredients are:

Sucrose, Methyl hydroxybenzoate, Propyl hydroxybenzoate, Citric acid anhydrous, Sodium citrate, Propylene glycol, Strawberry flavour wild TP, Banana flavour, Sodium hydroxide, Purified water.

Flavourants:

i) Strawberry flavour wild TP: Flavouring ingredients approved for use in a regulation of FDA or in a reliable, published industry list, Propylene Glycol, Water.

ii) **Banana flavour:** Flavouring ingredients approved for use in a regulation of FDA or in a reliable, published industry list, Propylene Glycol.

What **LAMILEOD 10 mg/mL** looks like and contents of the pack

LAMILEOD 10 mg/mL: Clear, colourless to pale yellow, flavoured liquid

Contents of the pack:

For HDPE bottle pack:

Solution is packed in a round white HDPE Bottle and closed with 28 mm white cap made up of Polypropylene with Induction Sealing Wad and packed in a pre-printed carton.

Pack sizes include 240 ml Bottle Pack.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD

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Bassonia Estate Office Park (East),

1 Cussonia drive, Bassonia rock ext12

Alberton, Gauteng

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LAMILEOD 10 mg/mL: 61/20.2.8/0316

Access to the corresponding Professional Information

The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169

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