

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Lamivudine 10 mg/ml Oral Solution*

lamivudine

Read all of this leaflet carefully before your child starts taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask the prescribing doctor, health care provider or pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as those of your child.
- If your child gets any side effects, talk to your child's doctor, health care provider or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Lamivudine 10 mg/ml Oral Solution is and what it is used for
2. What you need to know before your child takes Lamivudine 10 mg/ml Oral Solution
3. How to take Lamivudine 10 mg/ml Oral Solution
4. Possible side effects
5. How to store Lamivudine 10 mg/ml Oral Solution
6. Contents of the pack and other information

1. WHAT LAMIVUDINE 10 MG/ML ORAL SOLUTION IS AND WHAT IT IS USED FOR

Lamivudine 10 mg/ml Oral Solution 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.

Lamivudine 10 mg/ml Oral Solution is used in antiretroviral combination therapy for the treatment of HIV infection. Lamivudine 10 mg/ml Oral Solution reduces the amount of HIV in your child's body, and keeps it at a low level. It also increases CD4 cell counts. CD4 cells are a type of white blood cells that plays an important role in maintaining a healthy immune system to help fight infection. Response to treatment with Lamivudine 10 mg/ml Oral Solution varies between patients.

Your doctor or health care provider will be monitoring the effectiveness of your child's treatment.

Lamivudine 10 mg/ml Oral Solution may improve your child's condition, but it is not a cure for the HIV infection. HIV infection is a disease spread by contact with blood or sexual contact with an infected individual.

This product is intended for use in children. Safety information on use in adults is also provided.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

2. WHAT YOU NEED TO KNOW BEFORE YOUR CHILD TAKES LAMIVUDINE 10 MG/ML ORAL SOLUTION

Your child should not be given Lamivudine 10 mg/ml Oral Solution

- if he/she is hypersensitive (allergic) to lamivudine or any of the other ingredients of Lamivudine 10 mg/ml Oral Solution (see section 6, What Lamivudine 10 mg/ml Oral Solution contains).

Warnings and precautions

One can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

Before your child starts using Lamivudine 10 mg/ml Oral Solution, you should have told your child's doctor or health care provider:

- if your child suffers from kidney disease or liver disease (such as hepatitis),
- if your child has diabetes and is using insulin
- if your child is overweight

It is important that the doctor or health care provider treating your child knows about all his/her symptoms even when you think they are not related to HIV infection.

Liver disease

Please speak with your doctor or health care provider if your child has a history of liver disease. Patients with chronic hepatitis B or C and treated with antiretroviral agents are at increased risk for severe and potentially fatal liver adverse events and may require blood tests for control of liver function.

If your child has a chronic hepatitis B infection, he/she should not stop the treatment without instructions from his/her doctor or health care provider, as he/she may have a recurrence of his/her hepatitis. This recurrence may be more severe if he/she has serious liver disease.

Lactic acidosis

Females, particularly if very overweight, and patients with liver disease may be more at risk of getting a rare, but serious side effect called lactic acidosis, a build up of lactic acid in the body. If lactic acidosis occurs, it usually develops after a few months of treatment. Deep rapid breathing, tiredness, drowsiness, and non specific symptoms such as nausea, vomiting and stomach pain, might indicate the development of this condition (see section 4). While your child is being treated with Lamivudine 10 mg/ml Oral Solution, his/her doctor or health care provider will monitor him/her for any signs that he/she may be developing lactic acidosis.

Fat distribution

Redistribution, accumulation or loss of body fat may occur in patients receiving combination antiretroviral therapy. Contact your child's doctor or health care provider if you notice changes in your child's body shape.

Immune Reactivation Syndrome

In some patients with advanced HIV infection (AIDS) and a history of AIDS-associated (opportunistic) infection, signs and symptoms of inflammation from such previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present without obvious symptoms. Autoimmune disorders (the immune system attacking healthy body tissue) may also occur after your child starts taking medicines for the treatment of your HIV

infection. These may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms in your child such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform the doctor or health care provider immediately to seek necessary treatment.

Bone problems

Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue). The risk of developing this disease may be higher if the immune system is severely weakened, if one is taking anti-inflammatory medicines called corticosteroids, if one is overweight or if one drinks alcohol regularly. So far, this disease has been reported mainly in adults. However, if your child suffers from joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement, inform the doctor or health care provider.

Other

Your child will need to take Lamivudine 10 mg/ml Oral Solution every day. This medicine helps to control his/her condition, but it is not a cure for HIV infection. He/she may continue to develop other infections and other illnesses associated with HIV disease (e.g. opportunistic infections). These will require specific and sometimes preventive treatment. You should keep in regular contact with your child's doctor or health care provider. Your child should not stop taking his/her medicine without you first talking to his/her doctor or health care provider.

Lamivudine 10 mg/ml Oral Solution contains methyl paraben, propyl paraben and sucrose.

Lamivudine 10 mg/ml Oral Solution contains methyl paraben and propyl paraben, which may cause allergic reactions (possibly delayed).

Lamivudine 10 mg/ml Oral Solution also contains sucrose that may be harmful to the teeth. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor or health care provider before taking this medicinal product.

Other medicines and Lamivudine 10 mg/ml Oral Solution

Please tell your child's doctor, health care provider or pharmacist if he/she is taking or has recently taken any other medicines, including herbal medicines or other medicines obtained without a prescription. These may affect the action of Lamivudine 10mg/ml Oral Solution, or Lamivudine 10mg/ml Oral Solution may affect their action.

Lamivudine 10mg/ml Oral Solution should not be taken with other medications containing lamivudine (used to treat HIV infection or hepatitis B infection), emtricitabine, combination of tenofovir and abacavir or tenofovir and didanosine (medicines used to treat HIV infection), or large doses of co-trimoxazole or trimethoprim (an antibiotic), or cladribine (used to treat hairy cell leukaemia).

Taking Lamivudine 10 mg/ml Oral solution with food and drink

Lamivudine 10mg/ml Oral Solution may be taken with or without food.

Pregnancy

If a patient becomes pregnant, or is planning to become pregnant, she must contact her doctor or health care provider to discuss the potential adverse effects and the benefits and risks of her antiretroviral therapy to her and her child.

Children whose mothers took NRTIs (medicines like lamivudine) during pregnancy had a reduced risk of being infected with HIV. This benefit is greater than the risk of having side effects.

Breastfeeding

Lamivudine is excreted into breast milk. If one wants to breastfeed one's baby, one should ask a doctor or healthcare provider for advice on the risks and benefits.

Driving and using machines

Lamivudine 10 mg/ml Oral solution is unlikely to affect the ability to drive or use machines. However, one should take into account the state of one's health and the possible side effects of lamivudine before considering driving or using machines.

3. HOW TO TAKE LAMIVUDINE 10 MG/ML ORAL SOLUTION

Your child should always take Lamivudine 10 mg/ml Oral solution exactly as your/his/her doctor or health care provider has instructed. You should check with the child's doctor, health care provider or pharmacist if you are not sure.

Children above 6 weeks of age and weighing 3 to less than 14 kg

The amount of solution, by weight band, to be taken twice daily (approximately 12 hours apart) is shown in the table below:

Body weight	Solution in ml	
	Morning	Evening
3-5.9 kg	3	3
6-9.9 kg	4	4
10-13.9 kg	6	6

Lamivudine 10mg/ml Oral Solution may be taken with or without food.

Use the oral dosing syringe supplied with the pack to measure your child's dose accurately.

1. Remove the bottle cap. Keep it safely
2. Hold the bottle firmly. Push the plastic adapter into the neck of the bottle.
3. Insert the syringe firmly into the adapter.
4. Turn the bottle upside down.
5. Pull out syringe plunger until the syringe contains the first part of your full dose.
6. Turn the bottle the correct way up. Remove the syringe from the adapter.
7. Put the syringe into your child's mouth, placing the tip of the syringe against the inside of your child's cheek. Slowly push the plunger in, allowing time to swallow. Do not push too hard and squirt the liquid into the back of your child's throat or your child may choke.
8. Take the syringe out of the bottle and wash it thoroughly in clean water. Let it dry completely before you use it again.
9. Close the bottle tightly with the cap, leaving the adaptor in place.

Dose adjustments

If your child's dose of Lamivudine 10 mg/ml Oral Solution needs to be reduced, for example if your child has kidney problems. In this case, please consult with your doctor.

If one takes more Lamivudine 10 mg/ml Oral Solution than one should

If your child accidentally takes too much medicine you should tell your child's doctor, health care provider or pharmacist, or contact your nearest hospital emergency department for further advice. Your child may require medical attention. Remember to take the medicine with you, and show it to the doctor or the staff of the emergency unit. If you have run out of solution, take the empty packaging along with you.

If you forget to give Lamivudine 10 mg/ml Oral Solution

It is important not to miss doses of Lamivudine 10 mg/ml Oral Solution. If you forget to give a dose of your child's medicine, and notice this within 6 hours, give the missed dose as soon as possible. Give the next regular dose as scheduled. If you notice later, give the normal dose to the child when the next one is due. Do not give a double dose to make up for forgotten doses.

If one stops taking Lamivudine 10 mg/ml Oral Solution

Because this medicine controls and does not cure your child's condition, the child will normally need to take it continuously. You should not stop treatment unless the doctor or health care provider tells you to.

If you have any further questions on the use of this product, ask the prescribing doctor, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lamivudine 10 mg/ml Oral Solution can cause side effects, although not everybody gets them. When treating HIV infection, it is not always possible to differentiate between unwanted effects caused by Lamivudine 10 mg/ml Oral Solution and those caused by any other medicines you/your child may be taking at the same time, or by the HIV disease. For this reason, it is important that you inform the doctor or health care provider of any change in your/your child's health.

The following list of side effects is mainly based on data from adult patients.

Short-term adverse reactions to combination antiretroviral therapy are common. After your child starts taking Lamivudine 10 mg/ml Oral Solution headache, nausea and vomiting, abdominal pain, diarrhoea and fatigue may occur. These reactions are usually mild and disappear within a few weeks even if treatment is continued.

Common side effects (may affect up to 1 in 10 people) are nausea, vomiting, stomach pain, diarrhoea, headache, joint pain, muscle disorders, cough, nasal symptoms (irritation, runny nose), fever, tiredness, general feeling of being unwell, skin rash, hair loss and difficulty in sleeping.

The following side effects are uncommon (may affect up to 1 in 100 people): Anaemia (low red blood cell count), neutropenia (low white blood cell count), and reduction in platelets (which are important for blood clotting). If the number of red blood cells is reduced, you may feel tired or breathless. A reduction in your white blood cell count can make you more prone to infection. If you have a low platelet count you may bruise more easily.

Increases in some liver enzymes have also been noted in blood samples from patients being treated with lamivudine (see section 2, What you need to know before your child takes Lamivudine 10 mg/ml Oral Solution).

There are rare reports (may affect up to 1 in 1000 people) of breakdown of muscle tissue, inflammation of the liver (hepatitis), inflammation of the pancreas (pancreatitis), increase in an enzyme called amylase, and swelling beneath the skin (angioedema) often affecting hands, feet, eyes, lips and genitals and, in severe cases, throat.

Very rarely (may affect up to 1 in 10 000) numbness, tingling sensation or sensation of weakness in the limbs, a failure of the bone marrow to produce new red blood cells (pure red cell aplasia).

Frequency **not known**: hyperglycaemia (high sugar levels in the blood).

The following side effects have been reported in patients treated with medicines of the group of NRTIs, to which lamivudine also belongs. However, frequency estimates for these effects are not available:

- lactic acidosis (a build up of lactic acid in the body, that can cause dehydration and coma). Deep, rapid breathing, drowsiness, and non-specific symptoms such as nausea, vomiting and stomach pain, may indicate the development of lactic acidosis.
- changes in body shape due to changes in fat distribution. These may include loss of fat from legs, arms and face, increased fat in the abdomen (belly) and around internal organs, breast enlargement and fatty lumps on the back of the neck ('buffalo hump'). The cause and long-term health effects of these conditions are not known at this time.
- raised lactic acid and sugar in the blood, increased fats (cholesterol and triglycerides) in the blood
- osteonecrosis (death of bone tissue)
- immune reactivation syndrome (see "Warnings and precautions")

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your child's doctor or health care provider or pharmacist as soon as possible.

5. HOW TO STORE LAMIVUDINE 10 MG/ML ORAL SOLUTION

Keep out of the reach and sight of children.

Do not use Lamivudine 10 mg/ml Oral Solution after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not store above 30°C.

Discard the product 30 days after initial opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lamivudine 10 mg/ml Oral Solution

The active ingredient is lamivudine 10 mg/ml.

The other ingredients are:

Banana flavour, citric acid anhydrous, methyl paraben, propyl paraben, propylene glycol, purified water, sodium citrate dihydrate, strawberry flavour and sucrose.

What Lamivudine 10 mg/ml Oral Solution looks like and contents of the pack

Lamivudine 10mg/ml Oral Solution is a clear, colourless to pale yellow, flavoured liquid, supplied in a HDPE bottle with polypropylene screw cap closure with induction sealing wad, containing 100 ml or 240 ml oral solution.

A 10 ml oral dosing syringe and an adaptor for the bottle are included in the pack.

Supplier and Manufacturer

Supplier	Manufacturer
Macleods Pharmaceuticals Limited 304, Atlanta Arcade Marol Church road Andheri (East) Mumbai – 400 059, India Tel: +91-22-66762800 Fax: +91 -22-28216599	Macleods Pharmaceuticals Limited Block: N2, Village Theda P. O. Lodhi Majra Tehsil Nalagarh, Dist. Solan Himachal Pradesh, India Tel: +91-01795 661400 Fax: +91-01795 661452

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Detailed information on this medicine is available on the World Health Organization (WHO) web site:
<http://www.who.int/prequal/> .