

Lamivox 10mg/ml

(Lamivudine Oral Solution 10mg/ml)

Consumer Medication Information Leaflet (RiMUP)

Lamivudine (10mg/ml)

What is in this leaflet

What Lamivudine Oral Solution is used for

1. How Lamivox works
2. Before you take Lamivox
3. How to take Lamivudine Oral Solution
4. While you are using Lamivox
5. Side effects
6. Storage and disposal of Lamivox
7. Product description
8. Manufacturer and Marketing Authorization Holder
9. Date of Revision

What Lamivox is used for

Lamivudine Oral solution is used to treat HIV (human immunodeficiency virus) infection in adults and children

How Lamivox works

Lamivudine Oral Solution does not completely cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. It also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection

Before you use Lamivox

- When you must not use it

Don't take Lamivudine Oral solution:

- if you're allergic (hypersensitive) to Lamivudine or any of the other ingredients in Lamivudine Oral Solution.

Check with your doctor if you think this applies to you.

- Before you start use it

Some people taking Lamivudine Oral Solution or other combination treatments for HIV are more at risk of serious side effects. You need to be aware of the extra risks:

- if you have ever had liver disease, including hepatitis B or C (if you have hepatitis B infection, don't stop Lamivudine Oral Solution without your doctor's advice, as your hepatitis may come back)
- if you're seriously overweight (especially if you're a woman)

- if you're diabetic and using insulin.
- if you or your child has a kidney problem, your dose may be altered. Talk to your doctor if any of these apply to you. You may need extra check-ups, including blood tests, while you're taking your medicine.

Important information about some of the ingredients of Lamivudine Oral Solution

If you are a diabetic, please note that each ml contains 200.00mg sugar.

Lamivudine Oral Solution contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Lamivudine Oral solution. Sucrose may be harmful to the teeth. Lamivudine Oral solution also contains preservatives (paraben) which may cause allergic reactions (possibly delayed).

Pregnancy

If you are pregnant, if you become pregnant, or are planning to become pregnant, talk to your doctor about the risks and benefits and risks to you and your baby of taking Lamivudine Oral solution.

Lamivudine Oral solution and similar medicines may cause side effects in unborn babies. If you become pregnant while you're taking Lamivudine Oral solution, your baby may be given extra check-ups (including blood tests) to make sure it is developing normally.

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

Breast-feeding

Women who are HIV-positive must not breast-feed, because HIV infection can be passed on to the baby in breast milk. If you're breast-feeding, or thinking about breast-feeding: Talk to your doctor immediately.

Taking other medicines

Tell your doctor or pharmacist if you're taking any other medicines, or if you've taken any recently, including herbal medicines or other medicines you bought without a prescription.

Remember to tell your doctor or pharmacist if you begin taking a new medicine while you are taking Lamivudine Oral solution.

These medicines should not be used with Lamivudine Oral solution:

- other medicines containing Lamivudine, (used to treat HIV infection or hepatitis B infection)
- high doses of co-trimoxazole, an antibiotic. Tell your doctor if you are being treated with any of these.

How to use Lamivox

- How much to use

Adults and adolescents over 12 years of age the usual dose of Lamivudine Oral solution is 30 ml a day (300 mg) to be taken as 15 ml (150 mg) twice a day at regular times, leaving approximately 12 hours between each dose.

Children 3 months to 12 years of age the usual dose of Lamivudine Oral solution is 4 mg/kg twice daily up to a maximum of 300 mg daily. Give each dose to your child at regular times, leaving approximately 12 hours between each dose.

Use the oral dosing syringe supplied with the pack to measure your 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 mouth, placing the tip of the syringe against the inside of your cheek. Slowly push the plunger in, allowing time to swallow. Don't push too hard and squirt the liquid into the back of your throat or you may choke.
8. Repeat steps 3 to 7 in the same way until you have taken your whole dose. For example, if your dose is 15 ml, you need to take one and a half syringe-fulls of medicine.
9. Take the syringe out of the bottle and wash it thoroughly in clean water. Let it dry completely before you use it again.
10. Close the bottle tightly with the cap, leaving the adaptor in place.

If you or your child has a kidney problem, the dose may be altered. Talk to your doctor if this applies to you or your child.

When to use it

Lamivudine Oral solution helps to control your condition. You need to keep taking it every day to stop your illness getting worse. You may still develop other infections and illnesses linked to HIV infection.

How long to use it

Keep in touch with your doctor, and don't stop taking Lamivudine Oral solution without your doctor's advice.

If you forget to use it

If you forget to take a dose, take it as soon as you remember. Then continue your treatment as before. Don't take a double dose to make up for a missed dose.

- If you use too much (overdose)

accidentally taking too much Lamivudine Oral solution is unlikely to cause any serious problems. If you take too much, tell your doctor or your pharmacist, or contact your nearest hospital emergency department for further advice.

While you are using it

- Things you must do

Look out for important symptoms

Some people taking medicines for HIV infection develop other conditions, which can be serious. You need to know about important signs and symptoms to look out for while you're taking Lamivudine Oral solution

- Things you must not do

None

- Things to be careful of

None

Side effects

Like all medicines, Lamivudine Oral solution can cause side effects, but not everyone gets them.

When you're being treated for HIV, it can be hard to tell whether a symptom is a side effect of Lamivudine Oral solution or other medicines you are taking, or an effect of the HIV disease itself. So it is very important to talk to your doctor about any changes in your health.

As well as the side effects listed below for Lamivudine Oral solution, other conditions can develop during combination therapy for HIV.

It is important to read the information later in this section under 'Other possible side effects of combination therapy for HIV'.

Common side effects

These may affect up to 1 in 10 people:

1. Headache
2. feeling sick (nausea)
3. being sick (vomiting)
4. diarrhea
5. stomach pains
6. tiredness, lack of energy
7. fever (high temperature)
8. general feeling of being unwell
9. muscle pain and discomfort
10. joint pain
11. rash
12. Hair loss (alopecia).
13. Hyperlactatemia

If you get side effects

Tell your doctor or pharmacist if any of the side effects gets severe or

troublesome, or if you notice any side effects not listed in this leaflet.

Other possible side effects of combination therapy for HIV

Combination therapy such as Lamivudine Oral solution may cause other conditions to develop during HIV treatment.

Old infections may flare up

People with advanced HIV infection (AIDS) have weak immune systems, and are more likely to develop serious infections (opportunistic infections). When these people start treatment, they may find that old, hidden infections flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections. If you get any symptoms of infection while you're taking Lamivudine Oral solution:

Tell your doctor immediately. Don't take other medicines for the infection without your doctor's advice.

Your body shape may change

People taking combination therapy for HIV may find that their body shape changes, because of changes in fat distribution:

- Fat may be lost from the legs, arms or face.
- Extra fat may build up around the tummy (abdomen), or on the breasts or internal organs.

Fatty lumps (sometimes called buffalo hump) may appear on the back of the neck. It is not yet known what causes these changes, or whether they have any long-term effects on your health. If you notice changes in your body shape: Tell your doctor.

Lactic acidosis is a rare but serious side effect

Some people taking Lamivudine Oral solution, or other medicines like it (NRTIs), develop a condition called lactic acidosis, together with an enlarged liver.

Lactic acidosis is caused by a build-up of lactic acid in the body. It is rare; if it happens, it usually develops after a few

months of treatment. It can be life-threatening, causing failure of internal organs.

Lactic acidosis is more likely to develop in people who have liver disease, or in obese (very overweight) people, especially women.

Signs of lactic acidosis include:

Deep, rapid, difficult breathing, drowsiness, numbness, or weakness in the limbs, feeling sick (nausea), being sick (vomiting), stomach pain.

During your treatment, your doctor will monitor you for signs of lactic acidosis. If you have any of the symptoms listed above, or any other symptoms that worry you: See your doctor as soon as possible.

Other effects may show up in blood tests

Combination therapy for HIV can also cause:

- increased levels of lactic acid in the blood, which on rare occasions can lead to lactic acidosis
- increased levels of sugar and fats (triglycerides and cholesterol) in the blood resistance to insulin (so if you are diabetic, you may have to change your insulin dose to control your blood sugar).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Lamivox

- Storage

Keep out of the reach and sight of children

Do not take Lamivudine Oral solution after the expiry date shown on the container.

Discard one month after first opening.

Store below 30°C.

- Disposal

If you have any unwanted Lamivudine Oral solution, don't dispose of it in your waste water or your household rubbish. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

A clear, colorless to pale yellow, strawberry-banana flavored liquid.

- Ingredients

The active substance is Lamivudine Oral solution.

Other ingredients: sucrose, propylene glycol, methyl paraben, propyl paraben, anhydrous citric acid, sodium citrate, liquid strawberry flavour, liquid banana flavour, and purified water.

- MAL number(s):

MAL 12065069AZ

Manufacturer

Aurobindo Pharma Ltd.
Unit III, Sy.No. 313 & 314,
Bachupally, Bachupally Mandal,
Medchal-Malkajgiri District,
Telangana state, INDIA.

Product Registration Holder

UNIMED SDN BHD
No.53 Jalan Tembaga SD 5/2B,
Bandar Sri Damansara,
52200 Kuala Lumpur.

Date of revision

August 2023