

Package leaflet: Information for the patient

Lamivudine 150 mg Film-coated Tablets

Lamivudine 300 mg Film-coated Tablets

lamivudine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

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

What is in this leaflet

1. What Lamivudine is and what it is used for
2. What you need to know before you take Lamivudine
3. How to take Lamivudine
4. Possible side effects
5. How to store Lamivudine
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1. What Lamivudine is and what it is used for

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

Lamivudine belongs to a group of antiviral medicines, also known as antiretrovirals, called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

Lamivudine 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 CD4 cell count in your blood. CD4 cells are a type of white blood cell that are important in maintaining a healthy immune system to help fight infection.

Response to treatment with lamivudine varies between patients. Your doctor will be monitoring the effectiveness of your treatment.

2. What you need to know before you take Lamivudine

Do not take Lamivudine:

- if you are allergic to lamivudine or any of the other ingredients of this medicine (listed in section 6)

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Lamivudine:

- if you are currently being treated for HIV with tenofovir and abacavir or tenofovir and didanosine (other NRTIs)
- if you have ever had liver disease, including hepatitis B or C (if you have hepatitis B infection, do not stop taking Lamivudine without your doctor's advice, as your hepatitis may come back)
- if you are seriously overweight (especially if you are a woman)

- 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 are taking your medicine. See section 4 for more information.

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 are taking Lamivudine.

Read the information ‘Other possible side effects of combination therapy for HIV’ in section 4 of this leaflet.

Protect other people

HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). You 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.

Other medicines and Lamivudine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, 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.

Tell your doctor if you are being treated with any of these:

- other medicines containing lamivudine (used to treat HIV infection or hepatitis B infection)
- a group of medicines called cytidine analogues used to treat HIV such as emtricitabine
- co-trimoxazole (an antibiotic medicine used to treat infections)
- cladribine (used to treat cancer of the blood (leukaemia))

Pregnancy and breast-feeding

Pregnancy

If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Lamivudine and similar medicines may cause side effects in unborn babies. If you have taken Lamivudine during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of 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.

A small amount of the ingredients in this medicine can also pass into your breast milk.

If you are breast-feeding or thinking of breast-feeding **talk to your doctor immediately.**

Driving and using machines

Lamivudine is unlikely to affect your ability to drive or use machines.

3. How to take Lamivudine

Always take this medicine exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

Swallow the tablets with some water. Lamivudine can be taken with or without food.

If you cannot swallow the tablets whole, you may crush and combine them with a small amount of food or drink, and take all the dose immediately. Alternatively other forms of the medicine may be available, ask your doctor or pharmacist

[For 150 mg] The tablet can be divided into equal doses.

Stay in regular contact with your doctor.

Lamivudine 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.

Keep in touch with your doctor, and do not stop taking Lamivudine without your doctor's advice.

How much to take

[For 150 mg only]

Use in adults, adolescents and children who weigh at least 25 kg:

The recommended dose of Lamivudine is 300 mg a day. This may be taken as either:

- one 150 mg tablet twice a day, leaving approximately 12 hours between each dose, or
- two 150 mg tablets once a day as advised by your doctor

Use in children weighing at least 20 kg and less than 25 kg:

The recommended dose is 225 mg a day. This can be given as either:

- 75 mg (half a Lamivudine 150 mg tablet in the morning, and
- one whole Lamivudine tablet (150 mg) in the evening, or
- 225 mg (one and a half 150 mg tablets) once a day as advised by your doctor

Use in children weighing at least 14 kg and less than 20 kg:

The recommended dose is 150 mg a day. This can be given as either:

- 75 mg (half a Lamivudine 150 mg tablet twice a day, leaving approximately 12 hours between each dose, or
- 150 mg (one 150 mg tablet) once a day as advised by your doctor

[For 300 mg only]

The usual dose of Lamivudine for adults, adolescents and children who weigh at least 25 kg is:

- one 300 mg tablet once a day

Other forms of this medicine may be more suitable for children or for people who need a lower dose than normal, or those who cannot take the tablets; ask your doctor or pharmacist.

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

If you take more Lamivudine than you should

Accidentally taking too much Lamivudine is unlikely to cause any serious problems. However, you should tell your doctor or your pharmacist, or contact your nearest hospital emergency department for further advice.

If you forget to take Lamivudine

If you forget to take a dose of Lamivudine, take it as soon as you remember and then continue as before. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Like all medicines, this medicine can cause side effects, although not everybody gets them.

When you are being treated for HIV, it can be hard to tell whether a symptom is a side effect of lamivudine or other medicines you are taking, or an effect of the HIV disease itself. For this reason it is very important that you inform your doctor about any changes in your health.

As well as the side effects listed below for Lamivudine, 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’.

If you notice any of the following serious side effects contact your doctor immediately:

Uncommon (may affect up to 1 in 100 people):

- an increase in the number of infections you get which causes fever, severe chills, sore throat or mouth ulcers. This may be signs you have a low number of white blood cells in your blood (neutropenia).
- unexplained bruising or bleeding for longer than usual. These may be signs of a decrease in the number of cells involved in blood clotting (thrombocytopenia).

Rare (may affect up to 1 in 1,000 people):

- swelling in the face, mouth, lips, tongue or throat causing difficulty breathing or swallowing (angioedema).
- severe stomach pain which may radiate to your back. This may be signs of problems with your pancreas (pancreatitis).
- yellowing of your skin or whites of your eyes, dark urine, pale stools, tiredness, fever, feeling sick (nausea), weakness, drowsiness and abdominal pain. These may be signs you have serious problems with your liver (hepatitis).
- dark coloured urine with muscle weakness or tiredness. These may be signs of muscle breakdown (rhabdomyolysis).

Very rare (may affect up to 1 in 10,000 people):

- tiredness, weakness, pale coloured skin, shortness of breath. These may be signs of a disorder where you are not producing red blood cells (pure red cell aplasia).
- numbness and tingling (commonly known as pins and needles), burning, stabbing or shooting pain in the feet or hands leading to loss of balance and co-ordination. These may be signs of nerve damage (peripheral neuropathy).
- deep, rapid, difficult breathing, drowsiness, numbness or weakness in the limbs, feeling sick (nausea), being sick (vomiting) and stomach pain. These may be signs of excess lactic acid in the blood (lactic acidosis).

Other possible side effects include:

Common (may affect up to 1 in 10 people):

- feeling sick (nausea)
- being sick (vomiting)
- stomach pains
- diarrhoea
- headache
- joint pain
- muscle pain and discomfort
- cough
- irritated or runny nose
- fever (high temperature)
- tiredness, lack of energy
- general feeling of being unwell
- skin rash
- hair loss (alopecia)
- difficulty in sleeping (insomnia)

Uncommon (may affect up to 1 in 100 people):

- a low red blood cell count (anaemia)
- an increase in the level of liver enzymes

Rare (may affect up to 1 in 1,000 people):

- increase in an enzyme called amylase that can be seen in a blood test

Other possible side effects of combination therapy for HIV

Combination therapy including Lamivudine 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.

In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms 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 your doctor immediately to seek necessary treatment.

If you get any symptoms of infection while you are taking Lamivudine:

Tell your doctor immediately. Do not take other medicines for the infection without your doctor's advice.

You may have problems with your bones

Some people taking combination therapy for HIV develop a condition called osteonecrosis. With this condition, parts of the bone tissue die because of reduced blood supply to the bone. People may be more likely to get this condition:

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight

Signs of osteonecrosis include:

- stiffness in the joints
- aches and pains (especially in the hip, knee or shoulder)
- difficulty moving

If you notice any of these symptoms **tell your doctor**.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lamivudine

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle or blister or carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 film-coated tablets contain

The active substance is lamivudine. Each 150 mg film-coated tablet contains 150 mg of lamivudine. Each 300 mg film-coated tablet contains 300 mg of lamivudine.

The other ingredients are:

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

Tablet coating: hypromellose, titanium dioxide, propylene glycol.

What Lamivudine film-coated tablets look like and contents of the pack

Lamivudine 150 mg film-coated tablets are white to off-white, capsule shaped with two sides that curve out, marked with “M105” on one side and a functional scoreline on the other.

Lamivudine 300 mg film-coated tablets are white to off-white, oval shaped with two sides that curve out, marked with “M300” on one side and plain on the other.

Lamivudine is available in blisters of 30, 60, 90, 120 tablets and in bottles of 30 and 60 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturer

Generics [UK] Limited, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

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