

Package leaflet: Information for the patient

Lamivudine 100 mg film-coated tablets

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
6. Contents of the pack and other information

1. What Lamivudine is and what it is used for

Lamivudine is used to treat long term (chronic) hepatitis B infection in adults.

The active ingredient in Lamivudine is lamivudine. Lamivudine is an antiviral medicine that suppresses the hepatitis B virus and belongs to a group of medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

Hepatitis B is a virus which infects the liver, causes long term (chronic) infection, and can lead to liver damage. Lamivudine can be used in people whose liver is damaged, but still functions normally (compensated liver disease) and in combination with other medicines in people whose liver is damaged and does not function normally (decompensated liver disease).

Treatment with lamivudine can reduce the amount of hepatitis B virus in your body. This should lead to a reduction in liver damage and an improvement in your liver function. Not everyone responds to treatment with lamivudine in the same way. Your doctor will monitor the effectiveness of your treatment with regular blood tests.

2. What you need to know before you take Lamivudine

Your healthcare provider should offer you counselling and testing for HIV infection before you start treatment with lamivudine for hepatitis B infection and during treatment. If you have or get HIV infection, see section 3.

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.

Some people taking lamivudine or other similar medicines are more at risk of serious side effects. You need to be aware of the extra risks:

- if you have ever had other types of **liver disease**, such as hepatitis C
- if you're seriously **overweight** (especially if you're a woman).

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 medication. **See Section 4 for more information** about the risks.

Do not stop taking lamivudine without your doctor's advice, as there is a risk of your hepatitis getting worse. When you stop taking lamivudine your doctor will monitor you for at least four months to check for any problems. This will mean taking blood samples to check for any raised liver enzyme levels, which may indicate liver damage. See section 3 for more information about how to take this medicine.

Protect other people

Hepatitis B infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). Lamivudine will not stop you passing hepatitis B infection on to other people. To protect other people from becoming infected with hepatitis B:

- **Use a condom** when you have oral or penetrative sex.
- **Do not risk blood transfer** — for example, do not share needles.

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.

These medicines should not be used with Lamivudine:

- medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly
- other medicines containing lamivudine, used to treat **HIV infection** (sometimes called the AIDS virus)
- emtricitabine used to treat **HIV** or **hepatitis B infection**
- cladribine, used to treat **hairy cell leukaemia**

Tell your doctor if you're being treated with any of these.

Pregnancy and breast-feeding

Breast-feeding is not recommended in women living with HIV because HIV infection can be passed on to the baby in breast milk.

Pregnancy

If you are pregnant, think you may be pregnant, or are planning to have a baby:

Talk to your doctor about the risks and benefits of taking lamivudine during your pregnancy.

Do not stop treatment with lamivudine without your doctor's advice.

Breast-feeding

Lamivudine can pass into breast-milk. If you are breast-feeding, or thinking about breast-feeding:

Talk to your doctor before you take Lamivudine.

Driving and using machines

Lamivudine may make you feel tired, which could affect your ability to drive or use machines.

Do not drive or use machines unless you are sure you're not affected.

Lamivudine contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Lamivudine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Stay in regular contact with your doctor

Lamivudine helps to control your hepatitis B infection. You need to keep taking it every day to control your infection and stop your illness getting worse.

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

How much to take

The recommended dose of Lamivudine is one tablet (100 mg lamivudine) **once a day.**

Your doctor may prescribe a lower dose if you have problems with your kidneys. An oral solution of lamivudine is available for people who need a lower than usual dose, or who can't take tablets.

Talk to your doctor if this applies to you.

If you have or get HIV that is not being treated with medicines while taking lamivudine for the treatment of hepatitis B infection, the HIV virus may develop resistance to certain HIV medicines and become harder to treat. Lamivudine can also be used to treat HIV infection. Talk to your doctor if you have HIV infection. Your doctor may treat you with another medicine that contains a higher dose, of lamivudine, usually 150 mg twice a day, as the lower dose of 100 mg lamivudine is not enough to treat HIV infection. If you are planning to change your HIV treatment, discuss this change with your doctor first.

Talk to your doctor if this applies to you.

Swallow the tablet whole, with some water. Lamivudine can be taken with or without food.

If you take more Lamivudine than you should

Accidentally taking too much Lamivudine is unlikely to cause any serious problems. If you accidentally take too much, 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, take it as soon as you remember. Then continue your treatment as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Lamivudine

You must not stop taking Lamivudine without consulting your doctor. There is a risk of your hepatitis getting worse (see 'Warnings and precautions' in section 2).

When you stop taking this medicine your doctor will monitor you for at least four months to check for any problems. This will mean taking blood samples to check for any raised liver enzyme levels, which may indicate liver damage.

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

4. Possible side effects

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

Side effects that were commonly reported in lamivudine clinical trials were tiredness, respiratory tract infections, throat discomfort, headache, stomach discomfort and pain, nausea, vomiting and diarrhoea, increases in liver enzymes and enzymes produced in the muscles (see below).

If you notice any of the following side effects, stop taking lamivudine and contact your doctor immediately:

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

- swelling of eyelids, face, mouth, lips, tongue or throat causing difficulty breathing or swallowing (angioedema) and possibly with sudden wheeziness and chest pain or tightening (allergic reaction)

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

- 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)

Not known (frequency cannot be estimated from the available data):

- breakdown of muscle tissue with symptoms that may include muscle pains, vomiting and confusion (rhabdomyolysis)
- a worsening of liver disease after lamivudine is stopped or during treatment if the hepatitis B virus becomes resistant to lamivudine. This can be fatal in some people.
- a decrease in the number of cells involved in blood clotting (thrombocytopenia) resulting in bleeding or bruising more easily than normal, which may show up in blood tests

Other side effects:

Very common (may affect more than 1 in 10 people):

- an increase in the level of some liver enzymes (transaminases), which may show up in blood tests and be a sign of inflammation or damage in the liver

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

- cramps and muscle pains
- skin rash or 'hives' anywhere on the body
- an increase in the level of an enzyme produced in the muscles (creatine phosphokinase), which may show up in blood tests and be a sign that body tissue is damaged

Talk to your doctor or pharmacist if you get any side effects. This includes any possible side effects not listed in this leaflet.

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 the Yellow Card Scheme at: 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 this medicine out of the sight and reach of children.

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

This medicinal product does not require any special storage conditions.

Bottles only - After first opening, use within 100 days.

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 contains

The active substance is lamivudine. Each film-coated tablet contains 100 mg lamivudine.

The other ingredients are microcrystalline cellulose, sodium starch glycolate, magnesium stearate, hypromellose, titanium dioxide (E171), propylene glycol, iron oxide yellow (E172) and iron oxide red (E172).

What Lamivudine looks like and contents of the pack

Lamivudine 100 mg film-coated tablets are peach, film-coated, capsule shaped, biconvex, bevelled edge tablets marked with “LN1” on one side and “M” on the other side.

Lamivudine 100 mg film-coated tablets are available in blister packs of 28 or 84 tablets and bottles of 84 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan

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