

PACKAGE LEAFLET

Package leaflet: Information for the user

Lamivudine 100 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 100 mg is and what it is used for
2. What you need to know before you take Lamivudine 100 mg
3. How to take Lamivudine 100 mg
4. Possible side effects
5. How to store Lamivudine 100 mg
6. Contents of the pack and other information

1. What Lamivudine 100 mg is and what it is used for

The active ingredient in Lamivudine 100 mg is lamivudine

Lamivudine 100 mg is used to treat long term (chronic) hepatitis B infection in adults.

Lamivudine 100 mg 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 100 mg 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 100 mg 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 100 mg 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 100 mg

Do not take Lamivudine 100 mg:

- if you are **allergic** to lamivudine or to 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 100 mg.

Some people taking Lamivudine 100 mg 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.

Don't stop taking Lamivudine 100 mg without your doctor's advice, as there is a risk of your hepatitis getting worse. When you stop taking Lamivudine 100 mg 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 Lamivudine 100 mg.

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 100 mg 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.
- **Don't risk blood transfer** – for example, don't share needles.

Other medicines and Lamivudine 100 mg

Tell your doctor or pharmacist if you're 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're taking Lamivudine 100 mg.

These medicines should not be used with Lamivudine 100 mg:

- 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

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 100 mg during your pregnancy.

Do not stop treatment with Lamivudine 100 mg without your doctor's advice.

Breast-feeding

Lamivudine 100 mg can pass into breast-milk. If you are breast-feeding, or thinking about breast-feeding:

→ **Talk to your doctor** before you take Lamivudine 100 mg.

Driving and using machines

Lamivudine 100 mg may make you feel tired which could affect your ability to drive or use machines.

→ Don't drive or use machines unless you are sure you're not affected.

3. How to take Lamivudine 100 mg

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

Stay in regular contact with your doctor

Lamivudine 100 mg 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 don't stop taking Lamivudine 100 mg** without your doctor's advice.

How much to take

The usual dose of Lamivudine 100 mg 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 are already taking another medicine that contains lamivudine for HIV infection, your doctor will continue to treat you with the higher dose, (usually 150 mg twice a day), because the dose of lamivudine in Lamivudine 100 mg (100 mg) is not enough to treat HIV infection. If you are planning to change your HIV treatment, discuss this change with your doctor first.

Swallow the tablet whole, with some water. Lamivudine 100 mg can be taken with or without food.

If you take too much Lamivudine 100 mg

Accidentally taking too much Lamivudine 100 mg 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 100 mg

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.

Don't stop taking Lamivudine 100 mg

You must not stop taking Lamivudine 100 mg without consulting your doctor. There is a risk of your hepatitis getting worse (*see section 2*). When you stop taking Lamivudine 100 mg 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 100 mg 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*).

Allergic reaction

These are rare (may affect up to 1 in 1,000 people). Signs include:

- swelling of eyelids, face or lips.
- difficulty swallowing or breathing **Contact a doctor immediately** if you get these symptoms. **Stop taking Lamivudine 100 mg.**

Side effects thought to be caused by Lamivudine 100 mg

A very common side effect (these may affect **more than 1 in 10** people) which may show up in blood tests is:

- an increase in the level of some liver enzymes (*transaminases*) which may be a sign of inflammation or damage in the liver.

A common side effect (these may affect **up to 1 in 10** people) is:

- cramps and muscle pains
- skin rash or “hives” anywhere on the body

A common side effect which may show up in blood tests is:

- an increase in the level of an enzyme produced in the muscles (*creatine phosphokinase*) which may be a sign that body tissue is damaged.

A very rare side effect (these may affect up to 1 in 10,000 people) is:

- lactic acidosis (excess lactic acid in the blood).

Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown

- breakdown of muscle tissue
- a worsening of liver disease after Lamivudine 100 mg is stopped or during treatment if the hepatitis B virus becomes resistant to Lamivudine 100 mg. This can be fatal in some people.

A side effect which may show up in blood tests is;

- a decrease in the number of cells involved in blood clotting (*thrombocytopenia*).

If you get any side effects

➔ **Talk to your doctor or pharmacist.** 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 side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lamivudine 100 mg

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 pack.

This medicinal product does not require any special storage conditions

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

6. Contents of the pack and other information

What Lamivudine 100 mg contains

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

The other ingredients are: isomalt (E953), crospovidone A, magnesium stearate (E572), hypromellose (E464), titanium dioxide (E171), macrogol 400, polysorbate 80 (E433), red and yellow iron oxides (E172).

What Lamivudine 100 mg looks like and contents of the pack

Lamivudine 100 mg film-coated tablets are supplied in Alu/PVC-Alu-OPA blister pack containing 28 and 84 tablets.

The tablets are pink capsule shaped, biconvex, film coated tablets with a dimension of 12.00 x 6.00 mm, debossed with '37' on one side and 'I' on the other side.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Accord Healthcare Limited
Sage House, 319 Pinner Road,
North Harrow, Middlesex,
HA1 4HF, United Kingdom

Manufacturer

Pharmadox Healthcare Ltd.
KW 20A - Kordin Industrial Park
PLA 3000 Paola
Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

Italy : Lamivudina Accord
Netherland : Lamivudine Accord 100 mg, filmomhulde tabletten
Spain: Lamivudina Accord 100 mg, comprimidos recubiertos con película EFG
United Kingdom : Lamivudine 100 mg Film-coated tablets

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