

Package leaflet: Information for the patient

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

1. What Lamivudine Teva is and what it is used for

The active ingredient in Lamivudine Teva is lamivudine.

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

Lamivudine Teva 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 that infects the liver causes long term (chronic) infection, and can lead to liver damage. Lamivudine Teva can be used in people whose liver is damaged but still functions normally (*compensated liver disease*).

Treatment with Lamivudine Teva 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 Teva 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 Teva

Do not take Lamivudine Teva

- 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

Some people taking Lamivudine Teva 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 are seriously **overweight** (especially if you are a woman).
- ➔ **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 medication. **See Section 4** for more information about the risks.

Do not stop taking Lamivudine Teva without your doctor's advice, as there is a risk of your hepatitis getting worse. When you stop taking Lamivudine Teva 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 Teva.

Look out for important symptoms

Some people taking medicines for hepatitis B 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 Teva.

- ➔ Read the information 'Other possible side effects of therapy for Hepatitis B' in Section 4 of this leaflet.

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 Teva 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 Teva

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 Teva.

These medicines should not be used with Lamivudine Teva:

- 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 are being treated with any of these.

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 Teva during your pregnancy.

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

Breast-feeding

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

- ➔ **Talk to your doctor** before you take Lamivudine Teva.

Driving and using machines

Lamivudine Teva 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.

Information about ingredient of Lamivudine Teva

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

3. How to take Lamivudine Teva

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 Teva 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 Teva** without your doctor's advice.

How much to take

The usual dose of Lamivudine Teva 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 Teva (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 Teva can be taken with or without food.

If you take more Lamivudine Teva than you should

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

If you forget to take Lamivudine Teva

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 missed dose.

Do not stop taking Lamivudine Teva

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, but not everyone gets them.

As well as the side effects listed below for Lamivudine Teva, other conditions can develop during therapy for hepatitis B.

- ➔ It is important to read the information under ‘Other possible side effects of therapy for hepatitis B’.

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*).

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 Teva.**

Side effects thought to be caused by Lamivudine Teva

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.

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 Teva is stopped or during treatment if the hepatitis B virus becomes resistant to Lamivudine Teva. This can be fatal in some people.
- lactic acidosis (*see the next section, ‘Other possible side effects of therapy for Hepatitis B’*).

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.

Other possible side effects of therapy for Hepatitis B

Lamivudine Teva and related medicines (NRTIs) may cause other conditions to develop during hepatitis B treatment.

Lactic acidosis is a rare but serious side effect

Some people taking Lamivudine Teva, 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.**

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, 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 Teva

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date shown on the container or carton and blister pack after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions

Do not use Lamivudine Teva if you notice any change in the appearance of the tablet.

Do not throw away any medicines in your 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 Teva contains

- The active substance is lamivudine. Each film-coated tablet contains 100 mg of lamivudine.
- The other ingredients are;
Tablet core: Microcrystalline cellulose, sodium starch glycolate, magnesium stearate. Tablet film coat: Hypromellose, titanium dioxide (E171), macrogol, polysorbate 80, iron oxide yellow (E172), iron oxide red (E172).

What Lamivudine Teva looks like and contents of the pack

Orange, capsule shaped, biconvex film-coated tablet – engraved with “L100” on one side and plain on the other

Lamivudine Teva is available in aluminium blisters containing 28, 30, 84 or 100 tablets or HDPE containers containing 60 tablets.

Not all pack sizes may be available in your country .

Marketing Authorisation Holder

Teva UK Limited
Ridings Point
Whistler Drive
Castleford
WF10 5HX
United Kingdom

Manufacturer

Teva Pharmaceutical Works Private Limited Company
Pallagi út 13
Debrecen H-4042
Hungary

Pharmachemie B.V.
Swensweg 5
2031 GA Haarlem
The Netherlands

Teva Operations Poland Sp.z o. o.
Mogilska 80 Str.
31-546 Kraków
Poland

This leaflet was last revised in 05/2021.

PLGB 00289/2381