

## **WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET**

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities (term to be revised).  
The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

## Information for the patient

[HA644 trade name] <sup>1</sup>

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 questions about the medicine, ask your health care provider.
- 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 seem to be the same as yours.
- If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What [HA644 trade name] is and what it is used for
2. What you need to know before you take [HA644 trade name]
3. How to take [HA644 trade name]
4. Possible side effects
5. How to store [HA644 trade name]
6. Contents of the pack and other information

#### 1. What [HA644 trade name] is and what it is used for

[HA644 trade name] is used for the treatment of human immunodeficiency virus (HIV-1) infection in adults, adolescents and children weighing at least 25 kg.

The active ingredient in [HA644 trade name] is *lamivudine*. [HA644 trade name] is a type of medicine known as an anti-retroviral. It belongs to a group of medicines called nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs).

[HA644 trade name] 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 infections.

Not everyone responds to treatment with [HA644 trade name] in the same way. Your health care provider will monitor the effectiveness of your treatment.

#### 2. What you need to know before you take [HA644 trade name]

##### Do not take [HA644 trade name] if you

- are allergic (hypersensitive) to lamivudine or any of the other ingredients of [HA644 trade name] (see “What [HA644 trade name] contains”).

**Check with your health care provider** if you think that applies to you.

##### Take special care with [HA644 trade name]

Some people taking [HA644 trade name] 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, do not stop [HA644 trade name] without advice, as your hepatitis may come back)
- if you are seriously **overweight** (especially if you are a woman)
- if you have a **kidney problem**, your dose may be altered.

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<sup>1</sup>Trade names are not prequalified by WHO. This is the national medicines regulatory agency’s (NMRA) responsibility.

**Talk to your health care provider 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 [HA644 trade name].

**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 health care provider the precautions needed to avoid infecting other people.

### **Other medicines and [HA644 trade name]**

Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

#### **These medicines should not be used with [HA644 trade name]:**

- other medicines containing lamivudine, (used to treat **HIV infection** or **hepatitis B infection**)
- emtricitabine (used to treat **HIV infection**)
- high doses of **co-trimoxazole**, an antibiotic
- cladribine (used to treat hairy cell leukaemia)
- medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly

**Tell your health care provider** if you are being treated with any of these.

### **Pregnancy**

Current treatment guidelines recommend lamivudine in pregnant women and women of childbearing potential.

### **Breast-feeding**

If a mother wants to breastfeed her baby, she should ask her health care provider for advice on the risks and benefits.

### **Driving and using machines**

[HA644 trade name] is unlikely to affect your ability to drive or use machines.

## **3. How to take [HA644 trade name]**

Always take [HA644 trade name] exactly as your health care provider told you. You should check with your health care provider if you are not sure.

Swallow the tablets, with some water. [HA644 trade name] can be taken with food or between meals.

For patients not able to swallow the tablets whole, the tablets may be crushed and added to a small amount of semi-solid food or liquid, all of which should be swallowed immediately.

### **How much to take**

#### **Adults, adolescents and children who weigh at least 25 kg:**

The usual dose of [HA644 trade name] is 300 mg a day. This can 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 health care provider.

### **Children weighing less than 25 kg:**

This product should not be used in children weighing less than 25kg since appropriate dose adjustments cannot be made. For these patients another formulation should be used, e.g. a tablet which can be used to give a smaller dose of lamivudine or an oral solution.

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

### **If you take more [HA644 trade name] than you should**

Accidentally taking too much [HA644 trade name] is unlikely to cause any serious problems. If you take too much, tell your health care provider, or contact your nearest hospital emergency department for further advice. Try to take any remaining tablets, the packaging or this leaflet with you to show the health care provider what you have taken.

### **If you forget to take [HA644 trade name]**

It is important not to miss a dose.

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 are unsure about what to do, ask your health care provider.

### **If you stop taking [HA644 trade name]**

It is important that you complete the course of treatment even if you begin to feel better. Stopping this medicine can seriously affect your response to future treatment. If [HA644 trade name] is stopped, speak to your health care provider before you restart taking these tablets.

If you have any further questions on the use of this product, ask your health care provider.

## **4. Possible side effects**

Like all medicines, lamivudine can cause side effects, but not everybody gets them.

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 health care provider will test for these changes.

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. **So it is very important to talk to your health care provider about any changes in your or your child's 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'.

### **Common side effects**

These may affect **up to 1 in 10** people:

- headache
- feeling sick (nausea)
- being sick (vomiting)
- diarrhoea
- stomach pains

- tiredness, lack of energy
- fever (high temperature)
- general feeling of being unwell
- muscle pain and discomfort
- joint pain
- difficulty in sleeping (insomnia)
- cough
- irritated or runny nose
- rash
- hair loss (alopecia).

### **Uncommon side effects**

These may affect **up to 1 in 100** people:

Uncommon side effects that may show up in blood tests are:

- a decrease in the number of cells involved in blood clotting (thrombocytopenia)
- a low red blood cell count (anaemia) or low white blood cell count (neutropenia)
- an increase in the level of liver enzymes.

### **Rare side effects**

These may affect **up to 1 in 1000** people:

- serious allergic reaction causing swelling of the face, tongue or throat which may cause difficulty in swallowing or breathing
- inflammation of the pancreas (pancreatitis)
- breakdown of muscle tissue (rhabdomyolysis)
- liver disorders, such as jaundice, enlarged liver or fatty liver, inflammation (hepatitis)

A rare side effect that may show up in blood tests is:

- an increase in an enzyme called amylase.

### **Very rare side effects**

These may affect **up to 1 in 10,000** people:

- Lactic acidosis (excess lactic acid in the blood)
- tingling or numbness of the arms, legs, hands or feet.

A very rare side effect that may show up in blood tests is:

- a failure of the bone marrow to produce new red blood cells (pure red cell aplasia).

### **If you get side effects**

**Tell your health care provider** 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 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 health care provider immediately to seek necessary treatment.

If you get any symptoms of infection while you are taking [HA644 trade name]:

**Tell your health care provider immediately.** Do not take other medicines for the infection without 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 health care provider.**

### **Reporting of side effects**

If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store [HA644 trade name]**

Keep out of the sight and reach of children.

Do not store above 30°C. Protect from light.

Do not use Lamivudine 150 mg Tablets after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of the month.

## **6. Contents of the pack and other information**

### **What [HA644 trade name] contains**

The active substance is Lamivudine

The other ingredients are:

*Tablet core:* Microcrystalline cellulose, sodium starch glycolate, magnesium stearate

*Film coat:* Hypromellose, polyethylene glycol, polysorbate, titanium dioxide

### **What [HA644 trade name] looks like and contents of the pack**

[HA644 trade name] are white, round shaped, biconvex, film coated tablets with bevelled edge, scored on one side and debossed with 'I08' on the other side.

The score-line is only to facilitate breaking for ease of swallowing and not to divide into equal dose.

The tablets can be provided in

- blister packs: Blister strips of PVDC coated PVC film and aluminium foil containing 10 tablets. The blister strips are placed in one outer carton box (6 strips per box).
- HDPE bottle packs: Round opaque white coloured open mouth HDPE bottle with polypropylene child resistant caps. Each bottle contains 60 tablets.

**Supplier**

Micro Labs Limited  
31 Race Course Road  
Bangalore – 560001  
Karnataka  
India  
Tel: +91-80-2237 0451 to 2237 0457  
Fax: +91-80-2237 046  
Email : exp@microlabs.in

**Manufacturer**

Micro Labs Limited  
Plot No: S-155 to S-159 & N1  
Phase III & Phase IV  
Verna Industrial Estate  
Verna,  
Goa-403722  
India  
Tel: +91-832- 6628262  
Fax: +91-832-6628203

For any information about this medicinal product, please contact the supplier (see above).

This leaflet was last approved in November 2019.

Detailed information on this medicinal product is available on the website of the WHO Prequalification Programme <https://extranet.who.int/prequal>