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.[*]

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

[*] https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[HA668 trade name][†]
Lamivudine

The warnings and instructions in this leaflet are intended for the person taking the medicine. If you are a parent or carer responsible for giving the medicine to someone else such as a child, you will need to apply the instructions accordingly.

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 is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about 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 [HA668 trade name] is and what it is used for

[HA668 trade name] is used to treat HIV (human immunodeficiency virus) infection in adults, adolescents and children weighing at least 25 kg.

The active ingredient in [HA668 trade name] is lamivudine. [HA668 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).

[HA668 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 [HA668 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 [HA668 trade name]

Do not take [HA668 trade name] if you

- are allergic (hypersensitive) to lamivudine or any of the other ingredients of [HA668 trade name] (see "What [HA668 trade name] contains").

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

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

Take special care with [HA668 trade name]

Some people taking [HA668 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, do not stop taking [HA668 trade name] without your health care provider's 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.

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 what to look out for while you are taking [HA668 trade name].

Read the information in 'Other possible side effects of combination therapy for HIV' in Section 4 of this leaflet.

Other medicines and [HA668 trade name]

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

Tell your healthcare provider if you take any of the following:

- other medicines containing lamivudine, (used to treat HIV infection or hepatitis B infection) — you must not take these at the same time as [HA668 trade name]
- emtricitabine (used to treat **HIV infection**) — you must not take these at the same time as [HA668 trade name]
- high doses of sulfamethoxazole/trimethoprim, an antibiotic
- cladribine (used to treat hairy cell leukaemia)
- medicines (usually liquids) that you take regularly and contain sorbitol and other similar substances (such as lactitol, maltitol, mannitol, or xylitol)
- medicines such as sulfadiazine and cisplatin which may harm the kidneys and require your health care provider to monitor how well your kidneys are working
- medicines such as flucytosine which may affect blood and blood formation and may require your health care provider to change the dose of lamivudine

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

[HA668 trade name] is unlikely to affect your ability to drive or use machines.

3. How to take [HA668 trade name]

Always take [HA668 trade name] exactly as your health care provider has told you. Check with your health care provider if you are not sure.

Swallow the tablets, with some water. You can take [HA668 trade name] with food or between meals.

If you cannot swallow the tablet, break or crush the tablet and add it to a small amount of liquid or semi-solid food. Swallow all the mixture immediately.

How much to take

Adults, adolescents and children who weigh at least 25 kg

The usual dose of [HA668 trade name] is 1 tablet once daily.

Your health care provider may reduce your dose if you have a kidney problem.

Children weighing less than 25 kg

This medicine is not suitable for children weighing less than 25 kg. Another medicine such as a tablet that contains less lamivudine or an oral solution may be more suitable for these patients.

If you take more [HA668 trade name] than you should

If you accidentally take too many tablets, tell your health care provider immediately or contact your nearest hospital emergency department for advice. You may need medical attention. Remember to take the medicine container with you and show it to the health care provider.

If you forget to take [HA668 trade name]

If you miss a dose of [HA668 trade name]:

- if it is still more than 12 hours to the next usual dose, take a dose straight away and take the next one at the usual time;
- if it is less than 12 hours to the next dose, miss out the forgotten dose and take the next one at the usual time. Do not give a double dose to make up for a forgotten dose.

If you stop taking [HA668 trade name]

You should continue taking the medicine to keep the infection in control. Talk with your health care provider if you are thinking of stopping treatment and don't stop it unless the health care provider says you can.

If you have any questions on the use of this medicine, ask the 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 lifestyle, 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
- hairloss (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
- 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 [HA668 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 a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [HA668 trade name]

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

Store below 30°C. Store in the original container

Do not use this medicine after the expiry date stated on the label after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 [HA668 trade name] contains

- The active ingredient is lamivudine.
- The other ingredients of [HA668 trade name] are:
  Core tablet: microcrystalline cellulose, sodium starch glycolate, povidone and magnesium stearate
  Film coat: hypromellose, titanium dioxide, macrogol/PEG, polysorbate and iron oxide black.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [HA668 trade name] looks like and contents of the pack

Grey coloured, modified diamond-shaped, biconvex, bevelled edge film coated tablets, debossed with 'A' on one side and '101' on the other side.

The tablets are packed in a white opaque HDPE bottle with a white polypropylene child-resistant cap and an induction sealer.

Each bottle contains 30 tablets.

Supplier and Manufacturer

Supplier

Beximco Pharmaceuticals Limited,
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Dhaka-1205,
Bangladesh.
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Tongi 1711, Gazipur,
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For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in May 2023.

Detailed information on this medicine is available on the World Health Organization (WHO) website: https://extranet.who.int/pqweb/medicines