

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/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[HA572 trade name][†]
Lamivudine/zidovudine

*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 [HA572 trade name] is and what it is used for
2. What you need to know before you take [HA572 trade name]
3. How to take [HA572 trade name]
4. Possible side effects
5. How to store [HA572 trade name]
6. Contents of the pack and other information

1. What [HA572 trade name] is and what it is used for

[HA572 trade name] is used in combination with other HIV medicines to treat HIV infection in babies and children over 4 weeks of age who weigh between 3 and 25 kg.

The medicine reduces the amount of virus in your body and keeps it at a very low level. It is not a cure for HIV infection but if taken correctly, the combination will improve your immune system and reduce the risk of developing illnesses linked to HIV infection.

[HA572 trade name] contains the active substances lamivudine and zidovudine. They belong to a group of medicines called nucleoside reverse transcriptase inhibitors (NRTIs).

2. What you need to know before you take [HA572 trade name]

Do not take [HA572 trade name]:

- if you are allergic (hypersensitive) to lamivudine, zidovudine or to any of the other ingredients of [HA572 trade name] (see section 6, 'What [HA572 trade name] contains').
- if you have a very low red blood cell count (severe anaemia) or a very low white blood cell count (neutropenia or leucopenia).

Check with your health care provider if you think any of these apply to you.

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

Take special care with [HA572 trade name]

It is important to tell your health care provider about all your symptoms even when you think they are not related to HIV infection.

Some people taking [HA572 trade name] or other combination treatments for HIV have a higher risk of side effects. You are more likely to have side effects if you:

- have or ever had liver disease, including hepatitis B or C. If you have hepatitis B, do not stop taking [HA572 trade name] without checking with your health care provider, as the hepatitis may come back
- are seriously overweight (especially if you are a woman)
- have a kidney problem.

Talk to your health care provider if any of these apply to you before you start [HA572 trade name]. You may need extra check-ups, including blood tests, while you are taking this medicine.

Also tell your health care provider if you have kidney problems. In some cases, the health care provider might suggest taking different medicines.

Look out for certain illnesses

Contact your health care provider at once if you get the conditions described below.

If your immunity is weak when you start [HA572 trade name], you might develop infections or inflammation. With continuing treatment your immunity will recover. When your immune system has improved enough, you will no longer be at risk. An infection usually causes fever, as well as any of the following:

- headache
- stomach pain
- difficulty breathing

Do not take other medicines for the infection without checking with your health care provider first.

Rarely, as the immune system becomes stronger, it can also attack healthy body tissue (autoimmune disorders). The symptoms of autoimmune disorders may occur many months after you start taking HIV medicines. Autoimmune disorders can cause:

- rapid or irregular heartbeat or tremor
- restlessness and excessive movement
- weakness beginning in the hands and feet and moving up towards the trunk of the body

Some people taking medicines for HIV infection develop bone damage that can be serious. It causes joint pain, stiffness and bone problems.

A condition in which lactic acid builds up in your body (lactic acidosis) can occur rarely. It usually starts a few months after treatment with [HA572 trade name]. People who have liver disease and very overweight people are most likely to get lactic acidosis. It is a serious condition and can cause:

- deep, rapid, difficult breathing
- drowsiness
- numbness or weakness in the arms and legs
- feeling sick (nausea), being sick (vomiting)
- stomach pain.

Other medicines and [HA572 trade name]

Tell your health care provider if you are taking or have recently taken any other medicines, including herbal medicines or medicines obtained without a prescription. Also check with your health care provider if you begin taking a new medicine while you are taking [HA572 trade name].

- emtricitabine or stavudine, used to treat HIV infection
- other medicines containing lamivudine, used to treat HIV infection or hepatitis B infection

- high doses of trimethoprim/sulfamethoxazole, an antibiotic
- cladribine or doxorubicin, used to treat certain types of cancers
- ribavirin to treat viral infections

Some medicines can make it more likely that you will have side effects, or make side effects worse. Tell your health care provider if you are being treated with any of these:

- albendazole, used to treat infection with certain types of parasitic worms
- sodium valproate, used to treat epilepsy
- interferon, used to treat viral infections
- amodiaquine, primaquine or pyrimethamine, used to treat malaria
- dapsone, to prevent pneumonia and treat skin infections
- amphotericin, fluconazole or flucytosine, to treat fungal infections
- pentamidine or atovaquone to treat parasitic infections such as PCP
- sulfadiazine or trimethoprim/sulfamethoxazole, to treat infections
- fluphenazine or quetiapine, used to treat certain mental disorders
- probenecid, to treat gout and similar conditions.
- methadone, used as a substitute for opioids such as morphine and heroin
- methyldopa, used to treat high blood pressure
- medicines containing sorbitol (usually liquids) that you take regularly and medicines with other similar substances such as lactitol, maltitol, mannitol, or xylitol
- medicines to treat cancer.

Other medicines that can interact with [HA572 trade name] include:

- clarithromycin, used as an antibiotic, if you are taking clarithromycin, take your dose at least 2 hours before or after you take [HA572 trade name].
- phenytoin, used for treating epilepsy. Tell your health care provider if you are taking phenytoin. Your health care provider may need to monitor you while you are taking [HA572 trade name].

Pregnancy and breast-feeding

If you become pregnant, or are planning to become pregnant, you must contact your health care provider to discuss the potential benefits and risks of your HIV medicines to you and your child.

In children whose mothers took medicines like lamivudine and zidovudine during pregnancy, the reduced chance of getting HIV outweighs the risk of any side effects of the medicines.

If you want to breast-feed your baby, you should discuss the risks and benefits with your health care provider.

Driving and using machines

[HA572 trade name] may cause side effects such as dizziness, fatigue or headache, which can affect your ability to drive and to use machines. You should consider how you feel and the possible side effects of [HA572 trade name] before deciding to drive or use machines.

Other ingredients of [HA572 trade name]

[HA572 trade name] contains aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take [HA572 trade name]

[HA572 trade name] should be taken exactly as described by your health care provider. Check with your health care provider if you are not sure.

It is important to take [HA572 trade name] regularly. This helps to stop your infection becoming resistant to this medicine and reduces the chances of getting allergic (hypersensitivity) reactions.

Infants and children aged over 4 weeks and weighing 3 kg to less than 25 kg

Child's weight	Morning dose	Evening dose
3 to less than 6 kg	1 tablet	1 tablet
6 to less than 10 kg	1½ tablets	1½ tablet
10 to less than 14 kg	2 tablets	2 tablets
14 to less than 20 kg	2½ tablets	2½ tablets
20 to less than 25 kg	3 tablets	3 tablets

Patients weighing above 25 kg

Medicines containing higher amounts of the active substances are more suitable for patients weighing over 25 kg.

See below for advice on how to take the tablets.

If you take more [HA572 trade name] than you should

If you accidentally take too much medicine, tell your health care provider or contact your nearest hospital emergency department for advice.

You may need medical attention. Remember to take the medicine container with you to show to the health care provider.

If you forget to take [HA572 trade name]

It is important not to miss doses of [HA572 trade name].

If you take [HA572 trade name] twice daily and miss a dose:

- if it is still more than 6 hours to the next usual dose, take the dose straight away and take the next one at the usual time;
- if it is less than 6 hours to the next dose, miss out the forgotten dose and take the next one at the usual time.

Do not take a double dose to make up for a forgotten dose

If you stop taking [HA572 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 about using this medicine, ask the health care provider.

How to take the tablets

The tablets can be taken with food or between meals.

1. Pour into a small clean cup a small amount of drinking water (about 10 mL or 2 teaspoonfuls for each tablet)
2. Add the right number of tablets to the water and swirl it until each tablet has broken down completely
3. Get your child to drink all the mixture at once

Add another 10 mL (2 teaspoonfuls) to the cup, swirl it again and ask your child to drink this also. This makes sure that the child receives the full dose.

4. Possible side effects

Like all medicines, [HA572 trade name] can cause side effects, although not everybody gets them.

During HIV therapy your weight may increase and levels of blood lipids and glucose may rise. This is partly linked to improvement in your health and lifestyle and, for blood lipids, sometimes to the HIV medicines. Your health care provider will look out for these changes.

Treatment with [HA572 trade name] often causes a loss of fat from legs, arms and face (lipoatrophy). Tell your health care provider if you notice any loss of fat from your legs, arms, and face.

Unwanted effects during treatment may be caused by [HA572 trade name], by other medicines you take, or by the HIV disease. Tell your health care provider about changes in your health in case the health care provider needs to change your treatment in any way.

Very common side effects (these may affect more than 1 in 10 patients treated):

- headache
- feeling sick (nausea).

Common side effects (these may affect up to 1 in 10 patients treated):

- being sick (vomiting)
- diarrhoea
- stomach pains
- loss of appetite
- feeling dizzy
- tiredness, lack of energy
- fever (high temperature)
- general feeling of being unwell
- difficulty sleeping (insomnia)
- muscle pain and discomfort
- joint pain
- cough
- irritated or runny nose
- skin rash
- hair loss (alopecia).

Common side effects that might show up in blood tests are:

- a low red blood cell count (anaemia) or low white blood cell count (neutropenia or leucopenia)
- an increase in the level of liver enzymes (a sign of liver problems)
- an increased amount in the blood of bilirubin (a substance produced in the liver) which may make your skin appear yellow.

Uncommon side effects (these can affect up to 1 in every 100 patients treated):

- feeling breathless
- wind or gas (flatulence)
- itching
- muscle weakness
- feeling weak
- pain.

An uncommon side effect that may show up in blood test is:

- a decrease in the number of cells involved in blood clotting (thrombocytopenia) or in all blood cells (pancytopenia).

Rare side effects (these can affect up to 1 in 1000 patients treated):

- serious allergic reaction causing swelling of the face, tongue or throat which may cause difficulty in swallowing or breathing

- liver disorders, such as jaundice, enlarged liver or fatty liver, inflammation (hepatitis)
- lactic acidosis (excess lactic acid in the blood; see section 2, under ‘Look out for certain illnesses’)
- weight loss
- inflammation of the pancreas (pancreatitis)
- chest pain; disease of the heart muscle (cardiomyopathy)
- fits (convulsions)
- feeling depressed or anxious, not being able to concentrate, feeling drowsy
- indigestion, taste disturbance
- itchy rash (urticaria)
- changes in the colour of your nails, your skin or the skin inside your mouth
- a flu-like feeling – chills and sweating
- tingly feelings in the skin (pins and needles)
- sensation of weakness in the limbs
- breakdown of muscle tissue which may lead to kidney damage
- numbness
- passing urine more often
- enlarged breasts in men.

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

- an increase in an enzyme called amylase (sign of problems with the pancreas)
- a failure of the bone marrow to produce new red blood cells (pure red cell aplasia).

Very rare side effects (these can affect less than 1 in every 10,000 patients treated):

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

- a failure of the bone marrow to produce new red or white blood cells (aplastic anaemia).

Other side effects (not known how frequently they occur)

The following side effects are serious but it is not known how frequently they occur. Contact your health care provider if any of them occur. See section 2, under ‘Look out for certain illnesses’ for more information.

- bone damage (osteonecrosis)
- changes in your immune system which may lead to signs of infection or damage to body tissue

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.

For reporting of adverse events and PV related queries please write to Email: ProductSafety@viatris.com

5. How to store [HA572 trade name]

Do not store above 30°C. Store in the original container.

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

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

Do not use this medicine if you notice description of the visible signs of deterioration that it is different from the description below.

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 [HA572 trade name] contains

- The active ingredients are 30 mg lamivudine and 60 mg zidovudine.
- The other ingredients of [HA572 trade name] are; microcrystalline cellulose, colloidal silicon dioxide, sodium starch glycolate, croscarmellose sodium, aspartame, magnesium stearate and strawberry flavour (containing natural flavours and maltodextrin)

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

What [HA572 trade name] looks like and contents of the pack

White to off-white, round, uncoated dispersible tablets. They are biconvex tablet (rounded on top and bottom) with a bevelled edge. The tablets have a break line on one side with "LZ" debossed (stamped into the tablet) to the left and "1" debossed (stamped into the tablet) to the right of the break line. they are debossed (stamped into the tablet) with "M" on the other side.

The break line is intended for subdivision of [HA572 trade name] tablets into equal doses when half a tablet dose is to be administered.

[HA572 trade name] are packaged in round wide mouth opaque white HDPE bottle with white opaque polypropylene screw cap, containing absorbent cotton.

Pack size:60 tablets.

Supplier and Manufacturer

Supplier

Mylan Laboratories Limited
Plot No. 564/A/22, Road No.92, Jubilee Hills
Hyderabad - 500096,
Telangana, India
Email:ProductSafety@viatris.com

Manufacturer

Mylan Laboratories Limited
Plot No. H-12 & H-13
MIDC, Waluj Industrial Area
Aurangabad 431 136
Maharashtra State
India

Mylan Laboratories Limited,
Plot No. 11, 12 & 13 Indore special economic
zone, Phase II, Sector III, Pithampur – 454775
Dhar, Madhya Pradesh
India

For any information about this medicine, contact the local representative of the supplier:

Mylan Laboratories Limited
Plot No. 564/A/22, Road No.92, Jubilee Hills
Hyderabad - 500096, Telangana, India
Email :ProductSafety@viatris.com

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Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>