

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

[HA763 trade name][†]
Abacavir (sulfate)/lamivudine

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

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 [HA763 trade name] is and what it is used for
2. What you need to know before you take [HA763 trade name]
3. How to take [HA763 trade name]
4. Possible side effects
5. How to store [HA763 trade name]
6. Contents of the pack and other information

1. What [HA763 trade name] is and what it is used for

[HA763 trade name] is used in combination with other HIV medicines to treat HIV infection in infants and children over 4 weeks of age who weigh between 3 kg and 25 kg.

The medicines reduce the amount of virus in your child's body and keep it at a low level. They are not a cure for HIV infection but if taken correctly, the combination will improve your child's immune system and reduce the risk of developing illnesses linked to HIV infection.

[HA763 trade name] contains the active substances abacavir and lamivudine. They belong to a group of medicines called nucleoside reverse transcriptase inhibitors (NRTIs).

[HA763 trade name] can also be used if your child has just been exposed to the HIV virus, to reduce the risk of becoming infected (post-exposure prophylaxis, or PEP).

2. What you need to know before you take [HA763 trade name]

Do not take [HA763 trade name] if:

- you are allergic (hypersensitive) to the active substances abacavir, lamivudine, or any of the other ingredients of this medicine (see section 6, 'What [HA763 trade name] contains')

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

Warnings and precautions

Abacavir hypersensitivity reactions

[HA763 trade name] contains abacavir which can cause a serious allergic reaction known as a hypersensitivity reaction.

Who gets these reactions?

You could have a hypersensitivity reaction to abacavir during treatment with [HA763 trade name]. The hypersensitivity reaction could become very dangerous if you continue to take [HA763 trade name].

You are more likely to get this reaction if you have a gene called HLA-B*5701. Your health care provider will have tested you for this gene before you start [HA763 trade name]. If you have this gene, tell your health care provider before you take [HA763 trade name].

You can have a hypersensitivity reaction even if you don't have the HLAB*5701 gene.

What are the symptoms of the hypersensitivity reaction?

The most common symptoms are:

- fever (high temperature)
- skin rash.

Other common symptoms are:

- nausea (feeling sick)
- vomiting (being sick)
- diarrhoea
- abdominal (belly) pain
- severe tiredness.

Less common symptoms include:

- pain in the joints or muscles
- swelling of the neck
- shortness of breath
- sore throat
- cough
- occasional headaches
- redness and discomfort in the eye (conjunctivitis)
- mouth ulcers
- low blood pressure
- tingling or numbness of the hands or feet.

When can these reactions happen?

Hypersensitivity reactions can start at any time during treatment with [HA763 trade name] but they are more likely in the first 6 weeks.

Contact your doctor immediately:

1. if you get a skin rash, *or*
2. if you get symptoms from at least 2 of the following groups:
 - fever
 - shortness of breath, sore throat or cough
 - nausea or vomiting, diarrhoea or abdominal pain
 - severe tiredness or achiness, or generally feeling ill.

Your health care provider may stop [HA763 trade name].

Warnings and precautions

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

Some people taking [HA763 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 liver disease
- have ever had liver disease, including hepatitis B or C. If you have hepatitis B, do not stop taking [HA763 trade name] without your health care provider's advice, 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 [HA763 trade name]. You may need extra check-ups, including blood tests, while you are taking this medicine.

Immune reactivation syndrome and autoimmune disorders

People with advanced HIV infection (AIDS) have weak immune systems, and they can develop serious infections (opportunistic infections). Such infections may be 'silent' and not detected by the weak immune system before treatment is started. After starting treatment, as the immune system becomes stronger, it may attack the infections, which can cause the usual symptoms of infection or inflammation. Symptoms usually include fever, as well as any of the following:

- headache
- stomach ache
- difficulty breathing

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

- 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

If you get any symptoms of infection and inflammation or if you notice any of the symptoms above, tell your health care provider immediately. Do not take other medicines for the infection without checking with your health care provider first.

Heart problems

Tell your health care provider if you have heart problems, if you smoke, or if you have other illnesses that may increase your risk of heart disease, such as high blood pressure or diabetes. Do not stop taking [HA763 trade name] unless your health care provider tells you to.

Other medicines and [HA763 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 [HA763 trade name].

You **must not** take the following medicines when taking [HA763 trade name]:

- Emtricitabine, 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, used to treat a type of leukaemia

Medicines that can interact with [HA763 trade name] include:

- phenytoin, for treating epilepsy
- rifampicin, used to treat tuberculosis
- methadone, used as a substitute for opioids such as morphine and heroin. [HA763 trade name] increases the rate at which methadone is removed from the body. If you are taking methadone, you will be monitored for symptoms of withdrawal. Your dose of methadone may need to be changed.
- medicines containing sorbitol (usually liquids) that you take regularly and medicines with 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 check how well your kidneys are working
- medicines such as flucytosine which may cause blood disorders and may require your health care provider to change the dose of lamivudine
- riociguat, for treating pulmonary hypertension (high blood pressure in the blood vessels of the lungs). [HA763 trade name] may change the amount of riociguat in your blood, so your health care provider may need to change its dose.

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 continued taking medicines like abacavir and lamivudine during pregnancy, the reduced risk of getting HIV outweighs the risk of side effects.

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

Driving and using machines

You should consider the state of your health and the possible side effects of abacavir and lamivudine before deciding to drive or use machines.

Driving and using machines

No studies on the effects of [HA763 trade name] on the ability to drive and use machines have been performed. However, you should consider the state of your health and the possible side effects of abacavir and lamivudine before considering driving or using machines.

3. How to take [HA763 trade name]

Always take this medicine exactly as your health care provider has told you. This is to make sure that your medicine continues to work well. Do not change the dose unless your health care provider tells you to. Check with your health care provider if you are not sure how to take [HA763 trade name].

Infants and children aged over 4 weeks

Your health care provider will tell you if your child should take [HA763 trade name] once daily or twice a day (some of the dose in the morning and the rest in the evening).

The dose depends on the child's weight.

Child's Weight	Once daily dose	Twice daily dose
3 to less than 6 kg	½ tablet once daily	[HA763 trade name] not suitable for twice daily dosing
6 to less than 10 kg	1½ tablets once daily	½ tablets in the morning and 1 tablet in the evening
10 to less than 15 kg	2 tablets once daily	1 tablet in the morning and 1 tablet in the evening
15 to less than 20 kg	2½ tablets once daily	1 tablet in the morning and 1½ tablets in the evening
20 to less than 25 kg	3 tablets once daily	1½ tablets in the morning and 1½ tablets in the evening

It is **important** for your child to take [HA763 trade name] regularly at around the same time each day. Missing out doses can increase the risk of serious allergic (hypersensitivity) reactions.

See below for advice on how to take the tablets.

Patients weighing above 25 kg

[HA763 trade name] is not suitable for patients who weigh over 25 kg. Your health care provider will recommend a more suitable medicine to supply the correct dose.

If you take more [HA763 trade name] than you should

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

Remember to take the medicine container and this leaflet with you to show to the health care provider.

If you forget to take [HA763 trade name]

It is important not to miss doses of [HA763 trade name].

If your child misses a dose:

- if it is still more than 4 hours to the next usual dose, give a dose straight away and give the next one at the usual time;
- if it is less than 4 hours to the next dose, miss out the forgotten dose and give the next one at the usual time.

Do not give a double dose to make up for a forgotten dose.

If you stop taking [HA763 trade name]

Your child should continue taking the medicine to keep the infection in control.

If you have stopped giving [HA763 trade name] because of a side effect or if your child has become ill, speak with your health care provider at once.

Talk with your health care provider if you are thinking of stopping treatment. Don't stop this medicine unless your health care provider says you can.

If you have any questions about using this medicine, ask your health care provider.

How to take the tablets

Your child can take [HA763 trade name] with food or between meals.

To give [HA763 trade name] to your child:

1. Pour into a small clean cup a small amount of drinking water (about 10 mL or 2 teaspoonfuls for each tablet your child takes).
2. Add the right dose 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.
4. 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, [HA763 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.

Unwanted effects during treatment may be caused by [HA763 trade name], by other medicines you take, or by the HIV disease. For this reason, tell your health care provider about changes in your health in case the health care provider needs to change your treatment in any way.

A **hypersensitivity reaction** (serious allergic reaction) can occur with abacavir. This is described under ‘Abacavir hypersensitivity reactions’ in section 2 of this leaflet. You **must** read and understand the information about this serious reaction.

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

- hypersensitivity reaction (see above and section 2)
- loss of appetite
- skin rash (without any other illness)
- nausea (feeling sick), vomiting, diarrhea, stomach pain
- headache, insomnia (difficulty sleeping), dizziness
- cough, irritation in the nose, runny nose
- fever
- muscle pain and discomfort
- joint pain
- hair loss
- tiredness, lack of energy
- general feeling of being unwell

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

- anaemia (low red blood cell count)—this can cause tiredness or breathlessness
- neutropenia (low white blood cell count)—this can make you more prone to infection
- reductions in platelets (components important for blood clotting)—this can lead to bruising and bleeding
- increases in the blood levels of some liver enzymes—this may be a sign of liver injury.

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

- inflammation of the pancreas (pancreatitis)
- blood tests showing rise in serum amylase (a sign of pancreas damage)
- liver disorders, such as jaundice, enlarged liver or fatty liver, inflammation of the liver (hepatitis)
- breakdown of muscle tissue

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

- skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme)
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens–Johnson syndrome), and a more severe form causing skin peeling in large areas of the body surface (toxic epidermal necrolysis).
- pure red cell aplasia (a type of anaemia, with a reduction of red blood cells)
- lactic acidosis (build-up of lactic acid in the body, that can cause dehydration, coma. Deep, rapid breathing, drowsiness, and effects such as nausea, vomiting and stomach pain, may be signs of lactic acidosis.
- numbness, tingling sensation or sensation of weakness in the limbs (peripheral neuropathy)

Frequency not known:

The following side effects may occur with active substances like abacavir and lamivudine:

- osteonecrosis (permanent bone damage)—causing joint pain and reduced ability to move
- immune reactivation syndrome and autoimmune disorders (see ‘Warnings and precautions’ in section 2 of this leaflet).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, 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 [HA763 trade name]

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

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

Do not use this medicine after the expiry date stated on the bottle 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 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 [HA763 trade name] contains

- The active ingredients are abacavir (as sulfate) 120 mg and lamivudine 60 mg.
- The other ingredients of [HA763 trade name] are microcrystalline cellulose, sodium starch glycolate, sucralose, crospovidone, magnesium stearate and strawberry flavour.

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

What [HA763 trade name] looks like and contents of the pack

[HA763 trade name] are white to off-white coloured, oval-shaped, biconvex, uncoated dispersible tablets, scored on one side, debossed with '8' on one half and '0' on other half, and score line on the other side.

The tablet can be divided into two equal doses.

[HA763 trade name] is available in a white, opaque, HDPE bottle with a canister of 3g silica gel and purified cotton and closed with a white, round, polypropylene child-resistant cap with a head induction foil inner seal.

Pack sizes: 30s and 60s tablets.

Supplier and Manufacturer

Supplier

Micro Labs Limited
31, Race Course Road
Bengaluru - 560001, Karnataka, India.
Tel. No.: +91-80-2237 0451 to 2237 0457
Fax No. : +91-80-2237 0463
Email: info@microlabs.in

Manufacturer

Micro Labs Limited (ML06)
Plot No S-155 to S-159 & N1,
Phase III & Phase IV
Verna Industrial Estate
Verna, Goa, 403 722, India
Tel. No.: +91-832-6686262
Fax No.: +91-832-6686203
Email: jainethesh@microlabs.in

"For any information about this medicine, contact the supplier."

This leaflet was last revised in August 2026

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