Note: Pharmacode position will be changed according to printer feasibility

35 mm

480 mm

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PHARMACODE READING DIRECTION

Abacavir/ Lamivudine Dispersible Tablets 120 mg/60 mg
EXG-ML06-I-0142

Abacavir/ Lamivudine Dispersible Tablets 120 mg/60 mg
EXG-ML06-I-42

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

[HA763 trade name][1]
Abacavir (sulfate)/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 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 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 a combination product containing abacavir and lamivudine. Both drugs belong to a group of antiviral medicines, also known as antiretrovirals, called nucleoside analogue reverse transcriptase inhibitors (NRTIs). Abacavir and lamivudine are used in combination with other antiretroviral medicines for the treatment of HIV infection.

[HA763 trade name] reduces the amount of HIV in your child's body and keeps it at a low level. It also increases CD4 cell counts. CD4 cells are a type of white blood cell that are important in maintaining a healthy immune system to help fight infection. Response to treatment with abacavir and lamivudine varies between patients. Your child's health care provider will be monitoring the effectiveness of the treatment.

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 (or any other medicine containing abacavir), lamivudine or any of the other ingredients of this medicine (see section 6, "What [HA763 trade name] contains")

Carefully read all the information about hypersensitivity reactions in section 4. Do not take [HA763 trade name] if you think this applies to you. Check with your health care provider.

Warnings and precautions

It is important that your health care provider knows 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 should be aware of the extra risks:

- if you have moderate or severe liver disease
- if you have ever had hepatitis, including hepatitis B or C. If you have hepatitis B infection, do not stop taking [HA763 trade name] without your health care provider's advice, as the hepatitis may come back
- If you are seriously overweight (especially if you are a woman)
- If you have any problems with your kidneys

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. See section 4 for more information.

Heart attack
It cannot be excluded that abacavir might be associated with an increased risk of heart attack.
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 advises you to.

Read the information "Other possible side effects of combination therapy for HIV" in section 4.
General
You will need to take [HA763 trade name] every day. This medicine helps to control the condition, but it is not a cure for HIV infection. You may continue to develop other infections and other illnesses associated with HIV disease (e.g. opportunistic infections). These will require specific and sometimes preventive treatment. You should keep in regular contact with your health care provider. Do not stop the medicine without first talking to your health care provider.
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 [HA763 trade name]
Please 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. Remember to tell your health care provider if you begin taking a new medicine while you are taking [HA763 trade name].

These medicines should not be used 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

Some medicines interact with [HA763 trade name]
These 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 (usually liquids) that contain sorbitol or other sugar alcohols (such as xylitol or mannitol) if taken regularly
- Riociguat, for treating a condition called 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.

Tell your health care provider if you are taking any medications while you are taking [HA763 trade name], particularly those listed above.

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 antiretroviral therapy to you and your child.

In children whose mothers took nucleoside and nucleotide analogues during pregnancy, the benefit of the reduced risk of being infected with HIV is greater than the risk of suffering from side effects.

If you are interested in breast-feeding your baby, you should discuss the risks and benefits with your health care provider.

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]

[HA763 trade name] should be taken exactly as described by your health care provider. You should check with your health care provider if you are not sure.

Twice-daily dosing for infants and children four weeks and older

Weight	Morning Dose	Evening dose
3 – less than 6 kg	½ tablet (60 mg /30 mg)	½ tablet (60 mg /30 mg)
6 – less than 10 kg	½ tablet (60 mg/30 mg)	1 tablet (120 mg /60 mg)
10 – less than 14 kg	1 tablet (120 mg /60 mg)	1 tablet (120 mg /60 mg)
14 – less than 20 kg	1 tablet (120 mg /60 mg)	1 ½ tablets (180 mg /90 mg)
20 – less than 25 kg	1 ½ tablets (180 mg /90 mg)	1 ½ tablets (180 mg /90 mg)

Once-daily dosing for infants and children four weeks and older

Weight	Dose
3 – less than 6 kg	1 tablet (120 mg /60 mg)
6 – less than 10 kg	1.5 tablets (180 mg /90 mg)
10 – less than 14 kg	2 tablets (240 mg /120 mg)
14 – less than 20 kg	2.5 tablets (300 mg /150 mg)
20 – less than 25 kg	3 tablets (360 mg /180 mg)

Patients weighing above 25 kg
Patients who weigh more than 25kg should not be given [HA763 trade name]. Other suitable formulations are available for these patients and should be used.

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

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

If you forget to give your child [HA763 trade name]

If you forget to take a dose and there are more than 6 hours till your next dose, take the missed dose as soon as possible. Then continue your treatment as before. If there are less than 6 hours till your next dose, skip the missed dose. Do not take a double dose to make up for a missed dose. It is important to take [HA763 trade name] regularly, because irregular dosing may increase the risk of hypersensitivity reactions and of your infection becoming resistant to this medicine.

If you stop taking [HA763 trade name]

Because this medicine controls and does not cure your child's condition, you will normally need give your child continuously. You should not stop treatment unless your health care provider tells you to.

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

4. Possible side effects

During HIV therapy there may be an increase in weight and levels of blood lipids and glucose. This is partly linked to an improvement in your health and lifestyle. Changes in blood lipids may also be caused by the HIV medicines themselves. Your health care provider will test for these changes.

Like all medicines, [HA763 trade name] can cause side effects, although not everybody gets them.

When treating HIV infection, it can be hard to tell whether a symptom is a side effect of [HA763 trade name], other medicines that you are taking, or an effect of the HIV disease itself. For this reason, it is **very important** that you inform your health care provider about any changes in your health.

Hypersensitivity reaction (serious allergic reaction)

This is also described under "Warnings and precautions" in section 2 of this leaflet. It is important that you read and understand the information about this serious reaction. About 5 in every 100 patients who were treated with abacavir-containing medicines such as [HA763 trade name], developed a hypersensitivity reaction to the active ingredient abacavir. People with a genetic variant called HLA-B*5701 are more likely to have this reaction. **If you know you have this gene variant, be sure to tell your health care provider.**
However, even if you do not have this gene variant it is still possible to get this reaction. About 3 to 4 in every 100 patients treated with abacavir in a clinical trial who did not have the HLA-B*5701 gene developed a hypersensitivity reaction.

What are the symptoms?

The **most common** symptoms are fever and a skin rash.

Other **common** signs or symptoms include nausea (feeling sick), vomiting, diarrhoea, abdominal (stomach) pain and severe tiredness.

Other symptoms may include joint or muscle pain, swelling of the neck, shortness of breath, sore throat, cough and headache. Occasionally, inflammation of the eye (conjunctivitis), mouth ulcers or low blood pressure may occur.

When do these reactions happen?

Hypersensitivity reactions can occur at any time during treatment with [HA763 trade name]. However, if they occur, it is most likely to be during the first 6 weeks of treatment.
The symptoms of hypersensitivity reactions worsen with continued treatment and may be life-threatening if treatment is continued.

Contact your health care provider 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 feeling generally unwell

If your health care provider stops your [HA763 trade name] because of a hypersensitivity reaction, **you must NEVER AGAIN take [HA763 trade name], or any other medicine that contains abacavir. If you do, the reaction may happen again within a few hours and cause a severe fall in your blood pressure which could be fatal.**

If you have stopped taking [HA763 trade name] for any reason, particularly because of side effects or other illness, it is important that you contact your health care provider before restarting. Your health care provider will check whether your symptoms may have been related to a hypersensitivity reaction. If your health care provider thinks there is a possibility that they were related, you will be instructed never to take [HA763 trade name] or any other medicine containing abacavir again. It is important that you follow this advice.

Occasionally life-threatening hypersensitivity reactions have occurred when abacavir was restarted in patients who reported only one of the symptoms on the Alert Card before stopping it.

Very rarely, hypersensitivity has been reported when abacavir was restarted in patients who had no symptoms of hypersensitivity before stopping.

If you are hypersensitive to abacavir you should return all the unused [HA763 trade name] for disposal. Ask your health care provider for advice.

The [HA763 trade name] pack contains an **Alert Card**, to remind you and medical staff about hypersensitivity reactions. **Detach this card and always keep it with you.**

Other side effects that you might experience
Common side effects (these can affect up to 1 in every 10 patients treated):

- less severe hypersensitivity reactions
- anorexia
- skin rash (without any other illness)
- nausea, vomiting
- diarrhea
- stomach pain
- headache
- difficulty in sleeping (insomnia)
- dizziness
- cough
- irritated or runny nose
- fever (high temperature)
- muscle pain and discomfort
- joint pain
- hair loss
- tiredness, fatigue
- loss of appetite

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

- low red blood cell count (anemia)
- low white blood cell count (neutropenia)
- blood cells important for blood clotting (thrombocytopenia).

If the number of red blood cells is reduced, you may have symptoms of tiredness or breathlessness. A reduction in white blood cell count can make you more prone to infection. A low platelet count may cause you to bruise more easily.

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

- inflammation of the pancreas (pancreatitis)
- liver disorders, such as jaundice, enlarged liver or fatty liver, inflammation of the liver (hepatitis)
- breakdown of muscle tissue
- rise in serum amylase.

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

- numbness, tingling sensation or sensation of weakness in the limbs (peripheral neuropathy)
- 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 more than 30% of the body surface *(toxic epidermal necrolysis)*.
- a failure of the bone marrow to produce new red blood cells (pure red cell aplasia)
- lactic acidosis (a build-up of lactic acid in the body, that can cause dehydration and coma). Deep, rapid breathing, drowsiness, and nonspecific symptoms such as nausea, vomiting and stomach pain, may indicate the development of lactic acidosis.

Frequency not known:
The following side effects have been reported in patients treated with medicines of the group of NRTIs, to which also abacavir and lamivudine belong. However, frequency estimates for these effects are not available:

- immune reactivation syndrome and autoimmune

Symptoms of infection and inflammation
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. Symptoms usually include fever, plus some of the following:

- headache
- stomachache
- difficulty breathing

In rare cases, 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 medicine to treat your HIV infection. Symptoms may include:

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

If you get any symptoms of infection while you are taking Ziagen:

Tell your doctor immediately. Do not take other medicines for the infection without your doctor's advice.

Osteonecrosis

Some people taking combination therapy for HIV develop a condition called osteonecrosis. In this condition, some areas of bone die because of a reduced blood supply. This is more likely to happen in patients who:

- have been taking combination therapy for a long time
- are also taking anti-inflammatory medicines called corticosteroids
- drink alcohol regularly
- have a very weakened immune system
- 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
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please 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 improve understanding about the safety of 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, "EXP". The expiry date refers to the last day of that month.

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

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 size: 30 tablets.

Supplier

Micro Labs Limited
31, Race Course Road
Bangalore - 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 (M06)
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 May 2022.

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

EXG-ML06I-0142

Size: 480(L) x 540(W) mm
Folding size: 35 x 35 mm

Front Side: English text

PHARMACODE READING DIRECTION

3265

Pharma paper: 35 to 50 gsm