

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

[HA743 trade name][†]
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 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.

HYPERSENSITIVITY REACTION

Patients taking [HA743 trade name] may develop a hypersensitivity reaction (serious allergic reaction) to abacavir, which **can be life-threatening** if treatment with [HA743 trade name] is continued. It is essential you read the information on this reaction under “Warnings and precautions” in section 2 of this leaflet. There is also an **Alert Card** included in the [HA743 trade name] pack, to remind you and health care providers about abacavir hypersensitivity. This card should be removed and kept with you at all times.

CONTACT YOUR HEALTH CARE PROVIDER IMMEDIATELY for advice on whether you should stop taking [HA743 trade name] if:

- 1) **You get a skin rash OR**
- 2) **You get one or more symptoms from at least TWO of the following groups**
 - fever
 - shortness of breath, sore throat or cough
 - nausea or vomiting or diarrhoea or abdominal pain
 - severe tiredness or achiness or generally feeling ill

If you have discontinued [HA743 trade name] due to a hypersensitivity reaction, **YOU MUST NEVER TAKE** [HA743 trade name] or any other medicine containing abacavir again, as **within hours** you may experience a life-threatening lowering of blood pressure or death.

What is in this leaflet

1. What [HA743 trade name] is and what it is used for
2. What you need to know before you take [HA743 trade name]
3. How to take [HA743 trade name]
4. Possible side effects
5. How to store [HA743 trade name]
6. Contents of the pack and other information

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

1. What [HA743 trade name] is and what it is used for

[HA743 trade name] is used to treat HIV (human immunodeficiency virus) infection in adults, adolescents and in children weighing at least 25 kg. [HA743 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.

[HA743 trade name] does not completely cure HIV infection. It reduces the amount of HIV in your body and keeps it at a low level. It also increases CD4 cell count in your blood. 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 health care provider will be monitoring the effectiveness of the treatment.

2. What you need to know before you take [HA743 trade name]

Do not take [HA743 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 [HA743 trade name] contains”).

Carefully read all the information about hypersensitivity reactions in section 4.

Do not take [HA743 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 [HA743 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 [HA743 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 [HA743 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 [HA743 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 [HA743 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.

Other medicines and [HA743 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 [HA743 trade name].

These medicines should not be used when taking [HA743 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 [HA743 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. [HA743 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). [HA743 trade name] may change the amount of riociguat in your blood, so your health care provider may need to change its dose.

Tell you health care provider if you are taking any medications while you are taking [HA743 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 [HA743 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.

[HA743 trade name] contains sunset yellow FCF

Sunset yellow FCF may cause allergic reactions.

3. How to take [HA743 trade name]

[HA743 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.

Adults, adolescents and children weighing at least 25 kg:

The recommended dose of [HA743 trade name] is one tablet once daily.

Children weighing less than 25 kg:

[HA743 trade name] should not be administered to children who weigh less than 25 kg since appropriate dose adjustments cannot be made. [HA743 trade name] can be taken with or without food.

If you take more [HA743 trade name] than you should

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

If you forget to take [HA743 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 [HA743 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 [HA743 trade name]

Because this medicine controls and does not cure your condition, you will normally need to take it 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 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.

Like all medicines, [HA743 trade name] can cause side effects, although not everybody gets them. When treating HIV infection, it is not always possible to tell whether some of the undesirable effects that occur are caused by [HA743 trade name], by other medicines being taken at the same time, or by the HIV disease. For this reason, it is very important that you inform your health care provider about any changes in your health.

A hypersensitivity reaction (serious allergic reaction) has been reported in about 5 in every 100 patients who have been treated with abacavir. This is 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.

The following list of side effects is mainly based on data from adult patients.

Common side effects (these can affect at least 1 in every 100 patients treated, but less than 1 in every 10 patients treated):

- hypersensitivity reaction
- anorexia
- skin rash (without any other illness)
- nausea, vomiting, diarrhea, stomach pain
- headache, insomnia, dizziness
- cough, nasal symptoms (irritation, runny nose)
- fever
- muscle pain and discomfort
- joint pain
- hair loss
- tiredness, fatigue, loss of appetite
- difficulty in sleeping (insomnia)

Uncommon side effects (these can affect at least 1 in every 1000 patients treated, but less than 1 in every 100 patients treated):

- anaemia (low red blood cell count), neutropenia (low white blood cell count), and reductions in platelets (blood cells important for blood clotting). If the number of red blood cells is reduced one may have symptoms of tiredness or breathlessness. A reduction in white blood cell count can make you more prone to infection. If you have a low platelet count one may notice that he/she bruises more easily.
- increases in the blood levels of some liver enzymes.

Rare side effects (these can affect at least 1 in every 10,000 patients treated, but less than 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
- numbness, tingling sensation or sensation of weakness in the limbs (peripheral neuropathy)
- rise in serum amylase.

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 more than 30% of the body surface (*toxic epidermal necrolysis*).
- pure red cell aplasia (a type of anaemia affecting the precursors to red blood cells but not to white blood cells.)
- 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.
- peripheral neuropathy

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:

- osteonecrosis (death of bone tissue)
- 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, please 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 [HA743 trade name]

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

Do not store above 30°C.

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 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 [HA743 trade name] contains

- The active ingredients are 600 mg abacavir (as sulfate) and 300 mg lamivudine.
- The other ingredients of [HA743 trade name] are microcrystalline cellulose, sodium starch glycolate, hypromellose, corn starch, colloidal silicon dioxide, magnesium stearate, titanium dioxide, FD&C yellow #6/sunset yellow FCF aluminium lake, macrogol/polyethylene glycol and polysorbate 80.

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

What [HA743 trade name] looks like and contents of the pack

Orange coloured, capsule-shaped, biconvex, film-coated tablet, debossed with 'C' on one side and plain on the other side.

White HDPE container with 1g silica gel bag containing 30 tablets. The closures are either white non-child resistant HDPE, white polypropylene child resistant or blue polypropylene child resistant caps.

Supplier and Manufacturer

Supplier

Cipla Ltd.
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg
Lower Parel
Mumbai: 400013
India
Tel.: 912224826000
Fax: 912224826120

Manufacturer

Cipla Limited
Unit 2, Plot No A – 42
MIDC Industrial Area
Patalganga
District Raigad
Maharashtra 410 220
India.
Tel.: 91 2192 660900
Fax: 91 2192 250819

Cipla Limited
Unit 7, Plot No. S- 103 to S- 105
S-107 to S-112, L-147
L-147/1 to L-147/3
L-147/A & L-138
Verna Industrial Estate
Salcette
Goa – 403 722
India
Tel.: +91 832 2889 000/199
Fax No.: +91-832-2782805

For any information about this medicine, contact the supplier.

This leaflet was last revised in March 2023

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

<----->

Attachment:

ALERT CARD TEXT

SIDE 1 IMPORTANT - ALERT CARD
[HA743 trade name]
Carry this card with you at all times

Patients taking [HA743 trade name] may develop a hypersensitivity reaction (serious allergic reaction) which **can be life-threatening** if treatment with [HA743 trade name] is continued.

CONTACT YOUR HEALTHCARE PROVIDER IMMEDIATELY for advice on whether you should stop taking [HA743 trade name] if:

- 1) you get a skin rash OR**
- 2) you get one or more symptoms from at least TWO of the following groups**

- fever
- shortness of breath, sore throat or cough
- nausea or vomiting or diarrhoea or abdominal pain
- severe tiredness or achiness or generally feeling ill

If you have discontinued [HA743 trade name] due to this reaction, **you MUST NEVER TAKE** [HA743 trade name] or any other abacavir-containing medicine (e.g. Ziagen, Kivexa, Trizivir) again. If you take abacavir after suffering a previous hypersensitivity reaction, you may develop a severe lowering of blood pressure within hours, which could be fatal.

(see reverse of card)

SIDE 2

You should immediately contact your healthcare provider if you think you are having a hypersensitivity reaction to [HA743 trade name].

Write your healthcare provider's details below:

Health care provider:

Tel:

If the healthcare provider is not available, you must urgently seek alternative medical advice (e.g. the emergency unit of the nearest hospital).

For general information enquiries on [HA743 trade name],

Contact: *telephone number*

or email: