

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

[HA371 trade name][†]
Abacavir (sulfate)

*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 [HA371 trade name] is and what it is used for
2. What you need to know before you take [HA371 trade name]
3. How to take [HA371 trade name]
4. Possible side effects
5. How to store [HA371 trade name]
6. Contents of the pack and other information

1. What [HA371 trade name] is and what it is used for

[HA371 trade name] is a product containing abacavir. Abacavir belongs to a group of antiviral medicines, also known as antiretrovirals, called nucleoside analogue reverse transcriptase inhibitors (NRTIs). Abacavir is used in combination with other antiretroviral medicines for the treatment of Human Immunodeficiency Virus (HIV) infection.

[HA371 trade name] reduces the amount of HIV in your 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 varies between patients. Your health care provider will be monitoring the effectiveness of the treatment.

2. What you need to know before you take [HA371 trade name]

Do not take [HA371 trade name]:

- if you are allergic (hypersensitive) to the active component (abacavir) of [HA371 trade name], or any other medicine containing abacavir
- if you are allergic (hypersensitive) to any of the other ingredients of this medicine (see section 6, "What [HA371 trade name] contains")

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

Do not take [HA371 trade name] if you think this applies to you. Check with your health care provider.

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

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 [HA371 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 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 [HA371 trade name].

You may need extra check-ups, including blood tests, while you are taking this medicine. See section 4 for more information.

Abacavir hypersensitivity reactions

Even patients who don't have the HLA-B*5701 gene may still develop a **hypersensitivity reaction** (a serious allergic reaction) to abacavir.

Carefully read all the information about hypersensitivity reactions in Section 4 of this leaflet.

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 [HA371 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 [HA371 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 [HA371 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 [HA371 trade name].

Some medicines interact with [HA371 trade name]

These include:

- Phenytoin, for treating epilepsy
- Methadone, used as a substitute for opioids such as morphine and heroin. [HA371 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.
- Riociguat, for treating a condition called pulmonary hypertension (high blood pressure in the blood vessels of the lungs). [HA371 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 [HA371 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 such as [HA371 trade name] 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 [HA371 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 [HA371 trade name] before considering driving or using machines.

3. How to take [HA371 trade name]

[HA371 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.

Swallow the tablets with some water. Abacavir can be taken with or without food. If you cannot swallow the tablets, you may crush and combine them with a small amount of food or drink and take all the dose immediately.

Adults, adolescents and children weighing at least 25 kg:

The recommended dose of [HA371 trade name] is 600 mg daily. This can be taken either as one 300 mg tablet twice a day or two 300 mg tablets once daily.

Children from one year of age weighing less than 25 kg:

The dose given depends on the body weight of your child. The recommended dose is:

Children weighing at least 20 kg and less than 25 kg:

The usual dose of [HA371 trade name] is 450 mg a day. This can be given as 150 mg (half of a tablet) taken in the morning and 300 mg (one whole tablet) taken in the evening, or 450 mg (one and a half tablets) once a day as advised by your doctor.

Children weighing at least 14 kg and less than 20 kg:

The usual dose of [HA371 trade name] is 300 mg a day. This can be given as 150 mg (half of a tablet) twice daily, or 300 mg (one whole tablet) once a day as advised by your doctor. The tablet can be divided into equal doses.

Other formulations are available for children over three months of age and weighing less than 14 kg, or for people who need a lower than usual dose, or who cannot take tablets.

If you take more [HA371 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 [HA371 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 [HA371 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 [HA371 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 lifestyle, 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, [HA371 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 [HA371 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 [HA371 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 [HA371 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 [HA371 trade name] because of a hypersensitivity reaction, **you must NEVER AGAIN take [HA371 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 [HA371 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 [HA371 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 [HA371 trade name] for disposal. Ask your health care provider for advice.

The [HA371 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):

- hypersensitivity reaction
- anorexia
- skin rash (without any other illness)
- feeling sick (nausea)
- vomiting
- diarrhea
- headache
- fever (high temperature)
- tiredness, fatigue
- loss of appetite

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

- inflammation of the pancreas (pancreatitis)

Very rare side effects (these can affect up to 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*).
- 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 disorders

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 [HA371 trade name] :

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 healthcare 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 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 [HA371 trade name]

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

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 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 [HA371 trade name] contains

The active ingredient is abacavir.

The other ingredients of [HA371 trade name] are: colloidal silicon dioxide, corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, iron oxide yellow, polyethylene glycol, polysorbate 80 and titanium dioxide.

What [HA371 trade name] looks like and contents of the pack

Yellow coloured, capsule shaped, biconvex film-coated tablets, plain on both sides.

Round, white opaque HDPE bottle with a polypropylene child-resistant closure or polypropylene screw cap, containing 60 tablets.

Supplier

Cipla Limited
Cipla House, Peninsula Business Park,
Ganpatrao, Kadam Marg, Lower Parel,
Mumbai, Maharashtra 400013,
India
Tel. No.: + 91222482600
Fax No.: +912224826120

Manufacturer

Cipla Limited, Patalganga,
Manufacturing Division
Unit I and II
Patalganga Industrial Area,
District – Raigad
410220 Patalganga
Maharashtra
India.
Tel: +91 2192 250811
Fax: +91 2192 250819
E-mail: ciplaptg@cipla.com

For any information about this medicine, contact the supplier.

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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
[HA371 trade name]
Carry this card with you at all times

Patients taking [HA371 trade name] may develop a hypersensitivity reaction (serious allergic reaction) which **can be life-threatening** if treatment with [HA371 trade name] is continued.

CONTACT YOUR HEALTHCARE PROVIDER IMMEDIATELY for advice on whether you should stop taking [HA371 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 [HA371 trade name] due to this reaction, **you MUST NEVER TAKE** [HA371 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 [HA371 trade name].

Write your healthcare provider's details below:

Health care provider:

Tel:

If the health care 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 [HA371 trade name],

Contact: *telephone number*

or email: