

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

[HA698 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 [HA698 trade name] is and what it is used for
2. What you need to know before you take [HA698 trade name]
3. How to take [HA698 trade name]
4. Possible side effects
5. How to store [HA698 trade name]
6. Contents of the pack and other information

1. What [HA698 trade name] is and what it is used for

[HA698 trade name] is used in combination with other HIV medicines to treat HIV infection in adults, adolescents and in children weighing at least 25 kg.

The medicines reduce the amount of virus in your body and keep it at a very low level. They are 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.

[HA698 trade name] contains the active substances abacavir and lamivudine. They belong to a group of medicines called nucleoside reverse transcriptase inhibitors (NRTIs).

2. What you need to know before you take [HA698 trade name]

Do not take [HA698 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 [HA698 trade name] contains')

Warnings and precautions

Abacavir hypersensitivity reactions

[HA698 trade name] contains abacavir which can cause a serious allergic reaction known as a hypersensitivity reaction.

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

Who gets these reactions?

You could have a hypersensitivity reaction to abacavir during treatment with [HA698 trade name]. The hypersensitivity reaction could become very dangerous if you continue to take [HA698 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 [HA698 trade name]. If you have this gene, tell your health care provider before you take [HA698 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 [HA698 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 [HA698 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 [HA698 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 [HA698 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 [HA698 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 [HA698 trade name] unless your health care provider tells you to.

Other medicines and [HA698 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 [HA698 trade name].

You **must not** take the following medicines when taking [HA698 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 [HA698 trade name] include:

- phenytoin, for treating epilepsy
- rifampicin, used to treat tuberculosis
- methadone, used as a substitute for opioids such as morphine and heroin. [HA698 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). [HA698 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

[HA698 trade name] can make you dizzy. Do not drive or operate machinery until you are sure that you do not have side effects that affect driving or using machines.

Think about how you feel and the possible side effects of [HA698 trade name] before deciding to drive or use machines.

This medicine contains FD&C yellow #6/Sunset yellow FCF Aluminium Lake, may cause allergic reactions.

3. How to take [HA698 trade name]

[HA698 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 [HA698 trade name] regularly because irregular dosing may increase the risk of hypersensitivity reactions and of your infection becoming resistant to this medicine.

Adults, adolescents and children weighing at least 25 kg

The recommended dose of [HA698 trade name] is one tablet once daily. You can take [HA698 trade name] with food or between meals.

Children weighing less than 25 kg

[HA698 trade name] is not suitable for children who weigh less than 25 kg. Your health care provider will prescribe a more suitable medicine to provide the right dose.

If you take more [HA698 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 [HA698 trade name]

It is important not to miss doses of [HA698 trade name].

If you forget to take a dose and more than 12 hours are left until your next dose, take the missed dose at once. Take the next dose at the usual time and then continue your treatment as before.

If less than 12 hours are left until your next dose, skip the missed dose. Take the next dose at the usual time and then continue your treatment as before.

Do not take a double dose to make up for a missed dose.

If you stop taking [HA698 trade name]

You should continue taking the medicine to keep the infection in control.

If you have stopped taking [HA698 trade name] because of a side effect, speak with your healthcare provider at once.

Talk with your health care provider if you are thinking of stopping treatment and don't stop it unless your health care provider says you can.

If you have any questions about the use of this medicine, ask your health care provider.

4. Possible side effects

Like all medicines, [HA698 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 [HA698 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 [HA698 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 carton, bottle or aluminium blister card, 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 [HA698 trade name] contains

- The active ingredients are abacavir sulfate and lamivudine.
- The other ingredients of [HA698 trade name] are excipients; Microcrystalline cellulose, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide, macrogol, FD& C yellow #6/Sunset yellow FCF aluminium lake 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 [HA698 trade name] looks like and contents of the pack

[HA698 trade name] is an orange, capsule-shaped, film coated tablet. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have ‘RF 90’ debossed (stamped into) one side and a break line on the other side.

[HA698 trade name] are available in a round, opaque white plastic (HDPE) bottle containing 30 or 90 tablets. The bottle has an aluminum foil seal and an opaque white, plastic (polyethylene) screw or childproof cap.

Supplier and Manufacturer

Supplier

Sun Pharmaceutical Industries Limited
Sun House, 201 B/1
Western Express Highway
Goregaon (East)
Mumbai 400 063
India
Email:
Complaintdesk.Tandalja@sunpharma.com
pharmacovigilance.africasme@sunpharma.com

Manufacturer

Sun Pharmaceutical Industries Limited
Village Ganguwala, Paonta Sahib
District Sirmour, Himachal Pradesh
173 025, India
Email:
Complaintdesk.Tandalja@sunpharma.com
pharmacovigilance.africasme@sunpharma.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/prequal/medicines/prequalified/finished-pharmaceutical-products>*

Attachment:

ALERT CARD TEXT

SIDE 1
IMPORTANT - ALERT CARD
[HA698 trade name]
Carry this card with you at all times

Patients taking [HA698 trade name] may develop a hypersensitivity reaction (serious allergic reaction) which **can be life-threatening** if treatment with [HA698 trade name] is continued.

Contact your healthcare provider immediately for advice on whether you should stop taking [HA698 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 [HA698 trade name] due to this reaction, you must never take [HA698 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 [HA698 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 [HA698 trade name],

Contact: *telephone number*

or email: