

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

[HA809 trade name][†]

Abacavir (sulfate)/dolutegravir (sodium)/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 [HA809 trade name] is and what it is used for
2. What you need to know before you take [HA809 trade name]
3. How to take [HA809 trade name]
4. Possible side effects
5. How to store [HA809 trade name]
6. Contents of the pack and other information

1. What [HA809 trade name] is and what it is used for

[HA809 trade name] is an antiretroviral medicine used to treat HIV infection in babies and children over 4 weeks of age who weigh between 3 kg and 25 kg.

The medicine reduces the amount of virus in your body and keeps it at a very low level. It is not a cure for HIV infection but if taken correctly, it will improve your immune system. This reduces the risk of developing illnesses linked to HIV infection or of passing on the virus.

[HA809 trade name] contains the active substances abacavir, dolutegravir and lamivudine. Abacavir and lamivudine belong to a group of HIV medicines called nucleoside reverse transcriptase inhibitors (NRTIs). Dolutegravir belongs to a group of HIV medicines called integrase inhibitors.

This medicine is for use in children. However, information from its use in adults is also included to give a fuller picture of the medicine's effects.

2. What you need to know before you take [HA809 trade name]

Do not take [HA809 trade name] if:

- you are allergic (hypersensitive) to the active substances abacavir, dolutegravir, lamivudine, or to any of the other ingredients of this medicine (see section 6, 'What [HA809 trade name] contains')
- if you have had allergic (hypersensitivity) reactions after taking medicines containing abacavir in the past
Read the information on **hypersensitivity reactions**, below.

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

- you are taking a medicine called dofetilide (to treat heart conditions) or fampridine (also known as dalfampridine, used in multiple sclerosis).

If you think any of these apply to you, tell your health care provider.

Warnings and precautions

Hypersensitivity reactions

Two of the active substances in [HA809 trade name], abacavir and dolutegravir, can cause a serious allergic reaction known as a hypersensitivity reaction.

Read the **alert card** you have been given. Always keep it with you. The card reminds you about hypersensitivity reactions and you can show it to a health care provider if you get a reaction.

Who gets these reactions?

Anyone taking [HA809 trade name] can get a hypersensitivity reaction. The reaction could become very dangerous if you continue to take [HA809 trade name].

This reaction is more likely in people who have a gene called HLA-B*5701. If you know you have this gene, tell your health care provider at once. If you have this gene or if blood tests show that you have this gene, you should not take [HA809 trade name].

You can have a hypersensitivity reaction even if you don't have the HLA-B*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?

A hypersensitivity reaction can start at any time during treatment with [HA809 trade name] but it is more likely in the first 6 weeks.

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 generally feeling ill.

Your health care provider may stop [HA809 trade name] and may tell you to never again take [HA809 trade name] or any other medicine that contains abacavir or dolutegravir.

Stopping [HA809 trade name]

If you stop taking [HA809 trade name] because of a hypersensitivity reaction, you must **never again** take [HA809 trade name], or any other medicine containing abacavir or dolutegravir. Taking such a medicine can cause a dangerous fall in blood pressure, which could lead to death.

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

Talk to your health care provider if you:

- have ever had liver disease
- have hepatitis B or C
- are very overweight (especially if you are a woman)
- have a kidney problem.

You may need extra check-ups, including blood tests, while you are taking [HA809 trade name].

Look out for certain illnesses

If your immunity is weak when you start [HA809 trade name], you might develop infections or inflammation. With continuing treatment your immunity will recover. When your immune system has improved enough, you will no longer be at risk.

Some people taking medicines for HIV infection develop joint pain, stiffness and bone problems which can be serious.

Contact your health care provider at once if you get these conditions.

If you stop taking [HA809 trade name]

If you stop taking [HA809 trade name] for any reason – especially because you think you have side effects, or because you have other illness – talk to your health care provider before you start taking it again.

Risk of cardiovascular problems

Tell your health care provider if you have cardiovascular (heart and blood circulation) problems, if you smoke, or if you have other illnesses that may increase your risk of cardiovascular diseases, such as high blood pressure or diabetes. Do not stop taking [HA809 trade name] unless your health care provider tells you to.

Other medicines and [HA809 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 [HA809 trade name].

You **must not** take the following medicines when taking [HA809 trade name]:

- Emtricitabine, used to treat HIV infection
- Other HIV or hepatitis B medicines containing any of the ingredients in [HA809 trade name] (abacavir, dolutegravir or lamivudine)
- High doses of trimethoprim/sulfamethoxazole, an antibiotic

- Cladribine, used to treat a type of leukaemia
- Dofetilide used to treat heart conditions
- Fampridine (also known as dalfampridine) used in multiple sclerosis

Medicines that can react with [HA809 trade name], reducing the effect of treatment or increasing the risk of side effects, include:

- antacids, to treat indigestion and heartburn
- calcium supplements, iron supplements and multivitamins
- etravirine, efavirenz, nevirapine or tipranavir/ritonavir, to treat HIV infection
- carbamazepine and oxcarbazepine, to treat epilepsy or bipolar disorder
- phenytoin and phenobarbital, for treating epilepsy
- rifampicin, used to treat tuberculosis
- metformin, used to treat diabetes
- methadone, used as a substitute for opioids such as morphine and heroin
- 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 (an antibiotic) and cisplatin (a cancer medicine) which may harm the kidneys
- medicines such as flucytosine for fungal infection, which may cause blood disorders
- riociguat, for treating pulmonary hypertension (high blood pressure in the blood vessels of the lungs). [HA809 trade name] may change the amount of riociguat in your blood
- St John's wort (*Hypericum perforatum*), a herbal remedy used for treating depression

Pregnancy and breast-feeding

If you become pregnant, or are planning to become pregnant, talk to your health care provider about the benefits and risks of your HIV medicines to you and your child.

Do not stop taking [HA809 trade name] without checking with your health care provider, as this may harm you and your unborn child.

If you want to breast-feed your baby, talk to your health care provider about the risks and benefits.

Driving and using machines

[HA809 trade name] can make you dizzy. If you feel dizzy while taking [HA809 trade name], do not drive and do not use any hazardous tools or machines.

This medicine contains about 54.5mg of mannitol per tablet. May have a mild laxative effect.

3. How to take [HA809 trade name]

Always take this medicine exactly as your health care provider has told you to. 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 [HA809 trade name].

It is **important** for your child to take [HA809 trade name] regularly at around the same time each day.

Patients weighing between 3 to less than 25 kg

Your child should take [HA809 trade name] once daily. The dose depends on the child's weight.

Child's weight	Dose of [HA809 trade name]
3 to less than 6 kg	1 tablet once daily

6 to less than 10 kg	3 tablets once daily
10 to less than 15 kg	4 tablets once daily
15 to less than 20 kg	5 tablets once daily
20 to less than 25 kg	6 tablets once daily

See below for advice on how to take the tablets.

Patients weighing above 25 kg

[HA809 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 [HA809 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. Take the medicine and this leaflet with you to show to the health care provider.

If you forget to take [HA809 trade name]

It is important not to miss doses of [HA809 trade name].

If your child misses a dose:

- if it is still more than 4 hours before the next dose is due, give a dose straight away and give the next one at the usual time;
- if it is less than 4 hours before the next dose is due, 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 [HA809 trade name]

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

Talk with your health care provider if you are thinking of stopping treatment.

If you have stopped giving [HA809 trade name], talk to your health care provider before starting treatment again.

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

How to take the tablets

Your child can take [HA809 trade name] with food or between meals.

To give [HA809 trade name] to your child:

1. Use a teaspoon to pour drinking water (about 1 teaspoonful for each tablet and up to about 4 teaspoonfuls for 4 to 6 tablets) into a small, clean cup.
2. Add the right number of tablets to the cup and swirl it gently until the tablets break down completely. Take care not to spill any.
3. Give the mixture to the child as soon as you have mixed it.
4. After your child has taken the mixture, add about 2 teaspoonfuls of clean water to the cup and swirl it to catch any remaining medicine. Get your child to drink this also.

4. Possible side effects

Like all medicines, [HA809 trade name] can cause side effects, although not everybody gets them.

Unwanted effects during treatment may be caused by [HA809 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 or dolutegravir, two of the active substances in this medicine. This is described under ‘Hypersensitivity reactions’ in section 2 of this leaflet. You **must** read and understand the information about this serious reaction.

Very common side effects (may affect more than 1 in 10 people)

- headache
- diarrhoea
- feeling sick (nausea)
- difficulty sleeping (insomnia)
- feeling tired

Common side effects (may affect up to 1 in 10 people)

- hypersensitivity reaction (see section 2)
- loss of appetite
- skin rash (without any other illness), itching
- hair loss
- stomach pain, being sick (vomiting), abdominal (belly) pain and discomfort, wind (flatulence), indigestion
- weight gain
- feeling sleepy, abnormal dreams, depression, anxiety
- dizziness
- cough, irritation in the nose, runny nose
- fever
- muscle pain and discomfort
- joint pain
- feeling weak
- general feeling of being unwell
- blood tests showing changes in liver function
- blood tests with increased muscle enzymes (creatine kinase) indicating muscle damage

Uncommon side effects (may affect up to 1 in every 100 people)

- inflammation of the liver (hepatitis)
- suicidal thoughts and behaviours – tell your health care provider **at once** if you become very depressed or have any problems with your mental health
- panic attack
- blood tests showing:
 - o anaemia (low red blood cell count)—this can cause tiredness or breathlessness
 - o low levels of neutrophils, a type of white blood cell
 - o reduction in platelets (components important for blood clotting)—this can lead to bruising and bleeding
 - o increases in the levels of glucose
 - o increase in triglycerides (type of fat)

Rare side effects (these can affect up to 1 in 1000 people)

- 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)
- suicide (particularly in patients who have had depression or mental health problems before)
- increase in bilirubin (a test of liver function) in your blood

- breakdown of muscle tissue, leading to kidney damage

Very rare side effects (may affect less than 1 in every 10,000 people)

- skin rash, which may form blisters and looks like small targets (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, dolutegravir and lamivudine:

- a condition where red blood cells do not form properly (sideroblastic anaemia)
- 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).
- Weight, blood lipid and blood glucose effects – during HIV therapy there may be an increase in weight and levels of blood fats (lipids) and glucose; this may be linked to improved health and lifestyle changes or the medicines themselves.

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 [HA809 trade name]

Do not store above 30°C. Avoid excursions above 30°C.

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

The 180's container should be used within 30 days, once opened. When the bottle is first opened the “Discard after date” should be written on the bottle label in the place provided.

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 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 [HA809 trade name] contains

- The active ingredients are: abacavir (as sulfate), dolutegravir (as sodium) and lamivudine.
- The other ingredients of [HA809 trade name] are:

Core tablet: Microcrystalline cellulose, Sodium starch glycolate, Sucralose, Crospovidone, Strawberry flavour, Sodium stearyl fumarate, Mannitol, Povidone, Acesulfame potassium

Film coat: Polyvinyl alcohol- partially hydrolysed, Titanium dioxide, Macrogol/polyethylene glycol, Talc, Iron oxide yellow

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

What [HA809 trade name] looks like and contents of the pack

[HA809 trade name] are:

Yellow, oval, film-coated dispersible tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have 'E71' debossed (stamped into) one side and are plain on the other side.

[HA809 trade name] are packed in round, opaque white plastic (HDPE) bottle containing, 30, 90 or 180 tablets. It also contains a canister of desiccant (drying material). The bottle has an aluminium/plastic foil seal and a white, childproof plastic (polypropylene) screw cap.

Supplier and Manufacturer

Supplier

Micro Labs Limited
31, Race Course Road,
Bengaluru - 560001, Karnataka, India.
Tel: +91-80-2237 0451 to 2237 0457
Fax : +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 : +91(0)832-6686262
Fax : +91(0)832-6686203
Email: jainethesh@microlabs.in

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
[HA809 trade name]
Carry this card with you at all times

Patients taking [HA809 trade name] may develop a hypersensitivity reaction (serious allergic reaction) which **can be life-threatening** if treatment with [HA809 trade name] is continued.

Contact your healthcare provider immediately for advice on whether you should stop taking [HA809 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 [HA809 trade name] due to this reaction, you must never take [HA809 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 [HA809 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 [HA809 trade name], Contact:

Telephone number:

Or email: