

## **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](https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf)

## Information for the patient

### [HA779 trade name]<sup>†</sup>

Abacavir (as sulfate)/dolutegravir (as sodium)/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.

### **What is in this leaflet**

1. What [HA779 trade name] is and what it is used for
2. What you need to know before you take [HA779 trade name]
3. How to take [HA779 trade name]
4. Possible side effects
5. How to store [HA779 trade name]
6. Contents of the pack and other information

#### **1. What [HA779 trade name] is and what it is used for**

[HA779 trade name] is used to treat HIV infection in babies and children over 4 weeks of age who weigh between 6 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, the combination will improve your immune system and reduce the risk of developing illnesses linked to HIV infection.

[HA779 trade name] contains the active substances abacavir, dolutegravir and lamivudine. Abacavir and lamivudine belong to a group of medicines called nucleoside reverse transcriptase inhibitors (NRTIs). Dolutegravir belongs to a group of antiretroviral medicines called integrase inhibitors.

#### **2. What you need to know before you take [HA779 trade name]**

##### **Do not take [HA779 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 [HA779 trade name] contains')  
Read the information on **hypersensitivity reactions**, below.
- 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.

---

<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

### **Warnings and precautions**

#### **Hypersensitivity reactions**

Two of the active substances in [HA779 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 [HA779 trade name] can have a hypersensitivity reaction. The reaction could become very dangerous if you continue to take [HA779 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 [HA779 trade name]. If you have this gene, tell your health care provider before you take [HA779 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?**

A hypersensitivity reaction can start at any time during treatment with [HA779 trade name] but it is 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 [HA779 trade name] and may tell you to never again take [HA779 trade name] or any other medicine that contains abacavir or dolutegravir.

***Stopping [HA779 trade name]***

If you stop taking [HA779 trade name] because of a hypersensitivity reaction, you must **never again** take [HA779 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 [HA779 trade name].

*If you stop taking [HA779 trade name]*

If you stop taking [HA779 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.

*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 [HA779 trade name] unless your health care provider tells you to.

*Other medicines and [HA779 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 [HA779 trade name].

You **must not** take the following medicines when taking [HA779 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
- Dofetilide used to treat heart conditions
- Fampridine (also known as dalfampridine) used in multiple sclerosis

Medicines that can interact with [HA779 trade name] include:

- antacids, to treat indigestion and heartburn (see section 3)
- calcium supplements, iron supplements and multivitamins (see section 3)
- etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, to treat HIV infection
- oxcarbazepine and carbamazepine, to treat epilepsy or bipolar disorder
- phenytoin and phenobarital, 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. Your health care provider may check if your methadone dose needs 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). [HA779 trade name] may change the amount of riociguat in your blood, so your health care provider may need to change its dose.
- 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.

Taking [HA779 trade name] around the time you become pregnant or during the first weeks of pregnancy may slightly increase the risk of a birth defect called neural tube defect (e.g. spina bifida).

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

### **Driving and using machines**

[HA779 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 [HA779 trade name] before deciding to drive or use machines.

[HA779 trade name] contains 9.5 mg aspartame per tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly

### 3. How to take [HA779 trade name]

[HA779 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** for your child to take [HA779 trade name] regularly at around the same time each day.

*Patients weighing between 3 to less than 6 kg*

[HA779 trade name] is not suitable for patients who weigh 3 kg to less than 6 kg. Medicines containing lower amounts of the active substances are more suitable for them.

*Patients weighing between 6 to less than 25 kg*

Your child should take [HA779 trade name] once daily. The dose depends on the child's weight.

Child's weight	Dose of [HA779 trade name] tablets
6 to less than 10 kg	3 tablets once daily
10 to less than 14 kg	4 tablets once daily
14 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*

[HA779 trade name] is not suitable for patients who weigh over 25 kg. Medicines containing higher amounts of the active substances are more suitable for them.

#### **If you take more [HA779 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.

The child may need medical attention. Remember to take the medicine container with you to show to the health care provider.

#### **If you forget to take [HA779 trade name]**

It is important not to miss doses of [HA779 trade name].

If your child [HA779 trade name] misses a dose:

- if the next dose due after at least 4 hours, give a dose straight away and give the next one at the usual time;
- if it is less than 4 hours to the next dose, miss out the forgotten dose and give the next one at the usual time.

Do not give a double dose to make up for forgotten dose.

#### **If you stop taking [HA779 trade name]**

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

If you have stopped giving [HA779 trade name] because of a side effect or if your child has become ill, speak with your health care provider at once.

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

If you have stopped giving [HA779 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 [HA779 trade name] with food or between meals.

To give [HA779 trade name] to your child:

1. Pour into a small clean cup a small amount of drinking water (about 10 mL or 2 teaspoonfuls for each tablet your child takes)
2. Add the right dose of tablets to the water and swirl until the tablets have broken down completely.
3. Get your child all the mixture to drink at once
4. Add another 10 mL (2 teaspoonfuls) to the cup, swirl it again and ask your child to drink this also. This makes sure that the child receives the full dose.

### 4. Possible side effects

Like all medicines, [HA779 trade name] can cause side effects, although not everybody gets them.

Unwanted effects during treatment may be caused by [HA779 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 '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 patients treated)

- 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 patients treated)

- inflammation of the liver (hepatitis)
- suicidal thoughts and behaviours (particularly in patients who have had depression or mental health problems before)

- panic attack
- blood tests showing:
  - anaemia (low red blood cell count)—this can cause tiredness or breathlessness
  - reduction in platelets (components important for blood clotting)—this can lead to bruising and bleeding
  - increases in the levels of glucose
  - increase in triglycerides (type of fat)

**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)
- suicidal thoughts – tell your health care provider **at once** if have any problems with your mental health
- increase in bilirubin (a test of liver function) in your blood
- breakdown of muscle tissue

**Very rare side effects** (may affect less than 1 in every 10,000 patients treated):

- 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)
- blood tests showing a failure to produce new red blood cells (pure red cell aplasia)

**Frequency not known**

The following side effects may occur with active substances like abacavir, dolutegravir 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).
- Weight, blood lipid and blood glucose effects – during HIV therapy there may be an increase in weight and levels of blood lipid and glucose (partly linked to improved health, 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 [HA779 trade name]**

Do not store above 30°C. Store in the original container.

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

The 90’s container should be used within 90 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 label 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 [HA779 trade name] contains

- The active ingredients are: abacavir (as sulfate), dolutegravir (as sodium) and lamivudine.
- The other ingredients of [HA779 trade name] are:

*Core tablet:* Microcrystalline cellulose, sodium starch glycolate, povidone, crospovidone, strawberry cream flavour, aspartame, colloidal silicon dioxide, iron oxide red, mannitol, calcium sulphate dihydrate, magnesium stearate

*Film coat:* Polyvinyl alcohol-partially hydrolysed, macrogol/polyethylene glycol, Talc, titanium dioxide, iron oxide yellow, iron oxide red

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

### What [HA779 trade name] looks like and contents of the pack

[HP779 trade name] are:

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

[HA779 trade name] are packed in round, opaque, white plastic (HDPE) bottle containing 30 or 90 tablets. It also contains a desiccant (drying material). The bottle has an aluminium/plastic foil seal printed with "SFYP" in black and a white, childproof plastic (polypropylene) screw cap.

### Supplier and Manufacturer

#### *Supplier*

Cipla Limited  
Cipla House, Peninsula Business Park,  
Ganpatrao, Kadam Marg, Lower Parel,  
Mumbai, Maharashtra 400013,  
India  
Tel: 9122 24826000  
Email: [globalra@cipla.com](mailto:globalra@cipla.com)

#### *Manufacturer*

Cipla Limited, Indore Unit IV  
Plot No. 9 and 10 Indore Special Economic Zone,  
Phase II, Pithampur,  
District Dhar,  
454775, Madhya Pradesh,  
India

For any information about this medicine, contact the local representative of the supplier:

**This leaflet was last revised in May 2024**

*Detailed information on this medicine is available on the World Health Organization (WHO) website:*  
<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>

<----->

<The following information is intended for health care providers only:>  
Attachment:

**ALERT CARD TEXT**

<p><b>SIDE 1 IMPORTANT - ALERT CARD</b> <b>[HA779 trade name]</b> <b>Carry this card with you at all times</b></p>
--

Patients taking [HA779 trade name] may develop a hypersensitivity reaction (serious allergic reaction) which **can be life-threatening** if treatment with [HA779 trade name] is continued.

**CONTACT YOUR HEALTHCARE PROVIDER IMMEDIATELY for advice on whether you should stop taking [HA779 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 [HA779 trade name] due to this reaction, **you MUST NEVER TAKE** [HA779 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 [HA779 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 [HA779 trade name],  
*telephone number* - 1-866 604 3268  
or email: [drugsafety@cipla.com](mailto:drugsafety@cipla.com)