

## **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.*

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\*[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

**[HA765 trade name]<sup>†</sup>**  
Dolutegravir (as sodium)

*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 [HA765 trade name] is and what it is used for
2. What you need to know before you take [HA765 trade name]
3. How to take [HA765 trade name]
4. Possible side effects
5. How to store [HA765 trade name]
6. Contents of the pack and other information

#### 1. What [HA765 trade name] is and what it is used for

[HA765 trade name] contains the active ingredient dolutegravir. Dolutegravir belongs to a group of HIV medicines called integrase inhibitors.

[HA765 trade name] is used to treat HIV (human immunodeficiency virus) infection in children at least 4 weeks of age or older and weighing at least 3 kg. It is always used in combination with other antiretroviral medicines (combination therapy).

[HA765 trade name] may also be used with other HIV medicines to reduce the risk of getting HIV infection in children weighing more than 3 kg who have been exposed to HIV. This is called post-exposure prophylaxis (PEP).

[HA765 trade name] does not cure HIV infection; it reduces the amount of virus in your body and keeps it at a low level so it cannot be passed on. Reducing the amount of virus helps to increase the number of white blood cells, called CD4 cells, that are important for fighting infection.

[HA765 trade name] does not work equally well in everybody. Your health care provider will check how well your treatment is working.

To control your HIV infection, and to stop your illness from getting worse, you must take all your HIV medicines regularly, unless your health care provider tells you to stop taking any.

*This product is intended for use in children. Safety information on use in adults is also provided.*

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

## 2. What you need to know before you take [HA765 trade name]

### Don't take [HA765 trade name] if you are:

- allergic to dolutegravir or any of the other ingredients of this medicine (listed in section 6)
- taking another 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

#### *Look out for important symptoms*

Some people taking medicines for HIV infection develop other conditions, which can be serious. These include:

- infections and inflammation
- joint pain, stiffness and bone problems

You need to know about important signs and symptoms to look out for while you're taking [HA765 trade name].

Read the information, 'Other possible side effects' in Section 4 of this leaflet.

### Children

There is not yet enough information to recommend the use of dolutegravir in children weighing less than 3 kg.

### Other medicines and [HA765 trade name]

Tell your health care provider if you are taking, have recently taken or are planning to take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

Some medicines can affect how [HA765 trade name] works or increase side effects. [HA765 trade name] can also affect how some other medicines work.

You **must not** take [HA765 trade name] with **dofetilide**, which is used to treat heart conditions or **fampridine** (also known as dalfampridine), used in multiple sclerosis.

Tell your health care provider if you are taking any of the following:

- **metformin**, to treat diabetes
- **antacids**, to treat indigestion and heartburn (see section 3)
- **calcium supplements**, **iron supplements** and **multivitamins** (see section 3)
- **rifampicin**, to treat tuberculosis and other bacterial infections
- **phenytoin** and **phenobarbital**, to treat epilepsy
- **oxcarbazepine** and **carbamazepine**, to treat epilepsy or bipolar disorder
- **St John's wort** (*Hypericum perforatum*), a herbal remedy used for treating depression

If you are taking any of these, your health care provider may adjust your dose or arrange extra check-ups.

Your health care provider will work out what other HIV medicines you should take with [HA765 trade name] and explain to you how to take them. Some HIV medicines (such as **etravirine**, **efavirenz**, **fosamprenavir/ritonavir**, **nevirapine** or **tipranavir/ritonavir** may need adjustments of the dose of [HA765 trade name] if used together. Always take your HIV medicines as your health care provider advises, and talk to him or her if you are unsure or if you get any side effects.

### Pregnancy

Treatment guidelines recommend that this medicine can be used for HIV treatment in pregnancy. Effective treatment of HIV during pregnancy is important to protect you and your baby.

If you are pregnant, if you become pregnant, or if you are planning to have a baby talk to your health care provider about the risks and benefits of taking [HA765 trade name].

Do not stop taking [HA765 trade name] without checking with your health care provider, as this may harm you and your unborn baby.

### Breast-feeding

If you wish to breast-feed your baby, you should discuss the risks and benefits with your health care provider.

### Driving and using machines

[HA765 trade name] can make you dizzy and have other side effects that make you less alert. Do not drive or operate machinery until you are sure that you do not have side effects that affect driving or using machines.

### Other ingredients of [HA765 trade name]

[HA765 trade name] contains mannitol, which may have a mild laxative effect.

## 3. How to take [HA765 trade name]

[HA765 trade name] should be taken with other HIV medicines. Your health care provider will work out the right combination for you.

You should always take [HA765 trade name] exactly as your health care provider has told you. Do not stop taking it without checking with your health care provider. Check with the health care provider if you are not sure.

Your health care provider will decide on the correct dose of [HA765 trade name], depending on your weight. Dose recommendations according to weight are presented in table below:

Patient weight	Number of tablets of [HA765 trade name] per day
3 kg to less than 6 kg	0.5
6 kg to less than 10 kg	1.5
10 kg to less than 14 kg	2
14 kg to less than 20 kg	2.5
20 kg to less than 25 kg	3

The number of tablets given in the table above should normally be taken **once a day**. *If you are also taking certain other medicines*, your health care provider will tell you to take your dose **twice a day** (a double dose). This is because these medicines reduce the effect of [HA765 trade name].

The dose of [HA765 trade name] in children needs to be adjusted as they get older or gain weight. It is important therefore that you keep planned health care provider's appointments.

### Length of treatment

If you are **being treated for HIV**, you will need to keep on taking [HA765 trade name] unless your health care provider changes your HIV treatment.

If you are taking [HA765 trade name] **to reduce the risk of getting infected** after being exposed to HIV (known as post-exposure prophylaxis, or PEP), then you will only take the medicine for 28 days.

Check with your health care provider if you are unsure about your treatment.

### How to take [HA765 trade name]

You can take [HA765 trade name] with food or between meals.

### Instructions for use

1. Look up your weight in the table above.
2. Then look for the number of tablets that will be required.

3. Each tablet should be made into a mixture with 10 mL of water, so the total amount of mixture should be less than 50 mL.
4. Place the required volume of drinking water in a small clean cup and add the required number dolutegravir tablets.
5. Stir gently until the tablets disperse.
6. Drink the entire medicine mixture immediately.
7. Rinse the cup with an additional 10 mL of water, which you should drink.
8. The mixture must be drunk straight away after it is made up. If more than 30 minutes have gone by since the mixture was made up, do not take it. Instead, throw it away and make up a new mixture.

*Antacids, calcium supplements, iron supplements, multivitamins*

Ask your health care provider for advice if you are also taking:

- an antacid (a medicine used for treating indigestion and heartburn)
- calcium supplements
- iron supplements
- multivitamins.

You should take these medicines at least 6 hours before taking [HA765 trade name] or at least 2 hours after taking [HA765 trade name].

#### **If you take too many tablets of [HA765 trade name]**

If you take too many tablets of [HA765 trade name], contact your health care provider for advice. If possible, show them the [HA765 trade name] pack.

#### **If you forget to take [HA765 trade name]**

If you miss a dose of [HA765 trade name], take it as soon as you remember. But if your next dose is due within 4 hours, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before. You must not take a double dose to make up for a missed dose.

#### **Don't stop taking [HA765 trade name] without advice from your health care provider**

Take [HA765 trade name] for as long as your health care provider recommends it. Don't stop unless your health care provider advises you to. If you have any further questions on the use of this medicine, ask your health care provider.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects but not everybody gets them.

Talk to your health care provider if there is any worsening of your health. The changes could be caused by the medicine or the condition getting worse.

#### **Allergic reactions**

See a health care provider straightaway if you get an allergic reaction because the health care provider may decide that you should stop taking [HA765 trade name]. The signs of allergic reactions are:

- skin rash
- fever
- tiredness
- swelling under the skin which can involve the face or mouth and cause breathing difficulty
- muscle and joint ache

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

headache  
diarrhoea  
feeling sick (nausea)

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

weight gain  
rash, itching (pruritus)  
being sick (vomiting), abdominal (belly) pain and discomfort, wind (flatulence)  
insomnia, abnormal dreams  
depression  
dizziness, tiredness  
blood tests showing changes in liver function  
blood tests with increased muscle enzymes (creatine kinase) indicating muscle damage

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

inflammation of the liver (hepatitis)  
suicidal thoughts and behaviours (particularly in patients who have had depression or mental health problems before); some deaths from suicide have occurred in people taking the medicine  
panic attack  
joint and muscle pain

**Rare side effect** (which may affect up to 1 in 1000 people)

liver failure (signs may include yellowing of the skin and the whites of the eyes or unusually dark urine)  
increase in bilirubin (a test of liver function) in your blood

**Other possible side effects**

People taking medicines for HIV may get other side effects described below.

*Infection and inflammation*

People with advanced HIV infection (AIDS) have weak immune systems and they are more likely to develop serious infections (opportunistic infections). Such infections may have been 'silent' before starting HIV treatment. After starting treatment, the immune system becomes stronger, and may attack the infections, which can cause symptoms of infection or inflammation. Symptoms usually include fever, headache, stomach ache, and breathing difficulty.

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 taking medicine to treat your HIV infection. Symptoms may include palpitations (rapid or irregular heartbeat), tremor, excessive restlessness and movement, weakness beginning in the hands and feet and moving up towards the trunk of the body.

Speak to your health care provider **immediately** if you get any symptoms of infection and inflammation. Do not take other medicines for the infection without checking with your health care provider.

*Joint pain, stiffness and bone problems*

Some people taking combination therapy for HIV develop a condition called osteonecrosis. It is caused by damage to the bone tissue because of reduced blood supply to the bone. People taking combination therapy for a long time may be more likely to get this condition if they are also taking medicines called corticosteroids or bisphosphonates, drink alcohol, have a very weak immune system, or are overweight.

Signs of osteonecrosis include joint stiffness, aches and pains in the joints (especially in the hip, knee or shoulder), difficulty moving.

Speak to your health care provider if you notice any of these effects.

### *Weight, blood lipid and blood glucose effects*

During HIV therapy there may be an increase in weight and in 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.

### **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 [HA765 trade name]**

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

Do not store above 30°C. Store in the original package to protect from moisture. Keep the bottle tightly closed. Avoid excursions 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 [HA765 trade name] contains**

- The active ingredient is 10 mg dolutegravir.
- The other ingredients of [HA765 trade name] are mannitol, microcrystalline cellulose, sodium starch glycolate, povidone, silicified microcrystalline cellulose, croscopolvidone, calcium sulphate dihydrate, strawberry cream flavour, sucralose and sodium stearyl fumarate, hypromellose, titanium dioxide, macrogol/polyethylene glycol and 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 [HA765 trade name] looks like and contents of the pack**

Pink, capsule-shaped, film-coated tablets. They are biconvex (rounded on top and bottom) with a beveled edge. The tablet is debossed (stamped into) with 'K' and '1' separated by a break line on one side and another break line on the other side.

The break line can be used to divide [HA765 trade name] into equal doses.

[HA765 trade name] is available in round, opaque white plastic (HDPE) bottle containing 90 tablets. It may or may not contain a 2 x 1 g silica gel sachet (drying material). The bottle has a childproof (polypropylene) screw cap with pulp and white printed heat seal liner.

[HA765 trade name] is also available in round, opaque white plastic (HDPE) bottle containing 30 tablets. It also contains 2 x 1 g silica gel sachet (drying material). The bottle has a childproof (polypropylene) screw cap with pulp and white printed heat seal liner.

### **Supplier and Manufacturer**

#### ***Supplier***

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For any information about this medicine, contact the local representative of 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>*