

## **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/pqweb/sites/default/files/documents/75%20SRA%20clarification\\_Feb2017\\_newtempl.pdf](https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf)

## Information for the patient

**[HA682 trade name]<sup>†</sup>**  
Dolutegravir (sodium)

**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 has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness seem 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 [HA682 trade name] is and what it is used for
2. What you need to know before you take [HA682 trade name]
3. How to take [HA682 trade name]
4. Possible side effects
5. How to store [HA682 trade name]
6. Contents of the pack and other information

#### 1. What [HA682 trade name] is and what it is used for

[HA682 trade name] contains the active ingredient dolutegravir. Dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors.

[HA682 trade name] is used to treat HIV (human immunodeficiency virus) infection in adults and children who weigh at least 20 kg. It is always used in combination with other anti-retroviral medicines (combination therapy).

[HA682 trade name] does not cure HIV infection; it reduces the amount of virus in your body and keeps it at a low level. Reducing the amount of virus helps to increase the number of white blood cells, called CD4 cells, that are important for fighting infection.

[HA682 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.

#### 2. What you need to know before you take [HA682 trade name]

**Don't take [HA682 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.

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

## 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 [HA682 trade name].

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

### *Protect other people*

HIV infection is spread by sexual contact, or by transfer of infected blood (for example, by sharing injection needles). You can still pass on HIV when taking this medicine, but the risk is lowered by effective antiretroviral therapy. Discuss with your health care provider the precautions needed to avoid infecting other people.

## Children

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

## Other medicines and [HA682 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.

You **must not** take [HA682 trade name] with dofetilide, which is used to treat heart conditions or fampridine (also known as dalfampridine), used in multiple sclerosis.

Some medicines can affect how [HA682 trade name] works or increase side effects. [HA682 trade name] can also affect how some other medicines work.

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)
- etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, to treat HIV infection
- 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.

## Pregnancy

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 [HA682 trade name].

Taking [HA682 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).

Do not stop taking [HA682 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**

[HA682 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.

### **Important information about some of the ingredients of [HA682 trade name]**

[HA682 trade name] contains mannitol which may have a mild laxative effect.

This medicine also contains less than 1 mmol sodium per tablet, that is to say essentially 'sodium-free'.

### **3. How to take [HA682 trade name]**

Always take [HA682 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.

#### ***Adults***

The usual dose for adults is one tablet (50 mg) once a day.

In the following cases your health care provider will decide on a higher dose of one tablet **twice** a day:

- if you are taking certain other medicines at the same time
- if your HIV infection is resistant to medicines similar to [HA682 trade name].

#### ***Children and adolescents***

The dose of [HA682 trade name] in children and adolescents weighing at least 20 kg is one tablet (50 mg), once a day. If certain other medicines are taken at the same time, your health care provider will decide on a higher dose of one tablet **twice** a day.

Children and adolescents whose HIV infection is resistant to medicines similar to [HA682 trade name] should **not** take [HA682 trade name].

[HA682 trade name] is not suitable for children weighing less than 20 kg. Other medicines containing smaller amounts of dolutegravir may be more suitable.

This medicine is also available as dispersible tablets. Film-coated tablets and dispersible tablets are not the same, therefore do not switch between film-coated tablets and dispersible tablets without first talking to your health care provider.

The dose of [HA682 trade name] in children needs to be adjusted as they get older or gain weight.

→ It is important therefore that children keep planned health care provider's appointments.

### **Antacids, calcium supplements, iron supplements, multivitamins**

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

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

Take these medicines at least 6 hours before you take [HA682 trade name] or take [HA682 trade name] at least 2 hours after taking an antacid, calcium or iron supplement, or multivitamins.

You can take [HA682 trade name] **with food or between meals** but if you need to take the medicine twice a day, your health care provider may advise you take [HA682 trade name] with food.

### **If you take more [HA682 trade name] than you should**

If you take too many tablets of [HA682 trade name], contact your health care provider for advice. If possible, show them the [HA682 trade name] pack.

### **If you forget to take [HA682 trade name]**

If you miss a dose of [HA682 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 [HA682 trade name] without advice from your health care provider**

Take [HA682 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 [HA682 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)

rash, itching (pruritus)  
being sick (vomiting), abdominal (belly) pain and discomfort, wind (flatulence)  
insomnia, abnormal dreams, depression  
dizziness, lack of energy (fatigue)  
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)  
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, drink alcohol, have a weak immune system, are very weak 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 any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help improve understanding about the safety of this medicine.

### **5. How to store [HA682 trade name]**

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

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

Do not use this medicine after the expiry date stated on the blister label, bottle and carton, 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 [HA682 trade name] contains**

- The active ingredient of [HA682 trade name] is dolutegravir.
- The other ingredients of [HA682 trade name] are mannitol, povidone, sodium starch glycolate, microcrystalline cellulose and sodium stearyl fumarate, polyvinyl alcohol, macrogol/polyethylene glycol, talc, titanium dioxide, red iron oxide and yellow iron oxide

#### **What [HA682 trade name] looks like and contents of the pack**

Pink, round, biconvex, film coated tablets debossed with ‘H’ on one side and ‘D 13’ on the other side.

Dolutegravir (as sodium) 50 mg Tablets are available in:

#### *Bottle packs*

60cc high density polyethylene (HDPE) bottles closed with 33mm white opaque, polypropylene child resistant plastic caps with pulp liners.

Pack sizes: 30s and 90s tablets.

*Blister packs*

Alu-Alu blister cards containing 10 film-coated tablets, such 8 blister cards are packed in an outer carton.  
Pack size: 8 x 10 tablets.

**Supplier and Manufacturer**

***Supplier***

Hetero Labs Limited  
7-2-A2, Hetero Corporate  
Industrial Estates  
Sanath Nagar, Hyderabad-500 018  
Telangana,  
India  
Tel. No.: +91 40 23704923/ 24/25  
Fax: +91 40 23704035, 23813359  
Email.: [contact@heterodrugs.com](mailto:contact@heterodrugs.com)

***Manufacturer***

Hetero Labs Limited  
Unit – III (Formulations)  
# 22 – 110, IDA  
Jeedimetla, Hyderabad-500 055  
Telangana  
India.  
Tel No.: +91-40-23096171/172/173/174  
Fax No.: +91-40-23095105  
Email.: [contact@heterodrugs.com](mailto:contact@heterodrugs.com)

Hetero Labs Limited  
Unit-V, Survey No. 439, 440, 441 & 458  
TSIIC Formulation SEZ  
Polepally Village, Jadcherla Mandal  
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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/pqweb/medicines>*