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

[HA708 trade name][†]
Dolutegravir (sodium)

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 [HA708 trade name] is and what it is used for

[HA708 trade name] is a medicine used to treat HIV infection in adults, teenagers and children who weigh at least 20 kg.

[HA708 trade name] contains the active ingredient dolutegravir. Dolutegravir belongs to a group of HIV medicines called integrase inhibitors.

[HA708 trade name] is used in combination with other HIV medicines to reduce 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 passing on the virus.

[HA708 trade name] can also be used with other HIV medicines if you have just been exposed to HIV, to reduce the risk of becoming infected (post-exposure prophylaxis, or PEP).

2. What you need to know before you take [HA708 trade name]

Don't take [HA708 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.

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

Warnings and precautions

Look out for certain illnesses

If your immunity is weak when you start [HA708 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.

Children

There is not yet enough information to recommend the use of dolutegravir in children weighing less than 2 kg.

Other medicines and [HA708 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 [HA708 trade name] works or increase side effects. [HA708 trade name] can also affect how some other medicines work.

You **must not** take [HA708 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 c***arbamazepine***, 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 [HA708 trade name] and explain to you how to take them. Some HIV medicines (such as ***etravirine, efavirenz, , nevirapine*** or ***tipranavir/ritonavir*** may need adjustments of the dose of [HA708 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 [HA708 trade name].

Do not stop taking [HA708 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 talk to your health care provider. Your health care provider will advise you what is best for you.

Driving and using machines

[HA708 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.

3. How to take [HA708 trade name]

[HA708 trade name] should be taken with other HIV medicines. Your health care provider will work out the right combination for you.

Always take [HA708 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.

Dose

Adults

The usual dose for adults is one tablet of [HA708 trade name] once a day.

Your health care provider may tell you to take one tablet **twice** a day if:

- you are also taking certain other medicines that reduce the effect of [HA708 trade name], or
- your HIV infection is resistant to medicines like [HA708 trade name].

Children and teenagers

The dose of [HA708 trade name] in children and teenagers weighing at least 20 kg is one tablet of [HA708 trade name], once a day.

If you are also taking a medicine called rifampicin (for treatment of tuberculosis), your health care provider will tell you to take your dose **twice a day** (instead of once a day). This is because rifampicin reduces the effect of [HA708 trade name].

Children and teenagers whose HIV infection is resistant to medicines like [HA708 trade name] should **not** take [HA708 trade name].

[HA708 trade name] is not suitable for children weighing less than 20 kg. Other medicines containing smaller amounts of dolutegravir may be more suitable.

The active ingredient in this medicine is also available as dispersible tablets to make up a mixture with water. Film-coated tablets like [HA708 trade name] 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.

How to take [HA708 trade name]

You can take [HA708 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 [HA708 trade name] with food.

Take the medicine regularly at around the same time each day. This is to make sure that your medicine continues to work well.

Length of treatment

If you are **being treated for HIV**, you will need to keep on taking [HA708 trade name] unless your health care provider changes your HIV treatment.

If you are taking [HA708 trade name] **to reduce the risk of getting infected** after being exposed to HIV (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.

If you take antacids

Antacids, to treat indigestion and heartburn, can stop dolutegravir being absorbed into your body and make it less effective. You should take these medicines at least 6 hours before taking [HA708 trade name] or at least 2 hours after taking [HA708 trade name].

If you take nutritional supplements containing vitamins, calcium, iron or magnesium

Take the nutritional supplements at least 6 hours before taking [HA708 trade name] or at least 2 hours after taking [HA708 trade name]. However, if you regularly take [HA708 trade name] with food, then you can take the supplements at the same time as [HA708 trade name].

Talk to your health care provider for further advice on taking nutritional supplements containing vitamins, calcium, iron or magnesium with [HA708 trade name].

If you take more [HA708 trade name] than you should

If you take too many tablets of [HA708 trade name], contact your health care provider for advice. If possible, show them the [HA708 trade name] pack and this leaflet.

If you forget to take [HA708 trade name]

If you miss a dose of [HA708 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 [HA708 trade name] without advice from your health care provider

Take [HA708 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

Contact a health care provider straightaway if you get an allergic reaction. The health care provider may decide that you should stop taking [HA708 trade name]. The signs of allergic reactions include:

- 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)
difficulty sleeping (insomnia), abnormal dreams
depression, anxiety
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

Frequency not known

a condition where red blood cells do not form properly (sideroblastic anaemia)

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 medicines 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 (bone damage). It is caused by 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.

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 [HA708 trade name]

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

Do not store above 30°C.

Do not use this medicine after the expiry date stated on the bottle and carton. The expiry date refers to the last day of that month.

Unused tablets should be discarded 30 days after first opening of the bottle. When the bottle is first opened this "Discard after date" should be written on the bottle label in the place provided. (This is only applicable to pack size of 30 tablets).

Unused tablets should be discarded 90 days after first opening of the bottle. When the bottle is first opened this "Discard after date" should be written on the bottle label in the place provided. (This is only applicable to pack size of 90 tablets).

Do not use this medicine if you notice that there are 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 [HA708 trade name] contains

- The active ingredient is dolutegravir. Each tablet contains 50 mg of dolutegravir (as sodium)
- The other ingredients of [HA708 trade name] are mannitol, microcrystalline cellulose, povidone, sodium starch glycolate, sodium stearyl fumarate, talc, magnesium stearate, polyvinyl alcohol partially hydrolysed, titanium dioxide, macrogol/polyethylene glycol, talc, iron oxide yellow 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 [HA708 trade name] looks like and contents of the pack

The tablets are light brown to brown, capsule-shaped, film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have "RL75" debossed (stamped into) on one side and a break line on the other side.

The tablets are supplied with white, opaque plastic (HDPE) bottle containing 30 or 90 film-coated tablets. The bottle has a white, opaque plastic (polypropylene) child-resistant screw cap.

Supplier and Manufacturer

Supplier

Sun Pharmaceutical Industries Limited
Sun House, 201 B/1
Western Express Highway
Goregaon (East)
Mumbai 400 063
India
Tel. No.: (+91 22) 4324 4324
Fax. No.: (+91 22) 4324 4343
Email:pharmacovigilance.africasme@sunpharma.com
Complaintdesk.Tandalja@sunpharma.com

Manufacturer

Sun Pharmaceutical Industries Limited
Village Ganguwala, Paonta Sahib
District Sirmour
Himachal Pradesh
173 025
India
Tel. No.: (+91 1704) 227700, (+91 1704) 227779
Fax. No.: (+91-1704) 223492
Email:Complaintdesk.Tandalja@sunpharma.com

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

This leaflet was last revised in August 2026

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