

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/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[HA718 trade name][†]
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 [HA718 trade name] is and what it is used for
2. What you need to know before you take [HA718 trade name]
3. How to take [HA718 trade name]
4. Possible side effects
5. How to store [HA718 trade name]
6. Contents of the pack and other information

1. What [HA718 trade name] is and what it is used for

[HA718 trade name] contains the active ingredient dolutegravir. Dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors.

[HA718 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).

[HA718 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.

[HA718 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 [HA718 trade name]

Don't take [HA718 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 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 [HA718 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 [HA718 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 [HA718 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 [HA718 trade name] works or increase side effects. [HA718 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 [HA718 trade name].

Taking [HA718 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 [HA718 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

[HA718 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.

Excipients

Each tablet contains mannitol, which may have a mild laxative effect. In addition, each tablet contains 0.117 mg of sunset yellow FCF (E110), a colouring agent which may cause allergic reactions.

3. How to take [HA718 trade name]

Always take [HA718 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 [HA718 trade name].

Children and adolescents

The dose of [HA718 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 [HA718 trade name] should **not** take [HA718 trade name].

[HA718 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 [HA718 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 [HA718 trade name] or take [HA718 trade name] at least 2 hours after taking an antacid, calcium or iron supplement, or multivitamins.

You can take [HA718 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 [HA718 trade name] with food.

If you take more [HA718 trade name] than you should

If you take too many tablets of [HA718 trade name], contact your health care provider for advice. If possible, show them the [HA718 trade name] pack.

If you forget to take [HA718 trade name]

If you miss a dose of [HA718 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 [HA718 trade name] without advice from your health care provider

Take [HA718 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 [HA718 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 [HA718 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 bottle, after 'EXP'. The expiry date refers to the last day of that month.

For bottles containing 90 tablets, any unused tablets should be discarded 3 months after first opening the bottle. On the day when you first open the bottle, work out the 'Discard after date', which is 3 months from that day. Write this in the space provided in the labelling.

Do not use this medicine if you notice visible signs of deterioration.

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 [HA718 trade name] contains

The active ingredient is dolutegravir.

The other ingredients of [HA718 trade name] are:

Core tablet: mannitol, microcrystalline cellulose, sodium starch glycolate, povidone, sodium stearyl fumarate

Film coat: polyvinyl alcohol, titanium dioxide, macrogol/polyethylene glycol, talc, sunset yellow FCF (E 110)

What [HA718 trade name] looks like and contents of the pack

[HA718 trade name] is a light orange, round-shaped, biconvex, film-coated tablets debossed with 'LA54' on one side and plain on the other side.

[HA718 trade name] comes in a white opaque high-density polyethylene (HDPE) bottle with a polypropylene child-resistant closure and induction sealing wad.

Pack sizes: 30 and 90 tablets.

Supplier and Manufacturer

Supplier

Laurus Labs Limited
2nd Floor, Serene Chambers, Road No.7
Banjara Hills, Hyderabad, Shameerpet
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Email: rafdf@lauruslabs.com

Manufacturer

Laurus Labs Limited (Unit -2)
Plot No. 19, 20 & 21
Western Sector, APSEZ,
Gurajapalem Village,
Rambilli Mandal, Anakapalli,
Andhra Pradesh 531011
India

“For any information about this medicinal product, please contact the supplier”

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Section 6 updated in May 2023

Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/prequal/>.