

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
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Information for the patient

[HA746 trade name][†]

Dolutegravir (sodium)/lamivudine/tenofovir disoproxil fumarate

*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 [HA746 trade name] is and what it is used for
2. What you need to know before you take [HA746 trade name]
3. How to take [HA746 trade name]
4. Possible side effects
5. How to store [HA746 trade name]
6. Contents of the pack and other information

1. What [HA746 trade name] is and what it is used for

[HA746 trade name] is a medicine used to treat HIV (human immunodeficiency virus) infection in adults and adolescents who weigh at least 30 kg.

[HA746 trade name] may also be used to reduce the risk of getting HIV infection in patients who have been exposed to HIV. This is called post-exposure prophylaxis (PEP).

The medicine contains three active ingredients: dolutegravir, lamivudine and tenofovir disoproxil. Dolutegravir belongs to a group of HIV medicines called integrase inhibitors. Tenofovir is a nucleotide reverse transcriptase inhibitor, while lamivudine belongs to the group of the nucleoside analogue reverse transcriptase inhibitors.

[HA746 trade name] does not cure HIV infection but 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.

[HA746 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.

[†] 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 [HA746 trade name]

Do not take [HA746 trade name] if you are:

- allergic to dolutegravir, tenofovir disoproxil, lamivudine 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 are taking [HA746 trade name]. Read the information on side effects in Section 4 of this leaflet. Speak to your health care provider if you have any concerns.

Your health care provider will monitor your HIV treatment regularly. They may carry out blood tests or other checks to ensure your treatment is working correctly.

Kidney disease

[HA746 trade name] may affect your kidneys. Before starting this medicine you may need blood tests to check how well your kidneys are working. Blood tests may also be required during treatment to check the health of your kidneys.

Tell your health care provider if you have had kidney disease or if tests have shown problems with your kidneys. If so, your health care provider may give you a different treatment.

[HA746 trade name] is not usually taken with other medicines that can damage your kidneys (see “Other medicines and [HA746 trade name].”). If this is unavoidable, you may need regular tests to check how well your kidneys are working.

Liver disease

Tell your health care provider if you have a history of liver disease, including hepatitis.

HIV-infected patients with liver disease, including chronic hepatitis B or C, may be at higher risk of severe liver complications during treatment. If you are infected with HIV and hepatitis B virus, your health care provider will carefully consider the best treatment for you. If you have a history of liver disease or chronic hepatitis B infection your health care provider may conduct blood tests to monitor your liver function.

Bone problems

Tell your health care provider if you have bone problems such as osteoporosis (low bone density) or a history of fractures.

Some patients taking treatments for HIV may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). You should tell your health care provider if you get signs of this condition while taking [HA746 trade name]. See ‘Joint pain, stiffness and bone problems’ under section 4 of this leaflet, which describes the signs you should look out for.

Children

[HA746 trade name] is suitable only for adolescents who weigh at least 30 kg. Other medicines that contain smaller amounts of dolutegravir, lamivudine and tenofovir are needed for patients who weigh less than 30 kg.

Other medicines and [HA746 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 [HA746 trade name] works or increase side effects. [HA746 trade name] can also affect how some other medicines work.

You **must not** take [HA746 trade name] with dofetilide, which is used to treat heart conditions or fampridine (used in treatment of 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.
- calcium supplements, iron supplements and multivitamins
- rifampicin or rifapentine 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

Other HIV medicines

Tell your health care provider before you start this medicine if you are already taking any medicines for HIV.

[HA746 trade name] contains a combination of medicines to treat HIV. You may not need other medicines for HIV when you take [HA746 trade name], or doses may need to be adjusted to reduce the risk of side effects or ensure treatment works properly. Your health care provider will discuss your HIV treatment with you when prescribing this medicine.

Medicines that affect your kidneys

It is very important for your health care provider to know if you are taking other medicines that may damage your kidneys. These include:

- aminoglycosides, pentamidine or vancomycin (for bacterial infection)
- amphotericin B (for fungal infection)
- foscarnet, ganciclovir, or cidofovir (for viral infection)
- adefovir dipivoxil (for hepatitis B virus infection)
- tacrolimus (for suppression of the immune system)
- interleukin-2 (to treat cancer)
- non-steroidal anti-inflammatory drugs (NSAIDs, to relieve bone or muscle pains) such as aspirin and ibuprofen.

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

Medicines for hepatitis B or C

Some medicines for hepatitis B or C may contain similar active ingredients to [HA746 trade name]. Others may increase the risk of side effects or your treatment may not work properly. Make sure you tell your health care provider about any medicines you are taking for hepatitis B or C.

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 [HA746 trade name].

Do not stop taking [HA746 trade name] without checking with your health care provider, as this may harm you and your unborn baby.

Breastfeeding

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

Driving and using machines

[HA746 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 [HA737 trade name]

[HA746 trade name] contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance.

[HA746 trade name] contains mannitol, which may have a mild laxative effect.

It is important to consider the contribution of excipients from all the medicines that the patient is taking.

3. How to take [HA746 trade name]

Always take [HA746 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 and adolescents

The dose of [HA746 trade name] in adults and adolescents weighing at least 30 kg is one tablet once a day.

If your HIV infection is resistant to dolutegravir (one of the ingredients of [HA746 trade name], or to similar medicines, your health care provider may give you additional doses of a medicine containing dolutegravir to take as part of your treatment. He or she may also ask you to take your medicines with meals, to help them work better.

Adolescents whose HIV infection is resistant to such medicines will be given a different treatment instead, as [HA746 trade name] may not be suitable.

Your health care provider may also adjust your treatment if you are *taking some other medicines* that affect the way this medicine works. Discuss your treatment with your health care provider if you have any questions.

Children

[HA746 trade name] is not suitable for children weighing less than 30 kg and different formulations should be used.

Length of treatment

If you are **being treated for HIV**, you will need to keep on taking [HA746 trade name] unless your health care provider changes your HIV treatment.

If you are taking [HA746 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.

Taking [HA746 trade name] with food

You can usually take [HA746 trade name] with food or between meals. Swallow the tablets whole with some drinking water.

If your HIV infection is resistant to dolutegravir or similar medicines, your health care provider may recommend that you take your medicines with or just after a meal.

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 [HA746 trade name] or at least 2 hours after you take [HA746 trade name].

If you take more [HA746 trade name] than you should

If you take too many tablets of [HA746 trade name], contact your health care provider for advice. If possible, show them the [HA746 trade name] pack.

If you forget to take or if you vomit after taking [HA746 trade name]

If you forget to take a dose, take the missed dose as soon as you remember on the same day. If you do not remember on the same day, take the normal dose on the next day. Do not take a double dose to make up for forgotten dose. If you are unsure about what to do, ask your health care provider.

If you vomit within 1 hour of taking [HA746 trade name], then you should take an extra dose. If vomiting occurs more than an hour after taking the dose, then you do not need to take an extra dose and can take the next dose as usual when it is due.

Don't stop taking [HA746 trade name] without advice from your health care provider

Take [HA746 trade name] for as long as your health care provider recommends it. Don't stop unless your health care provider advises you to. Taking the tablets regularly is very important because the amount of virus may start to increase if the medicine is stopped for even a short time. The infection may then become harder to treat.

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

Allergic reactions are uncommon but can be serious. **See a health care provider straightaway** if you get an allergic reaction because the health care provider may decide that you should stop taking [HA746 trade name]. The signs of allergic reactions are:

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

Lactic acidosis

Lactic acidosis is a rare but serious side effect when too much of a waste product called lactic acid builds up in the blood. **Tell your health care provider right away** if your breathing changes and becomes fast and

deep, and you get muscle cramps, drowsiness or confusion, feel sick (nausea) or vomit, and have stomach pains. These may be signs of lactic acidosis.

Symptoms of infection and inflammation

People with advanced HIV infection (AIDS) have weakened immune systems and are more likely to develop other serious infections (opportunistic infections). Sometimes such infections may have spread in the body without symptoms, because the immune system was too weak to react to them. After starting treatment, the immune system becomes stronger, and may attack these hidden infections, which can cause symptoms of infection or inflammation. Symptoms usually include fever, plus some of the following:

- headache
- stomach ache
- difficulty breathing.

In rare cases, as the immune system becomes stronger, it can also mistakenly attack healthy body tissue (autoimmune disorders). The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection. Symptoms may include:

- palpitations (rapid or irregular heartbeat) or tremor
- hyperactivity (excessive restlessness and 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 right away**. Don't take other medicines for the infection without your health care provider's advice.

Other side effects

Very common side effects

These may affect more than 1 in 10 people

- rash
- headache
- lack of energy (asthenia)
- dizziness
- diarrhoea
- feeling sick (nausea) and vomiting

Tests may also show:

- abnormally low levels of phosphate in the blood

Common side effects

These may affect up to 1 in 10 people:

- weight gain
- cough, nasal symptoms
- tiredness
- hair loss
- fever
- itching (pruritus)
- muscle disorders and joint ache (arthralgia)
- abdominal (belly) pain and discomfort,
- wind (flatulence)
- difficulty sleeping (insomnia), abnormal dreams
- depression
- anxiety

Tests may also show:

- liver problems (increase in liver enzymes)

- increase in an enzymes produced in the muscle called creatine phosphokinase

Uncommon side effects

These may affect up to 1 in 100 people:

- yellow skin or eyes, itching, or pain in the abdomen (belly) caused by inflammation of the liver (hepatitis)
- muscle pain (myalgia) and muscle weakness
- breakdown of muscle fibres (rhabdomyolysis)
- panic attack
- suicidal thoughts and behaviours (particularly in patients who have had depression or mental health problems before)
- allergic reactions
- appearance of symptoms of infection (see 'Symptoms of infection and inflammation', above)

Tests may also show

- increased creatinine in your blood (a sign of kidney problems)
- a decreased number of cells involved in blood clotting (thrombocytopenia)
- a low red blood cell count (anaemia) or low white blood cell count (neutropenia)

Rare side effects

These may affect up to 1 in 1000 people:

- pain in the belly (abdomen) caused by inflammation of the pancreas
- lactic acidosis (excess of lactic acid in the blood)
- liver failure
- fatty liver
- swelling under the skin (angioedema)
- inflammation of the kidney, passing a lot of urine and feeling thirsty
- changes to your urine and back pain caused by kidney problems, including kidney failure
- softening of the bones (with bone pain and sometimes resulting in fractures)
- muscle disease causing weakness (myopathy)

Tests may also show

- damage to kidneys
- increase in an enzyme called amylase (pancreas problems)

Very rare side effects

These may affect up to 1 in 10 000 people

- nerve injury causing weakness and sensations of tingling, pricking, or numbness of the skin, especially in the feet and hands (peripheral neuropathy)
- a failure of the bone marrow to produce new red blood cells (pure red cell aplasia)

Tests may also show:

- damage to kidney tubule cells

Side effects with unknown frequency

- death of bone tissue (osteonecrosis)
- decreases in potassium in the blood

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

Joint pain, stiffness and bone problems

Some people taking combination therapy for HIV develop a condition called osteonecrosis. With this condition, parts of the bone tissue die because of reduced blood supply to the bone. People may be more likely to get this condition:

- if they have been taking HIV combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight.

Signs of osteonecrosis include:

- stiffness in the joints
- aches and pains in the joints (especially in the hip, knee or shoulder)
- difficulty moving.

If you notice any of these symptoms, tell your health care provider.

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.

If you get any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet.

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 [HA746 trade name]

Do not store above 30°C. Avoid excursions above 30°C.

90's HDPE Container

Should be used within 30 days, once opened

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

Do not use this medicine after the expiry date stated on the label and 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 [HA746 trade name] contains

- The active ingredients are dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate.
- The other ingredients of [HA746 trade name] are:

Core tablet: Lactose monohydrate, microcrystalline cellulose, pregelatinized starch,

croscarmellose sodium, magnesium stearate,mannitol, sodium starch glycolate, povidone, pigment yellow 42.

Film coat: Polyvinyl alcohol -partially hydrolysed, titanium dioxide, macrogol/polyethylene glycol, talc

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

What [HA746 trade name] looks like and contents of the pack

[HA746 trade name] is white, capsule-shaped, film coated tablet. They are biconvex (rounded on top and bottom) with a bevelled edge. The tablets have 'D15' debossed (stamped into the tablet) on one side and plain on the other side.

HDPE

[HA746 trade name] is provided in round, opaque white HDPE bottle containing 30 or 90 tablets. The bottle is closed with a white, polypropylene child resistant closure with white outer shell embossed with pictorial design and clear inner shell fitted with a heat seal and pulp liner. The bottle also contains one silica gel sachet as desiccant for 30's pack size and two silica gel sachet as desiccant for 90's pack size.

Supplier and Manufacturer

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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>