Information for the patient

[HA702 trade name]*
Dolutegravir/Lamivudine/Tenofovir disoproxil fumarate

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 get 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 [HA702 trade name] is and what it is used for
2. What you need to know before you take [HA702 trade name]
3. How to take [HA702 trade name]
4. Possible side effects
5. How to store [HA702 trade name]
6. Contents of the pack and other information

1. What [HA702 trade name] is and what it is used for

[HA702 trade name] is a medicine that contains three active ingredients: dolutegravir, tenofovir disoproxil and lamivudine. Dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors. Tenofovir is a nucleotide reverse transcriptase inhibitor, while lamivudine belongs to the group of the nucleoside analogue reverse transcriptase inhibitors.

[HA702 trade name] is used to treat HIV (human immunodeficiency virus) infection in adults and young people who weigh at least 30 kg.

[HA702 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 number of white blood cells, called CD4 cells, that are important for fighting infection.

[HA702 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 [HA702 trade name]

Do not take [HA702 trade name] if you are:

- allergic to dolutegravir, tenofovir disoproxil, lamivudine or any of the other ingredients of this medicine (listed in section 6)

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

- taking another medicine called dofetilide (to treat heart conditions).

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 [HA702 trade name].

Tell your healthcare provider about any flu-like illness – either in the month before starting [HA702 trade name], or at any time while taking [HA702 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.

Kidney disease

[HA702 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, the dose of tenofovir disoproxil and lamivudine may need to be reduced. In such cases formulations of tenofovir disoproxil and lamivudine other than [HA702 trade name]should be used.

[HA702 trade name]is not usually taken with other medicines that can damage your kidneys (see "Other medicines and [HA702 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, hepatitis. HIV-infected patients with liver disease, including chronic hepatitis B or C, who are treated with antiretrovirals, have a higher risk of severe and potentially fatal liver complications. 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.

Look out for infections

In some patients with advanced HIV infection (AIDS) and a history of AIDS-associated (opportunistic) infection, signs and symptoms of inflammation from such previous infections may occur soon after anti-HIV treatment is started. These symptoms may be due to an improvement in the body's immune response, enabling the body to fight infections that may have been present without obvious symptoms. Autoimmune disorders (the immune system attacking healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. They may occur many months after starting treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness

beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please tell your health care provider immediately to seek necessary treatment.

Bone problems

Some patients taking combination antiretroviral therapy may develop a bone disease called *osteonecrosis* (death of bone tissue caused by loss of blood supply to the bone). The duration of antiretroviral therapy, use of a corticosteroid such as dexamethasone or prednisolone, alcohol consumption, severe immunosuppression, and being overweight may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these, tell your health care provider. Bone problems (sometimes resulting in fractures) may also occur due to damage to the kidney cells (see section 4, Possible side effects).

Children

[HA702 trade name] is suitable only for children and young people who weigh at least 40 kg. Other medicines that contain smaller amounts of dolutegravir, tenofovir or lamivudine are needed for patients who weigh less than 30 kg.

Other medicines and [HA702 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 [HA702 trade name] with dofetilide, which is used to treat heart conditions.

Some medicines can affect how [HA702 trade name] works or increase side effects. [HA702 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. Do not take an antacid during the 6 hours before you take [HA702 trade name], or for at least 2 hours after you take it
- calcium supplements, iron supplements and multivitamins. Do not take a calcium supplement, iron supplement or multivitamin during the 6 hours before you take [HA702 trade name], or for at least 2 hours after you take it
- 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
- other medicines containing tenofovir disoproxil, emtricitabine, lamivudine or zalcitabine to treat HIV infection

It is very important to tell your health care provider 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).

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

Other medicines containing didanosine (for HIV infection):

Taking [HA702 trade name] with medicines that contain didanosine can increase the amount of didanosine in your blood. Rarely, inflammation of the pancreas and lactic acidosis (excess lactic acid in the blood), sometimes causing death, has been reported when medicines containing tenofovir disoproxil and didanosine were taken together. Combining tenofovir disoproxil with didanosine can also reduce the effects of antiretroviral therapy. Your health care provider will carefully consider whether to treat you with a combination of tenofovir disoproxil and didanosine.

If you are taking another antiviral medicine called a protease inhibitor to treat HIV, your healthcare provider may order blood tests to closely monitor your kidney function.

It is also important to tell your health care provider if you are taking ledipasvir/sofosbuvir, sofosbuvir/velpatasvir or sofosbuvir/velpatasvir/voxilaprevir to treat hepatitis C infection.

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 [HA702 trade name]. Your health care provider will review your treatment.

Taking [HA702 trade name] around the time you become pregnant or during the first weeks of pregnancy, may increase the risk of a type of birth defect, called neural tube defect (e.g. spina bifida).

Do not discontinue [HA702 trade name] without consulting your health care provider, as this may harm you and your unborn child.

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

[HA702 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 [HA702 trade name]

This medicine contains less than 1 mmol sodium (1 mg) per tablet, that is to say, is essentially 'sodium-free'. It is important to consider the contribution of ingredients from all the medicines that the patient is taking.

3. How to take [HA702 trade name]

Always take [HA702 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.

The usual dose is one tablet once a day.

You can take [HA702 trade name] with food or between meals.

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 [HA702 trade name] or take [HA702 trade name] at least 2 hours after taking an antacid, calcium or iron supplement, or multivitamins.

Children and adolescents

The dose of [HA702 trade name] in children and adolescents weighing at least 30 kg is one tablet once a day.

Children and adolescents whose HIV infection is resistant to medicines similar to [HA702 trade name] should **not** take [HA702 trade name].

[HA702 trade name] is not suitable for children weighing less than 30 kg and different formulations should be used.

If you take more [HA702 trade name] than you should

If you take too many tablets of [HA702 trade name], contact your health care provider for advice. If possible, show them the [HA702 trade name] pack.

If you forget to take [HA702 trade name]

If you miss a dose of [HA702 trade name], take it as soon as you remember. But if your next dose is due within 12 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.

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 [HA702 trade name]. The signs of allergic reactions are:

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

Lactic acidosis (excess lactic acid in the blood) is a **rare** (can affect up to 1 in every 1,000 patients) but serious side effect that can be fatal. The following side effects may be signs of lactic acidosis:

- deep, rapid breathing
- drowsiness
- feeling sick (nausea), being sick (vomiting) and stomach pain

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

headache
diarrhoea
feeling sick (nausea)

difficulty in sleeping (*insomnia*)

Tests may also show:

- abnormally low levels of phosphate in the blood

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, tiredness

Tests may also show:

- liver problems
- increase in an enzyme called creatine kinase

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

allergic reaction (see description above)
pain in the tummy (abdomen) caused by inflammation of the pancreas
yellow skin or eyes, itching, or pain in the abdomen (tummy) caused by inflammation of the liver
joint and muscle pain
bone pain and bone fracture which may be caused by kidney damage (see Warnings and precautions).
suicidal thoughts and behaviours (particularly in patients who have had depression or mental health problems before)

Tests may also show

- decreases in potassium in the blood
- pancreas 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 (which may affect up to 1 in 1000 people)

lactic acidosis (excess of lactic acid in the blood).
fatty liver
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

Tests may also show

- damage to kidneys
- increased creatinine in your blood
- increase in an enzyme called *amylase*

Very rare side effects (which may affect up to 1 in 10000 people)

numbness, tingly feelings in the skin (pins and needles)
a failure of the bone marrow to produce new red blood cells (pure red cell aplasia).

Side effects with unknown frequency:

- increases in blood fats (hyperlipaemia) and an abnormal increase in blood sugar. Your health care provider will test for these changes.
- appearance of symptoms of infection as part of the 'immune reactivation syndrome' (see Warnings and precautions).

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.

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 provide more information on the safety of this medicine.

5. How to store [HA702 trade name]

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

Do not store above 30ºC. Store in the original container.
Discard 90 days after first opening. (This is only applicable to pack sizes of 90 and 500).

Do not use this medicine after the expiry date stated on the label after 'EXP'. The expiry date refers to the last day of that month.

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 [HA702 trade name] contains

The active ingredients in this medicine are dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate. Each tablet contains 50mg dolutegravir (as sodium), 300mg lamivudine and 300mg tenofovir disoproxil fumarate.

The other ingredients are:
Core tablet: mannitol, microcrystalline cellulose, sodium starch glycolate, povidone, croscarmellose sodium magnesium stearate and hydroxypropyl methylcellulose.

Film coat: polyvinyl alcohol, talc, titanium dioxide, sodium lauryl sulfate, FD& C blue #2/indigo carmine and FD& C blue #1/brilliant blue FCF aluminium lake.
This medicine contains less than 1 mmol sodium (1 mg) per tablet, that is to say, is essentially 'sodium-free'.

What [HA702 trade name] looks like and contents of the pack

Blue-coloured, capsule-shaped, biconvex, film-coated tablet debossed with 'C' on one side and plain on the other side.

[HA702 trade name] is available in white HDPE bottle with two 2 gram silica gel bags and closed with white non-child resistant cap. Each bottle contains 30 or 90 tablets.

[HA702 trade name] is also available in white HDPE bottle with four 5 gram silica gel bags and closed with white non-child resistant cap. Each bottle contains 500 tablets.

Supplier
Cipla Limited
Cipla House, Peninsula Business Park,
Ganpatrao, Kadam Marg, Lower Parel,
Mumbai, Maharashtra 400013,
India
Tel. No.:+ 91222482600
Fax No.: +912224826120

Manufacturer
Cipla Limited, Goa Unit VII
Verna Industrial Estate
Verna, Salcette
Goa-403 722
India

Cipla Limited
Unit VII PD II
Verna Industrial Estate
Verna, Salcette
Goa-403 722
India
Tel. No.: +91 832 2889 000/199
Fax No.: +91-832-2782805

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

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

Label Artwork for Container of Pack Size of 30's enclosed