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

[HA732 trade name][†]
Efavirenz/lamivudine/tenofovir disoproxil fumarat

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 [HA732 trade name] is and what it is used for
2. What you need to know before you take [HA732 trade name]
3. How to take [HA732 trade name]
4. Possible side effects
5. How to store [HA732 trade name]
6. Contents of the pack and other information

1. What [HA732 trade name] is and what it is used for

[HA732 trade name] is an antiretroviral medicine used to treat HIV infection in patients weighing at least 30 kg.

[HA732 trade name] contains three active substances that are used to treat HIV infection:

- efavirenz, a medicine of a type called non-nucleoside reverse transcriptase inhibitor (NNRTI)
- lamivudine, a medicine of a type called nucleoside reverse transcriptase inhibitor (NRTI)
- tenofovir disoproxil, a medicine of a type called nucleotide reverse transcriptase inhibitor (NtRTI)

Each of these active substances blocks an enzyme (reverse transcriptase) that is essential for the virus to multiply.

[HA732 trade name] reduces 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 of passing on the virus.

2. What you need to know before you take [HA732 trade name]

Do not take [HA732 trade name] if:

- you are allergic (hypersensitive) to efavirenz, lamivudine, tenofovir disoproxil or any of the other ingredients of [HA732 trade name] listed at the end of this leaflet (section 6).
- you have severe liver disease.

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

- you have a heart condition, such as abnormal rhythm or rate of your heartbeat, a slow heartbeat, or severe heart disease.
- any member of your family (parents, grandparents, brothers or sisters) has died suddenly from a heart problem or has a condition that can affect their heart rhythm.
- your health care provider has told you that you have high or low levels of electrolytes such as potassium or magnesium in your blood.
- you are taking any of the following medicines:
  - **amiodarone** (used to correct irregular heart rhythm)
  - **amodiaquine** (used to treat malaria)
  - **astemizole** or **terfenadine** (used to treat hay fever or other allergies)
  - **bepridil** (used to treat heart disease)
  - **elbasvir** and **grazoprevir** (for hepatitis C infection)
  - **ergotamine, dihydroergotamine, ergonovine,** and **methylergonovine** (used to treat migraines and cluster headaches)
  - **midazolam** (used as a sedative before an operation or to control fits)
  - **pimozide** (used to treat certain mental conditions)
  - **St John´s wort** (*Hypericum perforatum*, a herbal remedy used for depression and anxiety)
  - **triazolam** (used to help you sleep)
  - **voriconazole** (a drug used against fungal infections)

If this applies to you, tell your health care provider immediately. Taking these medicines with [HA732 trade name] could cause serious or life-threatening side effects or stop these medicines from working properly.

Warnings and precautions

Tell your health care provider if you:

- have or have had **kidney disease**, or if tests have shown problems with your kidneys. This medicine may affect your kidneys. [HA732 trade name] is not recommended if you have moderate to severe kidney disease.

  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.
- have **bone problems**, including osteoporosis, or if you have had fractures. Because [HA732 trade name] can sometimes cause bone damage, tell your health care provider if you have bone or joint pain or if you get a fractures.
- have or have had **a mental illness**, including depression, or have been addicted to alcohol or other substances. Tell your health care provider immediately if you feel depressed, have suicidal thoughts or have strange thoughts (see section 4, *Possible side effects*).
- have or have had **convulsions (fits or seizures)** or if you are being treated with epilepsy medicines such as carbamazepine, phenobarbital and phenytoin. If you are taking any of these medicines, your health care provider may need to check the level of the epilepsy medicine in your blood. Your health care provider may give you a different epilepsy medicine.
- have or have had **liver disease, including hepatitis.** Patients being treated with [HA732 trade name] who also have liver disease (including chronic hepatitis B or C) have a higher risk of severe and potentially life-threatening liver problems. Your health care provider may arrange blood tests to check how well your liver is working or may switch you to another medicine. If you have severe liver disease, do not take [HA732 trade name].

- have **hepatitis B infection.** There is a risk of liver problems when you stop taking [HA732 trade name], so tell your health care provider of any new or unusual symptoms you associate with hepatitis B infection. Do not to stop taking [HA732 trade name] without talking to your health care provider. If you have stopped taking [HA732 trade name], your health care provider may recommend starting another hepatitis B treatment.
- have a **heart disorder**, such as abnormal electrical activity called prolongation of the QT interval.

Once you start taking [HA732 trade name], look out for:

- **dizziness, difficulty sleeping, drowsiness, difficulty concentrating or abnormal dreaming.** These side effects may start in the first 2 days of treatment and usually go away after the first 2 to 4 weeks.
- **skin rash.** [HA732 trade name] can cause rashes, which get better after a couple of weeks. However, if you have a severe rash with blistering or fever, stop taking this medicine and tell your health care provider at once. If you had a rash while taking a type of medicine called non-nucleoside reverse transcriptase inhibitor (NNRTI), you may be at higher risk of getting a rash with [HA732 trade name].
- **any signs of inflammation or infection.** If your immunity is weak when you start [HA732 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.
- **pancreatitis**. [HA732 trade name] can cause pancreatitis (sudden inflammation of the pancreas). Tell your health care provider at once if you get severe pain in your upper abdomen or if you feel sick (nausea) or you are sick (vomiting).

Other medicines and [HA732 trade name]

You must not take [HA732 trade name] with certain medicines. These are listed under "Do not take [HA732 trade name] if", at the start of Section 2. They include some common medicines and some herbal remedies (St. John's wort).

Also, you should not take [HA732 trade name] with any other medicines that contain efavirenz (unless recommended by your health care provider), lamivudine, tenofovir disoproxil, tenofovir alafenamide, emtricitabine or adefovir dipivoxil.

Tell your health care provider if you are taking other medicines that may damage your kidneys. These include:

- aminoglycosides, vancomycin (medicines for bacterial infections)
- amphotericin B (a medicine for fungal infections)
- cidofovir, foscarnet, ganciclovir (medicines for viral infections)
- interleukin-2 medicines such as aldesleukin (used to treat cancer)
- non-steroidal anti-inflammatory drugs (NSAIDs, to relieve bone or muscle pains)
- pentamidine (a medicine for *Pneumocystis jirovecii* pneumonia and parasite infections)

[HA732 trade name] may interact with other medicines, including herbal preparations. As a result, the amounts of [HA732 trade name] or other medicines in your blood may be affected. This may stop your medicines from working properly or may make any side effects worse. In some cases, your health care provider may need to adjust your dose or check your blood levels.

It is important to tell your health care provider if you are taking any of the following:

- Other medicines used for HIV infection including: atazanavir, darunavir, didanosine, lopinavir, maraviroc, raltegravir, and ritonavir.
- Adefovir dipivoxil, used to treat hepatitis B virus infection.

- Daclatasvir, glecaprevir/pibrentasvir, sofosbuvir, sofosbuvir/ledipasvir, sofosbuvir/velpatasvir, and sofosbuvir/velpatasvir/voxilaprevir used to treat hepatitis C virus infection.
- Clarithromycin, rifabutin, rifampicin, sulfadiazine, trimethoprim/sulfamethoxazole, used to treat bacterial infections, including tuberculosis and AIDS-related *Mycobacterium avium* complex.
- Flucytosine, itraconazole ketoconazole or posaconazole (antifungals), used to treat fungal infections.
- Praziquantel, used to treat parasitic infections.
- Halofantrine, lumefantrine, mefloquine, quinine, and combination of atovaquone with proguanil, and artemether with lumefantrine, used to treat malaria.
- Dronedarone, flecainide, and quinidine, used to correct irregular heart rhythm.
- Atorvastatin, pravastatin, simvastatin (statins), used to lower blood fats.
- Carbamazepine, phenytoin, phenobarbital, used to treat epilepsy.
- Hormonal contraceptive, such as birth control pills, an injected contraceptive, or a contraceptive implant.
- Hormone replacement therapy, to relieve symptoms of the menopause.
- Buprenorphine, methadone, morphine used for severe pain or for managing opioid addiction.
- Citalopram, escitalopram, imipramine and sertraline, used to treat depression.
- Chlorpromazine, haloperidol and quetiapine, medicines to treat certain psychiatric conditions.
- Bupropion, used to treat depression or to help you stop smoking.
- Diltiazem, felodipine, nicardipine, nifedipine and verapamil (calcium channel blockers), used to treat high blood pressure and conditions related to the heart.
- Ciclosporin, sirolimus, tacrolimus (immunosuppressants), used to prevent organ transplant rejection.
- Cisplatin, cladribine, ifosfamide, medicines for cancer.
- Acenocoumarol and warfarin, used to prevent blood clots.
- *Ginkgo biloba* extracts (herbal preparation).
- Medicines that contain lactitol, maltitol, mannitol, sorbitol or xylitol (these substances can be used to manage constipation or they may be additives in some medicines and foods).

[HA732 trade name] with food and drink

Taking [HA732 trade name] on an empty stomach may reduce some side effects. Do not take grapefruit juice when you are being treated with [HA732 trade name].

Pregnancy and breast-feeding

Effective treatment of HIV during pregnancy is important to protect you and your baby. Tell your health care provider if you are pregnant or trying to become pregnant. Do not stop taking [HA732 trade name] without checking with your health care provider, as this may harm you and your unborn baby.

If you are interested in breast-feeding your baby, discuss the risks and benefits with your health care provider.

Driving and using machines

[HA732 trade name] can make you feel dizzy and sleepy, and it can reduce concentration. If you have any of these side effects, do not drive and do not use any hazardous tools or machines.

Other ingredients of [HA732 trade name]

Lactose is a source of glucose and galactose. If you have one of the rare genetic disorders galactosaemia, or glucose-galactose intolerance or congenital lactase deficiency you must talk to your health care provider before taking this medicine.

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

3. How to take [HA732 trade name]

Always take this medicine exactly as your health care provider has told you to. This is to make sure that your medicine continues to work well. Do not change the dose unless your health care provider tells you to. Check with your health care provider if you are not sure how to take [HA732 trade name].

The recommended dose for patients weighing at least 30 kg is **1 tablet taken each day**.

Take [HA732 trade name] on an **empty stomach** (1 hour before or 2 hours after a meal), preferably at bedtime as this can make some side effects (for example, dizziness, drowsiness) less troublesome. Swallow [HA732 trade name] whole with water.

If you take more [HA732 trade name] than you should

If you accidentally take too many [HA732 trade name], contact your health care provider or the nearest emergency department for advice. Take the medicine pack and this leaflet with you so that you can easily describe what you have taken.

If you forget to take or if you vomit after taking [HA732 trade name]

It is important not to miss a dose.

If you do miss a dose and it's less than 12 hours after it was due, take it as soon as you can, and then take your next dose at its regular time.

However, if your next dose is due within 12 hours, do not take the missed dose. Wait and take the next dose at the regular time. Do not take a double dose to make up for a forgotten tablet.

If you vomit (throw up) within 1 hour of taking [HA732 trade name], you should take another tablet. Do not wait until your next dose is due. You do not need to take another tablet if you vomit more than an hour after taking [HA732 trade name].

Do not stop taking [HA732 trade name]

Do not stop taking this medicine without talking to your health care provider. If you stop this medicine any future treatment may not work well enough. If you have stopped taking [HA732 trade name], speak to your health care provider before you start taking the medicine again. Your health care provider may consider changing your medicines if you are having problems.

If you have both HIV infection and hepatitis B, it is especially important not to stop your [HA732 trade name] treatment without talking to your health care provider first.

If you have any further questions about this medicine, ask your health care provider.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible serious side effects: tell your health care provider immediately

- **Lactic acidosis** (excess lactic acid in the blood) is a rare but serious side effect that can be life-threatening. The following side effects may be signs of lactic acidosis:
  - deep rapid breathing
  - drowsiness
  - feeling sick (nausea), being sick (vomiting) and stomach pain.
- **Serious psychiatric symptoms** including severe depression, suicide attempts, aggressive behaviour, paranoia, and psychosis-like symptoms may occur. Talk to your health care provider at once if you think you are having these psychiatric symptoms.
- **Signs of inflammation or infection**. 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.

- **Rash.** Talk to your health care provider if you get a rash with blistering and flu-like effects, because some rashes may be serious. Rash is more common in children than in adults.
- **Kidney problems.** Talk to your health care provider if you pass a lot of urine and feel thirsty, if you notice a change to your urine and have back pain, since these may be signs of kidney problems, including kidney failure.
- **Pancreatitis.** Tell your health care provider if you get pain in the abdomen (belly) as this may be a sign of pancreatitis (inflammation of the pancreas).
- **Liver failure**, in some cases leading to death or liver transplant. Speak with your health care provider straightaway if you:
  - lose your appetite, or get nausea (feel sick), or feel tired all the time, or you have a rash

  and you have any of the following
  - belly pain, usually on the right side and near the chest
  - unexplained itching
  - yellowing of the white parts of your eyes, your nails or your skin
  - passing dark urine
  - passing stools that are very pale

  These are signs of a problem with your liver, which can become serious.

If you think that you may have any of these serious side effects, talk to your health care provider.

Nervous system side effects

Nervous system side effects such as dizziness, drowsiness and trouble concentrating usually occur when treatment is first started and usually improve in the first few weeks. If these effects are troublesome, your health care provider may suggest that you take [HA732 trade name] at bedtime and on an empty stomach.

Possible side effects

The following side effects are **very common** (*may affect more than 1 in 10 patients*):

- dizziness, diarrhoea, feeling sick (nausea), being sick (vomiting)
- rashes (including red spots or blotches sometimes with blistering and swelling of the skin), which may be allergic reactions
- feeling weak

Tests may also show:

- decreases in phosphate levels in the blood

The following side effects are **common** (*may affect up to 1 in 10 patients*):

- belly pain
- difficulty sleeping, abnormal dreams, difficulty concentrating, drowsiness
- feeling worried or depressed
- problems with digestion resulting in discomfort after meals, feeling bloated, wind (flatulence)
- tiredness
- itching
- hair loss
- disturbances of coordination and balance
- headache
- joint pain, muscle pain
- softening of the bones
- cough
- irritated or runny nose

- fever (high temperature)
- general feeling of being unwell

Tests may also show:

- increased fatty acids (triglycerides) in the blood
- liver problems

The following side effects are **uncommon** (*may affect up to 1 in 100 patients*):

- blurred vision
- a feeling of spinning or tilting (vertigo), whistling, ringing or other persistent noise in the ears
- flushing
- breast enlargement in males
- breakdown of muscle, muscle pain or weakness with kidney damage
- kidney problems
- allergic reactions
- suicidal thoughts and behaviours
- angry behaviour, mood swings, euphoria
- seeing or hearing things that are not really there (hallucinations)
- mania (mental condition with episodes of overactivity, elation or irritability)
- paranoia
- ataxia (difficulty with walking, speaking, swallowing, movement and eye control)
- catatonia (being motionless and speechless for a period)
- nervousness, forgetfulness, confusion
- fits (convulsions)
- tremor (shaking)
- abnormal thoughts
- pain in the abdomen (belly) caused by inflammation of the pancreas
- yellow skin or eyes, itching, or pain in the abdomen (belly) caused by inflammation of the liver (hepatitis)
- severe skin reactions with painful blistering and flu-like effects (erythema multiforme, Stevens-Johnson syndrome)

Tests may also show:

- low white blood cell count that help defend against infections and low red blood cell count (anaemia)
- low levels of blood platelets which can lead to bleeding and bruising
- increased cholesterol in the blood
- decreases in potassium in the blood
- increases in creatinine in the blood

The following side effects are **rare** (*may affect up to 1 in 1,000 patients*)

- lactic acidosis (see above, *Possible serious side effects*)
- itchy rash to the skin caused by a reaction to sunlight
- swelling of the face, lips, tongue or throat (angioedema)
- lactic acidosis (see above, *Possible serious side effects*)
- liver failure (signs may include yellowing of the skin and the whites of the eyes or unusually dark urine), build-up of fat in the liver (hepatic steatosis)
- inflammation of the kidney, passing a lot of urine and feeling thirsty, kidney failure, damage to kidney tubule cells
- unexplained feelings of distress not associated with hallucinations, but it may be difficult to think clearly or sensibly
- false beliefs
- suicide

- muscle disease causing weakness, cramps and tiredness
- softening of the bones (with bone pain and sometimes resulting in fractures)

Tests may also show:

- increase in an enzyme called amylase

The following side effects are **very rare** (*may affect up to 1 in every 10,000 patients*)

- a failure of the bone marrow to produce new red blood cells (pure red cell aplasia)
- tingling or numbness of the arms, legs, hands or feet

The frequency of the following side effects is **not known**:

- **Bone problems**. Some patients taking a combination of antiretroviral medicines such as [HA732 trade name] may develop a bone disease called osteonecrosis (permanent bone damage caused by loss of blood supply to the bone). Taking this type of medicine for a long time, taking corticosteroids, drinking alcohol, having a very weak immune system and being overweight may be some of the many risk factors for developing this disease. Signs of osteonecrosis are:
  - joint stiffness
  - joint aches and pains (especially of the hip, knee and shoulder)
  - difficulty with movement.

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 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 [HA732 trade name]

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

Do not store above 30°C. Avoid excursions above 30°C. Store in the original container. Keep the bottle tightly closed.

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.

Do not use this medicine if you notice 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 [HA732 trade name] contains

- The active ingredients are efavirenz 400 mg, lamivudine 300 mg and tenofovir disoproxil fumarate 300 mg.
- The other ingredients of [HA732 trade name] are:
  - *Core tablet*: microcrystalline cellulose, sodium lauryl sulfate, hydroxypropyl cellulose, croscarmellose sodium, lactose monohydrate, magnesium stearate, ferric oxide yellow
  - *Film coat*: polyvinyl alcohol, 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 [HA732 trade name] looks like and contents of the pack

[HA732 trade name] is white to off-white, oval film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have a 'L40' debossed (stamped into) on one side and are plain on the other side.

Bottle with silica gel canister
[HA732 trade name] is provided in a white, opaque HDPE bottle containing 30, 90 and 180 tablets. The HDPE container is sealed with an aluminium foil seal and an opaque white, childproof plastic (polypropylene) screw cap. The bottle also contains a 3g silica gel canister.

Bottle with molecular sieve canister
[HA732 trade name] is provided in a white, opaque HDPE bottle containing 30, 90 and 180 tablets. The HDPE container is sealed with an aluminium foil seal and an opaque white, childproof plastic (polypropylene) screw cap. The bottle also contains a 1g molecular sieve canister.

Supplier and Manufacturer

Supplier

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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