

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

[HA553 trade name][†]

Efavirenz/emtricitabine/tenofovir disoproxil fumarate

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 [HA553 trade name] is and what it is used for
2. What you need to know before you take [HA553 trade name]
3. How to take [HA553 trade name]
4. Possible side effects
5. How to store [HA553 trade name]
6. Contents of the pack and other information

1. What [HA553 trade name] is and what it is used for

[HA553 trade name] is an antiretroviral medicine used for the treatment of HIV infection in patients weighing at least 35 kg.

[HA553 trade name] contains three active substances that are used to treat HIV infection:

- Efavirenz is a medicine of a type called non-nucleoside reverse transcriptase inhibitor (NNRTI)
- Emtricitabine is a medicine of a type called nucleoside reverse transcriptase inhibitor (NRTI)
- Tenofovir disoproxil is a medicine of a type called nucleotide reverse transcriptase inhibitor (NtRTI)

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

[HA553 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 passing on the virus.

2. What you need to know before you take [HA553 trade name]

Do not take [HA553 trade name] if:

- you are allergic to efavirenz, emtricitabine, tenofovir disoproxil or to 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.

- you have severe liver disease.
- 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 was born with heart problems.
- 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 and terfenadine (used to treat hay fever or other allergies)
 - bepridil (used to treat heart disease)
 - elbasvir or 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*) (herbal remedy for depression and anxiety)
 - triazolam (used to help you sleep)
 - voriconazole (used to treat fungal infections)

If you are taking any of these medicines, tell your health care provider immediately. Taking these medicines with [HA553 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.

[HA553 trade name] may harm your kidneys. Before starting treatment, your health care provider may order blood tests to check how well your kidneys are working. The health care provider may also order blood tests during treatment to monitor your kidneys.

Taking [HA553 trade name] with certain medicines can increase the chances of kidney damage and your health care provider will keep a check on how well your kidneys are working.
- if you have **bone problems**, including osteoporosis or if you have had fractures. Because [HA553 trade name] can sometimes cause bone damage, tell your health care provider if you have bone or joint pain or if you get a fracture.
- if you have had a **mental illness**, including depression, or have been addicted to alcohol or to 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).
- if you have ever 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.

- if you have or have ever had **liver disease, including hepatitis**. Patients being treated with [HA553 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. If you have severe liver disease, do not take [HA553 trade name].
- if you have **hepatitis B**, there is a risk of liver problems when you stop taking [HA553 trade name]. Do not stop taking [HA553 trade name] without talking to your health care provider.
- if you have a **heart disorder**, such as abnormal electrical activity called prolongation of the QT interval.

Once you start taking [HA553 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.
- problems with your balance or coordination, becoming confused or drowsy, having a seizure (fit or convulsion), your speech becoming slurred or confused, or your personality changes. You or someone close to you must tell your health care provider about these problems right away.
- skin rash. [HA553 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 [HA553 trade name] 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 [HA553 trade name].
- any signs of inflammation or infection. If your immunity is weak when you start [HA553 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.

Other medicines and [HA553 trade name]

You must **not** take [HA553 trade name] with certain medicines. These are listed under “Do not take [HA553 trade name] if”, at the start of Section 2. They include some common medicines and herbal remedies (St John’s wort).

Also, you should not take [HA553 trade name] with other medicines that contain efavirenz (unless recommended by your health care provider), emtricitabine, tenofovir disoproxil, tenofovir alafenamide, lamivudine or adefovir dipivoxil.

Tell your health care provider if you are taking other medicines which may damage your kidneys. Some examples include:

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

[HA553 trade name] may interact with other medicines. As a result, the amounts of [HA553 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 to treat HIV infection:** abacavir, atazanavir, darunavir, didanosine, doravirine, etravirine, lamivudine, lopinavir, maraviroc, nevirapine, raltegravir, rilpivirine, ritonavir and tipranavir.

- **Medicine used to treat hepatitis B virus infection:** adefovir dipivoxil
- **Medicines used to treat hepatitis C virus infection:** daclatasvir, and the combinations of ledipasvir with sofosbuvir, sofosbuvir with velpatasvir and glecaprevir and pibrentasvir.
- **Medicines used to treat bacterial infections**, including tuberculosis and AIDS-related mycobacterium avium complex: clarithromycin, rifabutin and rifampicin.
- **Medicines used to treat parasitic infections:** praziquantel.
- **Medicines used to treat fungal infections (antifungals):** itraconazole, ketoconazole and posaconazole.
- **Medicines used to treat malaria:** halofantrine, lumefantrine, mefloquine, quinine, and combinations of atovaquone with proguanil and artemether with lumefantrine.
- **Medicines used to correct irregular heart rhythm:** dronedarone, flecainide and quinidine.
- **Medicines used to lower blood fats (also called statins):** atorvastatin, simvastatin and pravastatin.
- **Medicines used to treat epilepsy:** carbamazepine and phenytoin.
- **Medicines used to treat depression**, such as citalopram, escitalopram, imipramine and sertraline.
- **Bupropion**, a medicine used to treat depression or to help you stop smoking.
- **Medicines to treat certain psychiatric conditions**, such as chlorpromazine, haloperidol and quetiapine.
- **Hormonal contraceptives, such as birth control pills, an injected contraceptive, or a contraceptive implant.**
- **Hormone replacement therapy** (to relieve symptoms of the menopause).
- **Medicines used to treat opiate addiction and pain:** buprenorphine and methadone.
- **Medicines used to treat high blood pressure and heart conditions such as angina (calcium channel blockers):** diltiazem, felodipine, nifedipine, nifedipine and verapamil.
- **Medicines used to prevent organ transplant rejection and treat some immune diseases (immunosuppressants):** ciclosporin, sirolimus and tacrolimus.
- **Medicines to prevent blood clots:** acenocoumarol and warfarin.
- **Medicines used to treat cancer:** ifosfamide and cisplatin.
- **Morphine**, a medicine used to treat severe pain.
- **Ginkgo biloba extracts** (herbal preparation).

[HA553 trade name] with food and drink

Taking [HA553 trade name] on an empty stomach may reduce some side effects. Do not take grapefruit juice when you are being treated with [HA553 trade name].

Pregnancy and breast-feeding

Effective treatment of HIV during pregnancy is important to protect you and your baby. If you are pregnant, think you may be pregnant or are planning to have a baby, talk to your health care provider about the risks and benefits of taking this medicine. Do not stop taking [HA553 trade name] without checking with your health care provider, as this may harm you and your unborn baby.

If you have taken [HA553 trade name] during your pregnancy, your health care provider may request regular blood tests and other tests to monitor the development of your child.

If you wish to breast-feed your baby, discuss the risks and benefits with your health care provider.

Driving and using machines

[HA553 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.

This medicine contains lactose.

Lactose is a source of glucose and galactose. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance. If, however, you have one of the rare genetic disorders galactosaemia, glucose-galactose intolerance or congenital lactase deficiency you must talk to your health care provider before taking this medicine.

3. How to take [HA553 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 [HA553 trade name].

The recommended dose for patients weighing at least 35 kg is **1 tablet taken each day**.

Take [HA553 trade name] on an **empty stomach** (1 hour before or 2 hours after a meal) preferably at bedtime. This may make some side effects (for example, dizziness, drowsiness) less troublesome. Swallow [HA553 trade name] whole with water.

If you take more [HA553 trade name] than you should

If you accidentally take too many [HA553 trade name] contact your health care provider or nearest emergency department for advice. Take the medicine and this leaflet with you so that you can easily describe what you have taken.

If you forget to take [HA553 trade name]

It is important not to miss a dose of [HA553 trade name].

If you miss a dose of [HA553 trade name] 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 [HA553 trade name], 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 1 hour after taking [HA553 trade name].

Do not stop taking [HA553 trade name]

Do not stop taking [HA553 trade name] 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 [HA553 trade name], speak to your health care provider before you start taking the medicine again. Your health care provider may consider changing your medicine if you are having problems.

If you have both HIV infection and hepatitis B, it is especially important not to stop your [HA553 trade name] treatment without talking to your health care provider first. If you have stopped taking [HA553 trade name], your health care provider may recommend starting another hepatitis B treatment. You may also need blood tests for several months after stopping treatment to check how well your liver is working.

If you have advanced liver disease or cirrhosis, **do not** stop treatment because stopping treatment may make your hepatitis very much worse.

Tell your health care provider immediately about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection.

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, 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 side effect (may affect up to 1 in every 1000 patients) but it is serious and can be fatal. The following 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. Also tell your health care provider if you have had mental illness or have been addicted to alcohol or drugs.
- **Signs of inflammation or infection.** If your immunity is weak when you start [HA553 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.
- **Rash.** Talk to your health care provider if you get a rash with blistering and flu-like effects, because some rashes may be serious. However, in most cases the rash is mild and disappears without the need for any changes to the treatment with efavirenz, one of the active substances in [HA553 trade name]. 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 (stomach) as this may be a sign of pancreatitis (inflammation of the pancreas).
- **Side effects to the liver.** If you are also infected with hepatitis B virus, you may experience a worsening of hepatitis after stopping treatment (see section 3, How to take [HA553 trade name]).
- **Liver failure**, in some cases leading to death or liver transplant. Most cases occurred in patients who already had liver disease, but there have been a few reports in patients without any existing liver disease.

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 [HA553 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, headache, 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

- increased levels of creatine kinase in the blood that may result in muscle pain and weakness

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

- allergic reactions
- disturbances of coordination and balance
- feeling worried or depressed
- difficulty sleeping, abnormal dreams, difficulty concentrating, drowsiness
- pain, abdominal (belly) pain
- problems with digestion resulting in discomfort after meals, feeling bloated, wind (flatulence)
- loss of appetite
- tiredness
- itching, itchy rash
- changes in skin colour including darkening of the skin in patches often starting on hands and soles of feet

Tests may also show:

- low white blood cell count (a reduced white blood cell count can make you more prone to infection)
- liver and pancreas problems
- increased fatty acids (triglycerides), bilirubin or sugar levels in the blood
- loss of bone mass

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

- breakdown of muscle, muscle pain or weakness which may occur due to kidney damage
- anaemia (low red blood cell count)
- a feeling of spinning or tilting (vertigo), whistling, ringing or other persistent noise in the ears
- blurred vision
- chills
- 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 (stomach) caused by inflammation of the pancreas
- yellow skin or eyes, itching, or pain in the abdomen (belly) caused by inflammation of the liver (hepatitis)
- swelling of the face, lips, tongue or throat (angioedema)
- severe skin reactions (erythema multiforme, Stevens-Johnson syndrome)
- breast enlargement in males
- flushing

Tests may also show:

- decreases in potassium in the blood
- increases in creatinine in the blood
- proteins in urine
- increased cholesterol in the blood

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

- lactic acidosis (see above, *Possible serious side effects*)
- itchy rash to the skin caused by a reaction to sunlight

- 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)

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

- **Bone problems.** Some patients taking a combination of antiretroviral medicines such as [HA553 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 [HA553 trade name]

Do not store above 30°C. Keep in a tightly closed container.

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

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 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 [HA553 trade name] contains

- The active ingredients are 600 mg efavirenz, 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate (TDF) equivalent to 245 mg of tenofovir disoproxil
- The other ingredient(s) of [HA553 trade name] are:
 - Core tablet:
Microcrystalline cellulose, lactose, croscarmellose sodium, sodium lauryl sulfate, hydroxypropyl cellulose, magnesium stearate.
 - Film coat:
Polyvinyl alcohol (partly hydrolysed), titanium dioxide, macrogol/PEG, talc, FD&C blue #2/ indigo carmine aluminium lake

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

What [HA553 trade name] looks like and contents of the pack

Blue capsule shaped, film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets are engraved TEE on one side and plain on other side.

A round opaque white plastic (HDPE) bottle (100 cc) with white opaque plastic (HDPE) screw closure with 7 layered induction sealing liner printed “sealed for your protection” containing 24, 30, 84 and 90 film-coated tablets. It also contains a 2g silica gel sachet as desiccant (drying material).

Supplier and Manufacturer

Supplier

Strides Pharma Science Limited
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Manufacturer

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36/7, Suragajakkanahalli
Indlavadi Cross, Anekal Taluk
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Email: info@Strides.com

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>