

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

[HA306 trade name][†]

Efavirenz

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 [HA306 trade name] is and what it is used for
2. What you need to know before you take [HA306 trade name]
3. How to take [HA306 trade name]
4. Possible side effects
5. How to store [HA306 trade name]
6. Contents of the pack and other information

1. What [HA306 trade name] is and what it is used for

[HA306 trade name] is an antiretroviral medicine used for the treatment of human immunodeficiency virus (HIV) infection in adults and adolescents. It contains the active substance efavirenz, which belongs to a class of antiretroviral medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs).

[HA306 trade name] is used in combination with other HIV medicines to reduce the amount of virus in your body and keep it at a very low level. It is not a cure for HIV infection but if taken correctly the combination 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 [HA306 trade name]

Do not take [HA306 trade name] if:

- you are allergic to efavirenz or any of the other ingredients of this medicine listed at the end of this leaflet).
- you have severe liver disease.
- you have a heart condition, such as changes in the rhythm or rate of the heart beat, a slow heart beat, or severe heart disease.
- any member of your family (parents, grandparents, brothers or sisters) has died suddenly due to a heart problem or was born with heart problems.

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

- 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 currently taking any of the following medicines (see also “Other medicines and [HA306 trade name]”):
 - amiodarone (used to treat 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 or grazoprevir (used to treat hepatitis C infection)
 - ergotamine, dihydroergotamine, ergonovine, and methylergonovine (used to treat migraine 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)

If you are taking any of these medicines, tell your health care provider immediately. Taking these medicines with [HA306 trade name] could create the potential for serious and/or life-threatening side-effects or stop [HA306 trade name] from working properly.

Warnings and precautions

Tell your health care provider:

- **if you have or have ever had liver disease, including hepatitis.** Patients with chronic hepatitis B or C who are treated with combination of HIV medicines have a higher risk for severe and potentially life-threatening liver problems. Your health care provider may conduct blood tests in order to check how well your liver is working or may switch you to another medicine.
- **if you have had a mental illness,** including depression, or of substance or alcohol abuse. 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 epilepsy medicine in your blood while you are taking [HA306 trade name]. Your health care provider may give you a different epilepsy medicine or change the dose.
- **If you have a heart disorder,** such as an abnormal electrical signal called prolongation of the QT interval.

You need to take [HA306 trade name] every day. This medicine helps to control HIV infection, but it is not a cure. You may still develop other infections and other illnesses associated with HIV disease (e.g. opportunistic infections). These will require specific and sometimes preventive treatment. You should keep in regular contact with your health care provider. Do not stop your medicine without first talking to the health care provider.

Once you start taking [HA306 trade name], look out for:

- **dizziness, difficulty sleeping, drowsiness, difficulty concentrating or abnormal dreaming.** These side effects may start in the first 1 or 2 days of treatment and usually go away after the first 2 to 4 weeks. If at any time during treatment you get problems with your balance or coordination, become confused or drowsy and unresponsive, get seizures (fits or convulsions), your speech becomes

slurred or confused or you develop personality changes, you or someone close to you must let your health care provider know right away.

- **skin rash.** If you see any signs of a severe rash with blistering or fever, stop taking [HA306 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 a higher risk of getting a rash with [HA306 trade name].
- **any signs of inflammation or infection.** In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please tell your health care provider immediately. In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of 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 inform your health care provider immediately to seek necessary treatment.
- **bone problems.** Some patients taking combination of medicines to treat HIV may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination HIV medicines, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, 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 symptoms please inform your health care provider.

Children and adolescents

[HA306 trade name] is not recommended for children younger than 3 years and weighing less than 10 kg.

Other medicines and [HA306 trade name]

You must not take [HA306 trade name] with certain medicines. These are listed under “Do not take [HA306 trade name]”, at the start of Section 2. They include some common medicines and herbal remedies (St John's wort) which can cause serious interactions.

[HA306 trade name] may interact with other medicines. 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 order blood tests to check that you have the right amount of medicine in your blood.

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

- **Medicines used to treat infection with the hepatitis C virus:**
 - elbasvir/grazoprevir, sofosbuvir/velpatasvir, sofosbuvir/velpatasvir/voxilaprevir, glecaprevir/pibrentasvir.
- **Medicines used to treat bacterial infections** including tuberculosis and AIDs-related mycobacterium avium complex:
 - clarithromycin, rifabutin, rifampicin. Your health care provider may consider changing your dose or giving you an alternative antibiotic. In addition, your health care provider may prescribe a higher dose of [HA306 trade name].
- **Medicines used to treat fungal infections (antifungals):**
 - voriconazole. [HA306 trade name] may reduce the amount of voriconazole in your blood and voriconazole may increase the amount of efavirenz in your blood. If you take these two

medicines together, the dose of voriconazole must be increased and the dose of [HA306 trade name] must be reduced. You must check with your health care provider first.

- Itraconazole, ketoconazole. [HA306 trade name] may reduce the amount of itraconazole or ketoconazole in your blood and your health care provider may need to check the level or use a different medicine.
- posaconazole. [HA306 trade name] reduce the amount of posaconazole in your blood and your health care provider may recommend a different antifungal medicine.
- **Medicines used to treat malaria:**
 - artemether/lumefantrine: [HA306 trade name] may reduce the amount of artemether/lumefantrine in your blood.
 - atovaquone/proguanil: [HA306 trade name] may reduce the amount of atovaquone/proguanil in your blood.
- **Medicines used to treat epilepsy (epilepsy medicines):**
 - carbamazepine, phenytoin, phenobarbital. [HA306 trade name] can reduce or increase the amount of anticonvulsant in your blood. Carbamazepine may make [HA306 trade name] less likely to work. Your health care provider may need to consider giving you a different anticonvulsant.
- **Medicines used to lower blood fats (also called statins):**
 - atorvastatin, pravastatin, simvastatin. [HA306 trade name] can reduce the amount of statins in your blood. Your health care provider will check your cholesterol levels and will consider changing the dose of your statin, if needed.
- **Medicines known as calcium channel blockers, used to treat high blood pressure or heart problems:**
 - diltiazem and similar medicines. When you start taking [HA306 trade name], your health care provider may need to adjust your dose of the calcium channel blocker.
- **Medicines used to prevent organ transplant rejection and treat some immune diseases (also called immunosuppressants):**
 - cyclosporin, sirolimus or tacrolimus: when you start or stop taking [HA306 trade name], your health care provider will closely monitor your plasma levels of the immunosuppressant and may need to adjust its dose.
- **Hormonal contraceptives, such as birth control pills, an injected contraceptive (for example, Depo-Provera), or a contraceptive implant (for example, Implanon):**
 - you must also use a reliable barrier method of contraception (see Pregnancy, breast-feeding and fertility). [HA306 trade name] may make hormonal contraceptives, including emergency contraception, less likely to work. Pregnancies have occurred in women taking [HA306 trade name] while using a contraceptive implant, although it is not known for sure if the [HA306 trade name] therapy caused the contraceptive to fail.
- **Warfarin or acenocoumarol** (medicines used to reduce clotting of the blood):
 - your health care provider may need to adjust your dose of warfarin or acenocoumarol.
- **Ginkgo biloba extracts** (a herbal preparation).
- **Methadone** (used to treat opiate addiction): your health care provider may recommend an alternative treatment.
- **Morphine** (to control severe pain). Your health care provider may need to adjust your morphine dose.

- **Other medicines used for HIV infection:**

- protease inhibitors: darunavir, lopinavir/ritonavir, ritonavir, ritonavir-boosted atazanavir, your health care provider may consider giving you an alternative medicine or changing the dose of the protease inhibitors.
- dolutegravir. Your health care provider may need to increase the dolutegravir dose.
- maraviroc
- a combination tablet containing several HIV medicines. Some combination tablets should not be taken with [HA306 trade name].

[HA306 trade name] with food and drink

[HA306 trade name] should be taken on an empty stomach or with a low-fat meal. Grapefruit juice should be avoided when taking [HA306 trade name].

Pregnancy

Current treatment guidelines recommend efavirenz in pregnant women and women of childbearing potential.

Breast-feeding

If a mother wants to breast-feed her baby, her health care provider should be asked for advice on the risks and benefits.

Driving and using machines

[HA306 trade name] can cause 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.

[HA306 trade name] 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 [HA306 trade name]

Always take [HA306 trade name] exactly as your health care provider has told you. 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 [HA306 trade name].

Adults and teenagers weighing at least 35 kg

The recommended dose is **1 tablet** (600 mg) taken once daily.

The dose of [HA306 trade name] may need to be increased or decreased if you are also taking certain other medicines.

Patients weighing less than 35 kg

Since [HA306 trade name] cannot be divided, the tablets are not suitable for patients whose body weight is less than 35 kg.

How to take your dose

[HA306 trade name] should be taken on an empty stomach, preferably in the evening before going to bed.

[HA306 trade name] will always be taken in combination with other HIV medicines; please make sure that you also follow the instructions in the package leaflets supplied with the other products.

If you forget to take [HA306 trade name]

Take care not to miss a dose. If you do miss a dose, take the next dose as soon as possible. However, if the next regular dose is due within 12 hours, then simply take your normal next dose at its due time. Do not double the dose to make up for a missed dose.

If you stop taking [HA306 trade name]

Do not stop taking [HA306 trade name] unless you experience serious side effects or your health care provider has told 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 take more [HA306 trade name] than you should

If you have taken too many tablets or if someone accidentally takes some, consult your health care provider or local first aid hospital. Take the tablet container with you.

If you have any further questions on the use of this product, ask your health care provider.

4. Possible side effects

Like all medicines, [HA306 trade name] can cause side effects, but not everybody gets them. When treating HIV infection, it is not always possible to tell whether some of the unwanted effects are caused by [HA306 trade name] or by other medicines that you are taking at the same time, or by the HIV disease itself.

The most notable unwanted effects of efavirenz in combination with other antiretroviral medicines are skin rash and nervous system symptoms that include dizziness, insomnia, somnolence (drowsiness), impaired concentration and abnormal dreaming.

Consult your health care provider if you get a rash, because some rashes may be serious; however, in most cases the rash disappears without the need for any changes to the treatment with efavirenz. Rash is more common in children than in adults treated with efavirenz.

Nervous system side effects 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 [HA306 trade name] at bedtime and on an empty stomach. Some patients may have more serious side effects that affect mood or the ability to think clearly. Some patients have committed suicide. These effects may occur more frequently in those who have a previous history of mental illness. Tell your health care provider if you have these problems or if you have any other troublesome side effects.

Tell your health care provider if you notice any of the following side effects:

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

- rash

Common side effects (*may affect up to 1 to 10 people*):

- abnormal dreams, difficulty concentrating, dizziness, headache, difficulty sleeping, drowsiness, problems with coordination and maintaining balance
- stomach pain, diarrhoea, feeling sick (nausea), vomiting
- itching
- tiredness
- feeling worried, feeling depressed
- increase in certain liver or pancreatic enzymes
- increase in triglycerides

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

- nervousness, forgetfulness, confusion, fitting (seizures), abnormal thoughts

- blurred vision
- a feeling of spinning or tilting (vertigo)
- pain in the abdomen (stomach) caused by inflammation of the pancreas
- allergic reaction (hypersensitivity) that may cause severe skin reactions (erythema multiforme, Stevens-Johnson syndrome)
- yellow skin or eyes, itching, or pain in the abdomen (stomach) caused by inflammation of the liver
- breast enlargement in males
- angry behaviour, mood being affected, seeing or hearing things that are not really there (hallucinations), mania (mental condition with episodes of overactivity, elation or irritability), paranoia, suicidal thoughts, catatonia (condition in which the patient is rendered motionless and speechless for a period)
- whistling, ringing or other persistent noise in the ears
- tremor (shaking)
- flushing
- increase in cholesterol

Rare effects (*may affect up to 1 in 1,000 people*):

- itchy rash caused by a reaction to sunlight
- liver failure, in some cases leading to death or requiring liver transplantation. Most cases occurred in patients who already had liver disease, but there have been a few reports in patients who did not have liver disease.
- unexplained feelings of distress not associated with hallucinations, but it may be difficult to think clearly or sensibly
- suicide

The following side effect is of unknown frequency:

- encephalopathy (brain disorder which can be severe)

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

During treatment for HIV infection, you may experience an increase in weight and in levels of blood lipids and glucose. This is partly linked to an improvement in overall 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 [HA306 trade name]

Do not store above 30°C. Store in the original 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 [HA306 trade name] contains

- The active ingredient is efavirenz
- The other ingredients of [HA306 trade name] are:

Core tablet: microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, sodium lauryl sulphate, lactose monohydrate and magnesium stearate,

Film coat: hypromellose, titanium dioxide, PEG 400, iron oxide yellow and iron oxide red.

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

What [HA306 trade name] looks like and contents of the pack

[HA306 trade name] are pale orange, capsule-shaped, film-coated tablets. They are biconvex (rounded on top and bottom) with bevelled edges. The tablets have 'RC68' debossed (stamped into) on one side and are plain on the other side.

[HA306 trade name] are packed in

- Round, opaque white plastic (HDPE) bottle containing 30 tablets. The bottle has an aluminium foil seal and an opaque white plastic screw cap.
- Clear, colourless plastic (PVDC/PE/PVC) on aluminium foil blister cards, each containing 10 tablets. Available in cartons of 3x10 tablets.
- Aluminium foil on aluminium foil blister cards, each containing 10 tablets. Available in cartons of 3x10 tablets.

The HDPE bottles and blisters may be supplied with or without outer cartons.

Supplier and Manufacturer

Supplier

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For any information about this medicine, contact 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>