

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

SONKE EFAVIRENZ 200 Capsules

SONKE EFAVIRENZ 600 Film-coated Tablets

Efavirenz

Contains sugar:

SONKE EFAVIRENZ 200: Lactose monohydrate 62,50 mg.

SONKE EFAVIRENZ 600: Lactose monohydrate 237,60 mg.

Read all of this leaflet carefully before you start taking SONKE

EFAVIRENZ

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SONKE EFAVIRENZ has been prescribed for you personally and
- you should not share your medicine with other people. It may harm
- them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SONKE EFAVIRENZ is and what it is used for
2. What you need to know before you take SONKE EFAVIRENZ
3. How to take SONKE EFAVIRENZ
4. Possible side effects
5. How to store SONKE EFAVIRENZ
6. Contents of the pack and other information

1. What SONKE EFAVIRENZ is and what it is used for

SONKE EFAVIRENZ is used in combination with other medicines (antiretrovirals) for the treatment of HIV infection in adults, adolescents and children weighing 13 kg and above, and/or 3 years and above.

2. What you need to know before you take SONKE EFAVIRENZ

Do not take SONKE EFAVIRENZ

- If you are hypersensitive (allergic) to efavirenz or any of the other ingredients of SONKE EFAVIRENZ (listed in section 6).
- If you are pregnant or planning to become pregnant or are breastfeeding.
- If you had a liver disorder or liver failure attributed to treatment with SONKE EFAVIRENZ.
- If you are taking any of the following medicines:
 - Ergot derivatives such as ergotamine tablets – used for treatment of migraine.
 - Terfenadine or astemizole – used for treatment of allergies.
 - Cisapride – used for treatment of digestive problems.
 - Midazolam or triazolam – used as tranquilizers/sedatives.
 - Bepridil – used to treat heart disease.
 - Pimozide – used to treat certain mental conditions.
 - SONKE EFAVIRENZ 200 capsules: Children less than 3 years or weighing less than 13 kg and adults weighing less than 13 kg.
 - SONKE EFAVIRENZ 600 tablets: Adults and children who weigh less than 40 kg.

Warnings and precautions

- SONKE EFAVIRENZ must not be used as a single medicine to treat HIV. It must always be used in combination with other medicines (antiretrovirals).
- This medicine helps to control your condition, but it is not a cure for the HIV infection. You may continue to develop other infections or other illnesses associated with the HIV disease

Take special care with SONKE EFAVIRENZ:

- If you have problems with your liver.
- If you develop a severe rash associated with blistering, fever, etc.
- If you have a history of mental illness (e.g. severe depression) or substance abuse.
- If you have a history of convulsions (fits or seizures).
- If you have a heart disorder, such as abnormal electrical signal called prolongation of the QT interval.

Once you start taking SONKE EFAVIRENZ, look out for:

- Signs of dizziness, difficulty sleeping, drowsiness, difficulty concentrating or abnormal dreaming.
- Any signs of skin rash.
- Any signs of inflammation or infection.
- Joint aches and pain, joint stiffness or difficulty in movement
- Weight gain.
- An increase in your blood cholesterol and glucose levels may occur.

Children and adolescents

SONKE EFAVIRENZ 600 tablets should not be used in adults and children who weigh less than 40 kg.

Other medicines and SONKE EFAVIRENZ

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

The following medicines should be used with care when taking SONKE EFAVIRENZ:

Medicines used for HIV infection:

- protease inhibitors: darunavir, indinavir, lopinavir/ ritonavir, ritonavir, ritonavir boosted atazanavir, saquinavir or fosamprenavir/saquinavir. Your doctor may consider giving you an alternative medicine or changing the dose of the protease inhibitors.
- maraviroc
- the combination tablet containing efavirenz, emtricitabine and tenofovir should not be taken with SONKE EFAVIRENZ unless recommended by your doctor since it contains efavirenz.

Medicines used to treat infection with the hepatitis C virus:

- boceprevir, telaprevir, elbasvir/grazoprevir, simeprevir, sofosbuvir/velpatasvir, sofosbuvir/velpatasvir/voxilaprevir, glecaprevir/pibrentasvir.

Medicines used to treat bacterial infections,

- including tuberculosis and AIDS-related mycobacterium avium complex: clarithromycin, azithromycin, erythromycin rifabutin, rifampicin. Your doctor may consider changing your dose or giving you an alternative antibiotic. In addition, your doctor may prescribe a higher dose of SONKE EFAVIRENZ.

Medicines used to treat fungal infections (antifungals):

- voriconazole. SONKE EFAVIRENZ may reduce the amount of voriconazole in your blood and voriconazole may increase the amount of SONKE EFAVIRENZ in your blood. If you take these two medicines together, the dose of voriconazole must be increased and the dose of SONKE EFAVIRENZ must be reduced. You must check with your doctor first.
- itraconazole. SONKE EFAVIRENZ may reduce the amount of itraconazole in your blood.
- posaconazole. SONKE EFAVIRENZ may reduce the amount of posaconazole in your blood.

Medicines used to treat malaria:

- artemether/lumefantrine: SONKE EFAVIRENZ may reduce the amount of artemether/ lumefantrine in your blood.
- atovaquone/proguanil: SONKE EFAVIRENZ may reduce the amount of atovaquone/proguanil in your blood.

Medicines used to reduce amount of acid produced by the stomach

- Aluminium hydroxide-magnesium hydroxide-simethicone antacid, famotidine

Medicines used to reduce clotting of the blood:

- warfarin or acenocoumarol, your doctor may need to adjust your dose of warfarin or acenocoumarol

Medicines used to treat convulsions/seizures (anticonvulsants):

- carbamazepine, phenytoin, phenobarbital, valproic acid, vigabatrin, gabapentin. Efavirenz can reduce or increase the amount of anticonvulsant in your blood. Carbamazepine may make SONKE EFAVIRENZ

less likely to work. Your doctor may need to consider giving you a different anticonvulsant.

Medicines used to treat depression:

- Sertraline, paroxetine

Medicine used to treat depression or to help you stop a smoking:

- Bupropion, your doctor may need to change your dose of bupropion.

Medicines used to treat allergies

- Cetirizine

Calcium channel blockers which are medicines typically used for high blood pressure or heart problems):

- Diltiazem, verapamil, felodipine, nifedipine, nicardipine, when you start taking Efavirenz, your doctor may need to adjust your dose of the calcium channel blocker

Medicines used to lower blood fats (also called statins):

- atorvastatin, pravastatin, simvastatin, rosuvastatin. Efavirenz can reduce the amount of statins in your blood. Your doctor will check your cholesterol levels and will consider changing the dose of your statin, if needed.

Hormonal contraceptive, such as birth control pills, an injected contraceptive (for example,DMPA), or a contraceptive implant (for example, Etonogestrel):

- you must also use a reliable barrier method of contraception (see Pregnancy, breast-feeding and fertility).Efavirenz may make hormonal contraceptives less likely to work. Pregnancies have occurred in women taking Efavirenz while using a contraceptive implant, although it has not been established that the Efavirenz therapy caused the contraceptive to fail.

Medicines used to prevent organ transplant rejection (Immunosuppressants as cyclosporine,

sirolimus, or tacrolimus)

- when you start or stop taking Efavirenz, your doctor will closely monitor your plasma levels of the immunosuppressant and may need to adjust its dose.

Medicine used to treat opiate addiction (such as methadone, buprenorphine): your doctor may recommend an alternative treatment.

A herbal preparation (Ginkgo biloba extracts).

SONKE EFAVIRENZ with food and drink

SONKE EFAVIRENZ may be taken with or without food. You should avoid taking SONKE EFAVIRENZ with fatty meals.

Grapefruit juice should be avoided when taking Efavirenz.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Efavirenz is contraindicated in pregnancy, therefore pregnancy should be avoided in women receiving SONKE EFAVIRENZ. Barrier contraception e.g. condoms, must always be used in combination with other methods of contraception e.g. oral or other hormonal contraceptives. Women of childbearing age must have a pregnancy test before starting SONKE EFAVIRENZ therapy.

Mothers taking SONKE EFAVIRENZ should not breastfeed their infants. It is recommended that HIV-infected women do not breastfeed their infants under any circumstances in order to avoid transmission of HIV.

Driving and using machines

SONKE EFAVIRENZ may cause dizziness, sleepiness or impaired concentration. It is not always possible to predict to what extent SONKE EFAVIRENZ may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which

SONKE EFAVIRENZ affects them.

SONKE EFAVIRENZ contains lactose monohydrate.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take SONKE EFAVIRENZ

Do not share medicines prescribed for you with any other person.

Always take SONKE EFAVIRENZ exactly as your doctor or pharmacist has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual adult dosage for patients weighing more than 40 kg is 3 SONKE EFAVIRENZ 200 capsules or 1 SONKE EFAVIRENZ 600 tablet once daily in combination with other anti-retroviral medicines.

For children under 17 years, the dose will be decided by the doctor based on the child's weight. For children weighing more than 40 kg, the dose is the same as the adult dose. SONKE EFAVIRENZ 200 must not be used in children less than 3 years of age or less than 13 kg weight.

SONKE EFAVIRENZ 600 tablets can only be used in adults and children who weigh greater than or equal to 40 kg.

Swallow the capsule or tablet whole with a glass of water. SONKE EFAVIRENZ may be taken with or without food. You should avoid taking SONKE EFAVIRENZ with fatty meals. For best results, you may take this medicine at bedtime.

To help you remember to take your medicine, try to get into the habit of taking it at the same time each day. Your doctor will tell you how long your treatment with SONKE EFAVIRENZ will last.

If you have the impression that the effect of SONKE EFAVIRENZ is too strong or too weak, tell your doctor or pharmacist.

If you take more SONKE EFAVIRENZ than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet or some capsules or tablets with you so your doctor will know what you have taken.

If you forget to take SONKE EFAVIRENZ

Do not take a double dose to make up for forgotten individual doses.

If you stop taking SONKE EFAVIRENZ

Take your capsules/tablets as directed and for as long as directed. Do not stop them, even if you feel better, as the symptoms may return.

4. Possible side effects

SONKE EFAVIRENZ can have side effects.

Not all side effects reported for SONKE EFAVIRENZ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SONKE EFAVIRENZ, please consult your health care provider for advice.

If any of the following happens, stop taking SONKE EFAVIRENZ and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Rashes, hives, itching, chest constriction, shortness of breath or swelling of the face, lips, hands/feet, fainting, high temperature.
- Severe skin reactions with blisters, sores or ulceration.

These are all very serious side effects. If you have them, you may have had a serious reaction to SONKE EFAVIRENZ. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Depressed mood, strange thoughts, hallucinations.
- Fast or irregular heartbeat.
- Yellowing of skin and whites of eyes with decreased appetite, abdominal pain.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Increased triglycerides (fatty acids) in the blood.
- Rapid or exaggerated changes in mood, seeing or hearing things (hallucination).
- Dizziness, impaired concentration, headache, excessive sleepiness, difficulty in sleeping.
- Nausea, vomiting, loose stools.
- Increased sweating.
- Tiredness, abnormal physical weakness or lack of energy.

Less frequent side effects:

- Increased cholesterol in the blood.
- Mania, paranoia, suicidal thoughts, suicide attempt or completed suicide, delusion, neurosis,
- Abnormal dreams, loss of appetite, numbness, problems with balance or coordination, seizures, pins and needles sensation or nerve pain especially in the hands and feet, uncontrolled shaking (tremor), agitation, memory loss, anxiety, indifference, increased appetite, confusion, decreased or increased sexual desire or ability, speech disorder, a feeling of spinning or tilting (vertigo).
- Blurred vision.
- Ringing in ears.
- Flushing.
- Heartburn, pain in the abdomen (stomach) caused by inflammation of the pancreas.
- Inflammation of the liver, increased liver enzymes in the blood.
- Hair loss, skin problems.
- Joint and muscle pain.
- Breast enlargement in males.
- Altered sense of taste, a general sense of being unwell, fainting.

Frequency unknown:

- Weight gain or weight loss.
- Sinusitis, difficulty in breathing, respiratory infection.
- Gastrointestinal disturbances, acid reflux, constipation.
- Liver failure.

- Acne, oily skin, nail disorders, discolouration of the skin.
- Muscle disorders.
- Intolerance to alcohol, hot flushes, flu-like symptoms, pain, redistribution/accumulation of body fat.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of SONKE EFAVIRENZ.

5. How to store SONKE EFAVIRENZ

- Store all medicines out of reach of children.
- Store at or below 25 °C in the original package, protected from moisture. Do not remove the blister strip from the carton until required for use. Keep the bottle tightly closed.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label/ bottle.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SONKE EFAVIRENZ contains

SONKE EFAVIRENZ 200 capsule:

The active substance is efavirenz 200 mg.

The other ingredients are:

Capsule content: Lactose monohydrate, magnesium stearate, sodium lauryl sulphate, sodium starch glycollate.

Capsule shell: Gelatine, sodium lauryl sulphate, titanium dioxide.

Printing ink: Black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, propylene glycol,

potassium hydroxide, purified water, shellac, strong ammonia solution.

SONKE EFAVIRENZ 600 film-coated tablet:

The active substance is efavirenz 600 mg.

The other ingredients are:

Tablet core: Croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate.

Film-coat: Hypromellose, iron oxide red, iron oxide yellow, macrogol/polyethylene 400, titanium dioxide.

What SONKE EFAVIRENZ looks like and contents of the pack

SONKE EFAVIRENZ 200:

White/white, opaque, hard gelatine, self-locked capsules of size 0 elongated, imprinted twice with RD38 in black ink on cap and body and containing a white to pale yellow free flowing granular powder.

Cold form blister strips or Aclar laminated PVC blister strips contain 10 capsules each. Cold form blister strips comprise of cold forming aluminium foil (one side bright, soft tempered, plain; dull side lacquered to oriented polyamide film; bright side lacquer laminated to PVC film) with a backing of aluminium foil. PVC blister strips comprise of clear transparent PVC film laminated with Aclar film having backing of hard tempered aluminium foil coated with heat seal lacquer on inner side. Cartons contain 10, 30, 60, 90 or 100 capsules. Alternatively, 84 or 90 capsules are packed in a securitainer or in a white, opaque, HDPE bottle.

SONKE EFAVIRENZ 600:

Peach coloured, capsule shaped, biconvex, film-coated tablets, debossed with RC68 on one side and plain on other side with intact coating.

Cold form blister strips or PVdC/PE/PVC blister strips contain 10 tablets each. Cold form blister strips comprise of cold forming aluminium foil (one side bright, soft tempered, plain; dull side lacquered to oriented polyamide film; bright side lacquer laminated to PVC film) with a backing of aluminium foil. PVdC/PE/PVC blister strips comprise of clear transparent PVC film laminated with polyethylene and coated with PVdC on inner side having backing of hard tempered aluminium foil coated with heat seal lacquer. Cartons contain 10, 30, 60 or 100 tablets. Alternatively, 28 or 30 tablets are packed in a securitainer or in a white, opaque,

HDPE bottle.

Holder of Certificate of Registration

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SONKE EFAVIRENZ 200: A40/20.2.8/0507

SONKE EFAVIRENZ 600: A40/20.2.8/0508

This product is not for resale outside of the following countries: Angola, Democratic Republic of Congo, Lesotho, Madagascar, Mauritius, Namibia, Seychelles, South Africa, Swaziland, Zimbabwe and Botswana.

Use of Efavirenz patents with the consent of Merck & Co, Inc.

BOTSWANA: S2

SONKE EFAVIRENZ 200 – Reg. No.: BOT0801208

SONKE EFAVIRENZ 600 – Reg. No.: BOT0801209

NAMIBIA: NS2

SONKE EFAVIRENZ 200 – Reg. No.: 07/20.2.8/0176

SONKE EFAVIRENZ 600 – Reg. No.: 07/20.2.8/0177