

PATIENT INFORMATION LEAFLET MAY 2023

SCHEDULING STATUS: **S4**

MACLEODS EFAVIRENZ 600 mg tablets

Contains sugar (lactose monohydrate 400 mg)

This medicine contains less than 1 mmol sodium (23mg) per tablet that is to say is essentially 'sodium free'.

Read all of this leaflet carefully before you start taking MACLEODS EFAVIRENZ 600 mg

- 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.
- **MACLEODS EFAVIRENZ 600 mg** 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 **MACLEODS EFAVIRENZ 600 mg** is and what it is used for
2. What you need to know before you take **MACLEODS EFAVIRENZ 600 mg**
3. How to take **MACLEODS EFAVIRENZ 600 mg**
4. Possible side effects
5. How to store **MACLEODS EFAVIRENZ 600 mg**
6. Contents of the pack and other information

1. What MACLEODS EFAVIRENZ 600 mg is and what it is used for

MACLEODS EFAVIRENZ 600 mg is used to treat HIV (human immunodeficiency virus) infection. **MACLEODS EFAVIRENZ 600 mg** does not get rid of HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. **MACLEODS EFAVIRENZ 600 mg** also increases the *CD4 cell count* in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

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MACLEODS EFAVIRENZ 600 mg is used, in combination with other medicines ('combination therapy'), to treat HIV in adults, adolescents and children weighing more than or equal to 40 kg. To control your HIV infection, and to stop your illness getting worse, you must keep taking all your medicines.

2. What you need to know before you take MACLEODS EFAVIRENZ 600 mg

It is important that you tell your doctor or healthcare professional if you suffer from any of the conditions mentioned below, if you are taking MACLEODS EFAVIRENZ 600 mg or have been prescribed MACLEODS EFAVIRENZ 600 mg.

Do not take MACLEODS EFAVIRENZ 600 mg

- if you are hypersensitive to **MACLEODS EFAVIRENZ 600 mg** (efavirenz) or to any of the ingredients or to any of the other ingredients of **MACLEODS EFAVIRENZ 600 mg** (listed in section 6).
- if you have a rash or other skin condition.
- if you are pregnant or planning to become pregnant, or breastfeeding.
- If you have a liver disorder or liver failure
- If you are taking any of the following medicines:
 - o Ergot derivatives such as ergotamine tablets used to treat migraines
 - o Terfenadine or astemizole – used for treatment of allergies.
 - o Cisapride – used for treatment of digestive problems.
 - o Midazolam or triazolam – used as tranquilizers/sedatives
 - o Bepridil – used to treat heart disease.
 - o Pimozide – used to treat certain mental conditions.

Do not give **MACLEODS EFAVIRENZ 600 mg** to children and adults weighing less than 40 kg.

Warnings and precautions

Take special care with **MACLEODS EFAVIRENZ 600 mg**

Caution should be observed with the use of **MACLEODS EFAVIRENZ 600 mg** in the following patients:

- if you have ever had liver disease (including hepatitis B or C).
- if you ever had mental illness or are using drugs or alcohol.
- if you ever had seizures or are taking medicines for seizures.
- if you have high cholesterol or triglycerides.

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Tell to your doctor if any of these applies to you. You may need extra check-ups, including blood tests, while you're taking your medication.

- **MACLEODS EFAVIRENZ 600 mg** may change your body shape, by changing the way body fat is distributed. You may lose fat from your legs, arms and face and/or gain fat around the abdomen (tummy) and internal organs; get larger breasts or fatty lumps on the back of the neck (buffalo hump).
- If you have advanced HIV infection (AIDS) and have any infection, you may develop acute symptoms of the infection or inflammation and a worsening of the symptoms of an existing infection once treatment with **MACLEODS EFAVIRENZ 600 mg** is started. If you notice signs of inflammation or infection, or deterioration thereof, tell your doctor at once.
- Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). 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 inform your doctor.
- You will need to take **MACLEODS EFAVIRENZ 600 mg** every day. **MACLEODS EFAVIRENZ 600 mg** helps to control your condition and delay disease progression, but it is not a cure for HIV infection. You may continue to develop other infections and other illnesses associated with HIV disease. You should keep in regular contact with your doctor. Do not stop taking your medicine without first talking to your doctor.
- Treatment with **MACLEODS EFAVIRENZ 600 mg** has not been shown to reduce the risk of passing HIV infection on to others by unprotected sexual contact or by blood transfer (for example, blood transfusions or sharing needles). You should continue to use appropriate precautions to prevent this.
- Rashes may be caused by **MACLEODS EFAVIRENZ 600 mg**. If you see any signs of a severe rash with blistering or fever, stop taking **MACLEODS EFAVIRENZ 600 mg** and tell your doctor at once.

Tell your doctor if you have a history of mental illness, including depression, or of substance or alcohol abuse. Tell your doctor immediately if you feel depressed, have suicidal thoughts or have strange thoughts.

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Other medicines and MACLEODS EFAVIRENZ 600 mg

MACLEODS EFAVIRENZ 600 mg may change the effect of other medicines and other medicines may change the effect of **MACLEODS EFAVIRENZ 600 mg**.

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

When you are taking **MACLEODS EFAVIRENZ 600 mg**, it is especially important to tell your doctor or healthcare professional if you are taking any other medicine and especially:

- astemizole (antihistamine used for hay fever and other allergic conditions)
- cisapride (used to treat stomach reflux)
- midazolam (used as a sedative before surgical procedures)
- triazolam (used to treat anxiety, depression or for sleeplessness)
- pimozide (used to treat psychiatric conditions)
- bepridil (used to treat angina (chest pain))
- ergot derivatives (used to treat migraines and during labour/childbirth)

Some medicines can make it more likely that you'll have side effects, or make side effects worse. Your doctor may need to adjust your dosage while you are taking **MACLEODS EFAVIRENZ 600 mg**. These include:

- indinavir, ritonavir, saquinavir (medicines used to treat HIV)
- rifampicin (used in the treatment of tuberculosis (TB))
- clarithromycin (an antibiotic used to treat bacterial infections)
- oral contraceptives (used to prevent unwanted pregnancies)
- methadone (used in the treatment of pain and opioid (e.g. heroin) addiction)
- St. John's wort (a herbal product sold as a dietary supplement)

MACLEODS EFAVIRENZ 600 mg with food or drink

MACLEODS EFAVIRENZ 600 mg should be taken without food. Alcohol should be avoided.

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 health care provider for advice before taking this

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medicine.

Safety in pregnancy and breastfeeding has not been established.

- Do not take **MACLEODS EFAVIRENZ 600 mg** if you are pregnant. Malformations have been seen in foetuses from animals treated with **MACLEODS EFAVIRENZ 600 mg** during pregnancy; therefore, pregnancy should be avoided in women receiving **MACLEODS EFAVIRENZ 600 mg**.
- Inform your doctor immediately if you are pregnant or intend to become pregnant.
- If you are a woman receiving **MACLEODS EFAVIRENZ 600 mg**, a reliable form of barrier contraception (for example, a condom), should always be used together with other methods of contraception including, oral (pill) or other hormonal contraceptives (for example, implants, injection).
- Do not breastfeed if you are taking **MACLEODS EFAVIRENZ 600 mg**.

Driving and using machines

Dizziness, impaired concentration, and drowsiness have been reported during treatment with **MACLEODS EFAVIRENZ 600 mg**. If you experience these symptoms, you should avoid potentially hazardous tasks such as driving or operating machinery.

MACLEODS EFAVIRENZ 600 mg contains lactose:

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **[PRODUCT NAME]**

3. How to take MACLEODS EFAVIRENZ 600 mg

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

Always take **MACLEODS EFAVIRENZ 600 mg** exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are unsure.

You should take **MACLEODS EFAVIRENZ 600 mg** on an empty stomach, with water, preferably at bedtime.

Taking **MACLEODS EFAVIRENZ 600 mg** with food increases the amount of medicine in your body, which may increase the frequency of side effects.

The recommended adult dosage of **MACLEODS EFAVIRENZ 600 mg** is 600 mg orally, once daily. The recommended dosage for adolescents and children (17 years and under) is 600 mg orally, once daily

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and can only be used in adults and children who weigh greater than or equal to 40 kg. **MACLEODS EFAVIRENZ 600 mg** should only be administered to children who are able to reliably swallow tablets. **MACLEODS EFAVIRENZ 600 mg** must be taken in combination with other anti-HIV medicines. If you take only **MACLEODS EFAVIRENZ 600 mg**, the medicine may stop working.

If you have the impression that the effect of **MACLEODS EFAVIRENZ 600 mg** is too strong or too weak, talk to your doctor or pharmacist.

If you take more MACLEODS EFAVIRENZ 600 mg than you should

In the event of over dosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control center.

If you forget to take MACLEODS EFAVIRENZ 600 mg

Do not miss a dose of **MACLEODS EFAVIRENZ 600 mg**, as this could make the virus harder to treat. If you have missed a dose of **MACLEODS EFAVIRENZ 600 mg**, take it as soon as you remember. However if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Never double your dose to make up for a missed dose.

4. Possible side effects

MACLEODS EFAVIRENZ 600 mg can have side effects.

Not all side effects reported for **MACLEODS EFAVIRENZ 600 mg** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **MACLEODS EFAVIRENZ 600 mg**, please consult your health care-provider for advice.

If any of the following happens, stop taking **MACLEODS EFAVIRENZ 600 mg** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

These are all very serious side effects. If you have them you may have had a serious allergic reaction to **MACLEODS EFAVIRENZ 600 mg**. You may need urgent medical attention or hospitalisation.

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

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- psychiatric symptoms including confusion, severe depression, suicidal thoughts, aggression, extreme fear, hallucinations, or unusual behaviour.
- fever with a severe blistering, peeling and red skin rash or any severe skin reaction.
- seizures (have a “fit” or convulsion).
- nausea, stomach pain, loss of appetite, dark urine, clay-coloured stools, jaundice (yellowing of the skin or eyes).

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

Tell your doctor if you notice any of the following side effects and they worry you or if any of these symptoms are severe or do not go away:

Frequent side effects:

- unusual dreams, feeling anxious, feeling depressed, difficulty falling asleep
- dizziness, difficulty concentrating, headache, drowsiness
- nausea, vomiting, diarrhoea, indigestion, stomach pain
- skin rash, itching, increased sweating
- fatigue, pain

Less frequent side effects:

- forgetfulness, confusion, abnormally happy mood, nervousness
- **temporary loss of memory, disturbances of co-ordination and balance, tingling, pins and needles, tremor (shake)**
- blurred vision
- ringing in the ears, vertigo (spinning sensation)
- **feeling flushed, palpitations (rapid irregular action of heart), increased rate of heart beat**
- asthma
- increased appetite, taste disturbances
- eczema, hair loss, hives, changes in skin colour
- muscle or joint pain
- enlarged breasts in males
- lack of energy, generally feeling unwell, fainting

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Frequency not known:

- weight gain or weight loss, changes in shape or location of body fat (especially in your arms, legs, face, neck, breasts, and waist)
- having fixed, irrational ideas not shared by others, excessive and irrational anxiety or obsession
- numbness or weakness of the arms and legs
- upper respiratory tract infections, sinusitis (inflammation of the sinuses), shortness of breath
- stomach problems and stomach pain, infectious diarrhoea, heartburn, increased appetite, constipation and malabsorption (a condition in which the body does not effectively absorb nutrients from food in the small intestine)
- acne, seborrhea (oily skin with dandruff), increased sensitivity to sunlight
- muscle tenderness or weakness, not caused by exercise
- impotence (loss of male sexual ability); increased and decreased sexual drive (libido)
- flu-like symptoms.

Laboratory tests may show:

- increased liver enzyme values and amylase values (used for determining proper functioning of pancreas)
- increased glucose, cholesterol and triglyceride (fatty acid) values

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 **MACLEODS EFAVIRENZ 600 mg**.

5. How to store MACLEODS EFAVIRENZ 600 mg

Store at or below 30 °C. Keep well closed and protect from light. Any expired or outdated medicines and unused medicines can be returned to your nearest pharmacy.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

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What MACLEODS EFAVIRENZ 600 mg contains

The active substance is efavirenz 600 mg.

The other ingredients are: croscarmellose sodium, hydroxypropylcellulose, lactose monohydrate, microcrystalline cellulose, magnesium stearate, sodium laurel sulfate. Film coating, Opadry Yellow 03B52055 (contains hydroxypropyl methyl cellulose, iron oxide yellow (E172), polyethylene glycol 400, titanium dioxide (CI 77891)).

Contains sugar (lactose).

What MACLEODS EFAVIRENZ 600 mg looks like and contents of the pack

Yellow capsule shaped, biconvex, film coated tablets engraved with "ML 12" on one side and plain on the other side.

Round, white HDPE containers, and a white closure (cap), with 28 or 30 tablets.

Holder of Certificate of Registration

MACLEODS PHARMACEUTICALS SA (PTY) LTD.

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1 Cussonia Drive, Bassonia Rock, Ext. 12,

Alberton, South Africa.

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