

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

MACLEODS NEVIRAPINE 200 mg (Tablets)

Contains sugar (lactose monohydrate 70 mg)

Read all of this leaflet carefully before you start taking MACLEODS NEVIRAPINE 200 MG TABLETS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, ~~or your~~ pharmacist, nurse or other health care provider.
- **MACLEODS NEVIRAPINE 200 mg (Tablets)** 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 NEVIRAPINE 200 MG** is and what it is used for
2. What you need to know before you take **MACLEODS NEVIRAPINE 200 MG**
3. How to take **MACLEODS NEVIRAPINE 200 MG**
4. Possible side effects
5. How to store **MACLEODS NEVIRAPINE 200 MG**
6. Contents of the pack and other information

1. What MACLEODS NEVIRAPINE 200 MG is and what it is used for

MACLEODS NEVIRAPINE 200 mg is used in antiretroviral combination therapy for the treatment of HIV infection and reduces the amount of HIV virus in your body. Response to treatment with **MACLEODS NEVIRAPINE 200 mg** varies between patients. Your doctor will be monitoring the effectiveness of your treatment.

2. What you need to know before you take MACLEODS NEVIRAPINE 200 MG

Do not take MACLEODS NEVIRAPINE 200 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 or have been prescribed MACLEODS NEVIRAPINE 200 mg.

- if you are hypersensitive to (nevirapine) or to any of the ingredients or to any of the other ingredients of **MACLEODS NEVIRAPINE 200 MG** (listed in section 6).
- if you have liver disease.
- if you have kidney failure.
- If you had discontinued nevirapine containing medicines previously due to the development of severe rash or liver disease
- **MACLEODS NEVIRAPINE 200 mg** is not recommended if you are breast-feeding. It is recommended that HIV infected women do not breast-feed their infants under any circumstances in order to avoid transmission of HIV from mother to child.
- If you are not sure please ask your doctor.

Warnings and precautions

Take special care with **MACLEODS NEVIRAPINE 200 MG**

Caution should be observed with the use of **MACLEODS NEVIRAPINE 200 MG** in the following patients:

It is important that your doctor knows about all your symptoms even if you think they are not related to HIV infection.

The first 18 weeks of treatment with MACLEODS NEVIRAPINE 200 mg are an important period, which requires intensive monitoring to discover the occurrence of severe and life-threatening skin reactions and serious liver injury. During this period the dosage of MACLEODS NEVIRAPINE 200 mg prescribed by your doctor must be strictly adhered to, especially during the first 14 days of treatment, the so called “lead-in” period (see more information under HOW TO TAKE MACLEODS NEVIRAPINE 200 mg below).

If you experience clinical symptoms suggesting an injury of the liver, such as loss of appetite, nausea, vomiting, jaundice, you should promptly inform your doctor.

Hypersensitivity (allergic) reactions can occur. Such reactions may appear in the form of rash accompanied by other side-effects such as fever, blistering, mouth sores, eye inflammation, facial swelling, general swelling, muscle or joint aches, a reduction in white blood cells (granulocytopenia), general feeling of illness or severe problems with liver or kidneys.

If you experience rash and any of the other side-effects of a hypersensitivity reaction, **YOU MUST CONTACT** your doctor **IMMEDIATELY** as such reactions can be potentially life-threatening.

If you ever have any rash symptoms, please inform your doctor immediately and he/she will advise you whether you should stop taking **MACLEODS NEVIRAPINE 200 mg**.

If you develop a severe rash whilst taking **MACLEODS NEVIRAPINE 200 mg** **NEVER TAKE** **MACLEODS NEVIRAPINE 200 mg** again without first consulting your doctor.

- **MACLEODS NEVIRAPINE 200 mg** decreases bone mineral density which could result in fractures. Your doctor may prescribe calcium and vitamin D supplements while taking **MACLEODS NEVIRAPINE 200 mg**.
- 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.
- **MACLEODS NEVIRAPINE 200 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 NEVIRAPINE 200 mg** is started. If you notice signs of inflammation or infection, or deterioration thereof, tell your doctor at once.
- You will need to take **MACLEODS NEVIRAPINE 200 mg** every day. **MACLEODS NEVIRAPINE 200 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 NEVIRAPINE 200 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.
- If you are undergoing dialysis, your doctor may consider a dose increase for **MACLEODS NEVIRAPINE 200 mg**.
- It is possible that **MACLEODS NEVIRAPINE 200 mg** can affect oral contraceptives and you should, therefore, use an additional method of birth control such as barrier contraception (e.g. condoms).

Other medicines and MACLEODS NEVIRAPINE 200 MG

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

When you are taking **MACLEODS NEVIRAPINE 200 mg**, it is especially important to tell your doctor or healthcare professional if you are taking any of the following:

MACLEODS NEVIRAPINE 200 MG with food or drink

MACLEODS NEVIRAPINE 200 MG can be taken with or without food.

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 medicine.

Pregnancy:

- It is important to tell your doctor if you are pregnant.
- The safe use during pregnancy has not been established.

Breast-feeding:

- **MACLEODS NEVIRAPINE 200 mg** is not recommended if you are breast-feeding. It is recommended that HIV infected women do not breast-feed their infants under any circumstances in order to avoid transmission of HIV.

Driving and using machines

You may experience fatigue when taking **MACLEODS NEVIRAPINE 200 mg**. Use caution when engaging in activities such as driving, using any tools or machines. If you experience fatigue you should avoid potentially hazardous tasks such as driving or using any tools or machines.

It is not always possible to predict to what extent **[PRODUCT NAME]** 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 **[PRODUCT NAME]** affects them.

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

3. How to take MACLEODS NEVIRAPINE 200 MG

Take **MACLEODS NEVIRAPINE 200 MG** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure. Do not exceed the dose prescribed by your doctor, to do so may increase the chance of side-effects.

Recommended dose of MACLEODS NEVIRAPINE 200 mg:

Pregnant women:

One **MACLEODS NEVIRAPINE 200 mg** tablet to be taken during labour – preferably more than 2 hours before delivery.

MACLEODS NEVIRAPINE 200 mg must be taken by the mother and the baby (special suspensions of nevirapine are available for babies) to reduce the chances of the baby becoming infected with HIV during the birth process.

MACLEODS NEVIRAPINE 200 mg is given as one single dose to the mother and one single dose of nevirapine suspension to the baby.

Adults:

Initial dose (lead-in period): one 200 mg tablet once daily for 14 days.

Thereafter: one 200 mg tablet twice a day.

The total daily dose should not exceed 400 mg for any patient.

It is essential to follow the once a day dosage strictly during the 14-day “lead-in” period before increasing to the twice daily dosage.

If you have the impression that the effect of **MACLEODS NEVIRAPINE 200 MG** is too strong or too weak, talk to your doctor or pharmacist.

If you take more MACLEODS NEVIRAPINE 200 MG than you should

Get medical help immediately by calling your nearest doctor or healthcare professional if you have taken too much.

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

If you forget to take MACLEODS NEVIRAPINE 200 MG

If you have missed a dose of **MACLEODS NEVIRAPINE 200 MG**, take it as soon as you remember and then take your next scheduled dose at the right time. However if it is almost time for your next dose, do not take the missed dose. Wait and take the next dose at the right time. Never double your dose.

4. Possible side effects

MACLEODS NEVIRAPINE 200 MG can have side effects.

Not all side effects reported for **MACLEODS NEVIRAPINE 200 MG** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **MACLEODS NEVIRAPINE 200 MG**, please consult your health care provider for advice.

- General ill-feeling or flu-like symptoms
- Tiredness
- Nausea
- Lack of appetite
- Yellowing of your skin or white of your eyes
- Dark urine (tea coloured)
- Pale stools
- Pain, ache, or sensitivity on your right side below your ribs

These are all very serious side effects. If you have them you may have had a serious allergic reaction to **MACLEODS NEVIRAPINE 200 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:

- General ill-feeling or flu-like symptoms
- Fever
- Muscle or joint aches
- Conjunctivitis (red or inflamed eyes)
- Blisters
- Mouth sores
- Swelling of your face
- Tiredness

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

Other frequent side-effects of **MACLEODS NEVIRAPINE 200 mg** include nausea, fatigue, fever, headache, vomiting, diarrhoea, abdominal pain and muscle pain.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com. By reporting side effects, you can help provide more information on the safety of **MACLEODS NEVIRAPINE 200 MG**.

5. How to store MACLEODS NEVIRAPINE 200 MG

Store at or below 30 °C.

Keep the HDPE container tightly closed.

Any expired or outdated medicines and unused medicines can be returned to your nearest pharmacy.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

6. Contents of the pack and other information

What MACLEODS NEVIRAPINE 200 MG contains

The active substance is nevirapine 200 mg.

The other ingredients are: microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, colloidal silicon dioxide, povidone, magnesium stearate.

Contains sugar (lactose).

What MACLEODS NEVIRAPINE 200 MG looks like and contents of the pack

White to off white, oval, biconvex, uncoated tablets having “M” and “L” debossed on one side, with a deep score separating the “M” and “L” and “1” and “1” debossed on the other side with a breakline separating “1” and “1”.

Round, white HDPE containers with white closure containing 60 tablets.

Holder of Certificate of Registration

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This leaflet was last revised in

23 May 2025

REGISTRATION NUMBER

45/20.2.8/0886