Front Side

280 mm

MACLEODS
NEVIRAPINE 200 mg
PM02999602

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

MACLEODS NEVIRAPINE 200 mg (Tablets)
Contains sugar (lactose monohydrate 346 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, 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 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 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:
- Ketoconazole, fluconazole used for fungal infections
- Rifampicin, used for TB
- Clarithromycin, rifabutin antibiotics
- Cimetidine, used for ulcers
- Fluconazole, used for fungal infections
- Methadone, used for pain relief
- Warfarin, used for blood thinning
- St John's Wort, a herbal product used to improve depressive moods
- Saquinavir, indinavir, nelfinavir, ritonavir or lopinavir – used in HIV treatment
- Birth control pills

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 **MACLEODS NEVIRAPINE 200 mg** 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 **MACLEODS NEVIRAPINE 200 mg** affects them.
Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **MACLEODS NEVIRAPINE 200 mg.**

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.

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
MACLEODS PHARMACEUTICALS SA (PTY) LTD.
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

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REGISTRATION NUMBER
45/20.2.8/0886

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169

335 mm

Back Side

280 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

MACLEODS NEVIRAPINE 200 mg (Tablette)
Bevat suiker (laktosemonohidraat 346 mg)

Lees hierdie hele inligtingstuk noukeurig deur voordat jy MACLEODS NEVIRAPINE 200 mg TABLETTE begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **MACLEODS NEVIRAPINE 200 mg (Tablette)** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

1. Wat **MACLEODS NEVIRAPINE 200 mg** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **MACLEODS NEVIRAPINE 200 mg** neem
3. Hoe om **MACLEODS NEVIRAPINE 200 mg** te neem
4. Moontlike newe-effekte
5. Hoe om **MACLEODS NEVIRAPINE 200 mg** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat MACLEODS NEVIRAPINE 200 mg is en waarvoor dit gebruik word

MACLEODS NEVIRAPINE 200 mg word gebruik in anti-retrovirale kombinasieterapie vir die behandeling van MIV-infeksie en verminder die hoeveelheid MIV-virus in jou liggaam. Reaksie op behandeling met **MACLEODS NEVIRAPINE 200 mg** verskil tussen pasiënte. Jou dokter sal die doeltreffendheid van jou behandeling monitor.

2. Wat jy behoort te weet voordat jy MACLEODS NEVIRAPINE 200 mg neem

Moet nie MACLEODS NEVIRAPINE 200 mg neem nie
Indien jy MACLEODS NEVIRAPINE 200 mg neem of dit aan jou voorgeskryf is, is dit belangrik dat jy aan jou dokter of professionele gesondheidsorgwerker sal vertel indien jy ly aan enige van die toestande wat hieronder genoem word.

- indien jy hipersensitief is vir (nevirapien) of vir enige van die bestanddele van **MACLEODS NEVIRAPINE 200 mg** (gelys in afdeling 6).
- indien jy lewersiekte het.
- indien jy nierversaking het.
- Indien jy voorheen nevirapien bevattende medisyne gestaak het as gevolg van die ontwikkeling van 'n ernstige uitslag of lewersiekte.
- **MACLEODS NEVIRAPINE 200 mg** word nie aanbeveel as jy borsvoed nie. Dit word aanbeveel dat MIV-geïnfekteerde vrouens onder geen omstandighede hulle babas borsvoed nie om sodoende oordrag van MIV van moeder na kind te vermy.
- Indien jy nie seker is nie, vra asseblief jou dokter.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met **MACLEODS NEVIRAPINE 200 mg**
Versigtigheid moet gehandhaaf word met die gebruik van **MACLEODS NEVIRAPINE 200 mg** in die volgende pasiënte:
Dit is belangrik dat jou dokter van al jou simptome bewus is, selfs al dink jy dat dit nie met MIV-infeksie verband hou nie.
Die eerste 18 weke van behandeling met MACLEODS NEVIRAPINE 200 mg is 'n belangrike tydperk wat intensiewe monitering vereis om die voorkoms van ernstige en lewensgevaarlike velreaksies en ernstige lewerskade te ontdek. Gedurende hierdie tydperk moet die dosis van MACLEODS NEVIRAPINE 200 mg wat deur jou dokter voorgeskryf is, streng nagevolg word, veral gedurende die eerste 14 dae van behandeling, die sogenaamde " inleidingsperiode" (sien meer inligting onder HOE OM MACLEODS NEVIRAPINE 200 mg TE NEEM hieronder).
Indien jy kliniese simptome ervaar wat dui op 'n besering van die lewer, soos verlies aan eetlus, naarheid, braking, geelsug, moet jy onmiddellik jou dokter in kennis stel.
Hipersensitiwiteits (allergiese) reaksies kan voorkom. Sulke reaksies kan voorkom in die vorm van 'n uitslag, saam met ander newe-effekte soos koors, blase, mondsere, oogontsteking, gesigswelling, algemene swelling, spier- of gewrigspyne, 'n vermindering in witbloedselle (granulositopenie), algemene gevoel van siekte of ernstige probleme met die lewer of niere.
Indien jy 'n uitslag en enige van die ander newe-effekte van 'n hipersensitiwiteits reaksie ervaar, MOET JY ONMIDDELLIK jou dokter KONTAK, aangesien sulke reaksies potensieel lewensgevaarlik kan wees.
Indien jy ooit enige uitslagsimptome kry, stel asseblief onmiddellik jou dokter in kennis en hy/sy sal jou adviseer of jy moet ophou om MACLEODS NEVIRAPINE 200 mg te neem of nie.
Indien jy 'n ernstige uitslag ontwikkel terwyl jy MACLEODS NEVIRAPINE 200 mg neem, MOET JY NOOIT weer MACLEODS NEVIRAPINE 200 mg NEEM sonder om eers jou dokter te raadpleeg nie.
- **MACLEODS NEVIRAPINE 200 mg** verminder beenmineraaldigtheid wat tot frakture kan lei. Jou dokter kan kalsium- en vitamien D aanvullings voorskryf terwyl **MACLEODS NEVIRAPINE 200 mg** geneem word.
- Sommige pasiënte wat kombinasie anti-retrovirale terapie neem, kan 'n beensiekte naamlik osteonekrose ontwikkel (dood van beenweefsel wat veroorsaak word deur verlies aan bloedtoevoer na die been). Tekens van osteonekrose is gewrigstyfheid, pyn en aanhoudende pyn (veral van die heup, knie en skouer) en probleme met beweging. Indien jy enige van hierdie simptome opmerk, stel jou dokter in kennis.
- **MACLEODS NEVIRAPINE 200 mg** kan jou liggaamsvorm verander deur die manier waarop liggaamsvet versprei word, te verander. Jy kan vet van jou bene, arms en gesig verloor en/of vet rondom die buik (maag) en interne organe optel; groter borste of vetknoppe op die agterkant van die nek (buffelskof) kry.
- Indien jy gevorderde MIV-infeksie (VIGS) het en enige infeksie kry, kan jy akute simptome van die infeksie of ontsteking en 'n verergering van die simptome van 'n bestaande infeksie ontwikkel sodra behandeling met **MACLEODS NEVIRAPINE 200 mg** begin word. Indien jy tekens van ontsteking of infeksie, of agteruitgang daarvan opmerk, vertel onmiddellik jou dokter.
- Jy sal **MACLEODS NEVIRAPINE 200 mg** elke dag moet neem. **MACLEODS NEVIRAPINE 200 mg** help om jou toestand te beheer en vertraag die siekte se progressie, maar dit is nie 'n kuur vir MIV-infeksie nie. Jy kan voortgaan om ander infeksies en ander siektes wat met MIV-siekte geassosieer word, te ontwikkel. Jy moet gereeld in kontak met jou dokter bly. Moet nie ophou om jou medisyne te neem sonder om eers met jou dokter te praat nie.
- Behandeling met **MACLEODS NEVIRAPINE 200 mg** het nie getoon dat dit die risiko van die oordrag van MIV-infeksie aan ander deur onbeskermde seksuele kontak of deur bloedoordrag (byvoorbeeld bloedoortappings of die deel van naalde) verminder nie. Jy moet aanhou om gepaste voorsorgmaatreëls te tref om dit te verhoed.
- Indien jy dialise ondergaan, kan jou dokter 'n dosisverhoging vir **MACLEODS NEVIRAPINE 200 mg** oorweeg.
- Dit is moontlik dat **MACLEODS NEVIRAPINE 200 mg** orale voorbehoedmiddels kan affekteer en jy moet dus 'n addisionele metode van geboortebeperking soos versperringskontrasepsie (bv. kondome) gebruik.

Ander medisyne en MACLEODS NEVIRAPINE 200 mg
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Wanneer jy **MACLEODS NEVIRAPINE 200 mg** neem, is dit veral belangrik om jou dokter of professionele gesondheidsorgwerker te vertel indien jy enige van die volgende neem:
- Ketokonasool, flukonasool wat vir swaminfeksies gebruik word
- Rifampisien, wat vir TB gebruik word
- Klaritromisien, rifabutien antibiotika
- Simetidien, wat vir ulkusse gebruik word
- Flukonasool, wat vir swaminfeksies gebruik word
- Metadoon, wat vir pynverligting gebruik word
- Warfarien, wat vir bloedverdunning gebruik word
- Sint-Johanneskruid, 'n kruie produk wat gebruik word om depressiewe gemoedstoestande te verbeter
- Sakwinavir, indinavir, nelfinavir, ritonavir of lopinavir – wat in MIV-behandeling gebruik word
- Geboortebeperkings pille

MACLEODS NEVIRAPINE 200 mg met kos of vloeistowwe
MACLEODS NEVIRAPINE 200 mg kan met of sonder kos geneem word.

Swangerskap en borsvoeding
Indien jy swanger is of jou baba borsvoed, dink dat jy dalk swanger is of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat hierdie medisyne geneem word.
Swangerskap:
- Dit is belangrik om jou dokter te vertel as jy swanger is.
- Die veilige gebruik tydens swangerskap is nog nie vasgestel nie.

Borsvoeding:
- **MACLEODS NEVIRAPINE 200 mg** word nie aanbeveel as jy borsvoed nie. Dit word aanbeveel dat MIV-besmette vrouens onder geen omstandighede hul babas borsvoed nie, om die oordrag van MIV te vermy.

Bestuur en gebruik van masjinerie
Jy kan moegheid ervaar wanneer jy **MACLEODS NEVIRAPINE 200 mg** neem. Wees versigtig wanneer jy by aktiwiteite betrokke raak soos bestuur, die gebruik van enige gereedskap of masjiene. Indien jy moegheid ervaar moet jy potensieel gevaarlike take soos om te bestuur of enige gereedskap of masjiene te gebruik, vermy.
Dit is nie altyd moontlik om te voorspel tot watter mate **MACLEODS NEVIRAPINE 200 mg** met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet seker maak dat hulle nie in die bogenoemde aktiwiteite betrokke raak nie, totdat hulle bewus is van die mate waartoe **MACLEODS NEVIRAPINE 200 mg** hulle affekteer.
Pasiënte met die seldsame oorerflike toestande van laktose- of galaktose intoleransie moet nie **MACLEODS NEVIRAPINE 200 mg** neem nie.

3. Hoe om MACLEODS NEVIRAPINE 200 mg te neem

Neem **MACLEODS NEVIRAPINE 200 mg** presies soos wat jou dokter of apteker jou aangesê het. Bevestig met jou dokter of apteker indien jy nie seker is nie. Moet nie die dosis wat deur jou dokter voorgeskryf is oorskry nie, dit kan die kans op newe-effekte verhoog.
Aanbevole dosis van* MACLEODS NEVIRAPINE 200 mg*:
***Swanger vrouens*:**
Een **MACLEODS NEVIRAPINE 200 mg** tablet moet tydens kraam geneem word – verkieslik meer as 2 ure voor die bevalling.
MACLEODS NEVIRAPINE 200 mg moet deur die moeder en die baba geneem word (spesiale suspensies van nevirapien is beskikbaar vir babas) om die kanse te verminder dat die baba tydens die geboorteproses met MIV besmet raak.
MACLEODS NEVIRAPINE 200 mg word as een enkele dosis aan die moeder en een enkele dosis nevirapien suspensie aan die baba gegee.

Volwassenes:
Aanvangsdosis (inleidingsperiode): een 200 mg tablet een keer per dag vir 14 dae.
Daarna: een 200 mg tablet twee keer per dag.
Die totale daaglikse dosis moet nie 400 mg vir enige pasiënt oorskry nie.

Dit is noodsaaklik om die een keer per dag dosis streng na te volg gedurende die 14 dae "inleidingstydperk" voordat dit na die twee keer per dag dosis verhoog word.

Indien jy onder die indruk is dat die effek van **MACLEODS NEVIRAPINE 200 mg** te sterk of te swak is, praat met jou dokter of apteker.
Indien jy meer MACLEODS NEVIRAPINE 200 mg neem as wat jy moet
Kry onmiddellik mediese hulp deur jou naaste dokter of professionele gesondheidsorgwerker te skakel as jy te veel geneem het.

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om MACLEODS NEVIRAPINE 200 mg te neem
Indien jy 'n dosis van **MACLEODS NEVIRAPINE 200 mg** gemis het, neem dit sodra jy daarvan onthou en neem dan jou volgende geskeduleerde dosis op die regte tyd. Indien dit egter amper tyd is vir jou volgende dosis, moet nie die gemiste dosis neem nie. Wag en neem die volgende dosis op die regte tyd. Moet nooit jou dosis verdubbel nie.

4. Moontlike newe-effekte

MACLEODS NEVIRAPINE 200 mg kan newe-effekte hê.
Nie alle newe-effekte wat vir **MACLEODS NEVIRAPINE 200 mg** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verswak of indien jy enige ongunstige effekte ervaar terwyl jy **MACLEODS NEVIRAPINE 200 mg** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.
- Algemene siek gevoel of griepagtige simptome
- Moegheid
- Naarheid
- Gebrek aan eetlus
- Vergeling van jou vel of die wit van jou oë
- Donker uriene (teekleurig)
- Bleek stoelgang
- Pyn, aanhoudende pyn, of sensitiwiteit aan jou regterkant onder jou ribbes.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit kry, het jy moontlik 'n ernstige allergiese reaksie op **MACLEODS NEVIRAPINE 200 mg** gehad. Jy benodig moontlik dringende mediese aandag of hospitalisering.

Vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:
- Algemene siek gevoel of griepagtige simptome
- Koors
- Spier- of gewrigspyne
- Konjunktivitis (rooi of ontsteekte oë)
- Blase
- Mondsere
- Swelling van jou gesig
- Moegheid

Hierdie is alles ernstige newe-effekte. Jy mag dringend mediese aandag benodig.

Ander algemene newe-effekte van **MACLEODS NEVIRAPINE 200 mg** sluit naarheid, moegheid, koors, kopseer, braking, diarree, abdominale pyn en spierpyne in.
Indien enige van die newe-effekte ernstig raak, of as jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk gelys is nie, vertel asseblief jou dokter of apteker.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op SAHPRA se webwerf gevind word, of aan Macleods Pharmaceuticals SA (Edms) Bpk. by safety@macleodspharma.com. Deur newe-effekte aan te meld kan jy help om meer inligting te verskaf aangaande die veiligheid van **MACLEODS NEVIRAPINE 200 mg**.

5. Hoe om MACLEODS NEVIRAPINE 200 mg te bewaar

Bewaar by of benede 30 °C.
Hou die HDPE houer dig toe.
Enige vervalde of verouderde medisyne en ongebruikte medisyne kan teruggeneem word na jou naaste apteek.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.
BEWAAR ALLE MEDISYNE BUITE DIE BEREIK EN SIG VAN KINDERS.

6. Inhoud van die pak en ander inligting

Wat MACLEODS NEVIRAPINE 200 mg bevat
Die aktiewe bestanddeel is 200 mg nevirapien.
Die ander bestanddele is: mikrokristallyne sellulose, laktosemonohidraat, natriumstyselglikolaat kolloïdale silikondioksied, povidoon, magnesiumstearaat.
Bevat suiker (laktose).

Hoe MACLEODS NEVIRAPINE 200 mg lyk en inhoud van die pak
Wit tot af-wit, ovaal, bikonvekse, onbedekte tablette bedruk met "M" en "L" op een kant, met 'n diep keep wat die "M" en "L" skei en bedruk met "1" en "1" op die ander kant met 'n breeklyn wat "1" en "1" skei.
Ronde, wit HDPE houers met 'n wit afsluiting wat 60 tablette bevat.

7. HOUER VAN SERTIFIKAAT VAN REGISTRASIE

MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
1 Cussonia-rylaan, Bassonia Rock, Uitbr. 12
Alberton, Suid-Afrika

Hierdie inligtingstuk was laas hersien op
23 Mei 2025

Registrasienommers
45/20.2.8/0886.

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Exclusion of PI, text update, and dimension change.

1. Product : Nevirapine 200 mg	
2. Country: South Africa	**3. Packaging component: Patient Information Leaflet**
4. No. of Colours: 1 Colour	**5. Pantone Shade No.: Black**
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	**8. Dimensions: 335 (L) x 280 (W) mm**
9. Design / Style: NA	**10. Item code No.: PM02999602**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 40156 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: PM02999601**
15. Revision no: 01	**16. File Name Z:\South Africa\Nevirapine\02\MACLEODS NEVIRAPINE PI-PIL PM02999602.cdr**
Approved By:	**17. Location: Daman**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	29/07/2025				

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-01

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa	PM02999601	26/3/19	29/7/19
2) Exclusion of PI, text update, and dimension change.	PM02999602		