330 mm

CLOFAZIMINE TABLETS 50/100 mg MACLEODS
PM00439701

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CLOFAZIMINE TABLETS 50 mg MACLEODS and
CLOFAZIMINE TABLETS 100 mg MACLEODS (Film-coated Tablets)
Clofazimine
Sugar free

Read all of this leaflet carefully before you start taking CLOFAZIMINE TABLETS MACLEODS
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **CLOFAZIMINE TABLETS MACLEODS** 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 **CLOFAZIMINE TABLETS MACLEODS** is and what it is used for
2. What you need to know before you take **CLOFAZIMINE TABLETS MACLEODS**
3. How to take **CLOFAZIMINE TABLETS MACLEODS**
4. Possible side effects
5. How to store **CLOFAZIMINE TABLETS MACLEODS**
6. Contents of the pack and other information

1. What CLOFAZIMINE TABLETS MACLEODS is and what it is used for

CLOFAZIMINE TABLETS MACLEODS is used to treat tuberculosis (TB) when the disease has become resistant to other antibiotics. This is called multi-drug resistant pulmonary tuberculosis. **CLOFAZIMINE TABLETS MACLEODS** is used together with other medicines for treating tuberculosis.
CLOFAZIMINE TABLETS MACLEODS is also used for the treatment of leprosy (Hansen's disease) in combination with other antibiotic medicines dapsone and rifampicin.

2. What you need to know before you take CLOFAZIMINE TABLETS MACLEODS

Do not take CLOFAZIMINE TABLETS MACLEODS:
- If you are hypersensitive (allergic) to Clofazimine or to any of the ingredients of **CLOFAZIMINE TABLETS MACLEODS**.
- If you have a personal or family history of a heart problem called 'congenital long QT syndrome'.
- If you are taking other medicines known to prolong QTc interval up to the time intervals known to cause serious heart rhythm disorders (dysrhythmias).

Warnings and precautions
Take special care with **CLOFAZIMINE TABLETS MACLEODS**:
- **CLOFAZIMINE TABLETS MACLEODS** may accumulate over time in the stomach lining causing obstruction, nausea, vomiting, stomach upset, diarrhoea, bleeding and even death. If you experience nausea, vomiting, stomach upset and diarrhoea while receiving **CLOFAZIMINE TABLETS MACLEODS** inform your doctor or pharmacist.
- **CLOFAZIMINE TABLETS MACLEODS** may cause abnormal discolouration of the conjunctiva, tear fluid, sweat, sputum, urine, faeces, sperm, breast milk, hair and reddish to dark brown discolouration of the skin. After you stop taking **CLOFAZIMINE TABLETS MACLEODS**, your skin and eye colour should return to normal, however, this can take several months or years. If the discolouration becomes bothersome or makes you depressed or you have thoughts of suicide, please notify your doctor.
- **CLOFAZIMINE TABLETS MACLEODS** can cause irregular heart rhythms (referred to as a prolongation of the QT-interval, diagnosed by your doctor on an ECG) alone or when taken in combination with other medicines that cause irregular heart rhythms.
- **CLOFAZIMINE TABLETS MACLEODS** must be taken in combination with other medicines (rifampicin and dapsone) to treat leprosy. This is called multi drug therapy (MDT) to ensure that the bacteria causing leprosy does not develop resistance to treatment.
- Always take **CLOFAZIMINE TABLETS MACLEODS** in combination with other medicines prescribed by your doctor to treat tuberculosis.
- Take all your medicines for treatment of leprosy or tuberculosis regularly as prescribed by your doctor as poor compliance can delay healing or make it incomplete or you could become a source for infecting other people.

Other medicines and CLOFAZIMINE TABLETS MACLEODS
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).
Inform your doctor or pharmacist if you are taking any of the following:
- Rifampicin (used to treat tuberculosis or leprosy) - clofazimine in **CLOFAZIMINE TABLETS MACLEODS** may reduce rifampicin absorption in leprosy patients.
- Dapsone (used to treat leprosy) – may reduce the anti-inflammatory activity of **CLOFAZIMINE TABLETS MACLEODS**. If leprosy-associated inflammatory reactions develop when taking dapsone and **CLOFAZIMINE TABLETS MACLEODS**, it is still advisable to continue treatment with both medicines.
- Isoniazid- If you are taking high doses of **CLOFAZIMINE TABLETS MACLEODS** (150 mg daily) and isoniazid (300 mg daily), there may be higher than normal levels of clofazimine in your blood plasma and urine.
- **CLOFAZIMINE TABLETS MACLEODS** may increase the QT interval of your electrocardiogram (ECG) causing heart rhythm disturbances. Tell your doctor if you think this is happening to you.
- QT prolonging medicines such as bedaquiline, azithromycin and fluoroquinolones. Caution is recommended when **CLOFAZIMINE TABLETS MACLEODS** is taken with other medicines with known QT interval prolonging potential.
- Caution should be exercised when taking **CLOFAZIMINE TABLETS MACLEODS** together with medicines such as TB medicines (bedaquiline, delamanid, clarithromycin), selected unboosted anti-retrovirals (amprenavir, delaviridine, efavirenz, etravirine, indinavir, nelfinavir, raltegravir, rilpivirine, simeprevir, maraviroc), medicines to lower your blood pressure and cholesterol (simvastatin, lovastatin, losartan, verapamil, diltiazem, nitrendipine, amlodipine, nislodipine, nifedipine, eplerenone, felodipine, lercanidipine), medicines to reduce blood sugar levels (pioglitazone, repaglinide, saxagliptin).

CLOFAZIMINE TABLETS MACLEODS with food and drink and alcohol
CLOFAZIMINE TABLETS MACLEODS should be taken with food or with a glass of milk to ensure maximum absorption.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **CLOFAZIMINE TABLETS MACLEODS**.
The safe use of **CLOFAZIMINE TABLETS MACLEODS** in pregnancy has not been established.
The active substance of **CLOFAZIMINE TABLETS MACLEODS** crosses the placenta. Skin discolouration of your baby may occur if **CLOFAZIMINE TABLETS MACLEODS** were used during pregnancy.
If you are pregnant or breastfeeding, 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.
The active substance of **CLOFAZIMINE TABLETS MACLEODS** (clofazimine) passes into the breast milk and skin discolouration may occur in the infant. If you are taking **CLOFAZIMINE TABLETS MACLEODS**,you should not breast-feed your baby.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
CLOFAZIMINE TABLETS MACLEODS may cause dizziness, tiredness, headache or vision problems (decreased sharpness or clarity of vision, loss of peripheral vision or "tunnel vision", difficulty in adjusting to day and night vision), hence, use caution when driving or operating machinery until you know how **CLOFAZIMINE TABLETS MACLEODS** affects you.

CLOFAZIMINE TABLETS MACLEODS contains
CLOFAZIMINE TABLETS MACLEODS is sugar free.

3. How to take CLOFAZIMINE TABLETS MACLEODS

- Do not share medicines prescribed for you with any other person.
- Always take **CLOFAZIMINE TABLETS MACLEODS** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Your doctor will tell you how long your treatment with **CLOFAZIMINE TABLETS MACLEODS** will last. Do not stop treatment early.
- If you have the impression that the effect of **CLOFAZIMINE TABLETS MACLEODS** is too strong or too weak, tell your doctor or pharmacist.
- Stay under a healthcare provider's care when taking **CLOFAZIMINE TABLETS MACLEODS**. Do not change your treatment or stop treatment without first talking with your healthcare provider.
- **CLOFAZIMINE TABLETS MACLEODS** should be taken with food or with a glass of milk to ensure maximum absorption.
- ***Leprosy*:**

For the treatment of leprosy, adult patients usually take 300 mg **CLOFAZIMINE TABLETS MACLEODS** under supervision once a month and 50 mg **CLOFAZIMINE TABLETS MACLEODS** once daily, together with other medicines against leprosy. Children (10 to 14 years) usually take 150 mg **CLOFAZIMINE TABLETS MACLEODS** under supervision once a month and 50 mg every other day, together with other medicines against leprosy. For children less than 10 years, your doctor will decide on the most suitable dosage.
Treatment of children below 10 years of age is possible only if dapsone tablets of 25 mg are commercially available.

- **Multidrug-Resistant (MDR) TB:**

For the treatment of MDR-TB, adult's patient weighing at least 30 kg, the recommended dosage is 100 mg/day and adults weighing less than 30 kg, the recommended dosage is 50 mg/day.
Children (10 years of age and over) weighing at least 30 kg, usually are given 2-5 mg/kg/day, not exceeding 100 mg/day. For children weighing less than 30 kg, the recommended dosage is 2-5 mg/kg/day, not exceeding 50 mg/day. If a dose lower than 50 mg/day is required, the 50 mg dose can be given every other day.

If you take more CLOFAZIMINE TABLETS MACLEODS 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.
Symptoms of overdose may include a rapid heart rate of over 100 beats per minute leading to chest pain, fainting, dizziness and shortness of breath (torsade de pointes) and abnormal heart rhythm (QT prolongation).

If you forget to take CLOFAZIMINE TABLETS MACLEODS
It is important to take your **CLOFAZIMINE TABLETS MACLEODS** regularly as prescribed by your doctor. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking CLOFAZIMINE TABLETS MACLEODS
Take **CLOFAZIMINE TABLETS MACLEODS** for as long as your doctor recommends. Do not stop taking **CLOFAZIMINE TABLETS MACLEODS** unless your doctor tells you to. It is important that you complete the course of treatment even if you begin to feel better after a few days. If you stop taking **CLOFAZIMINE TABLETS MACLEODS** too soon your infection may not be completely cured and the infection may return or your condition may get worse. The bacteria causing your infection may become resistant to **CLOFAZIMINE TABLETS MACLEODS**.

4. Possible side effects

CLOFAZIMINE TABLETS MACLEODS can have side effects.
Not all side effects reported for **CLOFAZIMINE TABLETS MACLEODS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **CLOFAZIMINE TABLETS MACLEODS**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking CLOFAZIMINE TABLETS MACLEODS and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Feeling depressed with thoughts of suicide.
- Abnormal heart rhythm causing fainting and seizures (QT prolongation).
- Chest pain, fainting, dizziness and difficulty in breathing (symptoms of Torsades de pointe).
- General weakness, chills, fever, extreme exhaustion and development of infected ulcers in the mucous membranes that line the mouth, throat, and/or intestinal tract (symptoms that are associated with rapidly falling white blood cell levels (agranulocytosis))
- Vision problems (decreased sharpness or clarity of vision, loss of peripheral vision or "tunnel vision", difficulty in adjusting to day and night vision).
- Bowel obstruction with symptoms of nausea or feeling sick, vomiting, abdominal pain or stomach pain and diarrhoea.
- Gastrointestinal bleeding (Bloody or black, tarry stools).
- Severe pain in the left upper quadrant of the abdomen due to crystals in spleen (Splenic infarction).
- Widespread scaling of the skin with itching, skin redness and hair loss (symptoms of exfoliative dermatitis).
- Metabolic acidosis (A condition in which too much acid accumulates in the body). Symptoms include nausea, vomiting, fast breathing and lethargy.

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

Tell your doctor if you notice any of the following:
Frequently occurring side effects:
- Staining of the conjunctiva and pigmentation of the cornea of the eye.
- Dryness of eyes and eye irritation
- Nausea (feeling sick), vomiting, abdominal pain or stomach pain, diarrhoea, stool discolouration
- Abnormal colour of sweat, skin discolouration, change of hair colour
- Dry, scaly or thickened skin, rash and itching
- Abnormal colouration of urine
- Colouring of breast milk
- Weight loss

Less frequently occurring side effects:
- Headache
- Dizziness
- Drowsiness (feeling sleepy)
- Significant vision loss due to colouration of the back of the eye
- Deposits on the protective layer of your eye (corneal deposits)
- Decreased tear production
- Irregular heartbeat
- Swelling of arms or legs
- Ejecting coloured mucus from the throat or lungs by coughing, hawking, or spitting.
- Hepatitis (inflammation of the liver), jaundice (yellowing of skin or white of eyes)
- Decreased appetite
- Inflammation of the intestine due to crystal deposition in the small intestine
- Taste disorders (reduced ability to taste)
- Pain or discomfort in the abdomen
- Constipation
- Increased sensitivity of the skin to the sun
- Acne like skin reaction with redness, swelling and small blisters resulting from direct irritation of the skin
- Fever
- Weakness and lack of energy
- Increased blood sugar levels

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 **CLOFAZIMINE TABLETS MACLEODS**.

5. How to store CLOFAZIMINE TABLETS MACLEODS

Store all medicines out of reach of children.
Store at or below 30 °C (room temperature).
Keep the blister/strip in the carton until required for use.
Do not store in a bathroom.
Do not use after the expiry date stated on the label / carton / bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What CLOFAZIMINE TABLETS MACLEODS contains
- The active substance is Clofazimine 50 mg or 100 mg.
- The other ingredients are betadex, colloidal silicon dioxide, crospovidone, microcrystalline cellulose, polysorbate 80, polyoxyl 40 hydrogenated castor oil, povidone, sodium stearyl fumarate. The coating agent contains hypromellose, red iron oxide, titanium dioxide, triacetin and yellow iron oxide

What CLOFAZIMINE TABLETS MACLEODS looks like and contents of the pack
CLOFAZIMINE TABLETS 50 mg MACLEODS
Light brown coloured, circular shaped, biconvex, film-coated tablets plain on both sides.
CLOFAZIMINE TABLETS 100 mg MACLEODS
Light brown coloured, oval shaped, biconvex, film-coated tablets with scoreline on one side and plain surface on the other side.

Blister Pack
Tablets are packed in aluminium foil laminated on one side and laminated to PVC/PVdC on the other side.
Pack sizes include 10, 28, 56, 84, 100 or 112 tablets.
Strip Pack
Tablets are packed in aluminium foil laminated with polyethylene film on both sides.
Pack sizes include 6, 10, 28, 56, 84, 100 or 112 tablets
Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
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Alberton, South Africa.

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Registration number
CLOFAZIMINE TABLETS 50 mg MACLEODS: 54/20.2.3/0236
CLOFAZIMINE TABLETS 100 mg MACLEODS: 54/20.2.3/0237

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

330 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

CLOFAZIMINE TABLETS 50 mg MACLEODS en
CLOFAZIMINE TABLETS 100 mg MACLEODS (Filmbedekte Tablette)
Klofasimien
Suikervry

Lees hierdie hele inligtingstuk aandagtig deur voordat jy CLOFAZIMINE TABLETS MACLEODS begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer
- **CLOFAZIMINE TABLETS MACLEODS** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

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

1. Wat CLOFAZIMINE TABLETS MACLEODS is en waarvoor dit gebruik word

CLOFAZIMINE TABLETS MACLEODS word gebruik om tuberkulose (TB) te behandel wanneer die siekte weerstandig geword het teen ander antibiotika. Dit word multi-geneesmiddel weerstandige pulmonale tuberkulose genoem. **CLOFAZIMINE TABLETS MACLEODS** word saam met ander medisyne gebruik vir die behandeling van tuberkulose. **CLOFAZIMINE TABLETS MACLEODS** word ook gebruik vir die behandeling van melaatsheid (Hansen se siekte) in kombinasie met ander antibiotiese medisyne dapsoon en rifampisien.

2. Wat jy moet weet voordat jy CLOFAZIMINE TABLETS MACLEODS neem

Moet nie CLOFAZIMINE TABLETS MACLEODS neem nie:
- Indien jy hipersensitief (allergies) is vir Klofasimien of vir enige van die bestanddele van **CLOFAZIMINE TABLETS MACLEODS**
- Indien jy 'n persoonlike of familiegeskiedenis het van 'n hartprobleem genaamd 'aangebore lang QT-sindroom'.
- Indien jy ander medisyne neem wat bekend daarvoor is om die QTc-interval te verleng tot op die tydsintervalle wat bekend daarvoor is om ernstige hartritmesteurnisse (disritmieë) te veroorsaak.

Waarskuwings en voorsorgmaatreëls
Spesiale sorg moet geneem word met **CLOFAZIMINE TABLETS MACLEODS**
- **CLOFAZIMINE TABLETS MACLEODS** kan mettertyd in die maagvoering ophoop wat obstruksie, naarheid, braking, omgekrapte maag, diaree, bloeding en selfs die dood veroorsaak. Indien jy naarheid, braking, omgekrapte maag en diaree ervaar terwyl jy **CLOFAZIMINE TABLETS MACLEODS** ontvang, stel jou dokter of apteker in kennis.
- **CLOFAZIMINE TABLETS MACLEODS** kan abnormale verkleuring van die konjunktiva, traanvloeistof, sweet, sputum, uriene, ontlasting, sperm, borsmelk, hare en rooierige tot donkerbruin verkleuring van die vel veroorsaak. Nadat jy opgehou het **om CLOFAZIMINE TABLETS MACLEODS** te gebruik, moet jou vel- en oogkleur na normaal terugkeer, maar dit kan egter 'n paar maande of jare neem. Indien die verkleuring lastig raak of jou depressief maak of jy selfmoordgedagtes het, stel asseblief jou dokter in kennis.
- **CLOFAZIMINE TABLETS MACLEODS** kan onreëlmatige hartritmes veroorsaak (na verwys as 'n verlenging van die QT-interval, gediagnoseer deur jou dokter op 'n EKG) alleen of wanneer dit geneem word in kombinasie met ander medisyne wat onreëlmatige hartritmes veroorsaak.
- **CLOFAZIMINE TABLETS MACLEODS** moet in kombinasie met ander medisyne (rifampisien en dapsoon) geneem word om melaatsheid te behandel. Dit word multi-geneesmiddelterapie (MGT) genoem om te verseker dat die bakterieë wat melaatsheid veroorsaak nie weerstand teen die behandeling ontwikkel nie.
- Neem altyd **CLOFAZIMINE TABLETS MACLEODS** in kombinasie met ander medisyne wat deur jou dokter voorgeskryf is om tuberkulose te behandel.
- Neem gereeld al jou medisyne vir die behandeling van melaatsheid of tuberkulose soos deur jou dokter voorgeskryf, aangesien swak nakoming daarvan genesing kan vertraag of dit onvolledig maak, of jy kan 'n bron word om ander mense te infekteer.

Ander medisyne en CLOFAZIMINE TABLETS MACLEODS
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Lig jou dokter of apteker in indien jy enige van die volgende gebruik:
- Rifampisien (wat gebruik word om tuberkulose of melaatsheid te behandel) - klofasimien in **CLOFAZIMINE TABLETS MACLEODS** kan rifampisienabsorpsie in melaatsheidspasiënte verminder.
- Dapsoon (wat gebruik word om melaatsheid te behandel) – kan die anti-inflammatoriese aktiwiteit van **CLOFAZIMINE TABLETS MACLEODS** verminder. Indien melaatsheid-geassosieerde inflammatoriese reaksies ontwikkel wanneer dapsoon en **CLOFAZIMINE TABLETS MACLEODS** geneem word, is dit steeds raadsaam om met beide medisyne voort te gaan.
- Isoniasied - Indien jy hoë dosisse van **CLOFAZIMINE TABLETS MACLEODS** (150 mg per dag) en isoniasied (300 mg per dag) neem, kan daar hoër as normale vlakke van klofasimien in jou bloedplasma en uriene wees.
- **CLOFAZIMINE TABLETS MACLEODS** kan die QT-interval van jou elektrokardiogram (EKG) verhoog wat hartritmesteurnisse kan veroorsaak. Lig jou dokter in as jy vermoed dat dit met jou gebeur.
- QT verlengende medisyne soos bedakwilien, asitromisien en fluorokinolone. Versigtigheid word aanbeveel wanneer **CLOFAZIMINE TABLETS MACLEODS** geneem word saam met ander medisyne met 'n bekende QT-interval verlengingspotensiaal.
- Versigtigheid moet uitgeoefen word wanneer **CLOFAZIMINE TABLETS MACLEODS** saam met medisyne soos TB-medisyne (bedakwilien, delamanid, klaritromisien), geselekteerde onversterkte anti-retrovirale middels (amprenavir, delaviridien, efavirens, etravirien, indinavir, nelfinavir, raltegravir, rilpivirien, simeprevir, maravirok), medisyne om jou bloeddruk en cholesterol te verlaag (simvastatien, lovastatien, losartan, verapamil, diltiasem, nitrendipien, amlodipien, nisilodipien, nifedipien, eplerenoon, felodipien, lerkanidipien), medisyne om bloedsuikervlakke te verlaag (pioglitasoon, repaglinied, saksagliptien).

CLOFAZIMINE TABLETS MACLEODS met voedsel en vloeistof en alkohol
CLOFAZIMINE TABLETS MACLEODS moet saam met kos of met 'n glas melk geneem word om maksimum absorpsie te verseker.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **CLOFAZIMINE TABLETS MACLEODS** neem.
Die veilige gebruik van **CLOFAZIMINE TABLETS MACLEODS** gedurende swangerskap is nie vasgestel nie.
Die aktiewe bestanddeel van **CLOFAZIMINE TABLETS MACLEODS** kruis die plasenta.
Verkleuring van jou baba se vel kan voorkom indien **CLOFAZIMINE TABLETS MACLEODS** tydens swangerskap gebruik is.
Indien jy swanger is of borsvoed, vermoed dat jy swanger is of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne neem.
Die aktiewe bestanddeel van **CLOFAZIMINE TABLETS MACLEODS** (klofasimien) gaan oor in die borsmelk en verkleuring van die vel kan in die baba voorkom. Indien jy **CLOFAZIMINE TABLETS MACLEODS** neem, moet jy nie jou baba borsvoed nie.
Vra jou dokter of apteker vir advies voordat jy enige medisyne neem.

Bestuur en gebruik van masjinerie
CLOFAZIMINE TABLETS MACLEODS kan duiseligheid, moegheid, hoofpyn of probleme met visie veroorsaak (verminderde skerpte of helderheid van visie, verlies van perifere visie of "tonnelvisie", probleme om aan te pas by dag- en nagvisie), wees dus versigtig wanneer jy bestuur of masjinerie gebruik totdat jy weet tot hoe 'n mate **CLOFAZIMINE TABLETS MACLEODS** jou affekteer.

CLOFAZIMINE TABLETS MACLEODS bevat
CLOFAZIMINE TABLETS MACLEODS is suikervry.

3. Hoe om CLOFAZIMINE TABLETS MACLEODS te neem

- Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
- Neem altyd **CLOFAZIMINE TABLETS MACLEODS** presies soos jou dokter of apteker vir jou gesê het. Vra vir jou dokter of apteker indien jy nie seker is nie.
- Jou dokter sal vir jou sê hoe lank jou behandeling met **CLOFAZIMINE TABLETS MACLEODS** sal duur. Moet nie behandeling vroeg stop nie.
- Indien jy onder die indruk is dat die effek van **CLOFAZIMINE TABLETS MACLEODS** te sterk of te swak is, sê vir jou dokter of apteker.
- Bly onder die sorg van 'n gesondheidsorgverskaffer wanneer **CLOFAZIMINE TABLETS MACLEODS** geneem word. Moet nie jou behandeling verander of die behandeling stop sonder om eers met jou gesondheidsorgverskaffer te praat nie.
- **CLOFAZIMINE TABLETS MACLEODS** moet saam met kos of met 'n glas melk geneem word om maksimum absorpsie te verseker.
- ***Melaatsheid***:

Vir die behandeling van melaatsheid neem volwasse pasiënte gewoonlik een keer per maand 300 mg **CLOFAZIMINE TABLETS MACLEODS** onder toesig en 50 mg **CLOFAZIMINE TABLETS MACLEODS** een keer per dag, saam met ander medisyne teen melaatsheid. Kinders (10 tot 14 jariges) neem gewoonlik 150 mg **CLOFAZIMINE TABLETS MACLEODS** onder toesig een keer per maand en 50 mg elke ander dag, saam met ander medisyne teen melaatsheid. Vir kinders jonger as 10 jaar oud sal jou dokter besluit oor die mees geskikste dosis.
Behandeling van kinders jonger as 10 jarige ouderdom is moontlik, slegs indien 25 mg van dapsoon tablette kommersieel beskikbaar is.

- **Multi-geneesmiddel weerstandige (MGW) TB:**

Vir die behandeling van MGW-TB, volwassene pasiënt wat ten minste 30 kg weeg, is die aanbevole dosis 100 mg/dag en volwassenes wat minder as 30 kg weeg, is die aanbevole dosis 50 mg/dag.
Kinders (10 jarige ouderdom en ouer) wat minstens 30 kg weeg, word gewoonlik 2-5 mg/kg/dag gegee, nie meer as 100 mg/dag nie. Vir kinders wat minder as 30 kg weeg, is die aanbevole dosis 2-5 mg/kg/dag, nie meer as 50 mg/dag nie. Indien 'n dosis laer as 50 mg/dag benodig word, kan die 50 mg dosis elke ander dag gegee word.

Indien jy meer CLOFAZIMINE TABLETS MACLEODS neem as wat jy behoort te neem
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Simptome van oordosis kan 'n vinnige hartklop van meer as 100 slae per minuut insluit wat lei tot borskaspyn, floute, duiseligheid en kort van asem (torsade de pointes) en abnormale hartritme (QT-verlenging).

Indien jy vergeet om CLOFAZIMINE TABLETS MACLEODS te neem
Dit is belangrik om jou **CLOFAZIMINE TABLETS MACLEODS** gereeld te neem soos voorgeskryf deur jou dokter. Indien jy vergeet om 'n dosis te neem, neem dit so gou as wat jy daarvan onthou, tensy dit tyd is vir jou volgende dosis. In daardie geval, gaan voort met die volgende dosis soos normaal. Moet nie 'n dubbele dosis neem om vir 'n vergete dosis op te maak nie.

Indien jy ophou om CLOFAZIMINE TABLETS MACLEODS te neem
Neem **CLOFAZIMINE TABLETS MACLEODS** vir so lank as wat jou dokter aanbeveel. Moet nie ophou om **CLOFAZIMINE TABLETS MACLEODS** te neem nie, tensy jou dokter jou inlig om dit te doen. Dit is belangrik dat jy die kursus van behandeling voltooi, selfs al begin jy na 'n paar dae beter voel. Indien jy te gou ophou om **CLOFAZIMINE TABLETS MACLEODS** te gebruik, is jou infeksie dalk nie heeltemal genees nie en die infeksie kan terugkeer of jou toestand kan erger word. Die bakterieë wat jou infeksie veroorsaak, kan weerstandig word teen **CLOFAZIMINE TABLETS MACLEODS**.

4. Moontlike newe-effekte

CLOFAZIMINE TABLETS MACLEODS kan newe-effekte hê.
Nie al die newe-effekte wat vir **CLOFAZIMINE TABLETS MACLEODS** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl jy **CLOFAZIMINE TABLETS MACLEODS** neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om CLOFAZIMINE TABLETS MACLEODS te neem en lig onmiddellik jou dokter in, of gaan na die ongevalle afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk of asemhaling;
- uitslag of jeuk;
- floute.

Hierdie is almal baie ernstige newe-effekte. Jy benodig moontlik dringende mediese aandag of hospitalisasie.

Sê onmiddellik vir jou dokter, of gaan na die ongevalle afdeling van jou naaste hospitaal indien jy enige van die volgende waarneem:
- Voel depressief met gedagtes van selfmoord.
- Abnormale hartritme wat floute en aanvalle veroorsaak (QT verlenging).
- Borskaspyn, floute, duiseligheid en probleme met asemhaling (simptome van Torsades de pointe).
- Algemene swakheid, koue rillings, koors, uiterste uitputting en ontwikkeling van geïnfekteerde ulkusse in die slymvliese wat die mond, keel en/of dermkanaal voering (simptome wat geassosieer word met vinnig dalende witbloedsel vlakke (agranulositose))
- Visieprobleme (verminderde skerpte of helderheid van visie, verlies van perifere visie of "tonnelvisie", probleme om aan te pas by dag- en nagvisie).
- Dermobstruksie met simptome van naarheid of siek voel, braking, abdominale pyn of maagpyn en diaree.
- Gastroïntestinale bloeding (Bloederige of swart, teeragtige stoelgang).
- Erge pyn in die linker boonste kwadrant van die buik as gevolg van kristalle in milt (Miltinfarksie).
- Wydverspreide skilfering van die vel met jeuk, velrooiheid en haarverlies (simptome van eksfoliatiewe dermatitis).
- Metaboliese asidose ('n Toestand waarin te veel suur in die liggaam ophoop). Simptome sluit in naarheid, braking, vinnige asemhaling en lusteloosheid.

Hierdie is almal ernstige newe-effekte. Jy benodig moontlik dringende mediese behandeling.

Lig jou dokter in as jy enige van die volgende waarneem:
Newe-effekte wat gereeld voorkom:
- Kleuring van die konjunktiva en pigmentasie van die kornea van die oog.
- Droogheid van oë en oogirritasie
- Naarheid (siek voel), braking, abdominale pyn of maagpyn, diaree, verkleuring van ontlasting
- Abnormale kleur van sweet, velverkleuring, verandering van haarkleur
- Droë, skubberige of verdikte vel, uitslag en jeuk
- Abnormale kleur van uriene
- Verkleuring van borsmelk
- Gewigsverlies

Newe-effekte wat minder gereeld voorkom:
- Hoofpyn
- Duiseligheid
- Lomerigheid (voel slaperig)
- Beduidende sigverlies as gevolg van kleur van die agterkant van die oog
- Neerslae op die beskermende laag van jou oog (korneale neerslae)
- Verminderde traanproduksie
- Onreëlmatige hartklop
- Swelling van arms of bene
- Uitwerping van gekleurde slym vanuit die keel of longe deur te hoes, keel skoon te maak of te spoeg.
- Hepatitis (ontsteking van die lewer), geelsug (vergeling van vel of wit van oë)
- Verminderde eetlus
- Ontsteking van die ingewande as gevolg van kristalneerlegging in die dunderm
- Smaakversteurings (verminderde vermoë om te proe)
- Pyn of ongemak in die buik
- Hardlywigheid
- Verhoogde sensitiwiteit van die vel vir die son
- Aknee-tipe velreaksie met rooiheid, swelling en klein blasies as gevolg van direkte irritasie van die vel
- Koors
- Swakheid en gebrek aan energie
- Verhoogde bloedsuikervlakke

Indien jy enige newe-effekte ondervind wat nie in hierdie inligtingstuk genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld kan jy help om meer inligting rakende die veiligheid van **CLOFAZIMINE TABLETS MACLEODS** te verskaf.

5. Hoe om CLOFAZIMINE TABLETS MACLEODS te bewaar

Bewaar alle medisyne buite bereik van kinders
Bewaar by of benede 30 °C (kamertemperatuur).
Hou die stulpstroke/strook in die buitenste karton totdat dit benodig word vir gebruik.
Moet nie in 'n badkamer bêre nie.
Moet nie ná die vervaldatum gebruik wat op die etiket/karton/bottel gedruk is nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat CLOFAZIMINE TABLETS MACLEODS bevat
- Die aktiewe bestanddeel is Klofasimien 50 mg of 100 mg.
- Die ander bestanddele is betadeks, kolloïdale silikondioksied, krospovidoon, mikrokristallyne sellulose, polisorbaat 80, polioksiel 40 gehidrogeneerde kasterolie, povidoon, natriumstearielfumaraat. Die bedekkingsmiddel bevat hipromellose, rooi ysteroksied, titaandioksied, triasetien en geel ysteroksied

Hoe CLOFAZIMINE TABLETS MACLEODS lyk en inhoud van die pak
CLOFAZIMINE TABLETS 50 mg MACLEODS
Ligbruin gekleurde, sirkelvormige, bikonvekse, filmbedekte tablette, glad aan beide kante.
CLOFAZIMINE TABLETS 100 mg MACLEODS
Ligbruin gekleurde, ovaalvormige, bikonvekse, filmbedekte tablette met breeklyn aan die een kant en gladde oppervlak aan die ander kant.

Stulpverpakking
Tablette word verpak in aluminiumfoelie wat aan die een kant gelamineer is en aan die ander kant gelamineer is tot PVC/PVdC.
Verpakkingsgroottes sluit 10, 28, 56, 84, 100 of 112 tablette in.
Strookverpakking
Tablette word verpak in aluminiumfoelie gelamineer met poliëtileenfilm aan beide kante.
Verpakkingsgroottes sluit 6, 10, 28, 56, 84, 100 of 112 tablette in
Nie alle verpakkings en pakgroottes word noodwendig bemark nie.

Houer van die Sertifikaat van Registrasie en Vervaardiger
MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia-rylaan 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid-Afrika.

Hierdie inligtingstuk was laas hersien in
25 April 2023

Registrasienommer
CLOFAZIMINE TABLETS 50 mg MACLEODS: 54/20.2.3/0236
CLOFAZIMINE TABLETS 100 mg MACLEODS: 54/20.2.3/0237

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

1. Product: CLOFAZIMINE TABLETS 50/100 mg MACLEODS					
2. Country: South Africa (Tender)		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 330(W) mm			
9. Design / Style: Booklet type		10. Item code No.: PM00439701			
11. Artwork has been made: Actual Size		12. Pharma code No.: 40375 mini			
13. Barcode/NDC No: NA		14. Supersedes Item code No: NA			
15. Revision No: 00		16. A/W File name:Z:\South Africa\Clofazimine\Tender 2025\Clofazamine Tablet 100 mg PIL - PM00439701.cdr			
Approved By:		17. Location: OXALIS			
PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	19/08/2025				

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/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa - Private Market	PM00439701		