Front Top

180 mm

16 mm | 20 mm | 144 mm

260 mm Center folded

Grain Direction

32.5 mm

520 mm

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):
MACLEODS PYRAZINAMIDE 500 (Tablets)

COMPOSITION:
Each tablet contains 500 mg pyrazinamide.
Sugar free.
The inactive ingredients are: Maize starch, povidone K-30, sodium starch glycolate, purified talc, colloidal anhydrous silica and magnesium stearate.

PHARMACOLOGICAL CLASSIFICATION:
A 20.2.3 Tuberculostatics.

PHARMACOLOGICAL ACTION:
Pyrazinamide is the pyrazine analogue of nicotinamide, and is an antituberculous agent.
Pyrazinamide may be bacteriostatic or bactericidal against Mycobacterium tuberculosis depending on the concentration of the medicine attained at the site of infection. The mechanism of action is unknown.

Pharmacokinetic properties and metabolism:
Absorption:
Pyrazinamide is well absorbed from the gastrointestinal tract. After single oral dose administration of pyrazinamide in healthy volunteers, the peak plasma concentration (C_{max}) was 12, 29 mcg/ml and was achieved in 1,22 hours.
Distribution:
It is widely distributed in body tissues and fluids including the liver, lungs and cerebrospinal fluid (CSF).
The AUC_{0-t} was 123,35 mcg/hr/ml, $AUC_{0-\infty}$ was 167,96 mcg/hr/ml.
Metabolism:
Pyrazinamide is approximately 10 % bound to plasma proteins. Pyrazinamide is hydrolysed in the liver to its major active metabolite, pyrazinoic acid. Pyrazinoic acid is hydroxylated to the main excretory product, 5-hydroxypyrazinoic acid. The half-life ($t_{1/2}$) of pyrazinamide is 9,27 hours in patients with normal renal and hepatic function. The plasma half-life may be prolonged in patients with impaired renal or hepatic function.
Excretion:
Approximately 70 % of an oral dose is excreted in the urine, mainly by glomerular filtration within 24 hours.

INDICATIONS:
MACLEODS PYRAZINAMIDE 500 is indicated for the initial treatment of active tuberculosis in adults when combined with other antituberculous agents.

CONTRA-INDICATIONS:
MACLEODS PYRAZINAMIDE 500 is contra-indicated in patients hypersensitive to pyrazinamide and other chemically related medicines such as ethionamide, isoniazid, niacin (nicotinic acid) or to any of the excipients contained in **MACLEODS PYRAZINAMIDE 500.**
MACLEODS PYRAZINAMIDE 500 is contraindicated in patients with severe hepatic damage, and patients with a history of gout.

WARNINGS AND SPECIAL PRECAUTIONS:
General:
Patients started on **MACLEODS PYRAZINAMIDE 500** should have baseline serum uric acid and liver function determinations and during treatment thereafter.

Those patients with pre-existing liver disease or those at increased risk for medicine related hepatitis (e.g., alcohol abusers) should be followed closely.
MACLEODS PYRAZINAMIDE 500 should be discontinued and not be resumed if signs of hepatocellular damage or hyperuricaemia accompanied by an acute gouty arthritis appear.

Caution should be observed in patients with impaired renal function or gout.

Diabetes mellitus may become difficult to control in patients who are receiving **MACLEODS PYRAZINAMIDE 500.**

Ability to drive and use machines:
MACLEODS PYRAZINAMIDE 500 is unlikely to affect the patient's ability to drive or operate machinery. However, **MACLEODS PYRAZINAMIDE 500** can induce side effects which can affect the patient's ability to drive and operate machinery. Therefore, driving and operating complex machinery should be avoided if these effects occur during treatment.

INTERACTIONS:
Antigout medicines
MACLEODS PYRAZINAMIDE 500 may increase serum uric acid concentrations and decrease the efficacy of the following antigout medicines: allopurinol, colchicine, probenecid and sulfinpyrazone. Dosage adjustments of these medicines may be necessary to control hyperuricaemia and gout when antigout medicines are used concurrently with **MACLEODS PYRAZINAMIDE 500.**
Ciclosporin
Concurrent use with **MACLEODS PYRAZINAMIDE 500** may decrease the serum concentrations of ciclosporin, leading to inadequate immunosuppression. Ciclosporin serum concentrations should be monitored when used concurrently with **MACLEODS PYRAZINAMIDE 500.**
Laboratory value alterations
MACLEODS PYRAZINAMIDE 500 may react with sodium nitroprusside tests for the determination of ketones in urine, to produce an interfering pink-brown colour reaction with nitroprusside.
Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) values may be increased.
Uric acid serum concentrations may be increased.

PREGNANCY AND LACTATION:
Safety in pregnancy has not been established. It is not known whether **MACLEODS PYRAZINAMIDE 500** can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity.
Lactation
Pyrazinamide has been found in small amounts in breast milk. Therefore, it is advised that **MACLEODS PYRAZINAMIDE 500** should not be used in mothers breastfeeding their infants.

DOSAGE AND DIRECTIONS FOR USE:
MACLEODS PYRAZINAMIDE 500 should always be administered with other effective antituberculous medicines.
Patients with concomitant HIV infection may require longer courses of therapy. Medical practitioners treating such patients should be alert to any revised recommendations for this group of patients.

Adults:

	Adult
Daily dose	20 – 35 mg/kg body mass in a maximum of 3 g daily in 3 or 4 equally spaced doses

Paediatric use:
Safety and efficacy have not been established in paediatrics.

Geriatric use:
In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic or renal function, and of concomitant disease or other medicine therapy.

Impaired renal function:
It does not appear that patients with impaired renal function require a reduction in dose, however, it may be prudent to select doses at the lower end of the dosing range.

SIDE EFFECTS:
Side effects have been reported:
Hepatic disorders:
Frequent: Hepatotoxicity, transient increase in liver enzyme values, hepatomegaly, splenomegaly, jaundice.

Gastro-intestinal disorders:
Frequent: Nausea, vomiting, anorexia.

Blood and lymphatic system disorders:
Less frequent: Thrombocytopenia, sideroblastic anaemia with erythroid hyperplasia, vacuolation of erythrocytes, increased serum iron concentration and adverse effects on blood clotting mechanisms.

Musculoskeletal and connective tissue disorders:
Frequent: Myalgia, arthralgia.

Metabolism and nutritional disorders:
Frequent: Hyperuricaemia leading to gout.

Skin and subcutaneous tissue disorders:
Less frequent: Acne, photosensitivity, Hypersensitivity reactions, skin rashes, urticaria, pruritus.

Renal and urinary disorders:
Less frequent: Dysuria, interstitial nephritis.

General disorders and administration site conditions:
Less frequent: Fever, malaise.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Acute liver damage and hyperuricaemia have been reported. Treatment is essentially symptomatic. Emesis and gastric lavage may be of value if undertaken within a few hours of ingestion. There is no specific antidote and treatment is supportive.

IDENTIFICATION:
MACLEODS PYRAZINAMIDE 500: White, circular, flat, bevelled edged, uncoated tablets having a break line on the one side and plain surface on the other side.

PRESENTATION:
MACLEODS PYRAZINAMIDE 500:
High Density Polyethylene (HDPE) bottle pack comprises of 850 ml milky white, round container provided along with a white, polypropylene (PP), screw thread cap – 1000's, packed in a pre-printed unit carton.
Blister packs of 28's, 56's, 84's and 100's – silver coloured, printed aluminium, hard foil, tempered coated with VMCH on bright side and clear, transparent, thermoformable, rigid film (PVC), packed in a pre-printed unit carton.

STORAGE INSTRUCTIONS:
Store in a dry place, at or below 30 °C. Protect from light. Keep the bottle well closed. Do not remove tablets from blister until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
MACLEODS PYRAZINAMIDE 500: 45/20.2.3/0844

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Macleods Pharmaceuticals SA (Pty) Ltd.
Office Block 1,
Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock,
Ext 12, Alberton.

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
21 April 2016

Patient Information Leaflet

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
MACLEODS PYRAZINAMIDE 500 (Tablets)

Read this leaflet carefully before you start using MACLEODS PYRAZINAMIDE 500
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- **MACLEODS PYRAZINAMIDE 500** 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 MACLEODS PYRAZINAMIDE 500 CONTAINS:
Each tablet contains 500 mg pyrazinamide. Sugar free.
The inactive ingredients are: Maize starch, povidone K-30, sodium starch glycolate, purified talc, colloidal anhydrous silica and magnesium stearate.

WHAT MACLEODS PYRAZINAMIDE 500 IS USED FOR:
MACLEODS PYRAZINAMIDE 500 belongs to a group of medicines known as antituberculous agents.
MACLEODS PYRAZINAMIDE 500 is used for the treatment of tuberculosis in combination with other antituberculosis medicines.

BEFORE TAKING MACLEODS PYRAZINAMIDE 500:
Do not take MACLEODS PYRAZINAMIDE 500:
- If you are hypersensitive (allergic) to pyrazinamide or to medicines of the same class such as ethionamide, isoniazid, niacin (nicotinic acid) or to any of the other ingredients of **MACLEODS PYRAZINAMIDE 500.**
- If you have severe liver damage or acute gout.

Take special care with MACLEODS PYRAZINAMIDE 500:
- If you have known risk factors for liver disease; however, cases also have been reported in patients with no known risk factors. You should stop treatment with **MACLEODS PYRAZINAMIDE 500** if symptoms of toxicity develops.
- Inform your doctor if you have the following conditions:
  - Kidney disease
  - History of gout
  - Diabetes, as sugar levels may be difficult to control while taking **MACLEODS PYRAZINAMIDE 500**

Before you have any medical tests, tell the doctor that you are taking **MACLEODS PYRAZINAMIDE 500.**

Taking MACLEODS PYRAZINAMIDE 500 with food and drink:
MACLEODS PYRAZINAMIDE 500 can be taken with or without food.

Pregnancy and breastfeeding:
- Do not take **MACLEODS PYRAZINAMIDE 500** if you are pregnant or are planning to become pregnant.
- Pyrazinamide is found in breast milk and can be passed on to breastfed babies. Do not breastfeed your baby while you are taking **MACLEODS PYRAZINAMIDE 500.**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **MACLEODS PYRAZINAMIDE 500.**

Driving and using machinery:
MACLEODS PYRAZINAMIDE 500 is unlikely to affect your ability to drive or operate machinery. However, occasionally **MACLEODS PYRAZINAMIDE 500** can induce side effects that make you feel unwell. Therefore, driving and operating complex machinery should be avoided if these effects occur during treatment.

Taking other medicines with MACLEODS PYRAZINAMIDE 500:
When you are taking **MACLEODS PYRAZINAMIDE 500**, it is especially important to tell your doctor or healthcare professional if you are taking any of the following medicines:
- Allopurinol, colchicine, probenecid and sulfinpyrazone (used for the treatment of gout).
- Ciclosporin (used to suppress the immune system).

MACLEODS PYRAZINAMIDE 500 has been reported to interfere with urine tests to produce a pink-brown colour.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

HOW TO TAKE MACLEODS PYRAZINAMIDE 500:
Do not share medicines prescribed for you with any other person.
Always take **MACLEODS PYRAZINAMIDE 500** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Doses may be taken at any time of day with or without food.

MACLEODS PYRAZINAMIDE 500 should always be taken with other effective antituberculous medicines.
Take **MACLEODS PYRAZINAMIDE 500** exactly as described by your doctor. The dose depends on body mass and is different for each patient.
If you have the impression that the effect of **MACLEODS PYRAZINAMIDE 500** is too strong or too weak, talk to your doctor or pharmacist.

If you take more MACLEODS PYRAZINAMIDE 500 than you should:
If you accidentally take too much **MACLEODS PYRAZINAMIDE 500** (more than your usual daily dose), tell your doctor at once.

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

If you forget to take MACLEODS PYRAZINAMIDE 500:
If you missed a dose, take it as soon as possible. However, if you do not remember the missed dose until the next day, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with MACLEODS PYRAZINAMIDE 500 is stopped:
If **MACLEODS PYRAZINAMIDE 500** must be stopped, your doctor will discuss this with you and recommend alternative treatment.

SIDE EFFECTS:
MACLEODS PYRAZINAMIDE 500 can have side effects.
Not all the side effects reported for **MACLEODS PYRAZINAMIDE 500** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MACLEODS PYRAZINAMIDE 500**, please consult your doctor, pharmacist or healthcare professional for advice.

If any of the following side effects occur, speak to your doctor or pharmacist immediately:
Any unexpected allergic reaction or if you develop a rash.

If any of the following side effects occur, speak to your doctor or pharmacist as soon as possible:
Feeling sick (nausea), vomiting, loss of appetite (not feeling hungry), headache, changes to the results of blood tests, liver toxicity, skin rash, acne, sensitivity to the sun, allergic reactions, difficulty going to the toilet (urinating), fever, aches and pains in muscles, pain and swelling of joints (especially big toe, ankle and knee with times, hot skin over affected joints), unusual tiredness or weakness, and yellow eyes or skin.

STORAGE AND DISPOSING OF MACLEODS PYRAZINAMIDE 500:
KEEP OUT REACH OF CHILDREN.
Store in a dry place, at or below 30°C. Protect from light. Keep the bottle well closed. Do not remove tablets from blister until required for use.
Do not use after the expiry date stated on the label.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF MACLEODS PYRAZINAMIDE 500:
High Density Polyethylene (HDPE) bottle pack comprises of 850 ml milky white, round container provided along with a white, polypropylene (PP), screw thread cap – 1000's, packed in a pre-printed unit carton.
Blister packs of 28's, 56's, 84's and 100's – silver coloured, printed aluminium, hard foil, tempered coated with VMCH on bright side and clear, transparent, thermoformable, rigid film (PVC), packed in a pre-printed unit carton.

IDENTIFICATION OF MACLEODS PYRAZINAMIDE 500:
MACLEODS PYRAZINAMIDE 500: White, circular, flat, bevelled edged, uncoated tablets having a break line on the one side and plain surface on the other side.

REGISTRATION NUMBERS:
MACLEODS PYRAZINAMIDE 500: 45/20.2.3/0844

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:
Macleods Pharmaceuticals SA (Pty) Ltd.
Office Block 1,
Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock,
Ext 12, Alberton.

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:
21 April 2016

Back Top

180 mm

4 mm

20 mm

156 mm

Grain Direction

260 mm Center folded

520 mm

32.5 mm

SKEDULERINGSTATUS:

S4

EIENDOMSNAAM (EN DOSEERVORM):
MACLEODS PYRAZINAMIDE 500 (tablette).

SAMESTELLING:
Elke tablet bevat 500 mg pirasinamied, Suikervry.
Die oraktiewe bestanddele is: Mellestysel, povidoon K-30, natriumstyseiglikolaat, gesuiwerde talk, kolloidale anhidriese silika en magnesiumstearaat.

FARMAKOLOGIESE KLASSIFIKASIE:
A20.2.3 Tuberkulostatiese middels.

FARMAKOLOGIESE WERKING:
Pirasinamied is die pirasionanaloog van nikotienamied en is 'n teentuberkulosemiddel. Pirasinamied kan bakteriostaties of bakterisidies teen *Mycobacterium tuberculosis* wees, afhangende van die konsentrasie van die medisyne wat by die plek van infeksie verkry word. Die meganisme van werking is onbekend.

Farmakokinetiese eienskappe en metabolisme:
Absorpsie:
Pirasinamied word goed vanuit die maagdermkanaal geabsorbeer. Na die toediening van 'n enkel dosis pirasinamied in gesonde vrywilligers, was die piek plasmakonsentrasie (K_{max}) 12,29 mkg/ml en is in 1,22 ure bereik.

Verspreiding:
Dit word wyd in die liggaamsweefsels, insluitende die lewer, longe en serebrospinale vloeistof (SSV) verspreì.
Die AOK_{∞} was 123,35 mkg/uur/ml en die AOK_{∞} was 167,96 mkg/uur/ml.

Metabolisme:
Pirasinamied word ongeveer 10 % aan plasmaproteïene gebind. Pirasinamied word in die lewer na sy belangrike aktiewe metaboliet, pirasinoiensuur gehidroliseer. Pirasinoiensuur word na die belangrikste uitskeidingsproduk, 5-hidroksiepirasinoiensuur gehidrokaileer. Die halfleeftyd ($t_{1/2}$) van pirasinamied is 9,27 ure in pasiënte met normale nier- en lewerfunksie. Die plasmahalfleeftyd kan langer wees in pasiënte met ingekorte nier- of lewerfunksie.

Uitskeiding:
Ongeveer 70 % van 'n orale dosis word binne 24 uur in die urien uitgeskei, hoofsaaklik deur glomerulêre filtrasie.

INDIKASIES:
MACLEODS PYRAZINAMIDE 500 word aangedui vir die aanvanklike behandeling van aktiewe tuberkulose in volwassenes wanneer dit saam met ander teentuberkulosemiddels gebruik word.

KONTRA-INDIKASIES:
MACLEODS PYRAZINAMIDE 500 word teeneangedui in pasiënte wat hipersensitief teen pirasinamied en ander chemies verwante medisyne soos etionamied, isoniasied, niasien (nikotiensuur), of teen enige van die eksipiënte wat in **MACLEODS PYRAZINAMIDE 500** voorkom, is.

MACLEODS PYRAZINAMIDE 500 word teeneangedui in pasiënte met erg beskadigde lewerfunksie, asook in pasiënte met 'n geskiedenis van jig.

WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS:
Algemeen:
Pasiënte wat op **MACLEODS PYRAZINAMIDE 500** begin word behoort basislyn uriensuur- en lewerfunksiebepalings te ondergaan, asook tydens behandeling daarna.

Pasiënte met reeds bestaande lewersiekte of diegene met 'n verhoogde middelverwante hepatitis (bv. alkoholmisbruikers) behoort noukeurig gemonitor te word. **MACLEODS PYRAZINAMIDE 500** behoort ontrek te word en nie weer ingestel te word nie indien tekens van hepatosellulêre beskadiging of hiperurisemie met gepaardgaande akute jiggetige artritis voorkom.

Sorg behoort ook aan die dag gelê te word in pasiënte met ingekorte nierfunksie of jig.

Dit kan moeilik raak om diabetes mellitus in pasiënte wat **MACLEODS PYRAZINAMIDE 500** ontvang, te beheer.

Die vermoë om te bestuur en masjinerie te gebruik:
Dit is onwaarskynlik dat **MACLEODS PYRAZINAMIDE 500** die pasiënt se vermoë om te bestuur of met masjinerie te werk, sal beïnvloed. **MACLEODS PYRAZINAMIDE 500** kan egter newe-effekte veroorsaak wat die pasiënt se vermoë om te bestuur en met masjinerie te werk, kan beïnvloed. Daarom behoort bestuur en die gebruik van masjinerie vermy te word as hierdie effekte gedurende behandeling voorkom.

INTERAKSIES:
Teenjigmiddels:
MACLEODS PYRAZINAMIDE 500 kan die uriensuurkonsentrasies in serum verhoog en die effektiwiteit van die volgende teenjigmiddels verminder: allopurinol, lolgisien, probenesied en sulfinpirasoon. Dit mag nodig wees om die dosis van hierdie medisyne aan te pas om hiperurisemie en jig te beheer wanneer teenjigmiddels saam met **MACLEODS PYRAZINAMIDE 500** gebruik word.

Siklosporien:
Die gelyktydige gebruik saam met **MACLEODS PYRAZINAMIDE 500** kan die serumkonsentrasies van siklosporien verminder wat tot onvoldoende immuunonderdrukking lei. Die serumkonsentrasies van siklosporien behoort gemonitor te word wanneer dit saam met **MACLEODS PYRAZINAMIDE 500** gebruik word.

Veranderinge in laboratoriumwaardes:
MACLEODS PYRAZINAMIDE 500 kan met nitroprussiedtoetse vir die bepaling van ketone in urisete loets, inmeng deur 'n belemmerende pienk-bruin kleurreaksie met nitroprussied te lewer.
Alanienaminotransferase (ALT) en aspartaataminotransferase (AST) waardes kan verhoog wees.
Die serumkonsentrasies van uriensuur kan verhoog wees.

SWANGERSKAP EN LAKTASIE:
Die veiligheid in swangerskap is nie vasgestel nie. Dit is nie bekend of **MACLEODS PYRAZINAMIDE 500** fetale skade kan aanrig wanneer dit aan swanger vroue toegedien word an of dit hul reproduksievermoë kan beïnvloed nie.

Laktasie:
Pirasinamied is in klein hoeveelhede in borsmelk gevind. Dit word daarom aanbeveel dat **MACLEODS PYRAZINAMIDE 500** nie in vroue wat hul babas borsvoed gebruik word nie.

DOSIS EN GEBRUIKSAANWYSINGS:
MACLEODS PYRAZINAMIDE 500 behoort altyd saam met ander effektiewe teentuberkulosemiddels gebruik te word.
Pasiënte met meegaande MIV-infeksie mag moontlik langer kursusse van die terapie benodig. Mediese praktisyns wat sulke pasiënte behandel behoort op te let vir enige veranderinge in die aanbevelings vir hierdie groep van pasiënte.

Volwassenes:

	Volwassenes
Daaglikse dosis	20 - 35 mg/kg liggaamsmassa tot 'n maksimum 3 g daaglikse in 3 of 4 gelyk gespaseerde dosisse.

Pediatriese gebruik:
Die veiligheid en effektiwiteit is nie in pediatriese pasiënte vasgestel nie.

Gebruik in bejaardes:
Oor die algemeen behoort die keuse van dosis in bejaardes versigtig gedoen te word en teen die laagste vlak van die dosisreikwydte begin te word. Dit is weens 'n groter frekwensie van afname in lewer- en nierfunksie, asook meegaande siekte of ander mediseterapie.

Ingekorte nierfunksie:
Dit wil voorkom asof pasiënte met ingekorte nierfunksie nie 'n laer dosis vereis nie. Dit sal egter verstandig wees om dosisse aan die laer grens van die dosisreikwydte te kies.

NEWE-EFFEKTE:
Newe-effekte is aangemeld:

Lewersafwyking:
Dikwels: Verbygaande toename in lewersensienswaardes, hepatomegalie, splenomegalie en geelsug.

Gastrointestinale afwykings:
Dikwels: Naarheid, braking en anoreksie.

Afwykings van die bloed- en limfsisteem:
Minder dikwels: Trombositopenie, sideroblastiese anemie met eritroïede hiperplasie, vakuolisering van eritroïede, verhoogde ysterkonsentrasie en newe-effekte op bloedstollingsmeganismes.

Muskuloskeletale en bindweefselafwykings:
Dikwels: Mialgie en artralgie.

Metabolisme- en voedingsafwykings:
Dikwels: hiperurisemie wat tot jig lei.

Afwykings van die vel en subkutane weefsels:
Minder dikwels: Aknee, fotosensitiwiteit. Hipersensitiwiteitsreaksies, veluitslag, urtikarie en pruritus.

Nier- en urienafwykings:
Minder dikwels: Disurie en interstisiële nefritis.

Algemene afwykings en kondisies by die plek van toediening:
Minder dikwels: Koors en algemene ongesteldheid.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Akute lewerbeskadiging en hiperurisemie is aangemeld. Die behandeling is essensieel simptomaties. Emese en maagspoeling kan van waarde wees indien dit binne 'n paar ure van inname uitgevoer word. Daar bestaan geen spesifieke teenmiddel nie en die behandeling is ondersteunend.

IDENTIFIKASIE:
MACLEODS PYRAZINAMIDE 500: Wit, ronde, plat, skuinskantige, onbedekte tablette met 'n breeklyn aan die een kant en 'n glasde oppervlak aan die ander kant.

AANBIEDING:
MACLEODS PYRAZINAMIDE 500:
Hoë-digtheid polietileen (HDPE) bottel bestaan uit 'n 850 ml melkerige wit, ronde houer met 'n wit polipropileen (PP) skroefdop - 1000 verpak in 'n voorafgedrukte karton.

Stolpverpakking van 28, 56, 84 en 100 tablette - silwergeleurde gedrukte, harde aluminiumfoelie, getemper en bedek met VMCH aan die blink kant en helder, deurskyngige, termovormbare, stewige film (PVC), verpak in 'n voorafgedrukte eenheidskarton.

BERGINGSINSTRUKSIES:
Bewaar in 'n droë plek, by of onder 30 °C. Beskerm teen lig. Hou die bottel dig toe.
Moenie die tablette uit die stolpverpakking neem tot voor gebruik nie.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
MACLEODS PYRAZINAMIDE 500: 45/20.2.3/0844

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
Macleods Pharmaceuticals SA (Edms.) Bpk
Kantoorblok 1,
Bassonia Estate Office Park (Ooa),
Cussonlarylaan 1, Bassonia Rock,
Uitb. 12, Alberton.

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBLIJET:
21 April 2016

Pasiënt Inligtingsblad

SKEDULERINGSTATUS:

S4

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM:
MACLEODS PYRAZINAMIDE 500 (Tablette)

Lees die hele brosjure aangaande voordat u begin om MACLEODS PYRAZINAMIDE 500 te neem.
- Hou hierdie bladsy.
- Indien u enige vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **MACLEODS PYRAZINAMIDE 500** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense te deel nie. Dit mag hulle skade aandoen, ook al het hulle dieselfde simptome as u.

WAT MACLEODS PYRAZINAMIDE 500 BEVAT:
Elke tablet bevat 500 mg pirasinamied, Suikervry.
Die oraktiewe bestanddele is: Mellestysel, povidoon K-30, natriumstyseiglikolaat, gesuiwerde talk, kolloidale anhidriese silika en magnesiumstearaat.

WAARVOOR MACLEODS PYRAZINAMIDE 500 GEBRUIK WORD:
MACLEODS PYRAZINAMIDE 500 behoort aan 'n groep medisyne wat as teentuberkulosemiddels bekend staan.
MACLEODS PYRAZINAMIDE 500 word gebruik vir die behandeling van tuberkulose in kombinasie met ander teentuberkulosemiddels.

VOORDAT U MACLEODS PYRAZINAMIDE 500 NEEM:
Moenie MACLEODS PYRAZINAMIDE 500 neem nie:
- As u hipersensitief (allergies) teen pirasinamied of medisyne van dieselfde klas is, soos etionamied, isoniasied (nikotiensuur) of enige van die ander bestanddele van **MACLEODS PYRAZINAMIDE 500** is.
- As u aan erge lewerbeskadiging of siekte ly.ly.

Neem spesiale sorg met MACLEODS PYRAZINAMIDE 500:
- As u bekende risikofaktore vir lewersiekte het; gewoonlik is egter ook aangemeldtim pasiënte sonder risikofaktore. U behoort met die behandeling met **MACLEODS PYRAZINAMIDE 500** te staak as simptome van toksisiteit ontstaan.
- Stel u dokter in kennis as u aan enige van die volgende kondisies ly:
  - Niersiekte,
  - Geskiedenis van jig,
  - Diabetes, aangesien dit moeilik kan wees om suikervlakke te beheer terwyl u **MACLEODS PYRAZINAMIDE 500** neem.

Voordat u enige mediese toetse ondergaan, moet u u dokter in kennis stel dat u **MACLEODS PYRAZINAMIDE 500** neem.

Die neem van MACLEODS PYRAZINAMIDE 500 saam met voedsel en uitskrif
MACLEODS PYRAZINAMIDE 500 kan met of sonder voedsel geneem word.

Swangerskap en borsvoeding:
- Moenie **MACLEODS PYRAZINAMIDE 500** neem as u swanger is of beplan om swanger te raak nie.
- Pirasinamied word in die borsmelk gevind en kan deur borsvoeding na die baba oorgedra word. Moenie u baba borsvoed terwyl u **MACLEODS PYRAZINAMIDE 500** neem nie.

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander professionele gesondheidsbeampte vir advies raadpleeg voordat u **MACLEODS PYRAZINAMIDE 500** neem.

Bestuur en die gebruik van masjinerie:
Dit is onwaarskynlik dat **MACLEODS PYRAZINAMIDE 500** u vermoë om te bestuur of met masjinerie te werk, sal beïnvloed. **MACLEODS PYRAZINAMIDE 500** kan egter newe-effekte veroorsaak wat u ongesteld laat voel. Daarom behoort bestuur en die gebruik van masjinerie vermy te word as hierdie effekte gedurende behandeling voorkom.

Die neem van ander medisyne saam met MACLEODS PYRAZINAMIDE 500:
Wanneer u **MACLEODS PYRAZINAMIDE 500** neem is dit veral belangrik dat u dokter of professionele gesondheidswerker in kennis stel as u enige van die volgende medisyne neem:

- Allopurinol, lolgisien, probenesied en sulfinpirasoon (gebruik vir die behandeling van jig),
- Siklosporien (gebruik om die immuunstelsel te onderdruk).

Daar is aangemeld dat **MACLEODS PYRAZINAMIDE 500** met urienstoetse inmeng deur 'n belemmerende pienk-bruin kleurreaksie te lewer.

Stel altyd u professionele gesondheidswerker in kennis as u enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in).

HOE OM MACLEODS PYRAZINAMIDE 500 TE NEEM:
Moenie medisyne wat aan u voorgeskryf is met enigiemandanders deel nie.
Neem **MACLEODS PYRAZINAMIDE 500** presies soos deur u dokter voorgeskryf. Bevestig met u dokter of apteker as u onseker is.

Die dosisse kan enige tyd van die dag, met of sonder voedsel geneem word:

MACLEODS PYRAZINAMIDE 500 behoort altyd saam met ander effektiewe teentuberkulosemiddels geneem word.

Neem MACLEODS PYRAZINAMIDE 500 presies soos deur u dokter voorgeskryf. Die dosis hang van liggaamsmassa af en wissel van een pasiënt na die volgende. As u van mening is dat die effek van **MACLEODS PYRAZINAMIDE 500** te sterk of te swak is, moet u u dokter of apteker raadpleeg.

As u te veel MACLEODS PYRAZINAMIDE 500 geneem het:
As u per ongeluk te veel **MACLEODS PYRAZINAMIDE 500** geneem het (meer as u normale dosis), moet u onmiddellik u dokter raadpleeg.

In die geval van oordosering, raadpleeg u dokter of apteker. As hulle nie beskikbaar is nie, beeltek u naaste hospitaal of gifbeheersentrum.

As u vergeet het om MACLEODS PYRAZINAMIDE 500 te neem:
Neem die vergeetsende dosis sodra u daarvan onthou. As dit egter byna tyd vir die volgende dosis is, slaan die vergeetsende dosis oor en gaan met die gereelde doseringskedule voort. Moenie 'n dubbeldosis neem om vir 'n vergeetsende dosis op te maak nie.

Effekte wanneer behandeling met MACLEODS PYRAZINAMIDE 500 gestaak word:
Indien behandeling met **MACLEODS PYRAZINAMIDE 500** gestaak moet word, sal u dokter dit met u bespreek en alternatiewe behandeling aanbeveel.

NEWE-EFFEKTE:
MACLEODS PYRAZINAMIDE 500 kan newe-effekte hê.
Nie al die newe-effekte wat vir **MACLEODS PYRAZINAMIDE 500** aangemeld is, word in hierdie brosjure ingesluit nie. As u algemene gesondheid agteruitgaan of as u enige ongewone effekte ondervind terwyl u **MACLEODS PYRAZINAMIDE 500** neem, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker om advies raadpleeg.

As enige van die volgende newe-effekte voorkom, moet u onmiddellik u dokter of apteker raadpleeg:
Enige onverwagte allergiese reaksie of as u 'n uitslag ontwikkel.

As enige van die volgende newe-effekte voorkom, moet u so gou moontlik u dokter of apteker raadpleeg:
Naarheid, braking, verlies aan eetlus, hoofpyn, veranderings in bloedtoetsresultate, lewertoksisiteit, veluitslag, aknee, sensitiwiteit teen sonlig, moeite met urinering, koors, spierpyn, pyn en swelling van die gewrigte (veral grootteen, enkel en knie met stywe, warme vel oor die aangetaste dele); gewoonlik moeghied of swakheid en geelsug of vel.

OPBERGING EN WEGDOEN VAN MACLEODS PYRAZINAMIDE 500:
HOU BUITE BEREIK VAN KINDERS.
Bewaar in 'n droë plek by of onder 30 °C. Beskerm teen lig. Hou die bottel dig toe.
Moenie die tablette uit die stolpverpakking neem tot voor gebruik nie.
Moenie medisyne vervaldatum op die etiket gebruik nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moenie enige ongebruikte medisyne in die stroom of riolering (bv. toilette) weggooi nie.

AANBIEDING VAN MACLEODS PYRAZINAMIDE 500:
Hoë-digtheid polietileen (HDPE) bottel bestaan uit 'n 850 ml melkerige wit, ronde houer met 'n wit polipropileen (PP) skroefdop - 1000 verpak in 'n voorafgedrukte karton.
Stolpverpakking van 28, 56, 84 en 100 tablette - silwergeleurde gedrukte, harde aluminiumfoelie, gekarper en bedek met VMCH aan die blink kant en helder, deurskyngige, termovormbare, stewige film (PVC), verpak in 'n voorafgedrukte eenheidskarton.

IDENTIFIKASIE VAN MACLEODS PYRAZINAMIDE 500:
MACLEODS PYRAZINAMIDE 500: Wit, ronde, plat, skuinskantige, onbedekte tablette met 'n breeklyn aan die een kant en 'n glasde oppervlak aan die ander kant.

REGISTRASIENOMMER / WERKSNUMMER:
MACLEODS PYRAZINAMIDE 500: 45/20.2.3/0844

NAAM EN ADRES VAN DIE REGISTRASIEHOUER:
Macleods Pharmaceuticals SA (Edms.) Bpk
Kantoorblok 1,
Bassonia Estate Office Park (Ooa),
Cussonlarylaan 1, Bassonia Rock,
Uitb. 12, Alberton.

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PACKAGING RESEARCH & DEVELOPMENT

MACLEODS

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: MACLEODS PYRAZINAMIDE 500	
2. Country: South Africa	3. Packaging component: Package Insert & Patient Information Leaflet
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 50 gsm Maplitho paper	
7. Machine Layout No.: NA	8. Dimensions: 180 x 520 mm
9. Design / Style: NA	10. Item code No.: PM00260201
11. Artwork has been made: Actual Size	12. Pharma code No.: Front - 26361 mini / Back - 26362 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: NA
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Approved By:	17. Location: OXALIS

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
18/07/20	Rashmi Gosai	18/07/2020	24/07/20	24/07/20	24/07/20

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	PM00260201		