PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Front Side

335 mm

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ETHIONAMIDE MACLEODS 250 mg TABLETS
(film-coated tablets)
PM02461004

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ETHIONAMIDE MACLEODS 250 mg TABLETS (film-coated tablets)
Ethionamide
Sugar free

Read all of this leaflet carefully before you start taking ETHIONAMIDE MACLEODS 250 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.
- **ETHIONAMIDE MACLEODS 250 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 **ETHIONAMIDE MACLEODS 250 MG TABLETS** is and what it is used for
2. What you need to know before you take **ETHIONAMIDE MACLEODS 250 MG TABLETS**
3. How to take **ETHIONAMIDE MACLEODS 250 MG TABLETS**
4. Possible side effects
5. How to store **ETHIONAMIDE MACLEODS 250 MG TABLETS**
6. Contents of the pack and other information

1. What ETHIONAMIDE MACLEODS 250 MG TABLETS is and what it is used for

Tuberculosis (TB) treatment in combination with other medicine to treat tuberculosis when other first-line TB medicines do not help.

2. What you need to know before you take ETHIONAMIDE MACLEODS 250 MG TABLETS

Do not take ETHIONAMIDE MACLEODS 250 MG TABLETS
- If you are hypersensitive (allergic) to ethionamide, or to any of the ingredients of **ETHIONAMIDE MACLEODS 250 MG TABLETS** listed in section 6).
- If you are hypersensitive (allergic) to isoniazid, pyrazinamide or niacin (other medicines used to treat tuberculosis), as you may also be sensitive to **ETHIONAMIDE MACLEODS 250 mg TABLETS**.
- If you have liver disease.
- If you are pregnant or breastfeeding your baby.

Warnings and precautions
Inform your doctor if you have the following medical conditions before taking **ETHIONAMIDE MACLEODS 250 mg TABLETS**:
- Depression or other mental illness.
- Liver disease.
- Chronic alcoholism.
- Hypothyroidism (under functioning thyroid which leads to weight gain, lack of energy, thinning of hair, drying of skin and slowed mentality).
- Diabetes.
- Porphyria (**ETHIONAMIDE MACLEODS 250 mg TABLETS** should be avoided in porphyria).

ETHIONAMIDE MACLEODS 250 mg TABLETS will not be prescribed to you if you do not have normal liver function. Your doctor will monitor your liver function by performing blood tests before and during treatment (on a monthly basis) with **ETHIONAMIDE MACLEODS 250 mg TABLETS**. Your doctor will discontinue **ETHIONAMIDE MACLEODS 250 mg TABLETS** if your liver enzyme tests are abnormally high.
Your doctor may prescribe periodic eye examinations as **ETHIONAMIDE MACLEODS 250 mg TABLETS** may cause blurred vision, double vision and inflammation of the nerves of the eye causing loss of vision.
Your doctor may prescribe Vitamin B_6 (pyridoxine) or Vitamin B_3 (niacin) with **ETHIONAMIDE MACLEODS 250 mg TABLETS** to minimise adverse reactions such as dizziness, drowsiness or have neuropathy (damage to the nerves resulting in poor coordination, muscle weakness, pain in the fingers or toes, or numbness).
Diabetes may be difficult to manage. Your doctor will monitor your blood glucose levels on a regular basis.
ETHIONAMIDE MACLEODS 250 mg TABLETS may cause hypothyroidism or goitre (an abnormal swelling of the thyroid gland that causes a lump to form in the neck). Your doctor will monitor your thyroid function by doing regular blood tests.
In order to minimise gastrointestinal side-effects, **ETHIONAMIDE MACLEODS 250 mg TABLETS** may be taken at bedtime or in divided doses with meals. Your doctor may also prescribe medicine for nausea and vomiting.

Other medicines and ETHIONAMIDE MACLEODS 250 MG TABLETS
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).
When you are taking **ETHIONAMIDE MACLEODS 250 mg TABLETS,** it is especially important to tell your doctor or healthcare professional if you are taking any other medicine and especially:
- thioacetazone – a medicine used in the treatment of tuberculosis (TB)
- cicloserin – a medicine used in the treatment of tuberculosis (TB)
- isoniazid– a medicine used in the treatment of tuberculosis (TB)
- terizidone – a medicine used in the treatment of tuberculosis (TB)
- rifampicin – a medicine used in the treatment of tuberculosis (TB)

ETHIONAMIDE MACLEODS 250 MG TABLETS with food or drink
ETHIONAMIDE MACLEODS 250 mg TABLETS should preferably be taken with meals. Avoid alcohol. Excessive alcohol ingestion may cause a psychotic reaction (mental illness).

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.
ETHIONAMIDE MACLEODS 250 mg TABLETS should not be taken during pregnancy and breastfeeding.

Driving and using machines
ETHIONAMIDE MACLEODS 250 mg TABLETS may cause dizziness and/or drowsiness. If you feel dizzy or drowsy while taking **ETHIONAMIDE MACLEODS 250 mg TABLETS** do not drive and do not use any tools or machines.
It is not always possible to predict to what extent **ETHIONAMIDE MACLEODS 250 mg TABLETS** 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 **ETHIONAMIDE MACLEODS 250 mg TABLETS** affects them.

3. How to take ETHIONAMIDE MACLEODS 250 MG TABLETS

Do not share medicines prescribed for you with any other person.
Always take **ETHIONAMIDE MACLEODS 250 MG TABLETS** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.
In order to minimise gastrointestinal side-effects, **ETHIONAMIDE MACLEODS 250 mg TABLETS** may be taken at bedtime or in divided doses with meals.

Your doctor may prescribe pyridoxine (Vitamin B_6) to prevent damaging nervous tissue (brain and peripheral nerves).

Tablets should not be divided.

Adults:
15 – 20 mg/kg/day. Maximum of four tablets per day.
Children:
Over 10 years: Same as per adult dose.
Under 10 years: As determined by your doctor.
If you have the impression that the effect of **ETHIONAMIDE MACLEODS 250 MG TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

If you take more ETHIONAMIDE MACLEODS 250 MG TABLETS 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.
Too much **ETHIONAMIDE MACLEODS 250 mg TABLETS** can increase the intensity of side effects.

If you forget to take ETHIONAMIDE MACLEODS 250 MG TABLETS
If you have missed a dose of **ETHIONAMIDE MACLEODS 250 mg TABLETS**, take it as soon as you remember. However if it is almost time for your next dose, skip the missed dose and go back to your regular scheduling. Never double your dose.

4. Possible side effects

ETHIONAMIDE MACLEODS 250 MG TABLETS can have side effects.
Not all side effects reported for **ETHIONAMIDE MACLEODS 250 MG TABLETS** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **ETHIONAMIDE MACLEODS 250 MG TABLETS**, please consult your health care provider for advice.
If any of the following happens, stop taking **ETHIONAMIDE MACLEODS 250 mg TABLETS** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of face, tongue or throat
- difficulties in swallowing
- hives and difficulties in breathing
- severe skin reactions that can include blistering of the skin.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ETHIONAMIDE MACLEODS 250 mg TABLETS**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- low blood platelet count resulting in bleeding or bruising more easily than normal with red, pinpoint-sized rash
- low blood sugar (e.g., increased heartbeat, headache, chills, sweating, tremor, increased hunger, changes in vision, nervousness, weakness, dizziness, drowsiness, fainting)
- hypothyroidism (under functioning thyroid which leads to weight gain, lack of energy, thinning of hair, drying of skin and slowed mentality)
- goitre (abnormal swelling of the thyroid gland that causes a lump to form in the neck)
- mental illness
- seizures
- tingling of hands or feet
- vision changes (e.g., loss of vision)
- yellowing of the skin or eyes (signs of inflammation of the liver); blood tests may reveal increase in liver enzymes.

These are all serious side effects. You may need urgent medical attention.
Tell your doctor if you notice any of the following side-effects and they worry you or if any of these symptoms are severe or do not go away:
- feeling depressed, anxious, restless
- dizziness, drowsiness, headache
- double or blurred vision
- low blood pressure when standing up from sitting or lying down; this may make you feel faint or dizzy
- nausea, diarrhoea, vomiting, stomach pain, increased salivation, metallic taste, mouth sores, loss of appetite, weight loss
- hair loss, increased sensitivity of the skin to sunlight, acne, red and inflamed skin with itchy rash
- joint pain
- enlarged breasts, inability to maintain an erection in men, absence of monthly period in women
- weakness

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 **ETHIONAMIDE MACLEODS 250 MG TABLETS**.

5. How to store ETHIONAMIDE MACLEODS 250 MG TABLETS

Store at or below 25 °C.
Keep strip pack in carton and sachet in HDPE container until required for use.
Store this medicine away from light and moisture.
Any expired or outdated medicines and unused medicines can be returned to your nearest pharmacy.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ETHIONAMIDE MACLEODS 250 MG TABLETS contains
The active ingredient in each **ETHIONAMIDE MACLEODS 250 MG TABLETS** film-coated tablet is 250 mg ethionamide. Sugar free
The other ingredients are: maize starch, gelatin (Type B), sodium starch glycolate (Type A), colloidal anhydrous silica, acacia, purified talc, magnesium stearate, povidone (PVP K-30), hypromellose (5 cps), titanium dioxide (CI no. 77891), colour quinoline yellow supra (CI no. 47005) and diethyl phthalate.

What ETHIONAMIDE MACLEODS 250 MG TABLETS looks like and contents of the pack
ETHIONAMIDE MACLEODS 250 MG TABLETS: Yellow, circular, deep biconvex, film coated tablets having plain surface on both the sides.

A soft tempered silver aluminium strip containing 14 tablets. Strips are packed in a pre-printed outer carton. Pack sizes: 14's, 28's, 56's and 84's.
Silver aluminium sachet (PET/Al/LLDPE), kept in a white plastic container (HDPE), which is sealed at the mouth with an aluminium tagger and is closed with a white HDPE screw-on lid. Pack size: 250 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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Access to the corresponding Professional Information
The corresponding professional information can be accessed at at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

PACKAGING RESEARCH & DEVELOPMENT

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Back Side

335 mm

280 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

ETHIONAMIDE MACLEODS 250 mg TABLETS (filmbedekte tablette)
Etionamied
Suikervry

Lees hierdie hele inligtingstuk noukeurig deur voordat jy begin om ETHIONAMIDE MACLEODS 250 mg TABLETS te 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.
- **ETHIONAMIDE MACLEODS 250 mg TABLETS** 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 **ETHIONAMIDE MACLEODS 250 mg TABLETS** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **ETHIONAMIDE MACLEODS 250 mg TABLETS** neem
3. Hoe om **ETHIONAMIDE MACLEODS 250 mg TABLETS** te neem
4. Moontlike newe-effekte
5. Hoe om **ETHIONAMIDE MACLEODS 250 mg TABLETS** te bêre
6. Inhoud van die pak en ander inligting

1. Wat ETHIONAMIDE MACLEODS 250 mg TABLETS is en waarvoor dit gebruik word

Tuberkulose (TB) behandeling in kombinasie met ander medisyne om tuberkulose te behandel wanneer ander eerste-linie TB medisyne nie help nie.

2. Wat jy behoort te weet voordat jy ETHIONAMIDE MACLEODS 250 mg TABLETS neem

Moet nie ETHIONAMIDE MACLEODS 250 mg TABLETS neem nie
- Indien jy hipersensitief (allergies) is vir etionamied, of vir enige van die bestanddele van **ETHIONAMIDE MACLEODS 250 mg TABLETS** wat in afdeling 6 gelys word.
- Indien jy hipersensitief (allergies) is vir isoniasied, pirasinamied of niasien (ander medisyne wat gebruik word om tuberkulose te behandel), aangesien jy ook sensitief kan wees vir **ETHIONAMIDE MACLEODS 250 mg TABLETS**.
- Indien jy lewersiekte het.
- Indien jy swanger is of jou baba borsvoed.

Waarskuwings en voorsorgmaatreëls
Lig jou dokter in indien jy die volgende mediese toestande het voordat jy **ETHIONAMIDE MACLEODS 250 mg TABLETS** neem**.**
- Depressie of ander geestesongesteldheid.
- Lewersiekte.
- Chroniese alkoholisme.
- Hipotireose (onder funksionerende skildklier wat lei tot gewigstoename, gebrek aan energie, dunner word van hare, uitdroging van die vel en vertraagde denkwyse).
- Diabetes.
- Porfirie (**ETHIONAMIDE MACLEODS 250 mg TABLETS** moet vermy word in porfirie).

ETHIONAMIDE MACLEODS 250 mg TABLETS sal nie aan jou voorgeskryf word as jy nie normale lewerfunksie het nie. Jou dokter sal jou lewerfunksie monitor deur bloedtoetse te doen voor en tydens behandeling (op 'n maandelikse basis) met **ETHIONAMIDE MACLEODS 250 mg TABLETS**. Jou dokter sal **ETHIONAMIDE MACLEODS 250 mg TABLETS** staak indien jou lewerensiemtoetse abnormaal hoog is.
Jou dokter mag periodieke oogondersoeke voorskryf aangesien **ETHIONAMIDE MACLEODS 250 mg TABLETS** dowwe visie, dubbelvisie en ontsteking van die senuwees van die oog kan veroorsaak wat tot verlies van sig kan lei.
Jou dokter kan Vitamien B_6 (piridoksien) of Vitamien B_3 (niasien) saam met **ETHIONAMIDE MACLEODS 250 mg TABLETS** voorskryf om nadelige reaksies soos duiseligheid, slaperigheid of neuropatie (skade aan die senuwees wat lei tot swak koördinasie, spierswakheid, pyn in die vingers of tone, of gevoelloosheid) te verminder.
Diabetes mag moeilik wees om te bestuur. Jou dokter sal jou bloedglukosevlakke op 'n gereelde basis monitor.
ETHIONAMIDE MACLEODS 250 mg TABLETS kan hipotireose of struma (abnormale swelling van die skildklier wat veroorsaak dat daar 'n knop in die nek vorm) veroorsaak. Jou dokter sal jou skildklierfunksie monitor deur gereelde bloedtoetse te doen.
Om gastroïntestinale newe-effekte te verminder, kan **ETHIONAMIDE MACLEODS 250 mg TABLETS** voor slaaptyd of in verdeelde dosisse saam met maaltye geneem word. Jou dokter kan ook medisyne vir naarheid en braking voorskryf.

Ander medisyne en ETHIONAMIDE MACLEODS 250 mg TABLETS
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).
Wanneer jy **ETHIONAMIDE MACLEODS 250 mg TABLETS** neem, is dit veral belangrik om jou dokter of professionele gesondheidsorgwerker te vertel as jy enige ander medisyne neem, en veral:
- tioasetasoon - 'n medisyne wat gebruik word in die behandeling van tuberkulose (TB)
- sikloserien - 'n medisyne wat gebruik word in die behandeling van tuberkulose (TB)
- isoniasied - 'n medisyne wat gebruik word in die behandeling van tuberkulose (TB)
- terisidoon - 'n medisyne wat gebruik word in die behandeling van tuberkulose (TB)
- rifampisien - 'n medisyne wat gebruik word in die behandeling van tuberkulose (TB)

ETHIONAMIDE MACLEODS 250 mg TABLETS met voedsel of vloeistowwe
ETHIONAMIDE MACLEODS 250 mg TABLETS behoort verkieslik saam met maaltye geneem te word. Vermy alkohol. Oormatige alkoholinname mag 'n psigotiese reaksie (geestesongesteldheid) veroorsaak.

Swangerskap en borsvoeding
Indien jy swanger is of jou baba borsvoed, vermoed dat jy moontlik swanger is of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne neem.
ETHIONAMIDE MACLEODS 250 mg TABLETS moet nie tydens swangerskap en borsvoeding geneem word nie.

Bestuur en gebruik van masjinerie
ETHIONAMIDE MACLEODS 250 mg TABLETS kan duiseligheid en/of slaperigheid veroorsaak. Indien jy duiselig of slaperig voel terwyl jy **ETHIONAMIDE MACLEODS 250 mg TABLETS** neem, moet nie bestuur nie en moet nie enige gereedskap of masjiene gebruik nie.
Dit is nie altyd moontlik om te voorspel tot watter mate **ETHIONAMIDE MACLEODS 250 mg TABLETS** die daaglikse aktiwiteite van 'n pasiënt mag beïnvloed nie. Pasiënte moet seker maak dat hulle nie aan die bogenoemde aktiwiteite deelneem totdat hulle bewus is van die mate waartoe **ETHIONAMIDE MACLEODS 250 mg TABLETS** hulle affekteer nie.

3. Hoe om ETHIONAMIDE MACLEODS 250 mg TABLETS te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **ETHIONAMIDE MACLEODS 250 mg TABLETS** presies soos wat jou dokter of apteker vir jou gesê het. Bevestig met jou dokter of apteker indien jy nie seker is nie.
Om gastroïntestinale newe-effekte te verminder, kan **ETHIONAMIDE MACLEODS 250 mg TABLETS** voor slaaptyd of in verdeelde dosisse saam met maaltye geneem word.

Jou dokter kan piridoksien (vitamien B_6) voorskryf om skade aan senuweeweefsel (brein en perifere senuwees) te voorkom.
Tablette moet nie gebreek word nie.

Volwassenes:
15 – 20 mg/kg/dag. Maksimun van vier tablette per dag.
Kinders:
Oor 10 jaar: Dieselfde as per volwassene dosis.
Onder 10 jaar: Soos bepaal deur jou dokter.
Indien jy die indruk het dat die effek van **ETHIONAMIDE MACLEODS 250 mg TABLETS** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer ETHIONAMIDE MACLEODS 250 mg TABLETS neem as wat jy moet
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Te veel **ETHIONAMIDE MACLEODS 250 mg TABLETS** kan die intensiteit van newe-effekte verhoog.

Indien jy vergeet om ETHIONAMIDE MACLEODS 250 mg TABLETS te neem
Indien jy 'n dosis van **ETHIONAMIDE MACLEODS 250 mg TABLETS** oorgeslaan het, neem dit sodra jy onthou. Indien dit egter amper tyd is vir jou volgende dosis, slaan die vergete dosis oor en gaan terug na jou gewone skedulering. Moet nooit jou dosis verdubbel nie.

4. Moontlike newe-effekte

ETHIONAMIDE MACLEODS 250 mg TABLETS kan newe-effekte hê.
Nie alle newe-effekte wat vir **ETHIONAMIDE MACLEODS 250 mg TABLETS** aamgemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg, of indien jy enige ongunstige effekte ervaar terwyl **ETHIONAMIDE MACLEODS 250 mg TABLETS** geneem word, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.
Indien enige van die volgende gebeur, hou op om **ETHIONAMIDE MACLEODS 250 mg TABLETS** te neem en kontak onmiddellik jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- swelling van gesig, tong of keel
- probleme met sluk
- galbulte en probleme met asemhaling
- ernstige velreaksies wat kan insluit blaasvorming van die vel

Hierdie is alles baie ernstige newe-effekte. Indien jy dit kry, het jy moontlik 'n ernstige allergiese reaksie op **ETHIONAMIDE MACLEODS 250 mg TABLETS** 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:
- lae bloedplaatjietelling wat lei tot makliker as normale bloeding of kneusing met rooi, punt grootte uitslag
- lae bloedsuiker (bv. versnelde hartklop, hoofpyn, kouekoors, sweet, bewing, verhoogde honger, veranderinge in sig, senuweeagtigheid, swakheid, duiseligheid, slaperigheid, floutes)
- hipotireose (onder funksionele skildklier wat lei tot gewigstoename, gebrek aan energie, dunner word van hare, uitdroging van die vel en vertraagde denkwyse)
- struma (abnormale swelling van die skildklier wat veroorsaak dat daar 'n knop in die nek vorm)
- geestesongesteldheid
- aanvalle
- tinteling van hande of voete
- veranderinge in sig (bv. verlies van sig)
- vergeling van die vel of oë (tekens van ontsteking van die lewer); bloedtoetse kan 'n toename in lewerensieme toon.

Hierdie is alles ernstige newe-effekte. Jy benodig moontlik dringende mediese aandag.

Vertel onmiddellik jou dokter indien jy enige van die volgende newe-effekte opmerk, en dit jou bekommer, of as enige van hierdie simptome ernstig is of nie weggaan nie:
- voel depressief, angstig, rusteloos
- duiseligheid, slaperigheid, hoofpyn
- dubbele of dowwe visie
- lae bloeddruk wanneer jy opstaan van sit of lê; dit kan jou flou of duiselig laat voel
- naarheid, diarree, braking, maagpyn, verhoogde speekselafskeiding, metaalsmaak, mondsere, verlies aan eetlus, gewigsverlies
- haarverlies, verhoogde sensitiwiteit van die vel vir sonlig, aknee, rooi en ontsteekte vel met jeukerige uitslag
- gewrigspyn
- vergrote borste, onvermoë om 'n ereksie te handhaaf in mans, afwesigheid van maandelikse menstruasie in vrouens
- swakheid

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 **ETHIONAMIDE MACLEODS 250 mg TABLETS.**

5. Hoe om ETHIONAMIDE MACLEODS 250 mg TABLETS te bêre

Bewaar by of benede 25 °C.
Hou strookpak in karton en sakkie in HDPE-houer totdat dit benodig word vir gebruik.
Bêre hierdie medisyne weg van lig en vog.
Enige vervalde of verouderde medisyne en ongebruikte medisyne kan na jou naaste apteek teruggeneem word.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.
HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

6. Inhoud van die pak en ander inligting

Wat ETHIONAMIDE MACLEODS 250 mg TABLETS bevat
Die aktiewe bestanddeel in elke **ETHIONAMIDE MACLEODS 250 mg TABLETS** filmbedekte tablet is 250 mg etionamied. Suikervry.
Die ander bestanddele is: mieliestyssel, gelatien (tipe B), natriumstyselglikolaat (tipe A), kolloïdale watervrye silika, akasia, gesuiwerde talk, magnesiumstearaat, povidoon (PVP K-30), hipromellose (5 cps), titaandioksied (CI nr. 77891), kleurstof kinoliengeel supra (CI nr. 47005) en diëtielftalaat.

Hoe ETHIONAMIDE MACLEODS 250 mg TABLETS lyk en inhoud van die pak
ETHIONAMIDE MACLEODS 250 mg TABLETS: Geel, sirkelvormige, bikonvekse filmbedekte tablette met 'n gladde oppervlak aan beide kante.

'n Sagte, getemperde silwer aluminiumstrook wat 14 tablette bevat. Die strokies word verpak in 'n voorafgedrukte buitenste karton. Verpakkingsgroottes: 14's, 28's, 56's en 84's.
Silwer aluminium sakkie (PET/Al/LLDPE), gehou in 'n wit plastiekhouer (HDPE), wat by die mond verseël is met 'n aluminium etiket en toegemaak is met 'n wit HDPE skroefdeksel. Verpakkingsgrootte: 250 tablette.

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 is laas hersien in
08 Augustus 2025

Registrasienommer
49/20.2.3/0894

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

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Text matter revised, removed PI from artwork, dimensions and specification change.

1. Product: ETHIONAMIDE MACLEODS 250 mg TABLETS	
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: Booklets	**10. Item code No.: PM02461004**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 40443 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: PM02461003**
15. Revision no: 03	**16. File Name : Z:\South Africa\Ethionamide\04\Ethionamide PIL PM02461004.cdr**
Approved By:	**17. Location: Daman**

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
	03/09/2025				

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.

Format No: FRM/SOP/CO/CQA/021/03-003

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa	PM02461001	30/10/17	27/02/2018
2) Address change	PM02461002	14/05/18	25/10/2018
3) Text matter and storage change	PM02461003	15/10/22	14/11/2022
4) Text matter revised, removed PI from artwork, dimensions and specification change.	PM02461004		