Front Side

330 mm

MAKNID **200 mg**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MAKNID 200 mg (tablets)
Pretomanid
Contains sugar – lactose monohydrate
Contains 294,40 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking MAKNID 200 mg
- 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.
- **MAKNID 200 mg** 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 **MAKNID 200 mg** is and what it is used for
2. What you need to know before you take **MAKNID 200 mg**
3. How to take **MAKNID 200 mg**
4. Possible side effects
5. How to store **MAKNID 200 mg**
6. Contents of the pack and other information

1. What MAKNID 200 mg is and what it is used for

MAKNID 200 mg contains pretomanid.

MAKNID 200 mg is for use only as part of a combination antimycobacterial regimen that includes pretomanid, bedaquiline and linezolid.

What is the combination regimen of Pretomanid tablets, bedaquiline and linezolid?
MAKNID 200 mg is a prescription medicine used as part of a combination regimen with bedaquiline and linezolid. The combination of **MAKNID 200 mg,** bedaquiline and linezolid includes three prescription antibiotics that are used together in adults to treat tuberculosis of the lungs that is extensively drug resistant (XDR) or who cannot tolerate or do not respond to treatment for multidrug-resistant (MDR) TB.
It is used in adults 18 years and over.
MAKNID 200 mg is not for use in people who have
- TB that is not resistant to antibiotics
- An inactive (latent) TB infection
- A type of TB other than TB of the lungs
- MDR TB who can tolerate or who respond to medicines usually used to treat MDR TB.

2. What you need to know before you take MAKNID 200 mg

Do not take MAKNID 200 mg:
- If you are allergic to pretomanid or any of the other ingredients of this medicine, listed in section 6.
- If you are not allowed to take bedaquiline and/or linezolid. Please also refer to the individual patient information leaflets for these products.
- If you are using rifampicin (antibiotic used to treat several types of bacterial infections including tuberculosis) or efavirenz (antiretroviral drug used to treat human immunodeficiency disease).
- If you are pregnant or breastfeeding your baby (see pregnancy, breastfeeding and fertility)

Warnings and precautions
Talk to your doctor before taking MAKNID 200 mg
- If you have liver problems
- If you have kidney problems
- If you have a decrease in bone marrow activity resulting in a reduction in red blood cell production (myelosuppression), or a decrease in the haemoglobin concentration within red blood cells (anaemia).
- If you have a reduced number of white blood cells (leukopenia)
- If you have a deficiency of platelets in the blood (thrombocytopenia)
- If you have weakness, numbness and pain in your arms, hands, legs and feet as a result of nerve damage (peripheral neuropathy).
- If you experience loss of vision or colours appearing subtly washed out due to damage to the optic nerve (optic neuropathy).
- If you have or have had an abnormal heart rhythm (ECG) or other heart problems, including heart failure.
- If you have a family history of a heart problem called 'congenital long QT syndrome:,
- If you have decreased thyroid gland function (hypothyroidism).
- If you have been told that you have low levels of calcium, magnesium or potassium in your blood.
- If you suffer from a condition where the body produces too much lactic acid (lactic acidosis).
- If you are pregnant or plan to become pregnant. It is not known if pretomanid will harm your unborn baby. Talk to your healthcare provider about the possible risks to your baby if you take the combination regimen of **MAKNID 200 mg,** bedaquiline and linezolid while you are pregnant.
- If you are breastfeeding or plan to breastfeed. It is not known if pretomanid passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take the combination regimen of **MAKNID 200 mg,** bedaquiline and linezolid.

Children and adolescents
This medicine is not recommended for children and adolescents under 18 years, as its safety and efficacy has not been established.

Other medicines and MAKNID 200 mg
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including herbal therapies. These may affect the way **MAKNID 200 mg** works or increase the risk of side effects.
The combination regimen of **MAKNID 200 mg,** bedaquiline and linezolid regimen may affect how other medicines work, and other medicines may affect how the combination regimen of **MAKNID 200 mg,** bedaquiline and linezolid works.
Especially tell your healthcare provider if you take:
- A type of medicine called a CYP3A4 inducer, such as efavirenz or rifampicin. Ask your healthcare provider if you are not sure.

Avoid taking the following medicines together with **MAKNID**, as they may reduce the effect of **MAKNID**:
- Carbamazepine, phenytoin – medicines used to treat epilepsy.
- St John's wort – a herbal medicine used to treat anxiety and depression.

There may be an increased risk of side effects if MAKNID is taken with the following medicines:
- Methotrexate – a medicine used to treat severe joint inflammation, cancer and the skin disease psoriasis.
- Benzylpenicillin, ciprofloxacin, medicines to treat bacterial infections.
- Indomethacin a medicine to treat pain and inflammation.

MAKNID 200 mg with food and drink:
Avoid drinking while being treated with **MAKNID 200 mg** since this increases the risk of serious liver damage.

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 **MAKNID 200 mg.**

You should not take **MAKNID 200 mg** if you are pregnant or breastfeeding.

Driving and using machines
You may feel dizzy after taking **MAKNID 200 mg** or you may experience problems with your vision. Do not drive or operate machinery if this happens.
It is not always possible to predict to what extent **MAKNID 200 mg** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **MAKNID 200 mg** affects you.

Important information about some of the ingredients of MAKNID 200 mg
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **MAKNID 200 mg.**

3. How to take MAKNID 200 mg

Do not share medicines prescribed for you with any other person.

Always take **MAKNID 200 mg** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet of **MAKNID 200 mg** once daily.
Linezolid 1,200 mg daily
Bedaquiline: 400 mg once daily for 2 weeks, followed by 200 mg 3 times per week (with at least 48 hours between doses).
The duration of treatment of **MAKNID 200 mg**, bedaquiline and linezolid is 26 weeks.
Your doctor may adjust this period and may also adjust these dosages depending on your side effects.
Take **MAKNID 200 mg** at the same time as linezolid and bedaquiline.
Swallow the tablets with a glass of water and take them with food.
Your doctor will decide how long you must continue treatment for.

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

If you take more MAKNID 200 mg than you should

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

If you forget to take MAKNID 200 mg
Do not take a double dose to make up for a forgotten dose.
Any missed dose of pretomanid and bedaquiline is recommended to be made up at the end of treatment. Doses of linezolid missed due to linezolid adverse reactions are not recommended to be made up. Talk to your doctor or pharmacist if you have missed a dose and you are not sure what to do.

If you stop taking MAKNID 200 mg
Do not stop taking **MAKNID 200 mg** or its combination medicines linezolid or bedaquiline without your doctor's permission. Skipping doses or not completing the full course of therapy may make treatment ineffective and your tuberculosis could get worse. In addition, this would increase the chance that bacteria become resistant to these medicines.

4. Possible side effects

MAKNID 200 mg can have side effects.
Not all side effects reported for **MAKNID 200 mg** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MAKNID 200 mg**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **MAKNID 200 mg** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Reduced number of red blood cells. Possible signs are feeling tired, weakness, shortness of breath, loss of consciousness and increased thirst.
- Increased blood levels of liver enzymes called gamma GT (indicating how well your liver is working).; transaminases such as ALT, AST. Tell your doctor if you experience symptoms such as fatigue, lack or loss of appetite, nausea, yellowing of the skin and eyes, dark urine or abdominal pain.
- Reduced number of white blood cells or platelets. Possible signs are bruising, bleeding or infections
- Increased blood level of lactic acid. Contact your doctor if you have recurrent nausea or vomiting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **MAKNID 200 mg**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
Frequently occurring:
- Headache
- Nausea, vomiting, indigestion
- Abdominal pain
- Acne, itching skin, rash
- Decreased appetite
- Nerve problems in the hands or feet, such as pain, burning, abnormal sensation or numbness
- Muscle and skeleton pain, such as joint pain, back pain and muscle pain.
- Sleeping difficulties
- Weakness, fatigue
- Taste disturbance
- Dizziness
- Muscle spasm
- Diarrhoea, constipation
- Inflammation of stomach lining, pancreas inflammation which may cause pain in the stomach, bloating, passing wind.
- Reflux of stomach juices in the oesophagus
- Hair loss, dry skin
- Irritation or pain of the eye, vision problems
- Optic nerve damage and/or inflammation with swellings and visual disturbances
- Abnormal electrical activity of the heart (prolonged electrocardiogram QT interval) – you may experience a fast or irregular heartbeat, shortness of breath or feel faint.
- Increased blood levels:
  - Bilirubin which is the yellow breakdown substance of the blood pigment.
  - Lipase
  - Alkaline phosphatase
  - Creatinine phosphokinase
  - Urea

These will be picked up during a blood test.
- Decreased sugar level you may feel lightheaded, dizzy.

Less frequently occurring:

- Fungal (including candida yeast fungi) infection in the mouth or throat, which appears as white patches.
- Too much fluid loss, reduced body fluid volume, you may feel weak.
- Anxiety, depression
- Yellowing of the skin, internal organs and/or whites of the eyes (jaundice)
- Dry eye
- Worsening ability to focus clearly on close objects
- Eye itching, eye swelling
- Optic disc swelling (leading to vision loss)
- Deafness
- Feeling of increased heartbeat
- Low blood pressure
- Cough, nosebleed
- Feeling bloated
- Burning tongue, enlargement of the small, nipple-like structures on the upper surface of the tongue.
- eczema, excessive skin pigmentation
- muscles and skeleton stiffness
- inability to have or maintain an erection
- bleeding at irregular intervals, particularly between the expected menstrual periods
- feeling unwell
- abnormal presence of the protein albumin in the urine, your ankles, face, feet and belly may swell, you may urinate more frequently.
- vomiting blood
- acidity of the blood
- decreased elimination of the muscle tissue breakdown product creatinine through kidneys
- lack of white and red blood cells, and blood platelets
- decreased blood levels:
- calcium
- magnesium
- increased blood levels:
- creatinine and creatine phosphokinase
- uric acid

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 "Adverse drug reactions and quality roblem 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 **MAKNID 200 mg.**

5. How to store MAKNID 200 mg

Store at or below 30 °C.
KEEP OUT OF THE REACH OF CHILDREN.
Store in the original package / container.
Keep the blisters in the carton until required for use.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / 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 MAKNID 200 mg contains
The active ingredient is Pretomanid.
Contains sugar – lactose monohydrate
The other ingredients are:
Microcrystalline cellulose
Sodium starch glycolate
Sodium lauryl sulfate
Povidone
Colloidal silicon dioxide
Magnesium stearate

What MAKNID 200 mg looks like and contents of the pack
MAKNID 200 mg (tablet)**:** White to off white, oval shaped, biconvex, uncoated tablets debossed with "K31" on one side and plain on other side.

Contents of the pack:
Tablets are packed in blister pack containing plain 25 micron aluminium foil / 6-8 gsm HSL and cold form laminate (25 µ OPA/45 µ alu/60 µ PVC).
Pack sizes include 10's, 28's, and 30's tablets.
Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD
Ground Floor, Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock Ext 12
Alberton, Gauteng

This leaflet was last revised in

Registration numbers
MAKNID 200 mg: 57/20.2.3/0626.

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

335 mm

Back Side

280 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

MAKNID 200 mg (tablette)
Pretomanied
Bevat suiker - laktosemonohidraat
Bevat 294,40 mg laktosemonohidraat

Lees hierdie hele inligtingstuk noukeurig deur voordat jy begin om MAKNID 200 mg 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
- **MAKNID 200 mg** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik wees vir hulle, selfs al is hulle simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

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

1. Wat MAKNID 200 mg is en waarvoor dit gebruik word

MAKNID 200 mg bevat pretomanied.

MAKNID 200 mg is slegs vir gebruik as deel van 'n kombinasie antimikobakteriese regime wat pretomanied, bedakwillien en linesolied insluit.

Wat is die kombinasie regime van Pretomanied tablette, bedakwillien en linesolied?
MAKNID 200 mg is 'n voorskrifmedisyne wat gebruik word as deel van 'n kombinasie regime met bedakwillien en linesolied. Die kombinasie van **MAKNID 200 mg**, bedakwillien en linesolied sluit drie voorskrif antibiotika in wat saam gebruik word in volwassenes om tuberkulose van die longe te behandel, wat omvattend geneesmiddel weerstandig is (XDR) of wie dit nie kan verdra of nie reageer op behandeling vir multi-geneesmiddel weerstandige (MDR) TB nie.
Dit word gebruik in volwassenes, 18 jaar en ouer.
MAKNID 200 mg is nie vir gebruik in persone wat die volgende het nie
- TB wat nie weerstandig is teen antibiotika nie
- 'n Onaktiewe (latente) TB-infeksie
- 'n Tipe van TB anders as TB van die longe
- MDR TB wie medisyne kan verdra of wie teenoor medisyne reageer wat gewoonlik gebruik word om MDR TB te behandel.

2. Wat jy behoort te weet voordat jy MAKNID 200 mg neem

Moet nie MAKNID 200 mg neem nie:
- Indien jy allergies is vir pretomanied of enige van die ander bestanddele van hierdie medisyne, gelys in afdeling 6.
- Indien jy nie bedakwillien en/of linesolied mag neem nie. Verwys asseblief ook na die individuele pasiëntinligtingstukke van hierdie produkte.
- Indien jy rifampisien gebruik (antibiotika wat gebruik word om verskeie tipes van bakteriële infeksies te behandel, insluitend tuberkulose) of efavirens (antiretrovirale middel wat gebruik word om menslike immuniteitsgebreksiekte te behandel).
- Indien jy swanger is of jou baba borsvoed (sien swangerskap, borsvoeding en fertiliteit)

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter voordat jy MAKNID 200 mg neem
- Indien jy lewerprobleme het
- Indien jy nierprobleme het
- Indien jy 'n afname in beenmurgaktiwiteit het wat lei tot 'n vermindering in rooibloedselproduksie (miëlo-onderdrukking), of 'n afname in die hemoglobienkonsentrasie binne rooibloedselle (anemie).
- Indien jy 'n verminderde aantal witbloedselle het (leukopenie)
- Indien jy 'n tekort aan bloedplaatjies in die bloed het (trombositopenie)
- Indien jy swakheid, gevoelloosheid en pyn in jou arms, hande, bene en voete het as gevolg van senuweeskade (perifere neuropatie).
- Indien jy verlies van sig ervaar of kleure wat subtiel uitgewas voorkom as gevolg van skade aan die optiese senuwee (optiese neuropatie).
- Indien jy 'n abnormale hartritme (EKG) of ander hartprobleme het of gehad het, insluitend hartversaking.
- Indien jy 'n familiegeskiedenis het van 'n hartprobleem genaamd 'aangebore lang QT-sindroom:,
- Indien jy verminderde skildklierfunksie het (hipotireose).
- Indien jy meegedeel is dat jy lae vlakke van kalsium, magnesium of kalium in jou bloed het.
- Indien jy aan 'n toestand ly waar die liggaam te veel melksuur produseer (laktiese asidose).
- Indien jy swanger is of beplan om swanger te raak. Dit is nie bekend of pretomanied jou ongebore baba sal benadeel nie. Praat met jou gesondheidsorgverskaffer oor die moontlike risiko's vir jou baba indien jy die kombinasie regime van **MAKNID 200 mg**, bedakwillien en linesolied neem terwyl jy swanger is.
- Indien jy borsvoed of beplan om te borsvoed. Dit is nie bekend of pretomanied in jou borsmelk oorgaan nie. Praat met jou gesondheidsorgverskaffer oor die beste manier om jou baba te voed indien jy die kombinasie regime van **MAKNID 200 mg**, bedakwillien en linesolied neem.

Kinders en adolessente
Hierdie medisyne word nie aanbeveel vir kinders en adolessente onder 18 jaar nie, aangesien die veiligheid en doeltreffendheid daarvan nie vasgestel is nie.

Ander medisyne en MAKNID 200 mg
Vertel altyd jou professionele gesondheidsorgwerker indien jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in.)
Vertel jou dokter of apteker as jy enige ander medisyne neem, onlangs geneem het, of moontlik gaan neem, insluitend kruieterapieë. Dit kan die manier waarop **MAKNID 200 mg** werk beïnvloed of die risiko van newe-effekte verhoog.
Die kombinasie regime van **MAKNID 200 mg**, bedakwillien en linesolied regimen kan beïnvloed hoe ander medisyne werk, en ander medisyne kan beïnvloed hoe die kombinasie regime van **MAKNID 200 mg**, bedakwillien en linesolied werk.
Vertel veral vir jou gesondheidsorgverskaffer indien jy die volgende neem:
- 'n Tipe medisyne wat 'n CYP3A4-induseerder genoem word, soos efavirens of rifampisien. Vra jou gesondheidsorgverskaffer as jy nie seker is nie.

Vermy die neem van die volgende medisyne saam met **MAKNID 200 mg**, aangesien dit die effek van **MAKNID 200 mg** kan verminder:
- Karbamasepien, fenitoïen – medisyne wat gebruik word om epilepsie te behandel.
- St Johannes kruid – 'n kruie medisyne wat gebruik word om angs en depressie te behandel.

Daar kan 'n verhoogde risiko vir newe-effekte wees as **MAKNID 200 mg** saam met die volgende medisyne geneem word:
- Metotreksaat – 'n medisyne wat gebruik word om ernstige gewrigsontsteking, kanker en die velsiekte psoriase te behandel.
- Bensielpenisillien, siprofloksasien, medisyne om bakteriële infeksies te behandel.
- Indometasien 'n medisyne om pyn en ontsteking te behandel.

MAKNID 200 mg met voedsel en drank:
Vermy drank terwyl jy met **MAKNID 200 mg** behandel word, aangesien dit die risiko van ernstige lewerskade verhoog.

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 **MAKNID 200 mg** neem.

Jy moet nie **MAKNID 200 mg** neem as jy swanger is of borsvoed nie.

Bestuur en gebruik van masjinerie
Jy kan duiselig voel nadat jy **MAKNID 200 mg** geneem het of jy kan probleme met jou sig ervaar. Moet nie bestuur of masjinerie bedryf as dit gebeur nie.
Dit is nie altyd moontlik om te voorspel tot watter mate **MAKNID 200 mg** met jou daaglikse aktiwiteite kan inmeng nie. Jy moet seker maak dat jy nie aan bogenoemde aktiwiteite deelneem totdat jy bewus is van die mate waartoe **MAKNID 200 mg** jou affekteer nie.

Belangrike inligting oor sommige van die bestanddele van MAKNID 200 mg
Indien jy deur jou dokter meegedeel is dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy **MAKNID 200 mg** neem..

3. Hoe om MAKNID 200 mg te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem altyd **MAKNID 200 mg** presies soos wat jou dokter vir jou gesê het. Bevestig met jou dokter of apteker indien jy nie seker is nie.

Die aanbevole dosis is een tablet van **MAKNID 200 mg** een keer per dag.
Linesolied 1,200 mg daagliks
Bedakwillien: 400 mg een keer per dag vir 2 weke, gevolg deur 200 mg 3 keer per week (met ten minste 48 uur tussen doserings).
Die duur van behandeling van **MAKNID 200 mg**, bedakwillien en linesolied is 26 weke.
Jou dokter kan hierdie tydperk aanpas en kan ook hierdie dosisse aanpas, afhangende van jou newe-effekte.
Neem **MAKNID 200 mg** op dieselfde tyd as linesolied en bedakwillien.
Sluk die tablette met 'n glas water en neem dit saam met kos.
Jou dokter sal besluit hoe lank jy met behandeling moet aangaan.

Indien jy die indruk kry dat die effek van **MAKNID 200 mg** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer MAKNID 200 mg 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.

Indien jy vergeet om MAKNID 200 mg te neem
Moet nie 'n dubbele dosis neem om vir 'n vergete dosis op te maak nie.
Dit word aanbeveel om vir enige oorgeslane doserings pretomanied en bedakwillien aan die einde van die behandeling op te maak. Doserings van linesolied gemis as gevolg van linesolied nadelige reaksies word nie aanbeveel om opgemaak te word nie. Praat met jou dokter of apteker as jy 'n dosis gemis het en jy nie seker is wat om te doen nie.

Indien jy ophou om MAKNID 200 mg te neem
Moet nie ophou om **MAKNID 200 mg** of sy kombinasie medisyne linesolied of bedakwillien te neem sonder jou dokter se toestemming nie. Om dosisse oor te slaan of nie die volle kursus van die behandeling te voltooi nie, kan behandeling ondoeltreffend maak en jou tuberkulose kan erger word. Daarbenewens sal dit die kans verhoog dat bakterieë weerstandbiedend raak teen hierdie medisyne.

4. Moontlike newe-effekte

MAKNID 200 mg kan newe-effekte hê.
Nie alle newe-effekte wat vir **MAKNID 200 mg** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg, of indien jy enige ongunstige effekte ervaar terwyl **MAKNID 200 mg** geneem word, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgerker vir advies.

Indien enige van die volgende gebeur, hou op om **MAKNID 200 mg** te neem en kontak onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- Verminderde aantal rooibloedselle. Moontlike tekens kan wees, voel moeg, swakheid, kort van asem, verlies van bewussyn en verhoogde dors.
- Verhoogde bloedvlakke van lewerensieme naamlik gamma GT (wat aandui hoe goed jou lewer werk).; transaminases soos ALT, AST. Vertel jou dokter as jy simptome ervaar soos moegheid, gebrek aan of verlies van eetlus, naarheid, vergeling van die vel en oë, donker uriene of abdominale pyn.
- Verminderde aantal witbloedselle of bloedplaatjies. Moontlike tekens is kneusplekke, bloeding of infeksies
- Verhoogde bloedvlak van melksuur. Kontak jou dokter as jy herhalende naarheid of braking het.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit kry, het jy moontlik 'n ernstige reaksie op **MAKNID 200 mg** gehad. Jy het moontlik dringende mediese aandag of hospitalisasie nodig.

Vertel vir jou dokter indien jy enige van die volgende opmerk:
Kom dikwels voor:
- Hoofpyn
- Naarheid, braking, swak spysvertering
- Abdominale pyn
- Aknee, jeukende vel, uitslag
- Verminderde eetlus
- Senuwee probleme in die hande of voete, soos pyn, brand, abnormale sensasie of gevoelloosheid
- Spier- en skeletpyn, soos gewrigspyn, rugpyn en spierpyn.
- Probleme om te slaap
- Swakheid, vermoeidheid
- Smaakversteuring
- Duiseligheid
- Spierspasma
- Diarree, hardlywigheid
- Ontsteking van maagvoering, pankreas ontsteking wat pyn in die maag kan veroorsaak, opgeblasendheid, winde los.
- Terugvloei van maagsappe in die slukderm
- Haarverlies, droë vel
- Irritasie of pyn van die oog, probleme met sig
- Optiese senuweeskade en/of inflammasie met swellings en visuele steurnisse
- Abnormale elektriese aktiwiteit van die hart (langdurige elektrokardiogram QT-interval) – jy kan 'n vinnige of onreëlmatige hartklop, kortasemigheid ervaar of flou voel.
- Verhoogde bloedvlakke:
  - Bilirubien wat die geel afbreekstof van die bloedpigment is.
  - Lipase
  - Alkaliese fosfatase
  - Kreatinien fosfokinase
  - Ureum

Hierdie sal tydens 'n bloedtoets opgetel word.
- Verlaagde suikervlak kan jou lighoofdig, duiselig laat voel.

Kom minder dikwels voor:
- Swam (insluitend candida gis swamme) infeksie in die mond of keel, wat voorkom as wit kolle.
- Te veel vloeistofverlies, verminderde liggaamsvloeistof volume, jy kan swak voel.
- Angstigheid, depressie
- Vergeling van die vel, interne organe en/of wit van die oë (geelsug)
- Droë oog
- Verswakte vermoë om duidelik op naby voorwerpe te fokus
- Jeukende oog, swelling van oog
- Optiese skyf swelling (wat lei tot verlies van sig)
- Doofheid
- Gevoel van verhoogde hartklop
- Lae bloeddruk
- Hoes, neusbloeding
- Opgeblaas voel
- Brandende tong, vergroting van die klein, tepelagtige strukture op die boonste oppervlak van die tong.
- ekseem, oormatige velpigmentasie
- spiere- en skeletstyfheid
- onvermoë om 'n ereksie te kry of te onderhou
- bloeding met onreëlmatige tussenposes, veral tussen die verwagte menstruasieperiodes
- voel nie lekker nie
- abnormale teenwoordigheid van die proteïen albumien in die uriene, jou enkels, gesig, voete en maag kan swel, jy kan meer gereeld urineer.
- braking van bloed
- suurheid van die bloed
- verminderde eliminasie van die spierweefsel afbraakproduk kreatinien deur niere
- gebrek aan wit en rooibloedselle, en bloedplaatjies
- verlaagde bloedvlakke:
- kalsium
- magnesium
- verhoogde bloedvlakke:
- kreatinien en kreatienfosfokinase
- uriensuur

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

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 "Adverse drug reactions and quality problem reporting form", wat aanlyn gevind 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 beskikbaar te stel aangaande die veiligheid van **MAKNID 200 mg.**

5. Hoe om MAKNID 200 mg te bewaar

Bewaar by of benede 30 °C.
HOU BUITE DIE BEREIK VAN KINDERS.
Bewaar in die oorspronklike verpakking / houer
Hou die stulpstrook in die karton totdat dit benodig word vir gebruik.
Moet nie in die badkamer bêre nie.
Moet dit nie gebruik na die vervaldatum wat aangebring is op die stulpstrook / etiket / karton / bottel nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van pak en ander inligting

Wat MAKNID 200 mg bevat
Die aktiewe bestanddeel is Pretomanied.
Bevat suiker - laktosemonohidraat
Die ander bestanddele is:
Mikrokristallyne sellulose
Natriumstyselglukolaat
Natriumlaurielsulfaat
Povidoon
Kolloïdale silikondioksied
Magnesiumstearaat

Hoe MAKNID 200 mg lyk en inhoud van die pak
MAKNID 200 mg (tablet): Wit tot naaswit, ovaalvormige, bikonvekse, onbedekte tablette bedruk met "K31" aan die een kant en glad aan die ander kant.

Inhoud van die pak:
Tablette word verpak in stulpstrookpak met gewone 25 mikron aluminiumfoelie / 6-8 gsm HSL en koue vorm laminaat (25 µ OPA / 45 µ alu / 60 µ PVC).
Verpakkingsgroottes sluit 10'e, 28's en 30's tablette in.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

7. HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

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

Hierdie inligtingstuk is laas hersien in
July 2024

Registrasienommers
MAKNID 200 mg: 57/20.2.3/0626.

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 skakel 011 682 1169

335 mm

Vanita Rajool

Digitally signed by Vanita Rajool
DN: cn=Vanita Rajool, o=Macleods Pharmaceuticals SA (Pty) Ltd., ou=Responsible Pharmacist, email=vanitar@macleodspharma.com, c=ZA
Date: 2024.08.06 13:32:45 +02'00'