290 mm

MACLOGLYMIN 500/850/1000 mg (film-coated tablet)
PM04295501

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

MACLOGLYMIN 500 mg (Film-coated tablet)
MACLOGLYMIN 850 mg (Film-coated tablet)
MACLOGLYMIN 1000 mg (Film-coated Tablet)
Metformin hydrochloride
Sugar free

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

1. What MACLOGLYMIN is and what it is used for

MACLOGLYMIN is used to treat patients with type II diabetes (also called 'non-insulin dependent diabetes') when diet and exercise alone have not been enough to control your blood glucose levels. It is used particularly in overweight patients.
- Adults can take **MACLOGLYMIN** alone or together with other medicines to treat diabetes (medicines taken by mouth or insulin injection.
- Children 12 years and over and adolescents can take **MACLOGLYMIN** alone or together with insulin injection.

2. What you need to know before you take or give MACLOGLYMIN

Do not take or give MACLOGLYMIN:
- if you or your child are hypersensitive (allergic) to metformin hydrochloride or to any of the ingredients of **MACLOGLYMIN.**
- If you have, nausea, vomiting, dehydration, rapid weight loss or ketoacidosis. Ketoacidosis is a condition in which substances called 'ketone bodies' accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or unusual fruity odour of the breath.
- If you have been diagnosed with kidney failure or kidney dysfunction
- If you lost too much water from your body (dehydration), due to long-lasting or severe diarrhoea, or if you have vomited several times in a row. Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (see 'Take special care with **MACLOGLYMIN** below).
- If you have a severe infection, such as an infection affecting your lung or bronchial system or your kidney. Severe infections may lead to kidney problems, which can put you at risk for lactic acidosis (see 'Take special care with **MACLOGLYMIN** below).
- if you are treated for heart failure or recently had a heart attack or have severe problems with your circulation (such as shock) or have breathing difficulties. This may lead to a lack in oxygen supply to tissues which can put you at risk for lactic acidosis (see 'Take special care with **MACLOGLYMIN** below).
- if you have inflammation of the pancreas (symptoms like severe upper stomach pain, often with nausea and vomiting).
- if you drink a lot of alcohol or have liver problems.
- if you are pregnant or breastfeeding.
- if you need to have an injection of contrast medicines that contain iodine into your bloodstream for examinations such as X-ray or scans. You must stop taking **MACLOGLYMIN** for a certain period of time before and after the examination.

Warnings and precautions
Tell your doctor or health care professional before you take or give **MACLOGLYMIN.**
Take special care with **MACLOGLYMIN:**
- **MACLOGLYMIN** may cause a less frequent, but serious complication called lactic acidosis, particularly if your kidneys are not working properly. The risk of lactic acidosis is also increased with uncontrolled diabetes, prolonged fasting, liver problems or alcohol intake or if you become dehydrated due to severe diarrhoea or vomiting, fever or reduced fluid intake or if you taking medicines for high blood pressure, diuretics (medicines that help to reduce the amount of water in the body) or NSAIDs (anti-inflammatory medicines for pain and fever). Symptoms of lactic acidosis are vomiting, stomach ache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. If this happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma. Stop taking **MACLOGLYMIN** immediately and contact a doctor or the nearest hospital straight away.
- Your doctor will monitor your kidney function before starting treatment with **MACLOGLYMIN** and on a regular basis thereafter.
- Inform your doctor if you are taking medicines for high blood pressure, diuretics or NSAIDs as these medicines may cause your kidneys not to work properly.
- **Tell** your doctor if you have any heart conditions before starting **MACLOGLYMIN.** Your doctor will monitor your heart function before starting treatment with **MACLOGLYMIN.**
- Make sure you ask your doctor for advice:
  - if you need to have an examination such as X-ray or scan involving the injection of contrast medicines that contain iodine into your bloodstream.
  - if you need to have major surgery.

You must stop taking **MACLOGLYMIN** for a certain period of time before and after the examination or the surgery. Your doctor will decide whether you need any other treatment for this time. It is important that you follow your doctor's instructions precisely.

- **MACLOGLYMIN** will only be prescribed in children over 12 years and in adolescents who have type II diabetes confirmed by their doctor
- Continue your exercise and diet program and test your blood sugar regularly while taking **MACLOGLYMIN.** Your doctor will monitor your diabetes and may perform blood tests on you from time to time to make sure your kidneys and your liver are functioning normally.
- Long term use of **MACLOGLYMIN** may cause a deficiency of vitamin B_{12}. Inform your doctor if you have symptoms of fatigue, muscle weakness, loss of appetite/weight loss, diarrhoea, nausea, fast heartbeat, smooth or tender tongue, tingling in hands and feet, numbness in extremities. You doctor will test your vitamin B_{12} levels annually.
- Monitor your blood glucose levels regularly if you are taking **MACLOGLYMIN** with other anti-diabetic medicines such as a sulphonylurea or insulin.

Other medicines and MACLOGLYMIN
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).
Inform your doctor if you or your child is taking any of the following medicines and **MACLOGLYMIN** at the same time. You may need more frequent blood glucose tests or your doctor may adjust the dosage of **MACLOGLYMIN**:
- Alcohol
- Iodinated contrast agents
- Corticosteroids (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma)
- Diuretics (used to remove water and salt from the body by making more urine).
- Beta-2 agonists such as salbutamol or terbutaline (used to treat asthma)
- Other medicines used to treat diabetes.
- ACE inhibitors (for high blood pressure)
- Cimetidine (for stomach ulcer)
- Warfarin (to thin the blood)
- Sulphonylurea (used to increase insulin release)
- Medicines that may change the amount of metformin in your blood especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, Olaparib).

MACLOGLYMIN with food and drink and alcohol
MACLOGLYMIN should be taken with meals or after meals.
Do not drink alcohol while taking **MACLOGLYMIN** as the alcohol can increase the chance of getting lactic acidosis.

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 **MACLOGLYMIN**.
MACLOGLYMIN is not recommended for use during pregnancy and breastfeeding.

Driving and using machines
MACLOGLYMIN when taken alone do not cause hypoglycaemia (low blood sugar levels).
If you experience symptoms of hypoglycaemia (low blood sugar levels with symptoms of weakness, dizziness, increased sweating, fast heartbeat, vision disorders or difficulty in concentration) while taking **MACLOGLYMIN** in combination with other antidiabetic medicines you should stop driving or operating machinery.

3. How to take or give MACLOGLYMIN

- Do not share medicines prescribed for you or your child with any other person.
- Always take or give **MACLOGLYMIN** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- If you have the impression that the effect of **MACLOGLYMIN** is too strong or too weak talk to your doctor or pharmacist.
- Your doctor will tell you exactly how much medicine to take or give and when to take or give it.
- **MACLOGLYMIN** must be taken orally and swallowed with sufficient quantity of liquid and may be taken with or after a meal. This will avoid you having side effects affecting your digestion.
- The usual dose is:
  - Adults: Initially, one 500 mg tablet three times a day, or one 850 mg or 1 000 mg tablet twice a day, with or after a meal.
  - Children from 12 years of age and adolescents: The usual starting dose is 500 mg or 850 mg once daily, given during meals or after meals.

If you take or give more MACLOGLYMIN 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 sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, increase in heartbeat, vomiting, stomach ache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing.

If you forget to take or give MACLOGLYMIN
It is important to take your **MACLOGLYMIN** regularly at the same time each day. 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 forgotten individual doses.

If you stop taking or giving MACLOGLYMIN
Do not stop taking **MACLOGLYMIN** just because you feel better.
Take or give **MACLOGLYMIN** for as long as your doctor recommends. Do not stop taking or giving **MACLOGLYMIN** unless your doctor tells you to.

4. Possible side effects

MACLOGLYMIN can have side effects.
Not all side effects reported for **MACLOGLYMIN** are included in this leaflet. Should your or your child's general health worsen or if you or your child experiences any untoward effects while taking **MACLOGLYMIN**, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking or giving **MACLOGLYMIN** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Sudden signs of allergy – including skin rash, itching or hives; swelling of the face, lips or tongue, shortness of breath or difficulty breathing.

These are all very serious side effects. If you or your child have them, you or your child may have had a serious reaction to **MACLOGLYMIN**. 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:
- Lactic acidosis. This is a very rare but serious complication particularly if your kidneys are not working properly. Symptoms of lactic acidosis are vomiting, stomach ache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. If this happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma. Stop taking **MACLOGLYMIN** immediately and contact a doctor or the nearest hospital straight away.
- Hypoglycaemia – low sugar (glucose) levels in the blood, especially if you are taking **MACLOGLYMIN** with other anti-diabetic medicines such as a sulphonylurea or insulin. Symptoms may include sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heartbeat.
- Hepatitis (inflammation of the liver) - this may cause tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes. If this happens to you, stop taking **MACLOGLYMIN** and talk to your doctor.
- Pancreatitis - inflammation of the pancreas with severe upper stomach pain, often with nausea and vomiting.
- Paleness of the skin, shortness of breath, dizziness and irregular heartbeat (symptoms of megaloblastic anaemia).

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

Tell your doctor if you notice any of the following:
Frequent:
- Digestive problems such as feeling sick (nausea), being sick (vomiting), diarrhoea, stomach ache (abdominal pain) and loss of appetite.
- Taste disturbance.
- Decrease of vitamin B_{12} absorption

Less frequent:
- Decrease of folic acid absorption
- Weight loss
- Abnormal liver function tests
- Superficial reddening of the skin, usually in patches, hives, itching.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you or your child 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 **MACLOGLYMIN.**

5. How to store MACLOGLYMIN

Store all medicines out of reach of children.
Store at or below 25 °C.
Store in the original package / container.
Keep the HDPE containers tightly closed.
Protect from light and moisture.
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 MACLOGLYMIN contains
MACLOGLYMIN 500 mg
The active substance is Metformin hydrochloride 500 mg
MACLOGLYMIN 850 mg
The active substance is Metformin hydrochloride 850 mg
MACLOGLYMIN 1000 mg
The active substance is Metformin hydrochloride 1 000 mg

Contains magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycolate.
The tablets are coated with coating made up of hypromellose & polyethylene glycol.

What MACLOGLYMIN looks like and contents of the pack
MACLOGLYMIN 500 mg
White to off white, circular, biconvex, film coated, bevelled edge, tablet debossed with "**[1]**" on one side and plain on other side.
MACLOGLYMIN 850 mg
White to off white, circular, biconvex, film coated, bevelled edge, tablets debossed with "C75" on one side and plain on other side.
MACLOGLYMIN 1000 mg
White to off white, oval shaped, biconvex, film coated tablet, debossed with "C" and "76" separated by breakline on one side and also breakline on other side.

HDPE container pack:
MACLOGLYMIN 500 mg
Tablets are packed in a round white plastic container (HDPE) and are closed with a white child resistant closure or continuous thread closure. Pack sizes include 84, 90, 100, 112 and 500 tablets.
MACLOGLYMIN 850 mg
Tablets are packed in a round white plastic container (HDPE) and are closed with a white child resistant closure or continuous thread closure. Pack sizes include 60, 84, 90, 100 and 500 tablets.
MACLOGLYMIN 1000 mg
Tablets are packed in a round white plastic container (HDPE) and are closed with a white child resistant closure or continuous thread closure. Pack sizes include 60, 84, 90, 100 and 500 tablets.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

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Registration number
MACLOGLYMIN 500 mg: 49/21.2/0088
MACLOGLYMIN 850 mg: 49/21.2/0089
MACLOGLYMIN 1000 mg: 49/21.2/0090

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 11 69.

335 mm

290 mm

335 mm

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S3

MACLOGLYMIN 500 mg (Filmbedekte tablet)
MACLOGLYMIN 850 mg (Filmbedekte tablet
MACLOGLYMIN 1000 mg (Filmbedekte tablet)

Metformienhidrochloried
Suikervry

Lees die hele inligtingsblad voordat u begin om MACLOGLYMIN te neem

- Hou hierdie inligtingsblad. U mag dit moontlik weer wil lees.
- As u enige verdere vrae het, moet u asseblief u dokter of apteker, verpleegster of ander professionele gesondheidswerker raadpleeg.
- **MACLOGLYMIN** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense deel nie. Dit mag hulle skade aandoen, ook al toon hulle dieselfde simptome as u.

Wat is in hierdie blad

1. Wat **MACLOGLYMIN** is en waarvoor dit gebruik word.
2. Wat u behoort te weet voordat u begin om **MACLOGLYMIN** neem.
3. Hoe om **MACLOGLYMIN** te neem.
4. Moontlike newe-effekte
5. Hoe om **MACLOGLYMIN** op te berg
6. Inhoud van die verpakking en ander inligting

1. Wat MACLOGLYMIN is en waarvoor dit gebruik word.

MACLOGLYMIN word gebruik om pasiënte met tipe II diabetes, ook 'nie-insulien afhanklike diabetes' genoem, te behandel wanneer oefening en dieet alleen nie genoeg is om u bloedglukosevlakke te beheer nie. Dit word veral in pasiënte wat oorgewig is, gebruik.

- Volwassenes kan **MACLOGLYMIN** alleen of saam met ander medisyne om diabetes te beheer neem (medisyne wat per mond of inspuiting toegedien word).
- Kinders van 12 jaar oud en ouer kan **MACLOGLYMIN** alleen of saam met 'n insulieninspuiting neem.

2. Wat u behoort te weet voordat u MACLOGLYMIN neem of toedien:

Moenie MACLOGLYMIN neem nie:

- As u of u kind hipersensitief (allergies) teen metformienhidrochloried of enige van die bestanddele van **MACLOGLYMIN** is.
- As u aan naarheid, braking, dehidrasie, vinnige gewigsverlies of keto-asidose ly. Keto-asidose is 'n kondisie waartydens liggaampies nl. ketoonliggaampies in die bloed opbou wat tot diabetiese pre-koma kan lei. Simptome sluit maagpyn, vinnige en diep asemhaling, slaperigheid of 'n ongewone vrugtegeur op die asem in.
- As u met nierversaking of disfunksie van die niere gediagnoseer is.
- As u te veel water van u liggaam (dehidrasie) weens langdurige of erge diarree, of as u 'n aantal kere na mekaar gebraak het. Dehidrasie mag tot nierprobleme lei, wat u risiko vir melksuurasidose mag verhoog (sien 'Neem spesiale sorg met **MACLOGLYMIN**' hieronder).
- As u aan 'n erge infeksie, soos infeksie van die long, bronchiale of niersisteem ly. Erge infeksies mag tot nierprobleme lei wat u risiko vir melksuurasidose (sien 'Neem spesiale sorg met **MACLOGLYMIN**' hieronder).
- As u vir hartversaking behandel word of onlangs 'n hartaanval gehad het of aan erge sirkulatoriese probleme (soos skok), of asemhalingsprobleme ly. Dit mag tot 'n tekort aan suurstof na die weefsels, wat u risiko vir melksuurasidose verhoog, lei (sien 'Neem spesiale sorg met **MACLOGLYMIN**' hieronder).
- As u aan inflammasie van die pankreas ly (simptome soos erge boonste buikpyn, dikwels met naarheid en braking).
- As u baie alkohol gebruik of aan lewerprobleme ly.
- As u swanger is of borsvoed.
- As u 'n inspuiting van 'n jodium kontrasmedikasie in u bloedstroom vir ondersoeke soos X-strale of skanderings moet ontvang. U moet ophou om **MACLOGLYMIN** vir 'n sekere periode voor en na die ondersoeke neem.

Waarskuwings en voorsorgsmaatreëls

Stel u dokter of professionele gesondheidswerker in kennis voordat u **MACLOGLYMIN** neem.

Neem spesiale sorg met **MACLOGLYMIN**:

- **MACLOGLYMIN** mag af en toe 'n min voorkomende, dog 'n ernstige komplikasie nl. melksuurasidose veroorsaak, veral as u niere nie behoorlik werk nie. Die risiko van melksuurasidose neem ook toe met ongekontroleerde diabetes, langdurige uithongering, lewerprobleme of alkoholinname, of as u weens erge diarree of braking, koors of 'n afname in vloeistofinname of medisyne vir hoë bloeddruk, diuretika (medisyne wat help om die hoeveelheid water in die liggaam te verminder) of NSAIMs (Nie-steroïed anti-inflammatoriese middels vir pyn en koors) gebruik. Simptome van melksuurasidose is braking, maagpyn met spierkrampe, 'n algemene gevoel van ongesteldheid met erge moegheid en moeite met asemhaling. As dit met u gebeur, het u moontlik onmiddellike hospitaalbehandeling nodig, aangesien melksuurasidose tot koma kan lei. Hou op onmiddellik op om **MACLOGLYMIN** te neem en raadpleeg u dokter of besoek die naaste hospitaal.
- U dokter sal u nierfunksie monitor voordat die behandeling met **MACLOGLYMIN** begin, asook op 'n gereelde basis daarna.
- Stel u dokter in kennis as u medisyne vir hoë bloeddruk, diuretika, NSAIMs) neem, aangesien hierdie medisyne mag veroorsaak dat u niere nie behoorlik werk nie.
- Stel u dokter in kennis as u aan hartkondisies ly voordat u met **MACLOGLYMIN** begin. U dokter sal u hartfunksie monitor voordat u met **MACLOGLYMIN** begin.
- Raadpleeg u dokter voordat u met **MACLOGLYMIN** begin:
  - As u vir 'n ondersoek, soos 'n X-straal of skandering moet gaan waarby 'n binne-aarse inspuiting van 'n kontrasmiddel wat jodium bevat, betrokke is.
  - As u vir 'n groot operasie moet gaan.

U moet ophou om **MACLOGLYMIN** vir 'n periode van tyd te neem voor en nadat u 'n ondersoek vir 'n operasie. U dokter sal besluit of u enige ander behandeling gedurende hierdie tydperk moet ondergaan. Dit is belangrik dat u u dokter se instruksies noukeurig volg.

- **MACLOGLYMIN** sal slegs in kinders van 12 jaar oud en ouer en in adolessente wat aan diabetes tipe II, gediagnoseer deur hul dokter, voorgeskryf word.
- Gaan voort met u oefenings- en dieetprogram en toets u suiker gereeld terwyl u **MACLOGLYMIN** neem. U dokter sal u diabetes monitor en mag van tyd tot tyd bloedtoetse op u doen om te verseker dat u niere en lewer normaal funksioneer.
- Die langtermyn gebruik van **MACLOGLYMIN** mag 'n vitamien B_{12} veroorsaak. Stel u dokter in kennis as u simptome van moegheid, spierswakheid, verlies aan eetlus, massaverlies, diarree, naarheid, vinnige hartklop, gladde of gevoelige tong, prikkeling in die hande en voete, gevoelloosheid in die ledemate ondervind. U dokter sal u vitamien B_{12} vlakke jaarlikse toets.
- Monitor u bloedsuikervlakke gereeld as u **MACLOGLYMIN** saam met ander anti-diabetes medisyne soos sulfoniekureum of insulien gebruik.

Ander medisyne saam met MACLOGLYMIN

Stel altyd u professionele gesondheidswerker in kennis as u ander medisyne gebruik (dit sluit komplementêre of tradisionele medisyne in).
Stel u dokter in kennis as u of u kind enige van die volgende medisyne en **MACLOGLYMIN** saam neem. Dit mag nodig wees om meer gereeld bloedglukosetoetse uit te voer of u dokter mag besluit om die **MACLOGLYMIN** dosis aan te pas.

- Alkohol
- jodiumbevattende kontrasmiddels
- Kortikosteroïede (gebruik om 'n verskeidenheid van kondisies, soos erge inflammasie van die vel, of asma te behandel)
- Diuretika (gebruik om water en sout uit die liggaam te verwyder)
- Beta-2-agoniste soos salbutamol of terbutalien (gebruik om asma te behandel)
- Ander middels wat gebruik word om diabetes te behandel
- AOE-inhibeerders (vir hoë bloeddruk)
- Simetidien (vir maagsere)
- Warfarien (om die bloed te verdun)
- Sulfonikureum (gebruik om die insulienafskeiding te verhoog)
- Medisyne wat die hoeveelheid metformien in u liggaam verander, veral as u aan 'n afname van nierfunksie ly (soos verapamiel, rifampisien, simetidien, dolutegravir, ranolasien, trimetoprieem, vandetanieb, isavuconasool, krisotinieb, olaparieb)

MACLOGLYMIN met voedsel, vloeistof en alkohol

MACLOGLYMIN moet met of na 'n maaltyd geneem word.
Moenie alkohol gebruik terwyl u **MACLOGLYMIN** neem nie aangesien die alkohol die kans vir melksuurasidose mag verhoog.

Swangerskap, borsvoeding en vrugbaarheid
As u swanger is of u baba borsvoed, moet u asseblief u dokter apteker of professionele gesondheidswerker raadpleeg voordat u begin om **MACLOGLYMIN** te neem.
MACLOGLYMIN word nie vir gebruik gedurende swangerskap en borsvoeding aanbeveel nie.

Bestuur en die gebruik van masjinerie
Wanneer **MACLOGLYMIN** alleen geneem word, veroorsaak dit nie hipoglukemie (lae bloedsuikervlakke) nie. As u simptome van hipoglukemie (lae bloedsuikervlakke met simptome van swakheid, duiseligheid, toename in sweet, vinnige hartklop, gesigsafwykings of moeite met konsentrasie wanneer u **MACLOGLYMIN** in kombinasie met ander anti-diabetiese middels behoort u op te hou met bestuur of om met masjinerie te werk.

3. Hoe om MACLOGLYMIN te neem of toe te dien

- Moenie medisyne wat vir u of u kind voorgeskryf is met ander deel nie.
- Neem of dien **MACLOGLYMIN** toe presies soos deur u dokter of apteker voorgeskryf. Raadpleeg u dokter of apteker as u onseker is.
- As u voel dat die effek van **MACLOGLYMIN** te sterk of te swak is, moet u u dokter of apteker raadpleeg.
- U dokter sal u presies inlig hoeveel van die medisyne om te neem of toe te dien en wanneer om dit te neem of toe te dien.
- **MACLOGLYMIN** moet met genoeg vloeistof per mond geneem en kan met of na 'n maaltyd geneem word. Dit sal enige newe-effekte van die verteringstelsel vermy.
- Die normale dosis is:
  - Volwassenes: Aanvanklik, een 500 mg tablet drie, of een 850 mg of 1 000 mg twee keer per dag, met of na 'n maaltyd.
  - Kinders vanaf 12 jaar oud en adolessente: Die normale begindosis is 500 mg of 850 mg een keer per dagtoedien met of na 'n maaltyd

As u te veel MACLOGLYMIN geneem of toegedien het, behoort u:
In die geval van oordosering moet u u dokter of apteker raadpleeg. As hulle nie beskikbaar is nie, gaan na die gifbeheersentrum van u naaste hospitaal.

Simptome van oordosering mag die volgende insluit: sweet, swakheid, honger te, duiseligheid, bewerasie, hoofpyn, hittegloede of bleekheid, gevoelloosheid, braking, toename in hartklop, maagpyn (buikpyn) met spierkrampe, 'n algemene gevoel van ongesteldheid met erge moegheid en moeite met asemhaling.

As u vergeet het om MACLOGLYMIN te neem of toe te dien
Dit is belangrik dat u u medikasie **MACLOGLYMIN** op dieselfde tyd elke dag te neem. As u vergeet het om 'n dosis te neem, neem dit sodra u daarvan onthou, tensy dit byna tyd vir ou volgende dosis is. In daardie geval moet u net met die volgende dosis soos normaal voortgaan. Moenie 'n dubbel dosis neem om op te maak vir die vergete dosis nie.

As u ophou om MACLOGLYMIN te neem of dit toe te dien
Moenie ophou om **MACLOGLYMIN** te neem bloot omdat u beter voel nie.
Neem of dien **MACLOGLYMIN** toe vir so lank as wat u dokter voorgeskryf het.
Moenie met die gebruik van **MACLOGLYMIN** ophou nie tensy u dokter dit aanbeveel nie.

4. Moontlike newe-effekte

MACLOGLYMIN kan newe-effekte hê.
Nie al die newe-effekte van **MACLOGLYMIN** word in hierdie inligtingsblad genoem nie. As u of u kind se algemene gesondheid vererger of u of u kind ondervind enige ongewenste effekte terwyl u **MACLOGLYMIN** neem, moet u asseblief u dokter, apteker of professionele gesondheidswerker raadpleeg.
As enige van die volgende met u gebeur terwyl u **MACLOGLYMIN** neem, moet u ophou om **MACLOGLYMIN** te neem en onmiddellik u dokter raadpleeg of gaan na die ongevalle afdeling van u naaste hospitaal:

- Skielike tekens van allergie - insluitende veluitslag, jeuk of urtikarie, swelling van die gesig, lippe of tong, kortasemheid of moeite met asemhaling

Hierdie is almal baie ernstige newe-effekte. As u of u kind 'n ernstige reaksie teen **MACLOGLYMIN** hê. U mag moontlik ernstige mediese hulp of hospitalisasie benodig.

Stel u dokter onmiddellik in kennis of gaan na die ongevalle afdeling van u naaste hospitaal as u enige van die volgende waarneem.:

- Melksuurasidose. Dit is 'n baie selde voorkomende dog ernstige komplikasie, veral as u niere nie behoorlik werk nie. Simptome van melksuurasidose is braking, maagpyn (buikpyn) met spierkrampe, 'n algemene gevoel van ongesteldheid met erge moegheid, en moeite met asemhaling. As dit met u gebeur, het u moontlik dringende mediese hulp en hospitaalbehandeling, aangesien melksuurasidose tot koma kan lei. Hou onmiddellik op om **MACLOGLYMIN** te neem en raadpleeg onmiddellik u dokter of naaste hospitaal.
- Hipoglukemie - lae suikervlakke in die bloed, veral as u **MACLOGLYMIN** saam met ander anti-diabetiese medisyne soos sulfanilureum of insulien neem. Simptome mag die volgende insluit: sweet, swakheid, honger te, duiseligheid, bewerasie, hoofpyn, hittegloede of bleekheid, gevoelloosheid, vinnig bonsende hartklop.
- Hepatitis (inflammasie van die lewer) - dit mag moegheid, verlies aan eetlus, gewigsverlies met of sonder geel verkleuring van die vel of wit van die oë. Indien dit gebeur, hou op om **MACLOGLYMIN** te neem en raadpleeg u dokter.
- Pankreatitis - inflammasie van die pankreas met erge boonste buikpyn, dikwels met naarheid en braking.
- Bleekheid van die vel, kortademheid, duiseligheid en ongereelde hartklop (simptome van megaloblastiese anemie).

Hierdie is almal ernstige newe-effekte. U mag moontlik dringende mediese aandag benodig.

Stel u dokter in kennis as u een van die volgende opmerk:
Dikwels:

- Verteringsprobleme soos naarheid, braking, diarree, maagpyn (buikpyn) en verlies aan eetlus
- Smaakafwyking
- Afname van vitamien B_{12} absorpsie

Minder dikwels:

- Afname van foliensuurabsorpsie
- Gewigsverlies
- Abnormale lewerfunksietoetse
- Opvallende rooi verkleuring van die vel, gewoonlik in vlekke, urtikarie, jeuk

As u enige newe-effekte waarneem wat nie in hierdie inligtingsblad genoem word nie, moet u u dokter of apteker in kennis stel.

Aanmelding van newe-effekte

As u of u kind newe-effekte toon, moet u u dokter of verpleegster raadpleeg. Dit sluit enige newe-effekte wat moontlik nie in hierdie inligtingsblad genoem word nie. U kan ook enige newe-effekte aanmeld by SAHPRA deur die **"Adverse Drug Reaction Reporting Form"** aanmeld, wat aanlyn onder SAHPRA se publikasies https://www.sahpra.org.za/Publications/Index/8 gevind kan word. Deur newe-effekte aan te meld kan u help om meer inligtingoor die veiligheid van **MACLOGLYMIN** te verskaf.

5. Hoe om MACLOGLYMIN op te berg

Berg alle medisyne buite bereik van kinders.
Berg by of benede 25°C.
Berg in die oorspronklike verpakking/houer.
Hou die HDPE houer dig toe.
Beskerm teen lig en vogtigheid.
Moenie in die badkamer stoor nie.
Moenie na die vervaldatum op die etiket/karton/bottel gebruik nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moenie enige ongebruikte medisyne in die rioleringstelsel (toilet) wegdoen nie.

6. Inhoud van die verpakking en nader inligting

Wat MACLOGLYMIN bevat
MACLOGLYMIN 500 mg
Die aktiewe bestanddeel is metformienhidochloried 500 mg.
MACLOGLYMIN 850 mg
Die aktiewe bestanddeel is metformienhidochloried 850 mg.
MACLOGLYMIN 1000 mg
Die aktiewe bestanddeel is metformienhidochloried 1 000 mg.

Bevat magnesiumstearaat, mikrokristallyne sellulose, povidoon, natriumstyselglikolaat.
Die tablet word met wit laag van hipromellose & polietileenglikol bedek.

Hoe MACLOGLYMIN lyk en die inhoud van die verpakking
MACLOGLYMIN 500 mg
Wit tot byna-wit ronde, bikonvekse, filmbedekte tablet met "[illegible]" op die een kant gedruk en glad aan die ander kant.
MACLOGLYMIN 850 mg
Wit tot byna-wit ronde, bikonvekse, filmbedekte tablet met "C75" op die een kant gedruk en glad aan die ander kant.
MACLOGLYMIN 1000 mg
Wit tot byna-wit ovaalvormige, bikonvekse, filmbedekte tablet met "C" en "76" geskei deur breeklyn aan die een kant en ook breeklyn aan die ander kant.

HDPE houer
MACLOGLYMIN 500 mg
Tablette word in 'n ronde, wit plastiekhouer (HDPE) verpak, met 'n wit, vroetelvrye deksel met aanhoudende skroefdraad verpak. Pakgroottes sluit 84, 90, 100, 112 en 500 tablette in.
MACLOGLYMIN 850 mg
Tablette word in 'n ronde, wit plastiekhouer (HDPE) verpak, met 'n wit, vroetelvrye deksel met aanhoudende skroefdraad verpak. Pakgroottes sluit 60, 84, 90, 100 en 500 tablette in.
MACLOGLYMIN 1000 mg
Tablette word in 'n ronde, wit plastiekhouer (HDPE) verpak, met 'n wit, vroetelvrye deksel met aanhoudende skroefdraad verpak. Pakgroottes sluit 60, 84, 90, 100 en 500 tablette in.

Houer van die sertifikaat van registrasie en Vervaardiger
MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Kantoorblok 1 Bassonia Estate Kantoorpark (Oos)
Cussoniarylaan 1 Bassonia Rock, Uitbr.12 Alberton Suid Afrika

Hierdie inligtingsblad is laas hersien
11 September 2023

Registrasienommer
MACLOGLYMIN 500 mg: 49/21.2/0088
MACLOGLYMIN 850 mg: 49/21.2/0089
MACLOGLYMIN 1000 mg: 49/21.2/0090

Toegang tot die ooreenstemmende Professionele inligting

Die ooreenstemmende professionele inligting kan by http://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma verkry word of kontak 011 682 11 69

MASTER COPY

MACLEODS

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: MACLOGLYMIN 500/850/1000 mg TABLETS (Metformin Hydrochloride Tablets 500/850/1000 mg)	
2. Country: South Africa - OSD Tender	3. Packaging component: Patient Information
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 290(W) mm
9. Design / Style: Booklet type	10. Item code No.: PM04295501
11. Artwork has been made: Actual Size	12. Pharma code No.: 33528 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: NA
15. Revision no: 00	16. A/W File name: Z:\Metformin\OSD Tender 2022\OSD Commercialcartonlines pack PIL\MACLOGLYMIN PIL PM04295501.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
01/02/24	Vanita Rajool	02/02/24	10/02/24	13/02/24	14/02/24

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.

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa - OSD Tender	PM04295501		