SCHEDULING STATUS: S3

1. NAME OF THE MEDICINE

MACLOGLYMIN 500 mg TABLETS (Film-coated tablet)
MACLOGLYMIN 850 mg TABLETS (Film-coated tablet)
MACLOGLYMIN 1 000 mg TABLETS (Film-coated tablet)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

MACLOGLYMIN 500 mg TABLETS
Each film-coated tablet contains 500 mg metformin hydrochloride.

MACLOGLYMIN 850 mg TABLETS
Each film-coated tablet contains 850 mg metformin hydrochloride.

MACLOGLYMIN 1 000 mg TABLETS
Each film-coated tablet contains 1 000 mg metformin hydrochloride.
Sugar free.
Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Film-coated tablets.
MACLOGLYMIN 500 mg TABLETS
White to off white, circular, biconvex, film coated, bevelled edge, tablet debossed with "C74" on one side and plain on other side.

MACLOGLYMIN 850 mg TABLETS
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 TABLETS
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.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
MACLOGLYMIN TABLETS is indicated for the treatment of type II diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control.
- In adults **MACLOGLYMIN TABLETS** may be used as monotherapy or in combination with other oral anti-diabetic medicines or with insulin.
- In children over 12 years of age and adolescents with type II diabetes, **MACLOGLYMIN TABLETS** may be used as monotherapy or in combination with insulin.

4.2 Posology and method of administration
Posology:
It is important **MACLOGLYMIN TABLETS** be taken in divided doses with meals.

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 food. After 10 to 15 days the dose should be adjusted according to blood glucose measurements. A slow increase in dose may improve gastro-intestinal tolerability. Good diabetic control may be achieved within a few days, but it is not usual for the full effect to be delayed for up to two weeks. If control is incomplete, a cautious increase in dosage to a maximum of 2550 mg daily is justified. Once control has been obtained it may be possible to reduce the dosage of **MACLOGLYMIN TABLETS.**

Children and adolescents:
MACLOGLYMIN TABLETS can be used in 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. After 10 to 15 days the dose should be adjusted on the basis of blood glucose measurements. A slow increase of dose may improve gastrointestinal tolerability. The maximum recommended dose of metformin is 2000 mg daily, taken as 2 or 3 divided doses.

Elderly:
MACLOGLYMIN TABLETS dose in the elderly should be adjusted based on renal function.
Combination therapy and adolescents:
See section 4.4.

Method of administration:
Orally.

MACLOGLYMIN TABLETS should be administered with or after food.

4.3 Contraindications
- Hypersensitivity to metformin hydrochloride or any of the excipients of **MACLOGLYMIN TABLETS** (see section 6.1).
- Diabetic ketoacidosis, diabetic pre-coma.
- Renal failure or renal dysfunction (e.g. serum creatine levels > 135 µmol/L in males and > 110 µmol/L in females or creatinine clearance < 60 ml/min).
- Acute conditions with the potential to alter renal function such as:
  - dehydration
  - severe infection
  - shock
  - Intravascular administration of iodinated contrast agents (see section 4.4)
- Acute or chronic disease which may cause tissue hypoxia such as:
  - cardiac or respiratory failure
  - recent myocardial infarction
  - shock
  - pancreatitis
- Hepatic insufficiency, acute alcohol intoxication, alcoholism.
- Pregnancy and lactation.

4.4 Special warnings and precautions for use

Warnings

Lactic acidosis:
Lactic acidosis is a rare, but serious (high mortality in the absence of prompt treatment), metabolic complication that can occur due to **MACLOGLYMIN TABLETS** accumulation. Reported cases of lactic acidosis in patients on **MACLOGLYMIN TABLETS** have occurred primarily in diabetic patients with significant renal failure. The incidence of lactic acidosis can and should be reduced by assessing also other associated risk factors such as poorly controlled diabetes, ketosis, prolonged fasting, excessive alcohol intake, hepatic insufficiency and any condition associated with hypoxia.
In case of dehydration (severe diarrhoea or vomiting, fever or reduced fluid intake), **MACLOGLYMIN TABLETS** should be temporarily discontinued and contact with a healthcare professional is recommended.
Medicines that can acutely impair renal function (such as antihypertensives, diuretics and NSAIDs) should be initiated with caution in **MACLOGLYMIN TABLETS**-treated patients.
Diagnosis:
Lactic acidosis is characterised by acidotic dyspnoea, abdominal pain and hypothermia followed by coma. Diagnostic laboratory findings are decreased blood pH (< 7.35), plasma lactate levels above 5 mmol/l, and an increased anion gap and lactate/pyruvate ratio.
Lactic acidosis has occurred to a greater extent in patients with contraindications to therapy. In patients with a metabolic acidosis lacking evidence of ketoacidosis (ketonuria and ketonaemia) lactic acidosis should be suspected and **MACLOGLYMIN TABLETS** therapy stopped. Lactic acidosis is a medical emergency which must be treated in hospital.

Renal function:
As **MACLOGLYMIN TABLETS** is excreted by the kidney, serum creatinine levels should be determined before initiating treatment and regularly thereafter:
- At least annually in patients with normal renal function.
- At least two to four times a year in patients with serum creatinine levels at the upper limit of normal and in elderly subjects.

Decreased renal function in elderly subjects is frequent and asymptomatic.
Special caution should be exercised in situations where renal function may become impaired, for example when initiating antihypertensive therapy or diuretic therapy and when starting therapy with a NSAID.

Cardiac function
Patients with heart failure are more at risk of hypoxia and renal insufficiency. For patients with acute or chronic heart failure, **MACLOGLYMIN TABLETS** is contraindicated (see section 4.3).

Administration of iodinated contrast agents:
As the intravascular administration of iodinated contrast materials in radiological studies can lead to renal failure, **MACLOGLYMIN TABLETS** should be discontinued prior to, or at the time of the test and not reinstituted until 48 hours afterwards, and only after renal function has been re-evaluated and found to be normal.

Surgery:
MACLOGLYMIN TABLETS should be discontinued 48 hours before elective surgery with general anaesthesia and clinical investigations such as intravenous urography and intravenous angiography and it should not be usually resumed earlier than 48 hours afterwards and only after control of renal function has been regained.

Children and adolescents:
The diagnosis of type II diabetes mellitus must be confirmed before treatment with **MACLOGLYMIN TABLETS** is initiated.
No effect of **MACLOGLYMIN TABLETS** on growth and puberty has been detected during controlled clinical studies of one year duration but no long-term data on these specific points are available.
Therefore, a careful follow-up of the effect of **MACLOGLYMIN TABLETS** on these parameters in **MACLOGLYMIN TABLETS** treated children, especially pre-pubescent children, is recommended.

Other precautions:
- All patients should continue their diet with a regular distribution of carbohydrate intake during the day. Overweight patients should continue their energy-restricted diet.
- The usual laboratory test for diabetes monitoring should be performed regularly.
- Although **MACLOGLYMIN TABLETS** alone never causes hypoglycaemia, caution is advised when it is used in combination with insulin or sulphonylureas.
- As Vitamin B_{12} deficiency and megaloblastic anaemia may develop with long-term **MACLOGLYMIN TABLETS** use, Vitamin B_{12} levels should be assessed at least annually.
- **MACLOGLYMIN TABLETS** is excreted by the kidney and regular monitoring of renal function is advised in all diabetics.
- The use of **MACLOGLYMIN TABLETS** is not advised in conditions which may cause dehydration or in patients suffering from serious infections, trauma or on low calorie intake.
- During concomitant therapy with a sulphonylurea, blood glucose should be monitored because combined therapy may cause hypoglycaemia. Stabilisation of diabetic patients with **MACLOGLYMIN TABLETS** and insulin should be carried out in hospital because of the possibility of hypoglycaemia until the correct ratio of the two medicines has been obtained.
- Contraindications should be carefully observed.

4.5 Interaction with other medicines and other forms of interaction
Non advisable combinations:
Alcohol
Increased risk of lactic acidosis in acute alcohol intoxication, particularly in case of:
- fasting or malnutrition
- hepatic insufficiency

Avoid consumption of alcohol and alcohol-containing medicines.

Iodinated contrast agents:
Intravascular administration of iodinated contrast agents may lead to renal failure, resulting in **MACLOGLYMIN TABLETS** accumulation and a risk of lactic acidosis.
MACLOGLYMIN TABLETS should be discontinued prior to, or at the time of the test and not reinstituted until 48 hours afterwards, and only after renal function has been re-evaluated and found to be normal.

Combinations requiring precaution for use:
Glucocorticoids (systemic and local routes), beta-2-agonists and diuretics have intrinsic hyperglycaemic activity. Inform the patient and perform more frequent blood glucose monitoring, especially at the beginning treatment. If necessary, adjust the dosage of the antidiabetic medicine during therapy with the other medicine and upon its discontinuation.
ACE-inhibitors may decrease blood glucose levels. If necessary, adjust the dosage of the antidiabetic medicine during therapy with the ACE-inhibitor and upon its discontinuation.
Reduced renal clearance of **MACLOGLYMIN TABLETS** has been reported during cimetidine therapy, so a dose reduction should be considered.
An interaction between **MACLOGLYMIN TABLETS** and anticoagulants is a possibility and dosage of the latter may need adjustment.

Organic cation transporters (OCT)
Metformin is a substrate of both transporters OCT1 and OCT2.
Co-administration of metformin with
Inhibitors of OCT1 (such as verapamil) may reduce efficacy of metformin,
Inducers of OCT1 (such as rifampicin) may increase gastrointestinal absorption and efficacy of metformin.
Inhibitors of OCT2 (such as cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole) may decrease the renal elimination of metformin and thus lead to an increase in metformin plasma concentration.
Inhibitors of both OCT1 and OCT2 (such as crizotinib, olaparib) may alter efficacy and renal elimination of metformin.
Caution is therefore advised, especially in patients with renal impairment, when these drugs are co-administered with metformin, as metformin plasma concentration may increase. If needed, dose adjustment of metformin may be considered as OCT inhibitors/inducers may alter the efficacy of metformin.

4.6 Fertility, pregnancy and lactation
Pregnancy
Safety in pregnancy and lactation has not been established in humans (See section 4.3). However, animal studies do not indicate harmful effects with respect to pregnancy, embryonal or foetal development, parturition or postnatal development.
When the patient plans to become pregnant and during pregnancy, diabetes should not be treated with **MACLOGLYMIN TABLETS** but insulin should be used to maintain blood glucose levels as close to normal as possible in order to lower the risk of foetal malformations associated with abnormal blood glucose levels.
Lactation
Metformin is excreted in breastmilk. Limited data are available and therefore breastfeeding is not recommended during treatment with metformin (see Section 4.3)
Fertility
Fertility of male or female rats was unaffected by metformin when administered at doses as high as 600 mg/kg/day, which is approximately three times the maximum recommended human daily dose based on body surface area comparisons.

4.7 Effects on ability to drive and use machines
Metformin monotherapy does not cause hypoglycaemia and therefore has no effect on the ability to drive or use machines.

4.8 Undesirable effects
Table 1 side effects associated with MACLOGLYMIN TABLETS therapy

System Organ Class	Frequency	Undesirable effects
Blood and lymphatic system disorders	Less frequent	Megaloblastic anaemia, haemolysis
Immune system disorders	Less frequent	Hypersensitivity
Metabolism and nutrition disorders	Less frequent	Decrease of vitamin B_{12} and folic acid absorption with decrease of serum levels during long term use of **MACLOGLYMIN TABLETS.** Consideration of such aetiology is recommended if a patient presents with megaloblastic anaemia. Lactic acidosis **(see Section 4.4)**
Nervous system disorders	Frequent	Taste disturbance
Gastrointestinal disorders	Frequent	Nausea, vomiting, diarrhoea, abdominal pain and loss of appetite. These undesirable effects occur most frequently during initiation of therapy and resolve spontaneously in most cases. To prevent them, it is recommended that **MACLOGLYMIN TABLETS** be taken in 2 or 3 daily doses during or after meals. A slow increase of the dose may also improve gastrointestinal tolerability
	Less frequent	Weight loss, pancreatitis
Hepatobiliary disorders	Less frequent	Liver function tests abnormalities or hepatitis resolving upon **MACLOGLYMIN TABLETS** discontinuation.
Skin and subcutaneous tissue disorders	Less frequent	Skin reactions such as erythema, pruritus and urticaria.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose
Hypoglycaemia can occur when **MACLOGLYMIN TABLETS** is given concomitantly with a sulphonylurea, insulin or alcohol, in excessive dosage, and particularly if there is a possibility of accumulation, lactic acidosis may develop. Lactic acidosis is a medical emergency and must be treated in hospital. The most effective method to remove lactate and **MACLOGLYMIN TABLETS** is haemodialysis. Intense symptomatic and supportive therapy is recommended which should be particularly directed at correcting fluid loss and correcting blood glucose levels.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmaceutical groups: Oral Hypoglycaemics.
ATC code: A10BA02
A21.2 Oral Hypoglycaemic
Metformin is a biguanide oral anti-hyperglycaemic medicine, lowering both basal and postprandial plasma glucose. It does not stimulate insulin secretion and therefore does not produce hypoglycaemia.
Metformin may act via 3 mechanisms:
1. Reduction of hepatic glucose production by inhibiting gluconeogenesis and glycogenolysis.
2. In muscle, by increasing insulin sensitivity, improving peripheral glucose uptake and utilisation.
3. Delay of intestinal glucose absorption.

5.2 Pharmacokinetic properties
Absorption:
After an oral dose of metformin, T_{max} is reached in 2.5 hours. Absolute bioavailability of a 500 mg or 850 mg metformin tablet is approximately 50-60 % in healthy subjects. After an oral dose, the non-absorbed fraction recovered in faeces was 20-30 %.
After oral administration, metformin absorption is saturable and incomplete. It is assumed that the pharmacokinetics of metformin absorption is non-linear.
At the usual metformin doses and dosing schedules, steady state plasma concentrations are reached within 24 to 48 hours and are generally less than 1 µg/mL. In controlled clinical trials, maximum metformin plasma levels (C_{max}) did not exceed 4 µg/mL, even at maximum doses. Food decreases the extent and slightly delays the absorption of metformin. Following administration of a dose of 850 mg, a 40 % lower plasma peak concentration, a 25 % decreases in AUC (area under curve) and a 35 minute prolongation of time to peak plasma concentration were observed. The clinical relevance of these decreases is unknown.

Distribution:
Plasma protein binding is negligible. Metformin partitions into erythrocytes. The blood peak is lower than the plasma peak and appears at approximately the same time. The red blood cells most likely represent a secondary compartment of distribution. The mean volume of distribution ranged between 63 – 276 litres.

Biotransformation: Metformin is excreted unchanged in urine. No metabolites have been identified in humans.

Elimination:
Renal clearance of metformin is > 400 ml/min, indicating that metformin is eliminated by glomerular filtration and tubular secretion. Following an oral dose, the apparent terminal elimination half-life is approximately 6.5 hours.
When renal function is impaired, renal clearance is decreased in proportion to that of creatinine and thus the elimination half-life is prolonged, leading to increased levels of metformin in plasma.

Paediatrics:
Single dose study: After single doses of metformin 500 mg paediatric patients have shown similar pharmacokinetic profile to that observed in healthy adults.

5.3 Preclinical safety data
Preclinical data reveal no special hazard for humans based on conventional studies on safety, pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and reproductive toxicity.

6. PHARMACEUTICAL PARTICULARS

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

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months from the manufacturing date.

6.4 Special precautions for storage
Store at or below 25 °C.
Protect from light and moisture.
Keep the HDPE container tightly closed.
Store in the original package in order to protect from light and moisture.
KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container
MACLOGLYMIN 500 mg TABLETS:
HDPE Container Pack for 56's:
Tablets are packed in 75 ml white round heavy weight HDPE bottle with 38-400 mm screw neck finish closed with 38 mm child resistant or continuous thread closure with pulp and heat seal liner. Each HDPE bottle contains 1 absorbent cotton coil.
Pack size: 56 tablets

HDPE Container Pack for 84's, 90's and 100's:
Tablets are packed in 100 ml white round heavy weight HDPE bottle with 38-400 mm screw neck finish closed with 38 mm child resistant closure or continuous thread closure with pulp and heat seal liner. Each HDPE bottle contains 1 absorbent cotton coil.
Pack size: 84 tablets, 90 tablets and 100 tablets.

HDPE Container Pack for 112's:
Tablets are packed in 120 ml white round heavy weight HDPE bottle with 38-400 mm screw neck finish closed with 38 mm child resistant or continuous thread closure with pulp and heat seal liner. Each HDPE bottle contains 1 absorbent cotton coil.
Pack size: 112 tablets

HDPE Container Pack for 500's:
Tablets are packed in 500 ml (for 500 tablets) white round heavy weight HDPE bottle with 53-400 mm screw neck finish closed with 53 mm child resistant or continuous thread closure with pulp and heat seal liner. Each HDPE bottle contains 3 absorbent cotton coils.
Pack size: 500 tablets.

MACLOGLYMIN 850 mg TABLETS:
HDPE Container Pack for 28's and 30's:
Tablets are packed in 60 ml white round heavy weight HDPE bottle with 38-400 mm screw neck finish closed with 38 mm child resistant or continuous thread closure with pulp and heat seal liner. Each HDPE bottle contains 1 absorbent cotton coil.
Pack size: 28 tablets and 30 tablets

HDPE Container Pack for 56's:
Tablets are packed in 120 ml white round heavy weight HDPE bottle with 38-400 mm screw neck finish closed with 38 mm child resistant or continuous thread closure with pulp and heat seal liner. Each HDPE bottle contains 1 absorbent cotton coil.
Pack size: 56 tablets

HDPE Container Pack for 84's, 90's and 100's:
Tablets are packed in 150 ml white round heavy weight HDPE bottle with 38-400 mm screw neck finish closed with 38 mm child resistant closure or continuous thread closure with pulp and heat seal liner. Each HDPE bottle contains 1 absorbent cotton coil.
Pack size: 84 tablets, 90 tablets and 100 tablets.

HDPE Container Pack for 500's:
Tablets are packed in 750 ml white round heavy weight HDPE bottle with 53-400 mm screw neck finish closed with 53 mm child resistant closure or continuous thread closure with pulp and heat seal liner. Each HDPE bottle contains 3 absorbent cotton coils.
Pack size: 500 tablets.

MACLOGLYMIN 1000 mg TABLETS:
HDPE Container Pack for 84's, 90's and 100's:
Tablets are packed in 200 ml white round heavy weight HDPE bottle with 38-400 mm screw neck finish closed with 38 mm child resistant closure or continuous thread closure with pulp and heat seal liner. Each HDPE bottle contains 1 absorbent cotton coil.
Pack size: 84 tablets, 90 tablets and 100 tablets.

HDPE Container Pack for 500's:
Tablets are packed in 950 ml white round heavy weight HDPE bottle with 53-400 mm screw neck finish closed with 53 mm child resistant closure or continuous thread closure with pulp and heat seal liner. Each HDPE bottle contains 3 absorbent cotton coils.
Pack size: 500 tablets.

6.6 Special precautions for disposal and other handling
No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Mecleods Pharmaceuticals SA (Pty) Ltd
Office block 1, Bassonia Estate Office Park (East),
1 Cusaonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

4. REGISTRATION NUMBER(S)

MACLOGLYMIN 500 mg: 49/21.2/0068
MACLOGLYMIN 850 mg: 49/21.2/0069
MACLOGLYMIN 1000 mg: 49/21.2/0090

5. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13 July 2021

6. DATE OF REVISION OF THE TEXT

13 July 2021

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

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

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

1. What MACLOGLYMIN TABLETS is and what it is used for

MACLOGLYMIN TABLETS 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 TABLETS** 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 TABLETS** alone or together with insulin injection.

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

Do not take or give MACLOGLYMIN TABLETS:
- If you or your child are hypersensitive (allergic) to metformin hydrochloride or to any of the ingredients of **MACLOGLYMIN TABLETS.**
- 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 TABLETS** 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 TABLETS** 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 TABLETS** 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 TABLETS** 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 TABLETS.**
Take special care with **MACLOGLYMIN TABLETS:**
- **MACLOGLYMIN TABLETS** 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 TABLETS** immediately and contact a doctor or the nearest hospital straight away.
- Your doctor will monitor your kidney function before starting treatment with **MACLOGLYMIN TABLETS** 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 TABLETS.** Your doctor will monitor your heart function before starting treatment with **MACLOGLYMIN TABLETS.**
- 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 TABLETS** 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 TABLETS** 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 TABLETS.** 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 TABLETS** 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 TABLETS with other anti-diabetic medicines such as a sulphonylurea or insulin.

Other medicines and MACLOGLYMIN TABLETS
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 TABLETS** at the same time. You may need more frequent blood glucose tests or your doctor may adjust the dosage of **MACLOGLYMIN TABLETS:**
- 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

MACLOGLYMIN 500/850/1000 mg TABLETS (film-coated tablet)
PM03839201

400 mm

435 mm

400 mm

reduced kidney function (such as verapamil, rifamycin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, Olaparib).

MACLOGLYMIN TABLETS with food and drink and alcohol
MACLOGLYMIN TABLETS should be taken with meals or after meals.
Do not drink alcohol while taking **MACLOGLYMIN TABLETS** 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 TABLETS.**
MACLOGLYMIN TABLETS is not recommended for use during pregnancy and breastfeeding.

Driving and using machines
MACLOGLYMIN TABLETS 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 TABLETS** in combination with other antidiabetic medicines you should stop driving or operating machinery.

3. How to take or give MACLOGLYMIN TABLETS

- Do not share medicines prescribed for you or your child with any other person.
- Always take or give **MACLOGLYMIN TABLETS** 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 TABLETS** 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 TABLETS** 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 1000 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 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.
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 TABLETS
It is important to take your **MACLOGLYMIN TABLETS** 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 TABLETS
Do not stop taking **MACLOGLYMIN TABLETS** just because you feel better.
Take or give **MACLOGLYMIN TABLETS** for as long as your doctor recommends. Do not stop taking or giving **MACLOGLYMIN TABLETS** unless your doctor tells you to.

4. Possible side effects

MACLOGLYMIN TABLETS can have side effects.
Not all side effects reported for MACLOGLYMIN TABLETS 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 TABLETS**, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking or giving **MACLOGLYMIN TABLETS** 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 TABLETS.** 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 TABLETS** 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 TABLETS** 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 TABLETS** 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.

Less frequent:
- Decrease of vitamin B_{12} and 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/5. By reporting side effects, you can help provide more information on the safety of **MACLOGLYMIN TABLETS.**

5. How to store MACLOGLYMIN TABLETS

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 TABLETS contains
MACLOGLYMIN 500 mg TABLETS
The active substance is Metformin hydrochloride 500 mg
MACLOGLYMIN 850 mg TABLETS
The active substance is Metformin hydrochloride 850 mg
MACLOGLYMIN 1000 mg TABLETS
The active substance is Metformin hydrochloride 1000 mg

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

What MACLOGLYMIN TABLETS looks like and contents of the pack
MACLOGLYMIN 500 mg TABLETS
White to off white, circular, biconvex, film coated, bevelled edge, tablet debossed with "C74" on one side and plain on other side.
MACLOGLYMIN 850 mg TABLETS
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 TABLETS
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
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 56, 84, 90, 100, 112 and 500 tablets.
MACLOGLYMIN 850 mg TABLETS
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 28, 30, 56, 84, 90, 100 and 500 tablets.
MACLOGLYMIN 1000 mg TABLETS
Tablets are packed in a round white plastic container (HDPE) and are closed with a white child resistant closure or continuous thread closure, packed in an outer carton. Pack sizes include 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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13 July 2021.

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 1169.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S3

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

Metformienhidrochloried
Suikervry

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

1. Wat MACLOGLYMIN TABLETTE is en waarvoor dit gebruik word.

MACLOGLYMIN TABLETTE 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 TABLETTE** 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 TABLETTE** alleen of saam met 'n insulieninspuiting neem.

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

Moenie MACLOGLYMIN TABLETTE neem nie:

- As u of u kind hipersensitief (allergies) teen metforminhidrochloried of enige van die bestanddele van **MACLOGLYMIN TABLETTE** is.
- As u aan niersiekte, braking, dehidrasie, vinnige gewigsverlies of keto-asidose ly. Keto-asidose is 'n kondisie waarbydens liggaampies nl. ketonliggaampies 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 TABLETTE**' 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 TABLETTE**' hieronder).
- As u vir hartversaking behandel word of onlangs 'n hartaanval gehad het of aan erge sirkulatoriese probleme (soos sioek), 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 TABLETTE**' 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 TABLETTE** vir 'n sekere periode voor en na die ondersoeke neem.

Waarskuwings en voorsorgsmaatreëls

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

Neem spesiale sorg met **MACLOGLYMIN TABLETTE:**

- **MACLOGLYMIN TABLETTE** 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 alkoholmisbruik, 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 TABLETTE** te neem en raadpleeg u dokter of besoek die naaste hospitaal.
- U dokter sal u nierfunksie monitor voordat die behandeling met **MACLOGLYMIN TABLETTE** 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 TABLETTE** begin. U dokter sal u hartfunksie monitor voordat u met **MACLOGLYMIN TABLETTE** begin.
- Raadpleeg u dokter voordat u met **MACLOGLYMIN TABLETTE** begin:
  - As u vir 'n ondersoek, soos 'n X-straal of skandering moet gaan waarby 'n binneare inspuiting van 'n kontrasmiddel wat jodium bevat, betrokke is.
  - As u vir 'n groot operasie moet gaan.

U moet ophou om **MACLOGLYMIN TABLETTE** 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 TABLETTE** 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 TABLETTE** neem. U dokter sal u diabetes monitor en mag van tyd tot tyd bloedtoetse opdoen om te verseker dat u niere en lewer normaal funksioneer.
- Die langtermyn gebruik van **MACLOGLYMIN TABLETTE** meg 'n vitamien B_{12} veroorsaak. Stel u dokter in kennis as u simptome van moegheid, spierswakheid, verlies aan setlus, 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 TABLETTE** saam met ander anti-diabetes medisyne soos sulfonielureum of insulien gebruik.

Ander medisyne saam met MACLOGLYMIN TABLETTE

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 TABLETTE** saam neem. Dit mag nodig wees om meer gereeld bloedglukosetoetse uit te voer of u dokter mag besluit om die **MACLOGLYMIN TABLETTE** 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-agonista soos salbutamol of terbutaline (gebruik om asma te behandel)
- Ander middels wat gebruik word om diabetes te behandel
- ACE-inhibeerders (vir hoë bloeddruk)
- Simetidien (vir maagsere)
- Warfarien (om die bloed te verdun)
- Sulfonilureum (gebruik om die insulienafskeiding te verhoog)
- Medisyne wat die hoeveelheid metforminen in u liggaam verander, veral as u aan 'n slimerne van nierfunksie ly (soos verapamiel, rifampisien, simetidien, dolutegravir, ranolasien, trimetoprim, vandetanieb, isavuconasool, krisotinieb, olaparieb)

MACLOGLYMIN TABLETTE met voedsel, vloeistof en alkohol

MACLOGLYMIN TABLETTE moet met of na 'n maaltyd geneem word.

Moenie alkohol gebruik terwyl u **MACLOGLYMIN TABLETTE** neem nie aangesien die alkohol die kans vir melksuurasidose mag verhoog.

Swangerskap, borsvoeding en vrugbaarheid

As u swanger is of u babe borsvoed, moet u asseblief u dokter apteker of professionele gesondheidswerker raadpleeg voordat u begin om **MACLOGLYMIN TABLETTE** te neem.

MACLOGLYMIN TABLETTE word nie vir gebruik gedurende swangerskap en borsvoeding aanbeveel nie.

Bestuur en die gebruik van masjinerie

Wanneer **MACLOGLYMIN TABLETTE** 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 TABLETTE** in kombinasie met ander anti-diabetiese middels behoort u op te hou met bestuur of om met masjinerie te werk.

3. Hoe om MACLOGLYMIN TABLETTE te neem of toe te dien

- Moenie medisyne wat vir u of u kind voorgeskryf is met ander deel nie.
- Neem of dien **MACLOGLYMIN TABLETTE** 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 TABLETTE** 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 TABLETTE** moet met genoeg vloeistof per mond geneem en kan met of na 'n maaltyd geneem word. Dit sal enige newe-effekte van die verteringsstelsel vermy.
- Die normale dosis is:
  - Volwassenes: Aanvanklik, een 500 mg tablet drie, of een 850 mg of 1000 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 het om MACLOGLYMIN TABLETTE te neem

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, hongerte, 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 TABLETTE te neem of toe te dien

Dit is belangrik dat u u medikasie **MACLOGLYMIN TABLETTE** 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 TABLETTE te neem of dit toe te dien

Moenie ophou om **MACLOGLYMIN TABLETTE** te neem bloot omdat u beter voel nie.
Neem of dien **MACLOGLYMIN TABLETTE** toe vir so lank as wat u dokter voorgeskryf het.

Moenie met die gebruik van **MACLOGLYMIN TABLETTE** ophou nie tensy u dokter dit aanbeveel nie.

3. Moontlike newe-effekte

MACLOGLYMIN TABLETTE kan newe-effekte hê.

Nie al die newe-effekte van **MACLOGLYMIN TABLETTE** 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 TABLETTE** neem, moet u asseblief u dokter, apteker of professionele gesondheidswerker raadpleeg.

As enige van die volgende met u gebeur terwyl u **MACLOGLYMIN TABLETTE** neem, moet u ophou om **MACLOGLYMIN TABLETTE** te neem en onmiddellik u dokter raadpleeg of gaan na die ongevalle afdeling van u naaste hospitaal:

- Sikliëke 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 hulle ondervind, meg u of u kind 'n ernstige reaksie teen **MACLOGLYMIN TABLETTE** hê. U mag moontlik ernstige mediese hulp of hospitaalsorg 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 TABLETTE** te neem en raadpleeg onmiddellik u dokter of naaste hospitaal.
- Hipoglukemie - lae suikervlakke in die bloed, veral as u **MACLOGLYMIN TABLETTE** saam met ander anti-diabetiese medisyne soos sulfonilureum of insulien neem. Simptome mag die volgende insluit: sweet, swakheid, hongerte, duiseligheid, bewerasie, hoofpyn, hittegloede of bleekheid, gevoelloosheid, vinnig bonsende hartklop.
- Hepatitis (inflammasie van die lewer) - dit mag moegheid, verlies aan setlus, gewigsverlies met of sonder geel verkleuring van die vel of wit van die oë. Indien dit gebeur, hou op om **MACLOGLYMIN TABLETTE** te neem en raadpleeg u dokter.
- Pankreatitis - inflammasie van die pankreas met erge boonste buikpyn, dikwels met naarheid en braking.
- Bleekheid van die vel, kortasemheid, 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 setlus
- Smaakafwyking

Minder dikwels:

- Afname van vitamien B_{12}- en foliensuurabsorpsie
- Gewigsverlies
- Abnormale leverfunksietoetse
- Oppervlakkige rooi verkleuring van die vel, gewoonlik in vlekke, urtikaria, 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/5 gevind kan word. Deur newe-effekte aan te meld kan u help om meer inligtingoor die veiligheid van **MACLOGLYMIN TABLETTE** te verskaf.

4. Hoe om MACLOGLYMIN TABLETTE op te berg

Berg alle medisyne buite bereik van kinders.
Berg by of benede 25°C.
Berg in die oorspronklike verpakkingshouer.
Houdie HDPE houer digtoe.
Beskerm teen lig en vogtigheid.
Moenie in die badkamer stoor nie.
Moenie na die vervaldatum op die etiket/kartonfbottel gebruik nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moenie enige ongebruikte medisyne in die rioleringsteel (toilet) wegdoen nie.

5. Inhoud van die verpakking en nader inligting

Wat MACLOGLYMIN TABLETTE bevat

MACLOGLYMIN 500 mg TABLETTE
Die aktiewe bestanddeel is metforminehidrochloried 500 mg.

MACLOGLYMIN 850 mg TABLETTE
Die aktiewe bestanddeel is metforminehidrochloried 850 mg.

MACLOGLYMIN 1000 mg TABLETTE
Die aktiewe bestanddeel is metforminehidrochloried 1000 mg.

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

Hoe MACLOGLYMIN TABLETTE lyk en die inhoud van die verpakking

MACLOGLYMIN 500 mg TABLETTE
Wit tot byna-wit ronde, bikonvekse, filmbedekte tablet met "C74" op die een kant gedruk en glad aan die ander kant.

MACLOGLYMIN 850 mg TABLETTE
Wit tot byna-wit ovaalvormige, bikonvekse, filmbedekte tablet met "C75" met 'n breeklyn op die een kant gedruk en glad aan die ander kant.

MACLOGLYMIN 1000 mg TABLETTE
Wit tot byna-wit ronde, bikonvekse, filmbedekte tablet met "C76" op die een kant gedruk en glad aan die ander kant met 'n breeklyn.

HDPE houer

MACLOGLYMIN 500 mg TABLETTE
Tablette word in 'n ronde, wit plastiekhouer (HDPE) verpak, met 'n wit, vroeiselvrye deksel met aanhoudende skroefdraad verpak. Pakgroottes sluit 56, 84, 90, 100, 112 en 500 tablette in.

MACLOGLYMIN 850 mg TABLETTE
Tablette word in 'n ronde, wit plastiekhouer (HDPE) verpak, met 'n wit, vroeiselvrye deksel met aanhoudende skroefdraad verpak. Pakgroottes sluit 28, 30, 56, 84, 90, 100 en 500 tablette in.

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

Houer van die sertifikaat van registrasie en Vervaardiger

MACLEODS PHARMACEUTICALS SA (PTY) LTD
Kantoorblok 1 Bassonia Estate Office Park (Oos)
Cussoniarylaan 1 Bassonia Rock, Uitbr.12 Alberton Suid Afrika

Hierdie inligtingsblad is laas hersien
13 Julie 2021

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 1169

435 mm

MASTER COPY

MACLEODS

Restricted Circulation

PACKAGING RESEARCH & DEVELOPMENT

(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	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: 435(L) X 380(W) mm
9. Design / Style: Booklet type	10. Item code No.: PM03839201
11. Artwork has been made: Actual Size	12. Pharma code No.: 31477 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: NA
15. Revision no: 00	16. A/W File name: E:\ANDA Regulatory\South Africa\Macloglymin PI & PIL-PM03839201.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
23-02-2023	Vanita Rajool	20/02/23	02/03/23	1/3/23	21/03/23

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.

QA 21/03/23

FRM/CQA/021/04-01

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa	PM03839201		

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