

PATIENT INFORMATION LEAFLET MACLOGLYMIN

SCHEDULING STATUS:

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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.

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- 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.

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- 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

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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 B₁₂. 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 B₁₂ 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)

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- 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.

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- **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:
 - o 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.
 - o 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.

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Not all side effects reported for **MACLOGLYMIN** are included in this leaflet. Should you 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.

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- 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 B₁₂ 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.

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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 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 looks like and contents of the pack

MACLOGLYMIN 500 mg

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

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

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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 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, 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

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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 1169.

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