Product Name: Proglicem 25 mg	Component: English Patient Information Leaflet MCC Approval: 23 November 2017 Date Approved: 01 October 1974

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM

PROGLICEM® 25 mg Capsules

Read all of this leaflet carefully before you start taking PROGLICEM Capsules.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PROGLICEM Capsules 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.

1. WHAT PROGLICEM CAPSULES CONTAINS

- The active substance is diazoxide 25 mg.
- The other ingredients are: gelatin, lactose monohydrate, magnesium stearate.
- Contains 194,45 mg lactose monohydrate.

2. WHAT PROGLICEM CAPSULES IS USED FOR

PROGLICEM Capsules is a medicine used to treat certain types of hypoglycaemia (low blood sugar) in children and adults.

3. BEFORE YOU TAKE PROGLICEM CAPSULES

Do not take PROGLICEM Capsules

- If you are allergic to diazoxide or other thiazides.
- If you have an intolerance to lactose.

Take special care with PROGLICEM Capsules

- Only start taking PROGLICEM Capsules if you are under close medical observation in a hospital when you first start treatment.
- Regular medical and laboratory monitoring is necessary if you are on long-term treatment with PROGLICEM Capsules.

Pregnancy and Breastfeeding

Safety in pregnancy and breastfeeding has not been demonstrated. You should not be breastfeeding if you are taking PROGLICEM Capsules. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking PROGLICEM Capsules.

Important information about some of the ingredients of PROGLICEM Capsules

PROGLICEM Capsules contains a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact you doctor before taking PROGLICEM Capsules.

Taking other medicines with PROGLICEM Capsules

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Some possible interactions are:

- PROGLICEM Capsules may intensify the effect of anticoagulants (blood thinning medicines).
- PROGLICEM Capsules may weaken the effect of some medicines used for seizure control.
- PROGLICEM Capsules used together with diuretics may intensify the effect on blood sugar levels.
- PROGLICEM Capsules may enhance the effect of some antihypertensives (blood pressure medicines).

4. HOW TO TAKE PROGLICEM CAPSULES

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

The dose of PROGLICEM Capsules is to be gradually adapted by your doctor, based on your individual requirements. Your doctor will tell you how long your treatment with PROGLICEM Capsules will last. Always take PROGLICEM Capsules exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you take more PROGLICEM Capsules than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

5. POSSIBLE SIDE EFFECTS

PROGLICEM Capsules can have side effects. Not all side effects reported for PROGLICEM Capsules are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following very serious side effects:

- salt and water retention (frequent side effect)
- diabetic ketoacidosis (less frequent side effect).

You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following frequent side effects:

- hair loss, most commonly in children (this disappears on discontinuation of treatment)
- nausea, vomiting, abdominal pain, diarrhoea, loss of taste
- palpitations
- skin rash, headache and weakness.

Or less frequent side effects:

- chest pain, bleeding, anxiety, dizziness, insomnia, itching, blurred vision, fever, gout.

Side effects may need a dosage adjustment or discontinuation of treatment.

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

6. STORAGE AND DISPOSAL OF PROGLICEM CAPSULES

Store at or below 25 °C. Keep out of reach of children.

7. PRESENTATION OF PROGLICEM CAPSULES

Cartons of 100 capsules, packed as 4 blisters of 25 capsules.

8. IDENTIFICATION OF PROGLICEM CAPSULES

A hard gelatin capsule, having a clear cap and body containing a fine, white to off-white powder

9. REFERENCE NUMBER

G3217 (Act 101/1965)

10. NAME AND ADDRESS OF THE APPLICANT

MSD (Pty) Ltd

117 16th Road

Halfway House

1685

South Africa

Tel. No.: 011 655 3000

11. DATE OF PUBLICATION

Date of amendment: 01 October 1974

Date of most recent revision: 23 November 2017

MK6783-PRG-MTL-022013