Approved Professional Information for Medicines for Human Use:

GLICLAZIDE MR 30 mg AUSTELL

GLICLAZIDE MR 60 mg AUSTELL

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

GLICLAZIDE MR 30 mg AUSTELL modified-release tablets

Each modified-release tablet contains gliclazide 30 mg.

GLICLAZIDE MR 60 mg AUSTELL modified-release tablets

Each modified-release tablet contains gliclazide 60 mg.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

GLICLAZIDE MR 30 mg AUSTELL modified-release tablets

Each modified-release tablet contains gliclazide 30 mg.

GLICLAZIDE MR 60 mg AUSTELL modified-release tablets

Each modified-release tablet contains gliclazide 60 mg.

Contains sugar (lactose monohydrate).

Each GLICLAZIDE MR 30 mg AUSTELL modified-release tablet contains 56,80 mg lactose monohydrate equivalent to 53,96 mg lactose.

Each GLICLAZIDE MR 60 mg AUSTELL modified-release tablet contains 113,60 mg lactose monohydrate equivalent to 107,92 mg lactose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

GLICLAZIDE MR 30 mg AUSTELL modified-release tablets

White, oval, biconvex 5 mm x 11 mm modified-release tablet with ‘G’ on one side and plain on other side with no score.

GLICLAZIDE MR 60 mg AUSTELL modified-release tablets

White, oval, biconvex 7 mm x 15 mm modified-release tablet with ‘G’ on one side of the score and “60” on the other side of the score. Marked on both sides of the tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

In Type 2 diabetic patients, in association with dietary measures, life-style changes and exercise, when dietary measures, life-style and exercise alone are not sufficient to control blood glucose.

4.2 Posology and method of administration

Posology

For adult use only

The daily dose may vary from 30 mg to 120 mg taken as a single daily dose. It is recommended that GLICLAZIDE MR AUSTELL be taken with breakfast (see Method of administration).

If a dose is forgotten, the dose taken on the next day should not be increased.

The dose should be adjusted according to the individual patient's metabolic response (blood glucose levels and/or glycosylated haemoglobin HbA_{1C}).

Initial dose

The initial recommended dose is 30 mg once daily, taken with breakfast.

Dose adjustment

If fasting blood glucose levels have not decreased satisfactorily, the dosage can be increased progressively to 60, 90 or 120 mg per day, by successive increments, respecting an interval of at least one month between each increment, except in patients whose blood glucose levels have not decreased after 15 days of treatment. In this case, it is possible to propose a dosage increase at the end of the second week of treatment. The daily dose should not exceed 120 mg. Previously untreated patients should commence with a dose of 30 mg.

One GLICLAZIDE MR 60 mg AUSTELL is equivalent to two GLICLAZIDE MR 30 mg AUSTELL modified-release tablets.

The breakability of the GLICLAZIDE MR 60 mg AUSTELL modified-release tablet allows the use of a dose of 30 mg as a half tablet and of 90 mg as one and a half tablets.

Replacement of gliclazide 80 mg with GLICLAZIDE MR 60 mg AUSTELL

In patients stabilised on gliclazide 80 mg, the replacement of gliclazide 80 mg by GLICLAZIDE MR 60 mg AUSTELL may initially be based on:

1 tablet gliclazide 80 mg = one tablet of GLICLAZIDE MR 30 mg AUSTELL or 1 tablet gliclazide 80 mg = half a tablet of GLICLAZIDE MR 60 mg AUSTELL .

Replacement of another sulfonylurea with GLICLAZIDE MR AUSTELL:

GLICLAZIDE MR AUSTELL can replace other sulfonylurea treatment. For the transition to GLICLAZIDE MR AUSTELL, the dosage and the half-life of the previous oral hypoglycaemic medicine must be taken into account. If a patient is changed from another oral sulfonylurea with a prolonged half-life, a therapeutic window of a few days may prove to be necessary to avoid the additive effect of the two products and the subsequent risk of hypoglycaemia.

During such a changeover, it is recommended to follow the same procedure as for the initiation of the treatment with GLICLAZIDE MR AUSTELL, i.e., to initiate treatment with a dose of 30 mg per day and then increase the dosage by increments, according to the metabolic evolution of each patient.

Association with other oral antidiabetic medicines

GLICLAZIDE MR AUSTELL, can be given in combination with alpha glucosidase inhibitors or insulin, but in that case, diabetic control should be checked with blood sugar readings, because of the possibility of hypoglycaemia. In combined therapy with biguanides, there may be a greater risk of cardiovascular mortality than with the use of gliclazide alone.

Special populations

Elderly patients and patients with renal failure

The efficacy and tolerance of GLICLAZIDE MR AUSTELL, prescribed using the same therapeutic regimen in subjects over 65 years and patients with mild to moderate renal failure (30 – 80 mL/min) has been confirmed in clinical trials. The dosage will therefore be identical to that recommended for adults under the age of 65 years, and for patients with normal renal function, with careful patient monitoring.

Patient at risk of hypoglycaemia

See 4.4 Special warnings and precautions for use.

It is recommended that the minimum daily starting dose of 30 mg is used.

Paediatric population

The safety and efficacy of GLICLAZIDE MR AUSTELL in children have not been established. The use of GLICLAZIDE MR AUSTELL in children is contraindicated (see section 4.3).

Method of administration

GLICLAZIDE MR AUSTELL is for oral use.

The tablets should be swallowed whole with water without chewing or crushing.

GLICLAZIDE MR AUSTELL is administered as a single daily dose with breakfast.

4.3 Contraindications

This medicine is contraindicated in case of

- Hypersensitivity to gliclazide or to any of the excipients listed in section 6.1, other sulfonylureas, sulfonamides
- Type 1 diabetes (Juvenile Insulin Dependent Diabetes Mellitus), diabetic keto-acidosis, and diabetic pre-coma and coma

- Children
- Severe renal or hepatic insufficiency: in these cases the use of insulin is recommended
- Treatment with miconazole (see section 4.5)
- Pregnancy (see section 4.6)
- Lactation (see section 4.6).

4.4 Special warnings and precautions for use

Hypoglycaemia

Hypoglycaemia may occur following administration of sulfonylureas (see section 4.8). Some cases may be severe and prolonged. Hospitalisation may be necessary and glucose administration may need to be continued for several days.

Careful selection of patients, of the dose used, and clear patient directions are necessary to reduce the risk of hypoglycaemic episodes.

The administration of oral hypoglycaemia such as GLICLAZIDE MR AUSTELL may be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet with insulin.

Treatment with GLICLAZIDE MR AUSTELL can cause hypoglycaemia, if mealtimes are irregular and, in particular, if meats are skipped.

Symptoms of hypoglycaemia

Possible symptoms of hypoglycaemia are: headache, intense hunger, nausea, vomiting, lassitude, sleep disorders, agitation, aggression, poor concentration, reduced awareness and slowed reactions, depression, confusion, visual and speech disorders, aphasia,

tremor, paresis, sensory disorders, dizziness, feeling of powerlessness, loss of self-control, delirium, convulsions, shallow respiration, bradycardia, drowsiness and loss of consciousness, possibly resulting in coma and lethal outcome.

In addition, signs of adrenergic counter-regulation may be observed: sweating, clammy skin, anxiety, tachycardia, hypertension, palpitations, angina pectoris and cardiac dysrhythmia.

Factors which increase the risk of hypoglycaemia

- patient refuses or (particularly in elderly subjects) is unable to co-operate,
- malnutrition, irregular mealtimes, skipping meals, periods of fasting or dietary changes,
- imbalance between physical exercise and carbohydrate intake,
- renal insufficiency,
- severe hepatic insufficiency,
- overdose of GLICLAZIDE MR AUSTELL,
- certain endocrine disorders: thyroid disorders, hypopituitarism and adrenal insufficiency,
- withdrawal of prolonged and/or high dose corticosteroid therapy,
- concomitant administration of certain other medicines (see section 4.5),
- severe vascular disease (severe coronary heart disease, severe carotid impairment, diffuse vascular disease).

It is recommended that the minimum daily starting dose of 30 mg is used.

GLICLAZIDE MR AUSTELL should be prescribed only if the patient is likely to have a regular food intake (including breakfast). It is important to have a regular carbohydrate intake due to the increased risk of hypoglycaemia if a meal is taken late, if an inadequate

amount of food is consumed or if the food is low in carbohydrate. Hypoglycaemia is more likely to occur during periods of low-calorie diets, irregular carbohydrate intake, following prolonged or strenuous exercise, following alcohol intake or during the administration of a combination of hypoglycaemic medicines.

Symptoms of hypoglycaemia usually disappear after absorption of carbohydrates (sugar). However, despite initial effective measures, hypoglycaemia may occur.

Artificial sweeteners have no effect on hypoglycaemia. If a hypoglycaemic episode is severe or prolonged, and even if it is temporarily controlled by intake of sugar, immediate medical treatment or even hospitalisation is required.

Renal and hepatic insufficiency

The pharmacokinetics and/or pharmacodynamics of gliclazide may be altered in patients with hepatic insufficiency or severe renal failure. A reduction in dosage may be necessary in patients with mild to moderate renal dysfunction (see sections 4.2 and 4.3).

GLICLAZIDE MR AUSTELL is contraindicated in patients with severe renal or hepatic insufficiency (see section 4.3) A hypoglycaemic episode occurring in patients with renal and hepatic insufficiency may be prolonged, so appropriate management should be initiated.

Patient information

The risks of hypoglycaemia, together with its symptoms, treatment, and conditions that predispose to its development, should be explained to the patient and to family members.

The patient should be informed of the importance of following dietary advice, of taking regular exercise, and of regular monitoring of blood glucose levels.

Gastrointestinal side effects

Gastrointestinal side effects can be avoided or minimised if GLICLAZIDE MR AUSTELL is taken with breakfast.

Hepatobiliary symptoms

Hepatobiliary symptoms usually disappear after discontinuation of treatment. Discontinue GLICLAZIDE MR AUSTELL if cholestatic jaundice appears.

Patients with G6PD -deficiency

Treatment of patients with G6PD -deficiency with sulfonylurea medicines can lead lo haemolytic anaemia. Since gliclazide belongs to the chemical class of sulfonylurea medicines. caution should be used in patients with G6PD-deliciency and a non-sulfonylurea alternative should be considered.

Concomitant use with beta-blockers

Beta-blockers may decrease the efficacy of GLICLAZIDE MR AUSTELL (a sulfonylurea) by impairing the release of insulin. Beta-blockers may mask the typical sympathomimetic warning signs and symptoms of hypoglycaemia and may inhibit the normal physiological response to hypoglycaemia.

Poor blood glucose control

Blood glucose control in a patient receiving antidiabetic treatment may deteriorate in an exceptional stress situation e.g., any of the following: St. John's Wort (*Hypericum perforatum*) preparations (see section 4.5), fever, trauma, infection or surgical

intervention and a temporary change to insulin may be necessary to maintain good metabolic control.

The hypoglycaemic efficacy of any oral antidiabetic medicine, including GLICLAZIDE MR AUSTELL, is attenuated over time in many patients. This may be due to progression in the severity of the diabetes, or to a reduced response to treatment. This phenomenon is known as secondary failure, which is distinct from primary failure, when an active substance is ineffective as first-line treatment. Adequate dose adjustment and dietary compliance should be considered before classifying the patient as secondary failure.

Dysglycaemia

Disturbances in blood glucose, including hypoglycaemia and hyperglycaemia have been reported, in diabetic patients receiving concomitant treatment with fluoroquinolones, especially in elderly patients. Indeed, careful monitoring of blood glucose is recommended in all patients receiving GLICLAZIDE MR AUSTELL and a fluoroquinolone at the same time.

Laboratory tests

Measurement of glycated haemoglobin levels (or fasting venous plasma glucose) is recommended in assessing blood glucose control. Blood glucose self-monitoring may also be useful.

Excipient lactose

This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

The following medicines are likely to increase the risk of hypoglycaemia

Contraindicated combination

• **Miconazole** (systemic route, oromucosal gel)

Increases the hypoglycaemic effect with possible onset of hypoglycaemic symptoms, or even coma (see section 4.3).

Combinations which are not recommended

• **Phenylbutazone** (systemic route)

Increases the hypoglycaemic effect of sulfonylureas (displaces their binding to plasma proteins and/or reduces their elimination).

It is preferable to use a different anti-inflammatory medicine, or else to warn the patient and emphasise the importance of self-monitoring. Where necessary, adjust the dose during and after treatment with the anti-inflammatory medicine.

• **Alcohol**

Increases the hypoglycaemic reaction (by inhibiting compensatory reactions) that can lead to the onset of hypoglycaemic coma.

Avoid alcohol or medicines containing alcohol.

Combinations requiring precautions for use

Potentiation of the blood glucose lowering effect and thus, in some instances, hypoglycaemia may occur when one of the following medicines is taken:

- other anti-diabetic medicines (insulins, acarbose, metformin, thiazolidinediones, dipeptidyl peptidase-4 inhibitors, GLP-1 receptor agonists),
- beta-blockers (see section 4.4),

- fluconazole, ketoconazole (systemic route, oral gel),
- angiotensin converting enzyme inhibitors (ACE-inhibitors) (captopril, enalapril),
- H2-receptor antagonists (cimetidine, ranitidine),
- mono-amine-oxidase inhibitors (MAOIs),
- sulfonamides,
- clarithromycin,
- non-steroidal anti-inflammatory drugs (NSAIDs) (including salicylates),
- chloramphenicol.

The following medicines may cause an increase in blood glucose levels

Combination which is not recommended

• **Danazol**

Diabetogenic effect of danazol.

If the use of this active substance cannot be avoided, warn the patient and emphasise the importance of urine and blood glucose monitoring. It may be necessary to adjust the dose of the antidiabetic medicine during and after treatment with danazol.

Combinations requiring precautions during use

• **Chlorpromazine** (neuroleptic medicine)

High doses (> 100 mg per day of chlorpromazine) increase blood glucose levels (reduced insulin release).

Warn the patient and emphasise the importance of blood glucose monitoring. It may be necessary to adjust the dose of the antidiabetic active substance during and after treatment with the neuroleptic medicine.

• **Glucocorticoids** (systemic and local route: intra-articular, cutaneous and rectal preparations) **and tetracosactrin**

Increase in blood glucose levels with possible ketosis (reduced tolerance to carbohydrates due to glucocorticoids).

Warn the patient and emphasise the importance of blood glucose monitoring, particularly at the start of treatment. It may be necessary to adjust the dose of the antidiabetic active substance during and after treatment with glucocorticoids.

• **Ritodrine, salbutamol, terbutaline: (I.V.)**

Increased blood glucose levels due to beta-2 agonist effects.

Emphasise the importance of monitoring blood glucose levels. If necessary, switch to insulin.

• **Ephedrine, pseudoephedrine and common cold products**

• **Saint John's Wort (*Hypericum perforatum*) preparations**

Gliclazide exposure is decreased by Saint John's Wort (*Hypericum perforatum)*.

Emphasise the importance of blood glucose levels monitoring.

The following medicines may cause dysglycaemia

Combinations requiring precautions during use

• **Fluoroquinolones**

In case of a concomitant use of GLICLAZIDE MR AUSTELL and a fluoroquinolone, the patient should be warned of the risk of dysglycaemia, and the importance of blood glucose monitoring should be emphasised.

Combination which must be taken into account

• **Anticoagulant therapy** (e.g., Warfarin):

Sulfonylureas may lead to potentiation of anticoagulation during concurrent treatment. Adjustment of the anticoagulant may be necessary and INR should be monitored.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no or limited amount of data (less than 300 pregnancy outcomes) from the use of gliclazide in pregnant women, even though there are few data with other sulfonylureas.

In animal studies, gliclazide is not teratogenic.

The use of GLICLAZIDE MR AUSTELL during pregnancy is contraindicated (see section 4.3).

Control of diabetes should be obtained before the time of conception to reduce the risk of congenital abnormalities linked to uncontrolled diabetes.

Oral hypoglycaemic medicines are not suitable, insulin is the medicine of first choice for treatment of diabetes during pregnancy. It is recommended that oral hypoglycaemic therapy is changed to insulin before a pregnancy is attempted, or as soon as pregnancy is discovered.

Breastfeeding

It is unknown whether gliclazide or its metabolites are excreted in human milk. Given the risk of neonatal hypoglycaemia, the product is therefore contraindicated in breastfeeding mothers (see section 4.3). A risk to newborns/infants cannot be excluded.

Fertility

No effect on fertility or reproductive performance was noted in male and female rats

4.7 Effects on ability to drive and use machines

GLICLAZIDE MR AUSTELL has no or negligible influence on the ability to drive and use machines. However, patients should be made aware of the symptoms of hypoglycaemia and should be careful if driving or operating machinery, especially at the beginning of treatment.

4.8 Undesirable effects

Based on the experience with gliclazide, the following undesirable effects have been reported.

Hypoglycaemia

The most frequent adverse reaction with gliclazide is hypoglycaemia.

As for other sulfonylureas, treatment with GLICLAZIDE MR AUSTELL can cause hypoglycaemia, if mealtimes are irregular and, in particular, if meals are skipped. Possible symptoms of hypoglycaemia are: headache, intense hunger, nausea, vomiting, lassitude, sleep disorders, agitation, aggression, poor concentration, reduced awareness and slowed reactions, depression, confusion, visual and speech disorders, aphasia, tremor, paresis, sensory disorders, dizziness, feeling of powerlessness, loss of self-control, delirium, convulsions, shallow respiration, bradycardia, drowsiness and loss of consciousness, possibly resulting in coma and lethal outcome.

In addition, signs of adrenergic counter-regulation may be observed: sweating, clammy skin, anxiety, tachycardia, hypertension, palpitations, angina pectoris and cardiac dysrhythmia.

Usually, symptoms disappear after intake of carbohydrates (sugar). However, artificial sweeteners have no effect.

Hypoglycaemia can recur even when measures prove effective initially. If a hypoglycaemic episode is severe or prolonged, and even if it is temporarily controlled by intake of sugar, immediate medical treatment or even hospitalisation are required.

Other undesirable effects

Gastrointestinal disturbances, including abdominal pain, nausea, vomiting dyspepsia, diarrhoea, and constipation have been reported. If these should occur, they can be avoided or minimised if gliclazide is taken with breakfast.

The table below shows all adverse drug reactions (ADRs) observed during clinical trials and postmarket spontaneous reports with gliclazide.

System Organ Class	**Frequency**		
	Frequent	**Less Frequent**	**Not known**

Blood and lymphatic system disorders		anaemia, leucopenia, thrombocytopenia, granulocytopenia. These are in general reversible upon discontinuation of medication.	
Endocrine disorders			hypoglycaemia (see 4.4. Special warnings and precautions).
Eye disorders		Transient visual disturbances may occur especially on initiation of treatment, due to changes in blood glucose levels.	
Gastrointestinal disorders	abdominal pain, nausea, vomiting, dyspepsia,		

	diarrhoea and constipation. If these should occur, they can be avoided or minimised if GLICLAZIDE MR AUSTELL is taken with breakfast.		
Hepatobiliary disorders		raised hepatic enzyme levels (AST, ALT, alkaline phosphatase), hepatitis (isolated reports). Discontinue treatment if cholestatic jaundice appears. These symptoms usually disappear after discontinuation of treatment.	
Skin and subcutaneous tissue disorders	rash, pruritus	urticaria, erythema, maculopapular rashes,	angioedema

		bullous reactions (such as Stevens-Johnson syndrome and toxic epidermal necrolysis), and exceptionally, drug rash with eosinophilia and systemic symptoms (DRESS).	

Class attribution effects

As for other sulfonylureas, the following adverse events have been observed:

cases of erythrocytopenia, agranulocytosis, haemolytic anaemia, pancytopenia, allergic vasculitis, hyponatremia, elevated liver enzyme levels and even impairment of liver function (e.g., with cholestasis and jaundice) and hepatitis, which regressed after withdrawal of the sulfonylurea or led to life-threatening liver failure in isolated cases.

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. Healthcare professionals are asked to report any suspected adverse reactions 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

4.9 Overdose

An overdose of sulfonylureas may cause hypoglycaemia.

Moderate symptoms of hypoglycaemia, without any loss of consciousness or neurological signs, must be corrected by carbohydrate intake, dose adjustment and/or change of diet. Strict monitoring should be continued until the doctor is sure that the patient is out of danger.

Severe hypoglycaemic reactions, with coma, convulsions or other neurological disorders are possible and must be treated as a medical emergency, requiring immediate hospitalisation.

If hypoglycaemic coma is diagnosed or suspected, the patient should be given a rapid I.V. injection of 50 mL of concentrated glucose solution (20 to 30 %). This should be followed by continuous infusion of a more dilute glucose solution (10 %) at a rate that will maintain blood glucose levels above 1 g/L. Patients should be monitored closely and, depending on the patient's condition after this time, the doctor will decide if further monitoring is necessary.

Dialysis is of no benefit to patients due to the strong binding of gliclazide to proteins.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A 21.2 Oral Hypoglycaemics.

Pharmacotherapeutic group: sulfonamides, urea derivative

ATC Code: A10BB09

Mechanism of action

Gliclazide is a hypoglycaemic sulfonylurea oral antidiabetic active substance differing from other related compounds by an N-containing heterocyclic ring with an endocyclic bond.

Gliclazide reduces blood glucose levels by stimulating insulin secretion from the β-cells of the islets of Langerhans. Increase in postprandial insulin and C-peptide secretion persists after two years of treatment.

In addition to these metabolic properties, gliclazide has haemovascular properties.

Pharmacodynamic effects

Effects on insulin release

In type 2 diabetics, gliclazide restores the first peak of insulin secretion in response to glucose and increases the second phase of insulin secretion. A significant increase in insulin response is seen in response to stimulation induced by a meal or glucose.

Haemovascular properties

Gliclazide decreases microthrombosis by two mechanisms which may be involved in complications of diabetes:

- A partial inhibition of platelet aggregation and adhesion, with a decrease in the markers of platelet activation (beta thromboglobulin, thromboxane B2).
- An action on the vascular endothelium fibrinolytic activity with an increase in tPA activity.

5.2 Pharmacokinetic properties

Absorption

Plasma levels increase progressively during the first 6 hours, reaching a plateau which is maintained from the sixth to the twelfth hour after administration.

Intra-individual variability is low.

Gliclazide is completely absorbed. Food intake does not affect the rate or degree of absorption.

Distribution

Plasma protein binding is approximately 95 %. The volume of distribution is around 30 litres.

A single daily intake of GLICLAZIDE MR AUSTELL maintains effective gliclazide plasma concentrations over 24 hours.

Biotransformation

Gliclazide is mainly metabolised in the liver and excreted in the urine. Less than 1 % of the unchanged form is found in the urine. No active metabolites have been detected in plasma.

Elimination

The elimination half-life of gliclazide varies between 12 and 20 hours.

Linearity/non-linearity

The relationship between the dose administered ranging up to 120 mg and the area under the concentration time curve is linear.

Special populations

Elderly

No clinically significant changes in pharmacokinetic parameters have been observed in elderly patients.

Paediatric population

The safety and efficacy of GLICLAZIDE MR AUSTELL in children and adolescents have not been established. No data are available in children. The use of GLICLAZIDE MR AUSTELL in children is contraindicated (see section 4.3).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal anhydrous silica

Hypromellose

Lactose monohydrate

Magnesium stearate

Microcrystalline cellulose

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

- Store at or below 30 °C in original container.
- Keep in original packaging until required for use.

6.5 Nature and contents of container

GLICLAZIDE MR AUSTELL are packed in

- Clear PVC/PVDC/aluminium blister pack of 28, 30, 56, 60 tablets in an outer carton.
- Transparent PVC/PVDC/PVC/aluminium blister pack of 28, 30, 56, 60 tablets in an outer carton.
- White High Density Polyethylene (HDPE) container closed with white Low Density Polyethylene (LDPE) snap-on cap or white Polypropylene (PP) twist-off cap of 90, 100, 120 and 180 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Austell Pharmaceuticals (Pty) Ltd

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8. REGISTRATION NUMBERS

GLICLAZIDE MR 30 mg AUSTELL modified-release tablets: 50/21.2/1028

GLICLAZIDE MR 60 mg AUSTELL modified-release tablets: 50/21.2/1029

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02 November 2021.

10. DATE OF REVISION OF THE TEXT

02 November 2021.