GLILUPI MR TABLET 60 MG

Gliclazide Modified Release Tablets

1 NAME OFTHE MEDICINAL PRODUCT
Gliilupi MR Tablet 60 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each modified-release tablet contains 60 mg of gliclazide.
For the full list of excipients, see section 6.1.

3. Description of the appearance of the product
White to of f-white oval shape, uncoated tablets with breakline on both the surface and debossed '60' on one side of the break line on one surface.

4. PHARMACEUTICAL FORM
Modified release (MR) Tablets

5. CLINICAL PARTICULARS

5.1 Therapeutic indications
Gliclazide modified release tablets are indicated for the treatment of type II diabetes in association with dietary measures and with, physical exercise when these measures alone are inadequate to control blood glucose.
During controlled clinical trials in patients with type II diabetes, a modified release formulation of gliclazide (30mg - 120mg), taken as a single daily dose, was shown to be effective long term in controlling blood glucose levels, based on monitoring of HbA1c.

5.2 Posology and method of administration
Posology
The daily dose of Gliclazide 60 mg MR Tablets may vary from one half to 2 tablets per day, i.e., from 30 to 120 mg taken orally in a single intake at breakfast time.
It is recommended to swallow the dose without crushing or chewing.
If a dose is forgotten, there must be no increase in the dose taken the next day.
These products should be taken with food because there is an increased risk of hypoglycemia if a meal is taken late, if an inadequate amount of food is consumed or if the food is low in carbohydrate. It is recommended that the medication be taken at breakfast time.
As with any hypoglycaemic agent, the dose should be adjusted according to the individual patient's metabolic response (blood glucose, HbAlc).

Initial dose
The recommended starting dose is 30 mg daily (half a tablet of Gliclazide 60 mg MR Tablets).
If blood glucose is effectively controlled, this dose may be used for maintenance treatment.
If blood glucose is not adequately controlled, the dose may be increased to 60, 90 or 120 mg daily, in successive steps.
The interval between each dose increment should be at least 1 month except in patients whose blood glucose has not reduced after two weeks of treatment. In such cases, the dose may be increased at the end of the second week of treatment.
The maximum recommended daily dose is 120 mg.

Switching from another oral antidiabetic agent to Gliclazide 60 mg MR Tablets:
Gliclazide 60 mg MR Tablets can be used to replace other oral antidiabetic agents.
The dosage and the half-life of the previous antidiabetic agent should be taken into account when switching to Gliclazide 60 mg MR Tablets.
A transitional period is not generally necessary. A starting dose of 30 mg should be used and this should be adjusted to suit the patient's blood glucose response, as described above.

If a patient is switched from a hypoglycaemic sulfonylurea with a prolonged half-life, he/she should be carefully monitored (for one to two weeks) in order to avoid hypoglycaemia due to possible residual effects of the previous therapy.

Combination treatment with other antidiabetic agents:
Gliclazide 60 mg MR Tablets can be given in combination with biguanides, alpha glucosidase inhibitors or insulin.
In patients not adequately controlled with gliclazide, concomitant insulin therapy can be initiated under close medical supervision.

Special Populations
Older people (over 65 years of age)
The efficacy and tolerance of the modified release formulation of gliclazide (30mg - 120mg) has been confirmed in clinical trials in subjects over 65 years who were given the same dosage regimen as the general population. The dosage is therefore identical to that recommended for adults under the age of 65 years.

Patients with renal impairment
The efficacy and tolerance of the modified release formulation of gliclazide (30mg - 120mg) has been confirmed in clinical trials of subjects with mild to moderate renal failure (creatinine clearance of between 15 and 80mL/min) who were given the same dosage regimen as the general population. No dosage adjustment is therefore required in subjects with impaired renal function.

Patients at risk of hypoglycaemia
There is an increased risk of hypoglycaemia in the following circumstances:
- undernourished or malnourished patients,
- patients with severe or poorly compensated endocrine disorders (hypopituitarism, hypothyroidism, adrenal insufficiency),
- withdrawal of prolonged and/or high dose corticosteroid therapy,
- patients with severe vascular disease (severe coronary heart disease, severe carotid impairment, diffuse vascular disease)

It is recommended that treatment be systematically initiated with a minimal dose of 30mg / day.

Pediatric population
As per the information reported in literature, the safety and efficacy of gliclazide in children and adolescents have not been established. There are no data or clinical studies in children.

Method of Administration
Oral use.

5.3 Contraindications
This medicine is contra-indicated in case of:
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Hypersensitivity to sulphonylurea or sulphonamides,
  - Type 1 diabetes,
    - diabetic pre-coma and coma, diabetic ketoacidosis,
- Severe renal or hepatic insufficiency: in these cases, the use of insulin is recommended
- Treatment with miconazole,
- Pregnancy and Lactation

5.4 Special warnings and precautions for use
Hypoglycaemia
This treatment 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 delayed, an inadequate amount of food is consumed or if the food is low in carbohydrate. Hypoglycaemia is more likely to occur during low-calorie diets, following prolonged or strenuous exercise, following alcohol intake or during treatment with a combination of hypoglycaemic agents.
Hypoglycaemia may occur following administration of sulphonylurea. Some cases may be severe and prolonged. This may involve hospitalisation and glucose infusion may need to be continued for several days.
Careful selection of patients and of the dose used, as well as provision of adequate information to the patient are necessary to reduce hypoglycaemic episodes.
Hypoglycaemia may be difficult to recognise in elderly patients and those receiving beta-blockers.
Factors which increase the risk of hypoglycaemia:
- patient refuses or (particularly in elderly subjects) is unable to cooperate
- poor general health, 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
- certain endocrine disorders: thyroid disorders, hypopituitarism and adrenal insufficiency
- concomitant administration of certain other medicinal products.

Renal and hepatic insufficiency: The pharmacokinetics and/or pharmacodynamics of gliclazide may be altered in patients with hepatic insufficiency or severe renal failure. Hepatic insufficiency may also reduce the capacity for neoglucogenesis. A hypoglycaemic episode occurring in these patients 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.

Poor blood glucose control
Blood glucose control in treated patients may be jeopardised by: St John's Wort (Hypericum Perforatum) preparations, fever, trauma, infection or surgical intervention. It may be necessary to discontinue treatment and to administer insulin in these cases.
The efficacy of oral antidiabetic agents often decreases in the long term. 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 and should be distinguished from primary failure, when the drug is ineffective as first-line treatment. However, before classifying the patient as a secondary failure, dose adjustment and reinforcement of dietary measures should be considered.

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 at the same time Gliclazide and a fluoroquinolone.

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.
Glucose-6-phosphate dehydrogenase deficiency (G6PD): Treatment of patients with glucose-6-phosphate (G6PD)-deficiency with sulphonylurea agents can lead to haemolytic anaemia. Since Gliclazide belongs to the chemical class of sulphonylurea drugs, caution should be used in patients with G6PD-deficiency and a non-sulphonylurea alternative should be considered.
Porphyric patients: Cases of acute porphyria have been described with some other sulfonylurea drugs, in patients who have porphyria.

5.5 Interaction with other medicinal products and other forms of interaction
1) The following products are likely to increase the risk of hypoglycaemia
Contra-indicated combination
- **Miconazole (systemic route, or omucosal gel)**: increases the hypoglycaemic effect with possible onset of hypoglycaemic symptoms, or even coma.

Combinations which are not recommended
- **Phenylbutazone (**systemic route): increases the hypoglycaemic effect of sulphonylureas (shifts their binding to plasma proteins and / or reduces their elimination). It is preferable to use a different anti-inflammatory agent, otherwise warn the patient and emphasise the importance of self-monitoring:adjust the dose during and after treatment with the anti-inflammatory.
- **Alcohol:** increases the hypoglycaemic reaction (by inhibiting compensatory reactions) and may potentiate the onset of hypoglycaemic coma. Ingestion of alcohol may also cause a disulfiram-like reaction with characteristic flushing of the face, throbbing headache, giddiness, tachypnoea, tachycardia or angina pectoris. Chronic alcohol abuse may, as a result of liver enzyme induction, increase the metabolism of sulfonylurea drugs, shortening the plasma half life and duration of action. 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 during concomitant treatment with the following drugs: other antidiabetics (insulin, acarbose, metformin, thiazolidinediones, dipeptidyl peptidase-4 inhibitors, GLP-1 receptor agonists), clofibrate, salicylates (high doses), chloramphenicol, beta-blockers, fluconazole, angiotensin converting enzyme inhibitors (captopril, enalapril), H2-receptor antagonists, MAOIs, sulphonamides, clarithromycin, and nonsteroidal anti-inflammatory drugs.
Warn the patient and emphasize the importance of self-monitoring of blood glucose levels. It may be necessary to adjust the dose of the antidiabetic agent during treatment with these substances.

2) The following products 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 emphasize the importance of urine and blood glucose monitoring. It may be necessary to adjust the dose of the antidiabetic agent during and after treatment with danazol.

Combinations requiring precautions during use
As with all hypoglycaemics, caution should be observed in administering thiazide diuretics, since these diuretics have been reported to aggravate the diabetic state.
- *Chlorpromazine (neuroleptics):* high doses (>100 mg per day of chlorpromazine) increases blood glucose levels (reduced insulin release). Warn the patient and emphasize the importance of blood glucose self-monitoring. It may be necessary to adjust the dose of the antidiabetic agent during treatment with the neuroleptic agent and after its discontinuation.
- *Glucocorticoids (systemic route and local route: intra-articular, cutaneous and rectal preparations) and tetracosactrin:* increase in blood glucose levels with possible ketosis (reduced tolerance to carbohydrates by corticosteroids).

Warn the patient and emphasize the importance of blood glucose monitoring, particularly at the start of treatment. It may be necessary to adjust the dose of the antidiabetic during treatment with corticosteroids and after discontinuation.
- *Ritodrine, salbutamol, terbutaline: (I.V. administration):* Increased blood glucose levels due to beta-2 agonist . Emphasize the importance of monitoring blood glucose levels. If necessary, switch to insulin.
- *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.

Barbiturates, oestrogens and progestogens

3). The following products may cause dysglycaemia.
Combinations requiring precautions during use
- **Fluoroquinolones:** in case of a concomitant use of Gliclazide 60 mg MR Tablet and a fluoroquinolone, the patient should be warned of the risk of dysglycaemia, and the importance of blood glucose monitoring should be emphasized.

4). Combination which must be taken into account
Anticoagulant (e.g. Warfarin): Sulphonylureas may lead to potentiation of anticoagulation during concurrent treatment. It may be necessary to adjust the dose of the anticoagulant.

Laboratory tests
Glycated haemoglobin should be monitored regularly. Blood glucose measurement may also be useful.

5.6 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 sulphonylurea.
In animal studies, gliclazide is not teratogenic.
The use of gliclazide during pregnancy is contraindicated.
Control of diabetes should be obtained before the time of conception to reduce the risk of congenital abnormalities linked to uncontrolled diabetes.
Oral hypoglycaemic agents are not suitable, insulin is the drug 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.

Breast-feeding
It is unknown whether Gliclazide or its metabolites are excreted in breast milk. Given the risk of neonatal hypoglycaemia, the product is therefore contraindicated in breast-feeding mother. A risk to the newborns/infants cannot be excluded.

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

5.7 Effects on ability to drive and use machines
Gliclazide 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.

5.8 Undesirable effects
Good clinical acceptability of gliclazide, has been established in many studies as well as in medical practice.
As per literature data, the safety of a modified release formulation of gliclazide (30mg - 120mg) has been evaluated in controlled clinical trials in 955 patients, of which 728 patients were treated in long-term comparative trials, against a gliclazide immediate release formulation (80mg - 320mg), for up to 10 months. In these comparative trials, the overall incidence and type of adverse events were similar in both groups. Adverse events were generally mild and transient, not requiring discontinuation of therapy. However, where patients did discontinue due to adverse events, the percentage was lower in the modified release group (2.9%) than in the immediate release group (4.5%).
Based on the experience with gliclazide, the following undesirable effects have been reported.
The most frequent adverse reaction with gliclazide is hypoglycaemia
As is the case with all sulphonylurea drugs, hypoglycaemic reactions have been reported following gliclazide administration. However, a number of studies have shown that hypoglycaemia is less common with gliclazide than with glibenclamide.
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/or death.
In addition, signs of adrenergic counter-regulation may be observed: sweating, clammy skin, anxiety, tachycardia, hypertension, palpitations, angina pectoris, and cardiac arrhythmia.
Usually, symptoms disappear after intake of carbohydrates such as sugar. (artificial sweeteners have no effect). Experience with other sulphonylurea shows that hypoglycaemia can recur even when measures are initially effective .

If a hypoglycaemic episode is severe or prolonged, and even if it is temporarily controlled by intake of sugar, immediate medical treatment or even hospitalization is required.
Gastrointestinal disorders, 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.
In long-term comparative studies, the percentage of patients experiencing hypoglycaemic episodes was similar between patients treated with the modified release formulation of gliclazide (11.6%) and those treated with the immediate release formulation of gliclazide (11.1%). However, the number of hypoglycaemic episodes per 100 patient months was lower in the modified release group (3.5) than in the immediate release group (4.8). Analysis of elderly patients (over 65 years old) showed less hypoglycaemia than in the general population, with a prevalence of hypoglycaemic episodes lower in the modified release group (2.6 hypoglycaemic episodes for 100 patient months) than in the immediate release group (4.1).
The percentage of patients experiencing hypoglycaemic episodes in the sub-population with renal failure, was similar to that observed in the general population.

Other undesirable effects:
Adverse events reported during controlled clinical trials with the modified release formulation of gliclazide were those expected in an ageing population with diabetes. Adverse events that were reported in at least 2.0% of patients, in long-term controlled clinical studies, are presented in the following table. The most frequent adverse events were not specifically related to the disease (such as respiratory infections or back pain).

Treatment emergent adverse events* (listed by body system) occurring in ≥2.0% of patients in long-term controlled clinical trials

	Gliclazide modified release tablets (30mg-120mg) n=728	Gliclazide immediate release tablets (80mg – 320mg) n=734
Resistance mechanism		
Infection viral	7.7	5.6
Respiratory		
Rhinitis	4.4	4.6
Bronchitis	4.4	4.6
Pharyngitis	4.3	3.5
Upper respiratory infection	3.3	3.7
Coughing	2.1	2.0
Musculo-skeletal		
Back pain	5.2	4.1
Arthralgia	3.0	3.5
Arthrosis	2.2	2.2
Secondary term		
Inflicted injury	4.3	4.5
Body as a whole		
Headache	3.8	4.6
Asthenia	2.2	2.6
Cardiovascular		
Hypertension	3.2	3.7
Angina pectoris	2.1	2.2
Urinary		
Urinary tract infections	2.6	3.0
Gastrointestinal		
Diarrhoea	2.5	2.0
Central, periph., nervous system		
Dizziness	2.2	2.3
Metabolism and nutrition		
Hyperglycaemia	1.9	2.2

*whatever the relationship to treatment

Analysis of adverse events in sub-populations showed a similar pattern to that seen in the general population. Gender, age and renal insufficiency had no significant influence on the safety profile of the modified release formulation of gliclazide.
Gastrointestinal disturbances (reported with gliclazide), including nausea, dyspepsia, diarrhoea, abdominal pain, vomiting and constipation may be avoided or minimised if gliclazide is taken with breakfast.

The following undesirable effects have been more rarely reported:

- Skin and mucosae reactions pruritus, urticaria, angioedema, maculopapular rashes, rash, erythema and, bullous reactions (such as Stevens-Johnson syndrome and toxic epidermal necrolysis and autoimmune bullous disorders), and exceptionally, drug rash with eosinophilia and systemic symptoms (DRESS).
- Haematological disorders (as with other sulfonylurea drugs): a few rare cases of anaemia, leucopenia, thrombocytopenia and, agranulocytosis.
- Occasional elevations of serum creatinine, blood urea nitrogen, serum bilirubin and hepatic enzyme (AST, ALT, alkaline phosphatase) levels and exceptionally, hepatitis. Treatment should be discontinued if cholestatic jaundice appears. These symptoms usually disappear after discontinuation of treatment.
- As with any glucose lowering medication, transient visual disorders may occur on initiation of treatment, due to changes in blood glucose levels.

Class attribution effects: As for other sulphonylureas, 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 sulphonylurea or led to life-threatening liver failure in isolated cases.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system to the respective drug regulatory authorities.

5.9 Overdose
An overdose of sulphonylurea may cause hypoglycaemia.
Moderate symptoms of hypoglycaemia, without any loss of consciousness or neurological signs, should be corrected by carbohydrate intake, dose adjustment and/or modification of diet. Strict monitoring should be continued until the doctor is sure that the patient is out of danger.
Severe hypoglycaemic reactions are possible (with coma, convulsions or other neurological disorders) and should be treated as a medical emergency, requiring immediate hospitalization.
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 5 mmol/L.
It is recommended that patients should be monitored closely for a 48 hour period at least.
Plasma clearance of gliclazide may be prolonged in patients with hepatic disease. However, due to the strong binding of gliclazide to proteins, dialysis is not effective in these patients.

6. PHARMACOLOGICAL PROPERTIES
6.1 Pharmacodynamic properties
Pharmacotherapeutic group: sulfonamides, urea derivative; ATC code: A10BB09

Mechanism of action
Gliclazide is an oral hypoglycaemic sulfonylurea which differs from other related compounds. It has an N-containing heterocyclic ring with an endocyclic bond.

Pharmacodynamic effects
Gliclazide reduces blood glucose levels by stimulating insulin secretion from the β-cells of the islets of Langerhans. Gliclazide shows high affinity, strong selectivity and reversible binding to the β-cell K_{ATP} channels with a low affinity for cardiac and vascular K_{ATP} channels. Increased postprandial insulin and C-peptide secretion persists after two years of treatment. Gliclazide also has extra-pancreatic effects and haemovascular properties.

Effects on insulin release
In type 2 diabeties, 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.

Extra-pancreatic effects
Gliclazide has been shown to increase peripheral insulin sensitivity:

- In muscle, euglycaemic hyperinsulinaemic clamp studies with gliclazide have demonstrated significantly increased (35%) insulin mediated glucose uptake which may improve diabetes control. Gliclazide potentiates insulin action on muscle glycogen synthase. These effects are consistent with a post-transcriptional action of gliclazide on GLUT4 glucose transporters.
- Studies on glucose turnover have further shown that gliclazide decreases hepatic glucose production, leading to an improvement in fasting blood glucose levels.

Other actions
Gliclazide has been shown in some studies to have actions independent of that on glucose levels. These haemovascular effects of gliclazide include:

- Partial inhibition of platelet aggregation and adhesion with a decrease in markers of platelet activation (beta thromboglobulin, thromboxane B2)
- Increased vascular endothelial fibrinolytic activity (increased tPA activity)
- Anti-oxidant properties, notably a reduction in plasma lipid peroxides and increased erythrocyte superoxide dismutase activity
- Inhibition of the increased adhesiveness of type II diabetic patient's monocytes to endothelial cells *in vitro*.

The antioxidant, platelet inhibiting and fibrinolytic actions of gliclazide involve processes which have been implicated in the pathogenesis of vascular complications of type II diabetes. There is no clinical evidence that the haemovascular effects of gliclazide are of therapeutic benefit in type II diabetes patients.

6.2 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 liters. A single daily intake of gliclazide maintains effective gliclazide plasma concentrations over 24 hours.

Biotransformation
Gliclazide is mainly metabolized 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 and the area under the concentration curve as a function of time is linear for doses of gliclazide up to 90mg/day. At the highest evaluated dose (135mg/day), the AUC increases slightly more than proportionally to the dose.

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

6.3 Preclinical safety data
As per the information reported in literature, preclinical data reveal no special hazards for humans based on conventional studies of repeated dose toxicity and genotoxicity. Long term carcinogenicity studies have not been done. No teratogenic changes have been shown in animal studies, but lower foetal body weight was observed in animals receiving doses 25-fold higher than the maximum recommended dose in humans.

7. PHARMACEUTICAL PARTICULARS
7.1 List of excipients
Calcium hydrogen phosphate dihydrate (DITAB), Hypromellose (Methocel K100 Prem LV), Hypromellose (Methocel K4M PCR), Povidone (K-30), Purified water, Magnesium stearate.

7.2 Incompatibilities
None known.

7.3 Shelf life
2 years

7.4 Special precautions for storage
Store below 30 °C.

7.5 Nature and contents of container
Gliclazide Modified Release Tablets 60mg packed in following pack: 3 x 10 Tablets of Clear PVC blister and 10 x 10 Tablets of Clear PVC blister

7.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

8. PRODUCT REGISTRANT
Goldplus Universal Pte Ltd
103 Kallang Avenue #06-02, Singapore 339504

9. PRODUCT REGISTRATION NUMBER
SINXXXXXX

10. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11. DATE OF REVISION OF THE TEXT
08/12/2023

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