

# Glizihenz

Gliclazide Modified Release 30 mg & 60 mg Tablets

# Glizihenz-M

Gliclazide 40 mg/80 mg & Metformin 500 mg Tablets

### Background:

- Insulin is a hormone produced by the pancreas that helps unlock the body's cells so that sugar (glucose) from the food we eat can be used by the cells for energy. In people with type 2 diabetes, a combination of problems occurs.
- The person's body may not be producing enough insulin to meet their needs, so some glucose can't get into the cells. Glucose remains in the bloodstream, causing high blood glucose levels.

### Description:

- Glizihenz and Glizihenz-M are oral antihyperglycaemic agents used for the treatment of non-insulin-dependent diabetes mellitus (NIDDM).
- Glizihenz contains Gliclazide 30 mg & 60 mg is drug of Sulfonylurea class.
- Glizihenz-M is combination of Gliclazide 40 mg / 80 mg and Metformin 500 mg used to treat NIDDM.

### Composition:

- **Glizihenz** : Each Uncoated modified release Tablet contains Gliclazide 30 mg & 60 mg.
- **Glizihenz -M**: Each Uncoated Tablet contains Gliclazide 40 mg / 80 mg and Metformin 500 mg.

### Indication:

- For the treatment of Non-insulin dependent diabetes mellitus with or without obesity in adults.

### Mechanism of Action:

- Gliclazide is a second generation sulphonylurea which acts as a hypoglycemic agent.
- It stimulates  $\beta$  cells of the islet of Langerhans in the pancreas to release insulin.
- Gliclazide binds to the  $\beta$  cell sulfonyl urea receptor (SUR1). This binding subsequently blocks the ATP sensitive potassium channels.
- The binding results in closure of the channels and leads to a resulting decrease in potassium efflux leads to depolarization of the  $\beta$  cells.
- This opens voltage-dependent calcium channels in the  $\beta$  cell resulting in calmodulin activation, which in turn leads to exocytosis of insulin containing secretory granules.

### Dosage:

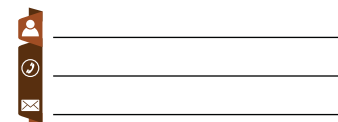
- The usual daily dose of GLIZIHENZ- MR is 1-2 tablets per day as a single dosage.
- Once daily administration of GLIZIHENZ- MR tablet must be taken whole with half-a -glass of water just before breakfast.
- Every administration of GLIZIHENZ-MR must be followed by a meal.
- Glizihenz-M is given 1-2 tablets once or twice daily with meals to a maximum of 4 tablets/day.

### Presentation:

**Glizihenz** and **Glizihenz- M** is available as a strip of 10 Tablet in Alu-Alu blister packing.

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*Release from  
Resistance*



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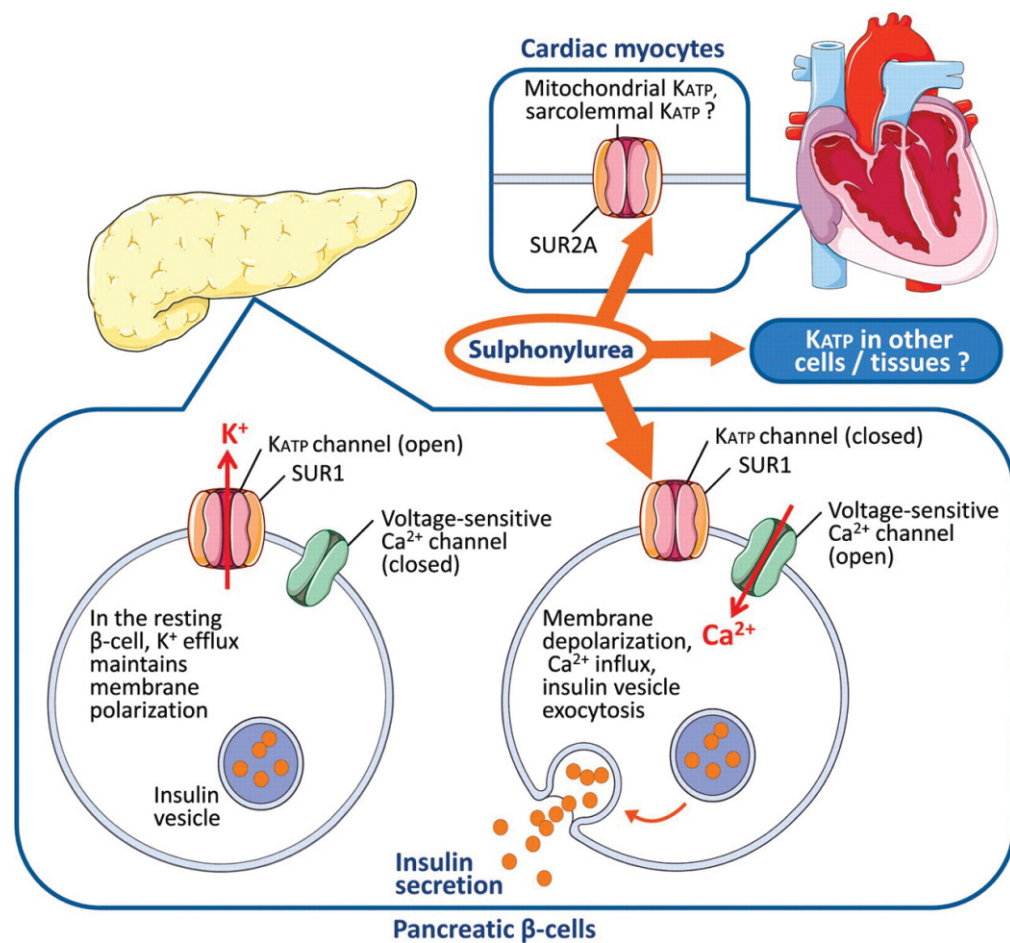
Gliclazide 40 mg/80 mg & Metformin 500 mg Tablets

## Combination Therapy – The Advantages:

- Sulfonylureas & Biguanides (Metformin) act complementary to each other.
- Both compounds have an additive antihyperglycaemic effect without increasing the adverse effects of either pharmacological class.
- Gliclazide acts via stimulating  $\beta$  cells of pancreas to release insulin & also increases peripheral sensitivity of insulin.
- Metformin acts via enhanced peripheral glucose uptake & utilization. It also reduces hepatic glucose production, thereby metformin diminishes insulin resistance.
- There are reports in which combination treatment of sulfonylurea with metformin has been reported to achieve satisfactory glycaemic control for several years.
- The combination may therefore provide additional glycaemic control (blood glucose lowering effect by 20%) & thus obviate the need for insulin in some patients.

## Mode of Action of Sulphonylurea:

- Sulphonylurea stimulates  $\beta$  cells of the islet of Langerhans in the pancreas to release insulin.
- It also enhances peripheral insulin sensitivity. Overall, it potentiates insulin release and improves insulin dynamics.



## Literature Review

- One study has been done on the comparison of Metformin, Gliclazide MR in Monotherapy and combination therapy for Diabetes Mellitus.
- 250 patients treated with oral antidiabetic agents for at least 24 weeks in monotherapy or in combination therapy.
- Metformin Group (n=60) were given 850-1000 mg, Gliclazide MR (n=40) were given 60-90 mg and Gliclazide and Metformin combination therapy was given to 65 patients. The study was done for 24 Weeks.
- Parameters (FPG, PPG, HbA1c (%), Total Cholesterol, HDL cholesterol, LDL cholesterol and Triglycerides) were evaluated for 24 weeks.

## Evaluation Parameters of Patients before introduction of Monotherapy and Combination Therapy:

Parameters	Metformin Group (n=60)	Gliclazide MR Group (n=40)	Gliclazide MR Metformin Group (n = 65)
FPG (mg/dL)	165 ± 13.1	168.8 ± 14.9	195.1 ± 10.7
PPG (mg/dL)	177.2 ± 15.4	182.5 ± 18.2	205.2 ± 19.4
HbA1c (%)	7.9 ± 2.6	8.3 ± 0.6	9.3 ± 0.6
Total cholesterol (mg/dL)	257.2 ± 30.4	267.5 ± 2	277.2 ± 36.8
HLD-cholesterol(mg/dL)	39.7 ± 4.2	8.238.6 ± 5.2	38.6 ± 6.6
LDL-cholesterol (mg/dL)	143.3 ± 10.7	141.3 ± 8.8	140.8 ± 14.3
Triglycerides (mg/dL)	274.7 ± 56.5	269.8 ± 53.9	282.5 ± 66.3

## Evaluation Parameters of Patients after 24 Weeks Monotherapy and Combination Therapy:

Parameters	Metformin Group (n=60)	Gliclazide MR Group (n=40)	Gliclazide MR Metformin Group (n = 65)
Mean reduction in FPG (%)	33.3 ± 4.5	34.0 ± 6.8	58.2 ± 5.3
Mean reduction in PPG (%)	32.0 ± 5.5	33.3 ± 6.8	50.6 ± 4.2
Mean reduction in HbA1c (%)	1.1 ± 0.3	1.2 ± 0.2	1.7 ± 0.2
Mean change in total cholesterol (%)	-7.7 ± 2.2	- 6.2 ± 2.5	9.6 ± 1.5
Mean increase in HDL-cholesterol (%)	4.6 ± 1.5	4.4 ± 1.2	6.6 ± 0.9
Mean change in LDL-cholesterol (%)	-8.5 ± 1.7	-6.4 ± 1.3	8.6 ± 1.4
Mean change in triglycerides (%)	-9.4 ± 1.8	-6.3 ± 1.4	10.7 ± 1.8

## Conclusion:

- In monotherapy of Gliclazide MR and Metformin were equally effective in improving glycemic control, whereas the combination of metformin plus gliclazide MR provided the best results concerning the improvement of both, glycemic control and lipid profile.

Reference: Arq Bras Endocrinol Metab. 2010; 54(3):311-8