# Temglip®

Glimepiride

**COMPOSITION:**

Temglip ® 1 Tablet: Each tablet contains Glimepiride BP 1 mg.

Temglip ® 2 Tablet: Each tablet contains Glimepiride BP 2 mg.

**PHARMACOLOGY:**

The primary mechanism of action of Glimepiride is lowering of blood glucose by stimulating the release of insulin from functioning pancreatic β-cells. In addition, extra pancreatic effects may also play vital role in the activity of Glimepiride. Administration of Glimepiride can lead to increase sensitivity of peripheral tissues to insulin.

**INDICATION:**

Glimepiride is indicated as an adjunct to diet and exercise to lower blood glucose in patients with non-insulin dependent (type 2) diabetes mellitus (NIDDM) whose hyperglycemia cannot be controlled by diet and exercise alone. Glimepiride may be used concomitantly with Metformin when diet, exercise and Glimepiride or Metformin alone do not result in adequate glycemic control. Glimepiride is also indicated for use in combination with insulin to lower blood glucose in patients whose hyperglycemia can not be controlled by diet and exercise or in conjunction with an oral hypoglycemic agent.

**DOSE & ADMINISTRATION:**

There is no fixed dosage regimen for the management of diabetes mellitus with Glimepiride or any other hypoglycemic agent. The initial and the maintenance dosage are set based on the results of regular check of glucose in blood and urine. Monitoring of glucose levels in blood and urine also serves to detect either primary or secondary failure of therapy. Usual starting dose: The usual starting dose of Glimepiride as initial therapy is 1-2 mg once daily, administered with breakfast or the first main meal. Those patients who may be more sensitive to hypoglycemic agents should be started with 1 mg once daily and should be treated carefully. There is no exact dosage relationship between Glimepiride and other oral blood glucose lowering agents. The maximum starting dose of Glimepiride should be no more than 2 mg. Usual maintenance dose: The usual maintenance dose is 1 to 4 mg once daily. The maximum recommended dose is 8 mg once daily. After reaching of a dose of 2 mg, dosage increase should be made in increments of no more than 2 mg at 1-2 weeks intervals based upon the patient's blood glucose response. Patients receiving other oral hypoglycemic agents: As with other sulfonylurea hypoglycemic agents, no transition period is necessary when transferring patients to Glimepiride. Patients should be observed carefully (1-2 weeks) for hypoglycemia when being transferred from longer-half life sulfonylureas (e.g. chlorpropamide) to Glimepiride due to potential overlapping of drug effect.

**CONTRA-INDICATION:**

Glimepiride is contraindicated in patients with

1. Known hypersensitivity to the drug.
2. Diabetic ketoacidosis with or without coma. This condition should be treated with insulin.

**WARNING AND PRECAUTION:**

Hypoglycemia: All sulfonylurea drugs are capable of producing severe hypoglycemia. Proper patient selection, dosage and instructions are important to avoid hypoglycemic episodes. Patients with impaired renal function may be more sensitive to the glucose lowering effect of Glimepiride. Debilitated and malnourished patients and those with adrenal, pituitary or hepatic insufficiency are particularly susceptible to the hypoglycemic action of glucose-lowering drugs.

Loss of control of blood glucose: When a patient is stabilized on any diabetic regimen is exposed to stress such as fever, trauma, infection or surgery, a loss of control may occur. At such times, it may be necessary to add insulin in combination with Glimepiride or even use insulin monotherapy.

Hemolytic anemia: Treatment of patients with glucose 6-phosphate dehydrogenase (G6PD) deficiency with sulfonylurea agents can lead to hemolytic-anemia. Since Glimepiride belongs to the class of sulfonylurea agents, caution should be used in patients with G6PD deficiency and a non-sulfonylurea alternative should be considered.

Geriatric or renally impaired patients: At risk for hypoglycemia with glimepiride. Use caution in dose selection and titration and monitor closely.

**SIDE EFFECTS:**

Hypoglycemia, nausea, vomiting, diarrhea, abdominal pain, allergic skin reactions e.g. pruritus, erythema, urticaria and blurred vision may be reported.

**USE IN PREGNANCY & LACTATION:**

Pregnancy: Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. On the basis of results from animal studies, Glimepiride should not be used during pregnancy. Patients who are planning a pregnancy should consult with their physician, and it is recommended that they change over to insulin for the entire course of pregnancy and lactation. Nursing mothers: Although it is not known whether Glimepiride is excreted in human milk, other sulfonylureas are excreted in human milk. Because the potential for hypoglycemia in nursing infants may exist, Glimepiride should be discontinued in nursing mothers. Insulin therapy should be considered in this situation.

**USE IN CHILDREN & ADOLESCENTS:**

Glimepiride is not recommended below 18 years old children and adolescents because of adverse effects on body weight and hypoglycemia.

**DRUG INTERACTION:**

The hypoglycemic action of sulfonylureas may be potentiated by certain drugs, including NSAIDs and other drugs that are highly protein bound such as salicylates, sulfonamides, chloramphenicol. coumarins, probenecid, MAO inhibitors, β-adrenergic blocking agents and clarithromycin. Certain drugs tend to produce hyperglycemia and may lead to loss of control. These drugs include thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics and isoniazide. A potential interaction between oral miconazole and oral hypoglycemic drugs leading to severe hypoglycemia has been reported.

**OVERDOSE:**

An overdosage of glimepiride can produce severe hypoglycemia. Mild episodes of hypoglycemia can be treated with oral glucose. Severe hypoglycemic reactions constitute medical emergencies requiring immediate treatment. Severe hypoglycemia with coma, seizure, or neurological impairment can be treated with glucagon or intravenous glucose.

**STORAGE:**

Store in a dry and cool place below $30^0$ C temperature and keep away from light and moisture. Keep out of reach of children.

**PACKING:**

Temglip ® 1 Tablet: Each box containing 5x10's tablets in Alu-PVC blister pack.

Temglip ® 2 Tablet: Each box containing 3x10's tablets in Alu-PVC blister pack.

*Manufactured by*
**Team Pharmaceuticals Ltd.**
B 75-79, BSCIC, Sopura, Rajshahi, Bangladesh

IST-0047