Glimitus

Glimepiride BP

Composition:
Glimitus 1: Each tablet contains Glimepiride BP 1 mg.
Glimitus 2: Each tablet contains Glimepiride BP 2 mg.
Glimitus 3: Each tablet contains Glimepiride BP 3 mg.
Glimitus 4: Each tablet contains Glimepiride BP 4 mg.

Pharmacology:
Glimitus primarily lowers the blood glucose level by stimulating the release of insulin from pancreatic beta cells.

Indication:
Glimitus is indicated as an adjunct to diet and exercise to improve glycemic control in patients with Type 2 Diabetes Mellitus, whose hyperglycemia cannot be controlled with diet and exercise alone. Glimitus can be used as a monotherapy, or in combination with Metformin when diet, exercise and Metformin alone cannot control the blood sugar level of the patient. Glimitus may also be used in combination with insulin in patients with high blood sugar levels that cannot be controlled adequately with diet, exercise and the administration of an oral hypoglycemic agent.

Dosage and Administration:
The initial and maintenance dose of Glimitus should be determined by frequent monitoring of glucose in blood or urine. The recommended starting dose of Glimitus is 1 mg or 2 mg once daily, with breakfast. Patients with increased risk of hypoglycemia (elderly or patients with renal impairment) should be started with 1 mg once daily. After reaching a daily dose of 2 mg once daily, increments can be made by 1 mg or 2 mg depending on the patient's glycemic response. Increments should not be made more frequently than every 1-2 weeks. The maximum recommended dose is 8 mg once daily. Due to the potential overlapping of side-effects, patients being transferred from longer half-life sulfonylureas (such as chlorpropamide) must be observed for 1-2 weeks by frequently monitoring the blood glucose levels.

Contraindication:
Glimepiride is contraindicated in patients with
1. Type 1 Diabetes or Diabetic Ketoacidosis
2. Hypersensitivity to Glimepiride
3. Hypersensitivity to Sulfonylureas and Sulfonamide derivatives

Warning and Precaution:
Hypoglycemia: All sulfonylureas including Glimepiride can cause Hypoglycemia. Caution should be maintained while initiating and increasing the dose of Glimepiride in patients who are most susceptible to hypoglycemia (e.g. the elderly, the patients with renal impairment, and patients on other anti-diabetic medications). Debilitated or malnourished patients, and those with adrenal, pituitary, or hepatic impairment are particularly susceptible to the hypoglycemic action of glucose-lowering medications. Hypoglycemia is also more likely to occur when caloric intake is deficient, after severe or prolonged exercise, or when alcohol is ingested.
Hemolytic anemia: Sulfonylureas cause hemolytic anemia in Glucose-6-Phosphate Dehydrogenase (G6PD) deficient patients. Use of non-sulfonylurea medication is recommended in those cases.
In Renal Impairment: Glimepiride metabolites may accumulate in patients with renal impairment. Use of Glimepiride is not recommended in patients with Chronic Kidney Disease (Stage 4 or 5), due to the risk of severe hypoglycemia. Glimepiride is not recommended in individuals with Glomerular Filtration Rate (GFR) < 30 ml/min.

Side effects:
Hypoglycemia, headache, dizziness, nausea, vomiting, diarrhea, flu-like syndrome, allergic skin reactions such as pruritis, erythema and urticaria, weight gain and elevated serum ALT levels may be reported.

Use in Pregnancy and Lactation:
During Pregnancy: There is insufficient data available for the use of Glimepiride in pregnant individuals. However, sulfonylureas (including Glimepiride) cross the placenta and cause hypoglycemia in neonates. Therefore, Glimitus should not be administered to pregnant women.
During Lactation: It is not known whether Glimepiride is excreted in human milk. However, studies on animals have shown that Glimepiride is present in rat milk. Therefore, Glimitus should not be administered to breast-feeding women due to the risk of hypoglycemia in the infant.
In both cases, switching to insulin therapy for the duration of pregnancy or lactation is recommended.

Use in Children and Adolescents:
Glimepiride is not recommended for use in children because of its adverse effects on body weight and hypoglycemia.

Drug interactions:
The susceptibility to hypoglycemia can be increased by co-administration of certain drugs with Glimepiride, such as other oral anti-diabetic medications, pramlintide acetate, insulin, angiotensin converting enzyme (ACE) inhibitors, H2 receptor antagonists, fibrates, propoxyphene, pentoxifylline, somatostatin analogs, anabolic steroids and androgens, cyclophosphamide, phenyramidol, guanethidine, fluconazole, sulfinpyrazone, tetracyclines, clarithromycin, disopyramide, quinolones, and those drugs that are highly protein-bound, such as fluoxetine, nonsteroidal anti-inflammatory drugs, salicylates, sulfonamides, chloramphenicol, coumarins, probenecid and monoamine oxidase inhibitors. The glucose-lowering effect of Glimitus is reduced by certain drugs leading to uncontrolled blood glucose levels, such as danazol, glucagon, somatropin, protease inhibitors, atypical antipsychotic medications (e.g., olanzapine and clozapine), barbiturates, diazoxide, laxatives, rifampin, thiazides and other diuretics, corticosteroids, phenothiazines, thyroid hormones, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics (e.g., epinephrine, albuterol, terbutaline), and isoniazid. Beta-blockers, clonidine, reserpine and acute or chronic alcohol intake may contribute to either potentiation or weakening of Glimepiride's glucose-lowering action. Miconazole can cause severe hypoglycemia when co-administered with Glimepiride. Colesevelam can reduce the maximum plasma concentration and total exposure of Glimitus when the two are co-administered.

Overdose:
Glimitus should only be taken in the appropriate dose prescribed by the physician. High doses of Glimitus may cause severe hypoglycemia with coma, seizures, or neurologic impairment. In case of overdose, consult your physician immediately.

Storage:
Do not store above 25°C. Protect from light. Keep all medicines out of the reach of children.

Packaging:
Glimitus 1: Each box contains 5x10's tablets in blister pack.
Glimitus 2: Each box contains 5x10's tablets in blister pack.
Glimitus 3: Each box contains 3x10's tablets in blister pack.
Glimitus 4: Each box contains 3x10's tablets in blister pack.

Manufactured by
ZISKA PHARMA
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