SUCORID

Glimepiride

Presentation
Sucorid 2 Tablet: Each film coated tablet contains Glimepiride USP 2 mg
Sucorid 4 Tablet: Each film coated tablet contains Glimepiride USP 4 mg

Description
Glimepiride is an oral blood glucose lowering drug of the sulfonylurea class. The primary mechanism of action of Glimepiride in lowering blood glucose appears to be dependent on stimulating the release of insulin from functioning pancreatic beta cells. In addition, extra pancreatic effects may also play a role in the activity of Glimepiride. This is supported by both preclinical and clinical studies demonstrating that Glimepiride administration can lead to increase sensitivity of peripheral tissues to insulin.

A mild glucose lowering effect first appeared following single oral doses as low as 0.5-0.6 mg in healthy subjects. The time required to reach the maximum effect was about 2 to 3 hours. After oral administration, Glimepiride is completely (100%) absorbed from the GI tract. Glimepiride is completely metabolized by oxidative biotransformation after an oral dose.

Indication
- Non insulin dependent (type II) diabetes, whenever blood sugar levels cannot be controlled adequately by diet.
- Physical exercise and weight reduction alone.

Glimepiride may also be used in combination with an oral anti-diabetic containing metformin or with insulin to lower blood glucose in patients whose hyperglycemia cannot be controlled by diet and exercise or in conjunction with an oral hypoglycemic agent.

Dosage and Administration
Initial dose and dose titration: The usual initial dose is 1-2 mg once daily. If necessary, the daily dose can be increased. Any increase should be based on regular blood sugar monitoring and should be gradual, i.e., at intervals of one to two weeks and carried out stepwise as follows: 1 mg - 2 mg - 3 mg - 4 mg - 6 mg.
Glimepiride tablets must be swallowed without chewing and with sufficient amounts of water (approximately 1/2 glass).
Dose range in patients with well controlled diabetes: The usual dose range in patients with well controlled diabetes is 1 to 4 mg daily.
Distribution of doses: Timing and distribution of doses are to be decided by the physician, taking into consideration the patient's current life-style. Normally, a single daily dose is sufficient. This dose should be taken immediately before a substantial breakfast, if none is taken- immediately before the first main meal. It is very important not to skip meals after taking Glimepiride.
Secondary dosage adjustment: As the control of diabetes improves, sensitivity to insulin increases; therefore Glimepiride requirements may fall as treatment proceeds. To avoid an excessive reduction in blood sugar (hypoglycemia), a timely dose reduction or cessation of Glimepiride therapy must be considered.
Duration of treatment: Treatment with Glimepiride is normally a long-term therapy.
Changeover from other oral anti-diabetics to Glimepiride: There is no exact dosage relationship between Glimepiride and other oral blood sugar lowering agents. When substituting Glimepiride for other such agents, the initial daily dose is 1-2 mg; this applies even in changeovers from the maximum dose of another oral blood-sugar-lowering agent.
Use in combination with insulin: Whenever blood sugar levels cannot be controlled adequately with the maximum daily dose of Glimepiride, insulin may be given concomitantly. In this case, the current dose of Glimepiride remains unchanged. Insulin treatment is started at a low dose, which is subsequently increased stepwise according to the desired blood sugar level. Combined treatment should be initiated under close medical supervision.
Special populations renal insufficiency: There is limited information available on the use of Glimepiride in renal insufficiency. Patients with impaired renal function may be more sensitive to the Glucose lowering effect of Glimepiride.

Contraindication
Glimepiride is not suitable for the treatment of insulin-dependent (type I) diabetes mellitus (e.g. for the treatment of diabetes with a history of ketoacidosis), of diabetic ketoacidosis or of diabetic precoma or coma. Glimepiride must not be used in patients of hypersensitive to Glimepiride or other sulfonylureas. In patients with severe impairment of renal or hepatic function, a changeover to insulin is indicated, not least to achieve optimal metabolic control.

Side Effect
Hypoglycemia, temporary visual impairment, nausea, vomiting, diarrhea, abdominal pain, urticaria, fall in blood pressure.

Warning and Precaution
To achieve the optimal control of blood sugar a correct diet, regular and sufficient physical exercise and, if necessary, reduction of body weight are just as important as regular intake of Glimepiride. Clinical signs of hyperglycemia are e.g. increased urinary frequency, intense thirst, dryness of the mouth and dry skin. In the initial week of treatment, the risk of hypoglycemia may be increased and necessitates especially careful monitoring. If such risk factors for hypoglycemia are present, it may be necessary to adjust the dosage of Glimepiride.
Hypoglycemia can almost always be promptly controlled by immediate intake of sugar, e.g. in the form of glucose, sugar cubes or sugar-sweetened beverages. Patients should always carry at least 20 gm of glucose with them for this purpose. They may require the assistance of other persons to avoid complications.

Use In Pregnancy and Lactation
Pregnancy category C. To avoid risk of harm to the child, Glimepiride must not be taken during pregnancy; a changeover to insulin is necessary. Patients planning a pregnancy must inform their physician and should change over to insulin.
Lactation: Ingestion of Glimepiride with the breast milk may harm the child. Therefore, Glimepiride must not be taken by breastfeeding women and a changeover to insulin or discontinuation of breastfeeding is necessary.

Drug Interaction
Potentiation of the blood-sugar-lowering effect may occur with Insulin and other oral anti-diabetic, ACE inhibitors, allopurinol, anabolic steroids and male sex hormones, chloramphenicol, coumarin derivatives, fluoxetine, MAO inhibitors, miconazole, para- aminosalicylic acid, pentoxifylline (high dose parenteral), phenylbutazone,oxyphenbutazone, quinolones, salicylates, sulfonamides, tetracyclines, beta blockers.
Weakening of the blood sugar-lowering effect may occur with acetazolamide, barbiturates, corticosteriods, diazoxide, diuretics, epinephrine and other sympathomimetic agents, laxatives, estrogens and progestogens, phenothiazines, phenytoin, rifampicin, thyroid hormones, H_2-receptor antagonists, clonidine and reserpine may lead to either potentiation or weakening of the blood- sugar-lowering effect. Both acute and chronic alcohol intake may potentiate or weaken the blood-sugar- lowering action of Glimepiride unpredictably.

Overdose
Glimepiride overdose may lead to severe and sometimes life-threatening hypoglycemia and may require hospitalization even as a precautionary measure. Significant overdose with severe reactions is a medical emergency and will necessitate immediate treatment and hospitalization.

Storage
Glimepiride tablets should be stored in a cool (25^0C) and dry place, protected from light & moisture and keep away from children.

Commercial Pack
Sucorid 2 Tablet: Each box contains 3 x 10 tablets in alu-alu blister strips.
Sucorid 4 Tablet: Each box contains 3 x 10 tablets in alu-alu blister strips.

Manufactured by:
Globe Pharmaceuticals Ltd.
Noakhali, Bangladesh