

Gluconor

Glimepiride USP

Description:

The primary mechanism of action of Glimepiride is lowering of blood glucose by stimulating the release of insulin from functioning beta cell. In addition, extrapancreatic effects may also play vital role in the activity of Glimepiride. Administration of Glimepiride can lead to increase sensitivity of peripheral tissues to insulin. After oral administration, Glimepiride is completely (100%) absorbed from GIT. Glimepiride is completely metabolized by oxidative biotransformation after oral dose.

Composition:

Gluconor-1 Tablet: Each tablet contains Glimepiride USP 1 mg.

Gluconor-2 Tablet: Each tablet contains Glimepiride USP 2 mg.

Indications:

Gluconor is indicated as an adjunct to diet and exercise to lower the blood glucose in patients with non-insulin dependent diabetes mellitus whose hyperglycemia cannot be controlled by diet and exercise alone. Gluconor is also indicated for use in combination with insulin in patient whose hyperglycemia can not be controlled by diet and exercise in conjunction with an oral hypoglycemic agent.

Dosage and Administration:

Initial dose: 1-2 mg once daily, given with breakfast or the first main meal. Patient's sensitive to hypoglycemic drugs should begin at 1 mg once daily. Maximum starting dose is < 2 mg.

Maintenance dose: 1-4 mg once daily. The maximum recommended dose, is 8 mg once daily after a dose of 2 mg is reached, increase dose at increments of < 2 mg at 1-2 week intervals based on the patients blood glucose response. Monitor long-term efficacy by measurements of HbA1c levels, for example, every 3-6 months.

Combination insulin therapy: The recommended dose is 8 mg once daily with the first main meal with low dose insulin.

Patients on other oral antidiabetic agents: When transferring patients to Glimepiride, no transition period is necessary. No exact dosage relationship exists between Glimepiride and the other oral hypoglycemic agents. Observe patients carefully when being transferred from longer half-life sulfonylureas to Glimepiride due to potential overlapping of drug effect.

Contraindications: Glimepiride is not suitable for the treatment of type 2 diabetes (e.g. for the treatment of diabetes with a history of ketoacidosis), or of diabetic precoma or coma. Glimepiride must not be used in-patients hypersensitivity to Glimepiride, other sulfonylureas, other sulfonamides.

Precautions: In the initial weeks of treatment, the risk of hypoglycemia may be increased and necessitates careful monitoring. If such risk is present it may be necessary to adjust the dosage of Glimepiride. Hypoglycemia can almost always be promptly controlled by immediate intake of carbohydrates (glucose or sugar. e.g. In the form of sugar lumps, sugar-sweetened fruit juice or sugar-sweetened tea).

Side Effects:

Hypoglycemia, temporary visual impairment, nausea, vomiting, diarrhoea, abdominal pain, urticaria & fall in blood pressure.

Drug interactions:

Potentiation of the blood-sugar-lowering effect may occur with insulin and other oral anti diabetics. ACE inhibitors, allopurinol, anabolic steroids and male sex hormones, chloramphenicol, coumarin derivatives, fluxetine MAOIs, miconazole, para-aminosalicylic acid, pentoxifylline (high dose potential). Phenylbutazone, oxyphenbutazone, quinolones, salicylates. sulfonamides, tetracyclines & beta blockers. Weakening of the blood sugar lowering effect may occur with acetazolamide, barbiturates, corticosteroids, diazoxide, diuretics. epinephrine and other sympathomimetic agents, laxatives, oestrogens and progesterone, phenothiazines, phenytoin, rifampicin, thyroid hormones. H2 receptors antagonists, clonidine and reserpine may lead to either potentiation or weakening of the blood sugar lowering effect. Both acute and chronic alcohol intakes may potentiate or weaken the blood sugar lowering action of Glimepiride unpredictably.

Use in Pregnancy and Lactation:

Pregnancy: Glimepiride must not be taken during pregnancy; a changeover to insulin is necessary. Patients planning a pregnancy must inform their physician, and should changeover to insulin.

Nursing mothers: Ingestion of Glimepiride with breast milk may harm the child. Therefore, breast-feeding women must not take Glimepiride. Either a changeover or a complete discontinuation of breast-feeding is necessary.

Storage:

- Store below 30°C, keep in dry place & protect from light.
- Keep out of the reach of children.

Packing:

Gluconor - 1 Tablet : Each box contains 50 tablets in blister pack.

Gluconor - 2 Tablet : Each box contains 30 tablets in blister pack.

Manufactured by:
 **ARISTOPHARMA LTD.**
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