Natrapharm

Rx

Gliclazide

Glicla-Natrapharm

30mg
Modified Release Tablet
Blood Glucose Lowering Drug

FORMULATION:
Each modified release tablet contains:
Gliclazide.....30mg

DESCRIPTION:
Gliclazide is a sulfonylurea antidiabetic. It is given by mouth in the treatment of type 2 diabetes mellitus and has duration of action of 12 hours or more. Because its effects are less prolonged than those of chlorpropamide or glibenclamide, it may be more suitable for elderly patients who are prone to hypoglycemia with longer-acting sulfonylureas.

PHARMACODYNAMIC
Gliclazide is a hypoglycaemic sulfonylurea oral antidiabetic active substance differing from other related compounds by an N-containing heterocyclic ring with an endocyclic bond. Gliclazide reduces blood glucose levels by stimulating insulin secretion from the ß-cells of the islets of Langerhans. Increase in postprandial insulin and C-peptide secretion persists after two years of treatment.

In addition to these metabolic properties, gliclazide has haemovascular properties.

PHARMACOKINETICS:
Gliclazide is readily absorbed from the gastrointestinal tract. It is extensively bound to plasma proteins. The half-life is about 10 to 12 hours. Gliclazide is extensively metabolized in the liver to metabolites that have no significant hypoglycemic activity. Metabolites and a small amount of unchanged drug are excreted in the urine.

INDICATIONS:
Gliclazide is used for the treatment of type 2 diabetes mellitus.

ADVERSE EFFECTS:
The most frequent adverse reaction with gliclazide is hypoglycaemia.

Gastrointestinal disturbances such as nausea, vomiting, heartburn, anorexia, diarrhea, and a metallic taste may occur with gliclazide and are usually mild and dose-dependent; increased appetite and weight gain may occur. Skin rashes and pruritus may occur and photosensitivity has been reported.

PRECAUTIONS:
Gliclazide should not be used in type 1 diabetes mellitus. Use in type 2 diabetes mellitus is contraindicated in patients with ketoacidosis and in those with severe infections, trauma or other severe conditions where the drug is unlikely to control the hyperglycemia; insulin should be administered in such situations. Gliclazide may be suitable for use in patients with renal impairment, but that careful monitoring of blood-glucose concentration is essential. It should not be used in patients with severe renal impairment

CONTRAINDICATIONS:
Hypersensitivity to gliclazide.
Severe hepatic and renal impairment. Porphyria; SU's may precipitate an acute post attack. Pregnancy and breastfeeding; insulin therapy be given instead. Sulfonylureas are contraindicated in the presence of ketoacidosis.

DRUG INTERACTIONS:
Numerous interactions have been reported with the sulfonylureas, largely representing either pharmacokinetics interactions (due to the displacement of the antidiabetic plasma proteins or alteration in its metabolism or excretion) or pharmacological interactions with drugs having an independent effect on blood glucose. In the former class most reports concern older sulfonylureas such as chlorpropamide and tolbutamide, although the possibility of such reactions with newer drugs should be borne in mind.

The following are likely to increase the risk of hypoglycaemia
Contra-indicated combination
• **Miconazole** (systemic route, oromucosal gel): increases the hypoglycaemic effect with possible onset of hypoglycaemic symptoms, or even coma.
Combinations which are not recommended
• **Phenylbutazone** (systemic route): increases the hypoglycaemic effect of sulfonylureas (displaces their binding to plasma proteins and/or reduces their elimination).
It is preferable to use a different anti-inflammatory agent, or else to warn the patient and emphasise the importance of self-monitoring. Where necessary, adjust the dose during and after treatment with the anti-inflammatory agent.
• **Alcohol:** increases the hypoglycaemic reaction (by inhibiting compensatory reactions) that can lead to the onset of hypoglycaemic coma.
Avoid alcohol or medicines containing alcohol.

Combinations requiring precautions for use
Potentiation of the blood glucose lowering effect and thus, in some instances, hypoglycaemia may occur when one of the following drugs is taken:
other anti-diabetic agents (insulins, acarbose, metformin, thiazolidinediones, dipeptidyl peptidase-4 inhibitors, GLP-1 receptor agonists), beta-blockers, fluconazole, angiotensin converting enzyme inhibitors (captopril, enalapril), H2-receptor antagonists, MAOIs, sulfonamides, clarithromycin and non-steroidal anti-inflammatory agents.

The following products may cause an increase in blood glucose levels
Combination which is not recommended
• **Danazol:** diabetogenic effect of danazol.
If the use of this active substance cannot be avoided, warn the patient and emphasise the importance of urine and blood glucose monitoring. It may be necessary to adjust the dose of the antidiabetic agent during and after treatment with danazol.
Combinations requiring precautions during use
• **Chlorpromazine** (neuroleptic agent): high doses (>100 mg per day of chlorpromazine) increase blood glucose levels (reduced insulin release).
Warn the patient and emphasise the importance of blood glucose monitoring. It may be necessary to adjust the dose of the antidiabetic active substance during and after treatment with the neuroleptic agent.
• **Glucocorticoids** (systemic and local route: intra-articular, cutaneous and rectal preparations) and tetracosactrin: increase in blood glucose levels with possible ketosis (reduced tolerance to carbohydrates due to glucocorticoids).
Warn the patient and emphasise the importance of blood glucose monitoring, particularly at the start of treatment. It may be necessary to adjust the dose of the antidiabetic active substance during and after treatment with glucocorticoids.
• **Ritodrine, salbutamol, terbutaline:** (I.V.)
Increased blood glucose levels due to beta-2 agonist effects.
Emphasise the importance of monitoring blood glucose levels. If necessary, switch to insulin.
• **Saint John's Wort (*Hypericum perforatum*) preparations:**
Gliclazide exposure is decreased by Saint John's Wort-*Hypericum perforatum*. Emphasise the importance of blood glucose levels monitoring.

The following products may cause dysglycaemia
Combinations requiring precautions during use
• **Fluoroquinolones:** in case of a concomitant use of Gliclazide 30 mg Tablets and a fluoroquinolone, the patient should be warned of the risk of dysglycaemia, and the importance of blood glucose monitoring should be emphasised.
Combination which must be taken into account
• **Anticoagulant therapy** (Warfarin ...):
Sulfonylureas may lead to potentiation of anticoagulation during concurrent treatment. Adjustment of the anticoagulant may be necessary.
After Dosage and Administration

OVERDOSE:
An overdose of sulfonylureas may cause hypoglycaemia.
Moderate symptoms of hypoglycaemia, without any loss of consciousness or neurological signs, must be corrected by carbohydrate intake, dose adjustment and/or change of diet. Strict monitoring should be continued until the doctor is sure that the patient is out of danger.
Severe hypoglycaemic reactions, with coma, convulsions or other neurological disorders are possible and must be treated as a medical emergency, requiring immediate hospitalisation.

DOSAGE AND ADMINISTRATION:
The usual initial dose is 30 mg once daily, increased if necessary up to maximum of 120 mg daily or as prescribed by the physician. It has a duration of action of 12 to 24 hours.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY:
30mg Modified Release Tablet - Box of 60's (10 tablets per blister)
- Box of 15's (15 tablets per blister)

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

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STORE AT TEMPERATURES NOT EXCEEDING 30°C

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