GLIBAMID® Brand of Glibenclamide, BP Antidiabetic

DESCRIPTION:

GLIBAMID®, brand of Glibenclamide, is an oral antidiabetic agent of the sulphonylurea type.

PROPERTIES:

GLIBAMID® is a sulphonylurea hypoglycaemic agent wich is given by mouth in the treatment of non-insulin - dependent diabetes mellitus. **GLIBAMD®** appears to lower blood glucose by stimulating insulin release from the pancreas, an effect dependent upon functioning beta cells in the pancreatic islets. It specially blocks K⁺-ATP-dependant channels increasing insulin secretion. **GLIBAMID®** has a duration of action of up to 24 hours.

PHARMACOKINETICS:

GLIBAMID® is readily absorbed from the gastrointestinal tract. Peak plasma concentrations are attained 2 to 6 hours after oral absorption. It is about 99% bound to plasma proteins. It is metabolised, almost completely, in the liver, the principle metabolite being only very weakly active. Approximately 50% of a dose is excreted in the urine and 50% via the bile into the faeces. The elimination half-life is approximately 5 - 7 hours.

INDICATIONS:

GLIBAMID® is indicated for the treatment of maturity onset diabetes which is not adequately controlled by diet alone.

CONTRAINDICATIONS:

- GLIBAMID® is contraindicated in patients with known hypersensitivity or with ketoacidosis, a condition requiring insulin treatment. Also in the treatment of iuvenile or unstable diabetes.
- Association with miconazole, may enhance severe hypoglycemic effects, which may lead to coma.
- Disadvice in pregnant woman and contraindicated in lactating woman.

PRECAUTIONS:

GLIBAMID® is capable of producing severe hypoglycemia. Proper patient selection, dosage and instructions are important to avoid hypoglycemic episodes. Patients should be instructed to contact their physicians promptly if they experience symptoms of hypoglycemia or other side effects.

DRUG INTERACTIONS:

- The hypoglycemic action of **GLIBAMID®** may be enhanced by sulfonamides, salicylates, phenylbutazone, coumarin derivatives, beta-blocking agents, MAO inhibitors, cyclophosphamide, chloramphenicol, tuberculostatic drugs, NSAI, alcohol and miconazole. Other drugs like thiazides, furosemide, ethacrynic acid, estrogens and corticosteroids may diminish hypoglycemic activity.
- Beta-blockers may mask some hypoglycaemic symptoms such as tachycardia.

ADVERSE REACTIONS:

Gastrointestinal disturbances are the most common reactions i.e. nausea, diarrhea, vomiting, anorexia and hunger. Other side effects include pruritis, urticaria, photosensitivity and transient elevation in aminotransferases.

DOSAGE & ADMINISTRATION:

Adults usual:

Initial dose is 5 mg daily preferably with or immediately after the first main meal; 2.5 mg in debilitated or elderly patients. Dose adjusted weekly, if necessary, by increments of 2.5 or 5 mg/day up to max. dose of 15 mg/day.

Children usual:

Dose has not been established.

AVAILABILITY:

Tablets: Packs of 30 tablets each containing Glibenclamide 5 mg, Excipient

q.s. 1 tablet. Reg. No.:

Lebanon: 27509