Tablets of

Glibenclamida

BP 5 mg

Composition:
Each uncoated tablet contains:
Glibenclamide BP ..... 5 mg
Excipients ..... q.s.

Pharmacology: Glibenclamide is rapidly absorbed and extensively bound to plasma proteins, but is not readily displaced by acidic drugs. The drug is extensively metabolized in the liver and excreted as metabolites in urine and bile.

Indication: Glibenclamide is a hypoglycemic agent indicated for the treatment of non-insulin-dependent diabetes in patients who respond inadequately to dietary measures alone.
Dosage: Initially, 2.5 mg daily as a single dose at breakfast, increasing gradually by an additional 2.5 mg (only after repeating laboratory tests). Maximum 15 mg per day or as directed by the physician.

Contraindication: Glibenclamide must not be used in the following groups: patients who have experienced diabetic ketoacidosis or diabetic coma/pre-coma; insulin-dependent diabetes mellitus; severe renal, hepatic, thyroid, or adrenocortical impairment; circumstances of unusual stress, such as surgery, severe infection, and trauma; hypersensitivity to glibenclamide; 'brittle' or juvenile diabetes; pregnancy; breastfeeding women; and patients treated with bosentan.

Special warnings and precautions for use: Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption should not take this medicine. Treatment with sulfonylureas has been associated with occasional liver function disorders and cholestatic jaundice. If clinical jaundice occurs, glibenclamide must be discontinued.

Interaction with other medicines and other forms of interaction: Bosentan: An increased incidence of elevated liver enzymes was observed in patients treated with glibenclamide concomitantly with bosentan.

Both glibenclamide and bosentan inhibit the bile salt export pump, leading to the intracellular accumulation of cytotoxic bile salts. Therefore, this combination should not be used.

Both glibenclamide and bosentan inhibit the bile salt export pump, leading to the intracellular accumulation of cytotoxic bile salts. Therefore, this combination should not be used.

The hypoglycemic effect of glibenclamide may be enhanced by: anti-infective agents, anti-inflammatory/analgesic agents, dicoumarol-type anticoagulants and heparin, lipid-regulating agents, certain antidepressants, ACE inhibitors (captopril, enalapril), H2-receptor antagonists (cimetidine, ranitidine), fenfluramine, methyldopa, and sulfinpyrazone, necessitating a dose reduction.

The hypoglycemic effect of glibenclamide may be reduced by rifampicin, thiazide diuretics, and beta-blockers, requiring a dose increase. Beta-blockers can mask some symptoms of hypoglycemia. Alcohol may interact with sulfonylureas, causing facial flushing, and has a variable effect on blood sugar levels.

Glibenclamide may potentiate or diminish the effect of coumarin derivatives; there is a possibility that glibenclamide increases plasma levels of cyclosporine, which would require a reduction in the cyclosporine dose.

Fertility, pregnancy, and lactation: There is no specific information regarding the use of glibenclamide during human pregnancy, but it has been widely used for many years without apparent adverse effects. It has not yet been established whether glibenclamide passes into human milk. However, other sulfonylureas have been found in breast milk, and there is no evidence to suggest that glibenclamide differs from the rest of the group in this regard.

Undesirable effects: Blood disorders, immune system disorders, endocrine system disorders, metabolism and nutritional disorders, eye disorders, gastrointestinal disorders, hepatobiliary disorders, skin and subcutaneous tissue disorders.

Side effects: nausea, vomiting, anorexia or a sense of fullness, pruritus, urticaria, leukopenia, thrombocytopenia.

Overdose: Activated charcoal may be considered in cases of acute intoxication. Hypoglycemia in a conscious patient must be treated urgently with oral glucose.

If the patient is comatose, glucose should be administered as an intravenous infusion. Bolus glucose injections are not recommended due to the possibility of rebound hypoglycemia. Alternatively, a 1 mg dose of glucagon may be administered subcutaneously or intramuscularly to restore consciousness. The patient should be observed for several days in case of recurrent hypoglycemia.

Storage: Store below 30ºC in a cool, dry place.

Keep medicines out of the reach of children.

Presentation: Blister pack of 10 tablets.

Manufactured by:

US Pharma®
(INDIA) Private Limited
Pioneering Excellence. Redefining Quality.
www.uspharma.in