

# Glucostat

## Gliclazide BP

### Composition:

**Glucostat 80 mg Tablet:** Each tablet contains Gliclazide BP 80 mg.

### Properties:

Gliclazide BP is a second-generation sulfonylurea that has hypoglycaemic and potentially useful hemobiological properties. It stimulates the influx of calcium ions into the pancreatic beta cells and as a result increases insulin secretion and decrease hepatic glucose output. Moreover, in vivo studies have demonstrated that Gliclazide reduces the thrombin-induced platelet aggregation in NIDDM patients.

### Indications:

Gliclazide (**Glucostat**) is indicated for the treatment of maturity onset diabetes mellitus (NIDDM) of patients who cannot be controlled on diet alone and who require oral antidiabetic treatment.

### Dosage and Administration:

This is the drug for oral use.

Duration of action is 12 hours or more.

*Adult:* The usual initial dose is 40 to 80 mg daily, gradually increased, if necessary up to 320 mg daily until adequate control is achieved. A single Dose should not exceed 160 mg. When higher doses are required, it should be taken twice daily and according to the main meals of the day.

*Elderly:* Plasma clearance of Gliclazide is not altered in the elderly and steady state plasma levels are similar to those in adults under 65 years. Clinical experiences in the elderly show that it is effective and well tolerated.

*Children:* Gliclazide as with other sulfonylureas is not indicated for the treatment of juvenile onset diabetes mellitus.

### Contraindications:

Gliclazide should not be used in

- Juvenile onset diabetes
- Diabetes complicated by ketosis and acidosis
- Pregnancy
- Diabetics undergoing surgery, after severe trauma or during infections
- Patients known to hypersensitivity to other sulfonylureas and related drugs
- Diabetic pre-coma and coma
- Severe renal or hepatic insufficiency
- Combination with miconazole tablets

### Precautions:

Care should be exercised in patients with hepatic and/or renal impairment and a small starting dose should be used with careful patient monitoring. In long-term clinical trials, patients with renal insufficiency have been treated satisfactorily using **Glucostat** (Gliclazide) at reduced doses. Using **Glucostat** does not dispense with the need to follow the physician's dietary recommendations.

### Use in Pregnancy and Lactation:

*Pregnancy:* Gliclazide should not be used in pregnancy.

*Nursing mothers:* No study has reported its presence in human breast milk.

### Side effects:

Hypoglycaemia may occur in concurrent conditions such as hepatic & renal diseases, alcohol intoxication and adrenal & pituitary insufficiency. Gastro-intestinal disturbances nausea, dyspepsia, diarrhea and constipation have been reported but this type of adverse reaction can be avoided if **Glucostat** is taken during a meal. Allergic dermatological reactions including rash, pruritus erythema, bullous eruption have been reported during treatment with the drug but are unknown to be directly attributable to it. More serious reaction like leucopenia, thrombocytopenia, agranulocytosis, pancytopenia, hemolytic anemia, cholestatic jaundice and GI hemorrhage which have been reported with other sulfonylureas, have not been reported with **Glucostat**. Nor has hyponatraemia been noted with this particular sulfonylurea.

### Drug Interactions:

The hypoglycaemic effect of **Glucostat** (Gliclazide) may be potentiated by NSAIDs (in particular aspirin), phenylbutazone, sulfonamides, coumarin derivatives, MAOIs, beta adrenergic blockers, tetracycline, chloramphenicol, clofibrate, cimetidine and miconazole. Ingestion of alcohol may also increase the hypoglycaemic effect of **Glucostat** (Gliclazide). Some drugs may, on the contrary, reduce its activity e.g. barbiturates, corticosteroids, thiazide diuretics, thyroid hormone, laxatives and oral contraceptives.

### Overdosage:

Accidental or deliberate overdosage leads essentially to signs of hypoglycaemia. The treatment is gastric lavage and correction of the hypoglycaemia. In severe cases, if there is clouding of consciousness, 10% or 30% hypertonic glucose solution must be administered intravenously without delay and the patient removed to hospital urgently.

### Pharmaceutical Precautions:

Store below 30°C. Keep out of the reach of children.

### Commercial Pack:

**Glucostat 80 mg Tablet:** Each Box contains 5 X 10 tablets in alu blister Pack.

Manufactured by



**BIOPHARMA**

L I M I T E D  
A-116, BSCIC Industrial Estate  
TONGI, GAZIPUR, BANGLADESH

For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.