SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Gliclazide Tablets BP 80mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Gliclazide Tablets BP contain Gliclazide 80 mg.

3. PHARMACEUTICAL FORM

Tablets.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Gliclazide Tablets are used for the treatment of maturity onset diabetes mellitus.

4.2. Posology and Method of Administration

Gliclazide Tablets are for oral administration.

Adults
The total daily dose may vary from 40-320 mg taken orally. The dose should be adjusted according to the patient's response, commencing with 40-80 mg daily (½-1 tablet) and increasing until adequate control is achieved. A single dose should not exceed 160 mg (2 tablets) and when higher doses are required a twice daily split dosage is advised and should be divided according to the main meals of the day.

In obese patients or those not showing adequate response to Gliclazide alone additional therapy should be considered.

Elderly
Plasma clearance of Gliclazide is not altered in the elderly and steady state plasma levels can therefore be expected to be similar to those in adults under

65 years. There is evidence to indicate that Gliclazide is effective and well tolerated in elderly patients. Care should be exercised however, when prescribing sulphonylureas in the elderly due to a possible age related increased tendency for hypoglycaemia.

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

4.3. Contra-Indications

Gliclazide should not be used in juvenile onset diabetes, diabetes complicated by ketosis and acidosis, porphyria, during pregnancy and breast feeding, diabetics undergoing surgery, after severe trauma or during infections, patients with known hypersensitivity to Gliclazide or chemically related drugs (including other sulphonylureas), diabetic pre-coma and coma and severe renal or hepatic insufficiency.

4.4 Special warnings and precautions for use

Care should be exercised in patients with hepatic and/or renal impairment and a small starting dose should be used with careful patient monitoring. As with other sulphonylureas, hypoglycaemia will occur if the patient's dietary intake is reduced or if they are receiving a higher dose of Gliclazide than required. Hypoglycaemia: Gliclazide, like all sulphonylureas, is capable of inducing moderate or severe hypoglycaemia, especially under the following conditions;

- In patients controlled by diet alone
- Overdose
- When calorie or glucose intake is insufficient
- In patients with hepatic and/or renal impairment (however, long term clinical trials in patients with renal insufficiency have demonstrated that treatment is satisfactory at reduced doses).

The following recommendations apply in order to reduce the risk of hypoglycaemia:

- To commence treatment for non-insulin dependent diabetics by diet alone, if possible
- To take into account the age of the patient
- To adjust the dosage in accordance with blood glucose levels and the 24 h urinary glucose during the first few days of treatment

Dosage adjustments may be necessary under the following circumstances:

- On the occurrence of mild symptoms of hypoglycaemia (sweating, pallor, hunger, tachycardia, malaise). These symptoms should be treated with oral glucose and adjustments made to the dosage of Gliclazide and/or the patient's meal patterns.
- On the occurrence of severe hypoglycaemic reactions (coma or neurological impairment).
- Loss of control of blood glucose (hyperglycaemia). This may occur when a patient who is stable on any diabetic regimen is exposed to stress, such as fever, trauma, infection or surgery. Under such circumstances it may be necessary to progressively increase the dose of Gliclazide. If the response is insufficient, consideration should be given to the discontinuation of Gliclazide therapy and administration of insulin.
- Treatment of patients with G6PD-deficiency with sulfonylurea agents can lead to haemolytic anaemia. Since gliclazide belongs to the class of sulfonylurea agents, caution should be used in patients with G6PD-deficiency and a non-sulfonylurea alternative should be considered.

4.5. Interactions with other Medicinal Products and other Forms of Interaction

Care should be taken when giving Gliclazide with drugs which are known to alter the diabetic state or potentiate the drug's action. Phenylbutazone, salicylates, sulphonamides, coumarin derivatives, MAOI's, β-blocking agents, tetracycline compounds, chloramphenicol, clofibrate, disopyramide, miconazole (oral forms), cimetidine and alcohol may potentiate the hypoglycaemic effect of Gliclazide, and corticosteroids, oral contraceptives, thiazide diuretics, phenothiazine derivatives, thyroid hormones and laxative abuse may diminish it.

4.6. Pregnancy and Lactation

Gliclazide should not be used in pregnancy or during breast feeding.

Although it is not known whether Gliclazide is excreted in milk, other sulphonylureas have been detected in milk and there is no evidence that Gliclazide differs in this respect.

4.7. Effects on Ability to Drive and Use Machines

The ability of the patient to concentrate may be affected if control of diabetes is unsatisfactory, particularly at the start of treatment.

4.8. Undesirable Effects

Hypoglycaemia (see 4.4 Special Warnings and Precautions).

Abnormalities of hepatic function are not uncommon with Gliclazide therapy and there are rare reports of hepatic failure, hepatitis and jaundice.

Mild gastro-intestinal disturbances, such as nausea, dyspepsia, diarrhoea and constipation have been reported but effects of this type may be avoided by taking Gliclazide with meals.

Side effects associated with hypersensitivity may occur and may be severe. Skin reactions (including rash, pruritis, erythema and bullous eruption) are likely to be manifestations of hypersensitivity and there are rare reports of progression to erythema multiforme and exfoliative dermatitis. There are also rare reports of blood dyscrasias (aplastic anaemia, haemolytic anaemia, leucopenia, thrombocytopenia, granulocytopenia), cholestatic jaundice and fever and these effects may also be manifestations of hypersensitivity.

4.9. Overdose

The symptom to be expected of overdose would be hypoglycaemia. The treatment is gastric lavage and correction of the hypoglycaemia by appropriate means with continued monitoring of the patients blood sugar.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Gliclazide acts primarily by enhancing the release of endogenous insulin. Residual function of B cells is, therefore, necessary for this activity. The mechanism of action is not fully understood but it is believed to involve degranulation of pancreatic B cells, a phenomenon associated with an increased rate of insulin secretion.

At normal therapeutic doses in man, Gliclazide reduces platelet adhesiveness and aggregation.

5.2. Pharmacokinetic Properties

Absorption: Gliclazide is readily absorbed from the gastro-intestinal tract. Its half life is approximately 10-12 hours.

Distribution: Gliclazide is distributed to the extracellular fluid. In animals, high concentrations of the drug were found in the liver, kidneys, skin, lungs, skeletal muscle, intestinal and cardiac tissue. Penetration of Gliclazide into the CNS was negligible. It crossed the placental barrier and penetrated the foetus.
Gliclazide is strongly bound to plasma proteins in the blood.

Gliclazide is extensively metabolised in the liver to metabolites without significant hypoglycaemic activity. Both unchanged drug and metabolites are excreted in the urine.

5.3. Pre-clinical Safety Data

There are no additional preclinical data of relevance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Lactose Monohydrate EP, Microcrystalline Cellulose EP, Povidone K29/32 EP, Sodium Starch Glycollate (Type A) EP, Talc EP and Magnesium Stearate EP.

6.2. Incompatibilities

None known.

6.3. Shelf Life

3 years.

6.4. Special Precautions for Storage

Store at or below 25ºC.

6.5. Nature and Content of Container

Gliclazide Tablets BP are available in blister packs of 7, 10, 28, 30, 56, 60, 100, 120 and 250 tablets.

6.6 Special precautions for disposal

There are no special handling instructions for Gliclazide tablets.

7 MARKETING AUTHORISATION HOLDER

Generics (U.K.) Limited T/A Viatris,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

8. MARKETING AUTHORISATION NUMBER

PL/4569/0274

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

08/06/2010

10 DATE OF REVISION OF THE TEXT

08/05/2026