

For the use only of a registered medical practitioner or a hospital or a laboratory.

BETIX
Glimepiride Tablets USP 4 mg

COMPOSITION

Each film coated tablet contains:

Glimepiride USP 4 mg

PHARMACOLOGY

Pharmacological Action:

Blood glucose lowering drugs, excl. insulins; Sulfonamides, urea derivatives.

Mechanism of Action

The primary mechanism of action of glimepiride in lowering blood glucose appears to be dependent on stimulating the release of insulin from functioning pancreatic beta cells. In addition, extrapancreatic effects may also play a role in the activity of sulfonylureas such as glimepiride.

PHARMACODYNAMIC

Glimepiride is an orally active hypoglycaemic substance belonging to the sulphonylurea group. It may be used in non-insulin dependent (type 2) diabetes mellitus.

Glimepiride acts mainly by stimulating insulin release from pancreatic beta cells. As with other sulfonylureas this effect is based on an increase of responsiveness of the pancreatic beta cells to the physiological glucose stimulus. In addition, glimepiride seems to have pronounced extrapancreatic effects also postulated for other sulfonylureas.

PHARMACOKINETIC

Absorption

The bioavailability of glimepiride after oral administration is complete. Food intake has no relevant influence on absorption, only the absorption rate is slightly diminished. Maximum serum concentrations (C_{max}) are reached approx 2.5 hours after oral intake

Distribution

Glimepiride has a very low distribution volume (approx. 8.8 litres), which is roughly equal to the albumin distribution space, high protein binding (>99%) and a low clearance (approx. 48 ml/min).

Biotransformation and elimination

Mean dominant serum half-life, which is of relevance for the serum concentrations under multiple-dose conditions, is about 5 to 8 hours. After high doses, slightly longer half-lives were noted.

After a single dose of radiolabelled glimepiride, 58% of the radioactivity was recovered in the urine, and 35% in the faeces. No unchanged substance was detected in the urine. Two metabolites most probably resulting from hepatic metabolism (major enzyme is CYP2C9) were identified both in urine and faeces: the hydroxy derivative and the carboxy derivative. After oral administration of glimepiride, the terminal half-lives of these metabolites were 3 to 6 and 5 to 6 hours respectively.

INDICATIONS

Glimepiride is indicated for the treatment of type 2 diabetes mellitus, when diet, physical exercise and weight reduction alone are not adequate.

DOSAGE AND ADMINISTRATION

For oral administration.

The basis for successful treatment of diabetes is a good diet, regular physical activity, as well as routine checks of blood and urine. Tablets or insulin cannot compensate if the patient does not keep to the recommended diet.

Posology

The dosage is determined by the results of blood and urinary glucose determinations.

The starting dose is 1 mg glimepiride per day. If good control is achieved, this dosage should be used for maintenance therapy.

For the different dosage regimens appropriate strengths are available.

If control is unsatisfactory, the dosage should be increased, based on the glycaemic control, in a stepwise manner with an interval of about 1 to 2 weeks between each step, to 2, 3, or 4 mg glimepiride per day.

A dosage of more than 4 mg glimepiride per day gives better results only in exceptional cases.

The maximum recommended dose is 6 mg glimepiride per day.

In patients not adequately controlled with the maximum daily dose of metformin, concomitant glimepiride therapy can be initiated. While maintaining the metformin dose, the glimepiride therapy is started with a low dose, and is then titrated up depending on the desired level of metabolic control up to

the maximum daily dose. The combination therapy should be initiated under close medical supervision.

CONTRAINDICATION

Glimepiride is contraindicated in patients with the following conditions:

- hypersensitivity to glimepiride
- insulin dependent diabetes
- diabetic coma
- ketoacidosis
- severe renal or hepatic function disorders.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Glimepiride must be taken shortly before or during a meal.

When meals are taken at irregular hours or skipped altogether, treatment with "Glimepiride Tablets" may lead to hypoglycaemia. Possible symptoms of hypoglycaemia include: headache, ravenous hunger, nausea, vomiting, lassitude, sleepiness, disordered sleep, restlessness, aggressiveness, impaired concentration, alertness and reaction time, depression, confusion, speech and visual disorders, aphasia, tremor, paresis, sensory disturbances, dizziness, helplessness, loss of self-control, delirium, cerebral convulsions, somnolence and loss of consciousness up to and including coma, shallow respiration and bradycardia. In addition, signs of adrenergic counter-regulation may be present such as sweating, clammy skin, anxiety, tachycardia, hypertension, palpitations, angina pectoris and cardiac arrhythmias.

DRUG INTERACTIONS

If glimepiride is taken simultaneously with certain other medicinal products, both undesired increases and decreases in the hypoglycaemic action of glimepiride can occur. For this reason, other medicinal products should only be taken with the knowledge (or at the prescription) of the doctor.

OVERDOSAGE

Treatment primarily consists of preventing absorption by inducing vomiting and then drinking water or lemonade with activated charcoal (adsorbent) and sodium-sulphate (laxative). If large quantities have been ingested gastric lavage is indicated, followed by activated charcoal and sodium-sulphate. In case of (severe) overdosage hospitalisation in an intensive care department is indicated.

PACKING

10 Tablets are packed in a Blister, 10 blister are packed in carton with the package insert.

STORAGE

Store below 30°C.

SHELF LIFE

36 months

Mfd. in India.

ALCHEMY MEDICINE PVT. LTD.

Bhagwanpur, Roorkee,

Dist. Haridwar, Uttarakhand

Manufactured for:

Takki HealthCare Limited

A3 Royal Pearl Plaza, Opposite Our Lady Queen

of Matrys catholic church Enoch Jarumi Road,

Sabon Lugbe, Abuja, Nigeria.