PACKAGE INSERT: AUSTELL-GLICLAZIDE 40/80 mg

SCHEDULING STATUS

S3

PROPRIETARY NAME (and dosage form)

AUSTELL–GLICLAZIDE 40 mg TABLETS

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COMPOSITION

AUSTELL-GLICLAZIDE 40 mg:

Each tablet contains gliclazide 40 mg.

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Each tablet contains gliclazide 80 mg.

PHARMACOLOGICAL CLASSIFICATION

A 21.2 Oral Hypoglycaemics.

PHARMACOLOGICAL ACTION

Gliclazide belongs to the second generation of hypoglycaemic Sulphonylureas.

Gliclazide causes hypoglycaemia by stimulating insulin release from pancreatic ß cells.

The acute administration of Gliclazide to type 2 Diabetes Mellitus patients increases insulin release from the pancreas. It may further increase insulin levels by reducing hepatic clearance of the hormone.

The effect of Gliclazide is initiated by binding to and blocking an ATP – sensitive K^+ channel, which has been cloned.

Reduced K^+ conductance causes membrane depolarization and influx of Ca^{2+} through voltage sensitive Ca^{2+} channels.

Gliclazide is effectively absorbed from the gastro–intestinal tract. In plasma it is largely bound to protein, especially albumin. The volume of distribution is 0.2 lts/kg.

The half–life of the drug is short (3 to 5 hours), but the hypoglycaemic effect is evident for 12 to 24 hours. Gliclazide is metabolized by the liver, and all the metabolites are excreted in the urine.

INDICATIONS

Therapy of maturity onset Diabetes Mellitus (non – insulin dependent or Type II), where dietary management alone has been insufficient.

CONTRA-INDICATIONS

Should not be used in Type I Diabetes Mellitus.

Use in Type II Diabetes Mellitus is contraindicated in patients with ketoacidosis and in those with severe infection, trauma, or other severe conditions where sulphonylurea is unlikely to control the hyperglycaemia. In such situations insulin should be administered.

Safety in pregnant and breastfeeding mothers has not been established. **(see Pregnancy and Lactation)**

WARNINGS

Should be avoided in patients with impairment of renal or hepatic function especially in the elderly, debilitated or malnourished patients, and those with adrenal or pituitary insufficiency.

The administration of AUSTELL-GLICLAZIDE may be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet with insulin. Reduction in dose may be necessary in patients with renal dysfunction.

INTERACTIONS

Potentiation of the hypoglycaemic action of the drug may occur with the concomitant administration of sulphonamides, salicylates, phenylbutazone, beta- adrenoreceptor blocking agents, monoamine oxidase inhibitors, ketoconazole, miconazole, chloramphenicol, clofibrate, or halofenate, cyclophosphamide, dicoumarol, and cimetidine.

Diminution of hypoglycaemic action of medicine may occur with the concomitant administration of thiazide diuretics, corticosteroids, oestrogen, and adrenaline. Beta–blockers may mask symptoms of hypoglycaemia and may inhibit normal physiological response to hypoglycaemia.

PREGNANCY AND LACTATION

Safety in pregnant and breastfeeding mothers has not been established.

DOSAGE AND DIRECTIONS FOR USE

AUSTELL–GLICLAZIDE is a sulphonylurea antidiabetic. It is given by mouth in the treatment of type 2 Diabetes Mellitus and has a duration of action of 12 hours or more.

The usual initial dose is 40 to 80 mg daily, gradually increased if necessary, up to 320 mg daily. Doses of more than 160 mg daily are given in 2 divided doses.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

Side-effects:

Gastro-intestinal disturbances

Less frequent: Nausea, vomiting, heartburn, anorexia, diarrhoea, and a metallic taste may occur. This is usually dose dependant.

Hypersensitivity reactions

Less frequent: Skin rashes and pruritus may occur and photosensitivity has been reported. Rashes may progress to more serious disorders.

Other severe effects may be manifestations of hypersensitivity reactions. They include altered liver enzyme values and cholestatic jaundice, leucopenia, thrombocytopenia, aplastic anaemia, agranulocytosis, haemolytic anaemia, erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis and erythema nodosum.

Special precautions:

AUSTELL-GLICLAZIDE may be suitable for use in patients with renal impairment, but careful monitoring of blood glucose concentrations is essential.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Hypoglycaemic reactions should be treated by gastric lavage and correction of the hypoglycaemia by the administration of intravenous glucose. The patients blood sugar should be continuously monitored until the effect of the medicine has ceased.

Hypoglycaemic reactions should alert the physician to the possibility of the renal dysfunction.

IDENTIFICATION

AUSTELL–GLICLAZIDE 40 mg:

White to off white, round, flat bevelled edged, uncoated tablets with breakline on one side.

AUSTELL–GLICLAZIDE 80 mg:

White to off white, round, flat bevelled edged, uncoated tablets with breakline on one side.

PRESENTATION

AUSTELL–GLICLAZIDE 40 mg:

Blister pack (Clear PVDC coated PVC film and Aluminium foil) of 3 x 10 and 6 x 10 tablets.

Bulk pack (White HDPE containers) of 250 tablets.

AUSTELL–GLICLAZIDE 80 mg:

Blister pack (Clear PVDC coated PVC film and Aluminium foil) of 3 x 20, 2 x 14 and 4 x 14 tablets.

Bulk pack (White HDPE containers) of 250 tablets.

STORAGE INSTRUCTIONS

Store in a dry place below 25 °C. Protect from light.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER

AUSTELL–GLICLAZIDE 40 mg: 38/21.2/0206

AUSTELL–GLICLAZIDE 80 mg: 38/21.2/0207

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Austell Laboratories (Pty) Ltd.

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