Approved Patient Information Leaflet:

GLICLAZIDE 40 mg/ 80 mg AUSTELL

Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM

GLICLAZIDE 40 mg AUSTELL

GLICLAZIDE 80 mg AUSTELL

WHAT GLICLAZIDE AUSTELL CONTAINS

GLICLAZIDE 40 mg AUSTELL:

Each tablet contains gliclazide 40 mg.

GLICLAZIDE 80 mg AUSTELL:

Each tablet contains gliclazide 80 mg.

The inactive ingredients are: Lactose monohydrate, microcrystalline cellulose, polyvinyl pyrrolidone, purified talc, croscarmellose sodium, magnesium stearate.

WHAT GLICLAZIDE AUSTELL IS USED FOR

GLICLAZIDE AUSTELL tablets are used for the treatment of diabetes mellitus when insulin is not necessary and when dietary management alone has been insufficient.

BEFORE YOU TAKE GLICLAZIDE AUSTELL

GLICLAZIDE AUSTELL should not be used:

- in Type I diabetes mellitus.
- in patients with ketoacidosis.
- in diabetics undergoing surgery, after trauma or during serious infections.
- where there is a known allergy to sulphonylurea and other related medicines.
- if you experience symptoms of hypoglycaemia (low blood sugar) such as sweating.

Warnings:

Talk to your doctor or pharmacist if you are suffering from liver or kidney disease especially in the elderly, debilitated or malnourished patients, and those with adrenal or pituitary insufficiency.

Interactions:

Talk to your doctor if you are taking the following medication: sulphonamides, salicylates (asprin), phenylbutazone (used to treat arthritis), beta-adrenoreceptor blocking agents, monoamine oxidase inhibitors, ketoconazole, miconazole, chloramphenicol (antibiotic), clofibrate (used to reduce fat), halofenate, cyclophosphamide, dicoumarol, and cimetidine (used to treat stomach ulcers).
The effect of **GLICLAZIDE AUSTELL** may be lessened by thiazide diuretics, corticosteroids, eostrogen and adrenaline. Beta-blockers may mask symptoms of hypoglycaemia and may inhibit normal physiological response to hypoglycaemia.

Pregnancy and lactation

If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO TAKE GLICLAZIDE AUSTELL

GLICLAZIDE AUSTELL 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.

In the event of over dosage consult your doctor or pharmacist.

POSSIBLE SIDE EFFECTS

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist, or other health care professional for advice.

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.

STORING AND DISPOSING OF GLICLAZIDE AUSTELL

Keep this medicine in a dry place below 25 °C. Protect from light.

Return all unused medicines to your pharmacist.

Do not dispose unused medicines in drains and sewerage system (e.g. toilets).

DO NOT USE AFTER THE DATE WHICH IS STAMPED ON THE PACK.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF GLICLAZIDE AUSTELL

GLICLAZIDE 40 mg AUSTELL:

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.

GLICLAZIDE 80 mg AUSTELL:

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

IDENTIFICATION OF GLICLAZIDE AUSTELL

GLICLAZIDE 40 mg AUSTELL:

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

GLICLAZIDE 80 mg AUSTELL:

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

REGISTRATION NUMBER/REFERENCE NUMBER

GLICLAZIDE 40 mg AUSTELL: 38/21.2/0206

GLICLAZIDE 80 mg AUSTELL: 38/21.2/0207

NAME AND ADDRESS OF REGISTRATION HOLDER

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG, 2193

Tel: +27 11 611 1400 or +27 860 287 835

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