SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Glibenclamide 2.5mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glibenclamide 2.5mg
For excipients, see 6.1

3 PHARMACEUTICAL FORM

Tablet for oral use
Glibenclamide 2.5mg Tablets are white, circular tablets marked ‘GL 2.5’ on one face and plain on the reverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Glibenclamide is a hypoglycaemic agent indicated in the treatment of noninsulin dependent diabetes in patients who respond inadequately to dietary measures alone.

4.2 Posology and method of administration

Treatment of previously untreated diabetes:
Stabilisation can be started with one 5mg tablet daily with or immediately after breakfast or the first main meal. If control is satisfactory one tablet is continued as the maintenance dose. If control is unsatisfactory, the dose can be adjusted by increments of 2.5 or 5mg at weekly intervals. The total daily dosage rarely exceeds 15mg and increasing the daily dosage above this does not generally produce any additional effect.

The total daily requirement should normally be given as a single dose at breakfast, or with the first main meal. The patient’s diet and activity should be taken into account.

Children: Glibenclamide is not recommenced for use in children.

Elderly: In debilitated patients or aged patients who may be more liable to hypoglycaemia, treatment should be initiated with one 2.5mg tablet daily.

Changeover from other sulphonylureas:
The changeover to glibenclamide from other drugs with similar mode of action can be carried out without any break in therapy.

Treatment is commenced with the equivalent dose of glibenclamide without exceeding an initial dose of 10mg. If response is inadequate, the dose can be raised in a stepwise fashion to 15mg daily. One 5mg tablet of glibenclamide is approximately equivalent to 1g tolbutamine or glymidine, 250mg chlorpropamide or tolazamide, 500mg acetohexamide, 25mg glibornuride or 5mg glipizide.

Changeover from biguanides: The biguanide should be withdrawn and glibenclamide treatment started with one 2.5mg tablet. The dosage should then be adjusted by increments of 2.5mg to achieve control.

Combination with biguanides: If adequate control is not possible with diet and 15mg of glibenclamide, control may be established by combined administration of glibenclamide and a biguanide derivative.

Changeover from insulin:
While it is appreciated that most patients who are on insulin therapy will continue to need it, there may be a few patients, particularly those on low daily doses, who will remain stabilised if transferred from insulin to glibenclamide.

4.3 Contraindications

i) Those patients who have or have ever had diabetic ketoacidosis.

ii) Insulin dependent diabetes mellitus.

iii) Severe impairment of renal, hepatic, thyroid or adrenocortical function.

iv) Circumstances of unusual stress such as surgery, severe infection and trauma.

v) Hypersensitivity to glibenclamide.

4.4 Special warnings and precautions for use

Care is necessary in elderly, debilitated or malnourished patients who are particularly susceptible to the hypoglycaemic effects of sulphonylureas, and during excessive exercise as hypoglycaemia may be provoked.

4.5 Interaction with other medicinal products and other forms of interaction

The hypoglycaemic effect of glibenclamide may be increased by: antiinfective agents (eg: chloramphenicol, fluconazole, miconazole, sulphonamides including co-trimoxazole), anti-inflammatory/analgesic agents (e.g.: phenylbutazone, salicylates), dicoumarin anticoagulants and heparin, lipid regulating agents (e.g. clofibrate), some antidepressants (monoamine oxidase inhibitors, doxepin, nortriptyline), ACE-inhibitors captopril, enalapril, H2-blockers, cimetidine, ranitidine, fenfluramine, methyldopa and sulphinpyrazone, necessitating dosage reduction.

The hypoglycaemic effect of glibenclamide may be diminished by rifampicin, thiazide diuretics and beta-blockers, necessitating dosage increase. Betablockers may mask some of the symptoms of hypoglycaemia. Alcohol may interact with the sulphonylureas, provoking facial flushing, and has a variable effect on blood sugar levels.

4.6 Fertility, Pregnancy and lactation

There is no specific information on glibenclamide in pregnancy – insulin therapy is usually substituted. Glibenclamide may be secreted in breast milk and caution should be exercised when prescribing for nursing mothers, as there is a possibility of causing hypoglycaemia in the infant.

4.7 Effects on ability to drive and use machines

None (unless there is a risk of hypoglycaemia).

4.8 Undesirable effects

Hypoglycaemia occurs with all hypoglycaemic agents. Gastrointestinal disturbances (e.g.: nausea, vomiting, heartburn, anorexia, diarrhoea, metallic taste) are usually mild and dose dependant. Increased appetite and weight gain may occur, also rashes (usually hypersensitivity reactions), pruritus and photosensitivity. Severe manifestations of hypersensitivity include cholestatic jaundice, leucopenia, thrombocytopenia, aplastic anaemia, agranulocytosis, haemolytic anaemia, erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis and erythema nodosum. Infrequently a syndrome of inappropriate secretion of antidiuretic hormone may be induced.

4.9 Overdose

In acute poisoning the stomach should be emptied by emesis or lavage.

Hypoglycaemia should be treated urgently in the conscious patient with oral glucose. If the patient is comatose glucose should be administered as an intravenous infusion. Alternatively glucagon, administered in a dose of 1mg subcutaneously or intramuscularly may be used. The patient should be observed over several days in case hypoglycaemia recurs.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Glibenclamide is an orally active hypoglycaemic agent, which acts by stimulating insulin secretion.

ATC Code: A10BB01

5.2 Pharmacokinetic properties

Glibenclamide is rapidly absorbed and is extensively bound to plasma proteins, but is not readily displaced by acidic drugs. It is excreted as metabolites in the urine and bile.

5.3 Preclinical safety data

There are no pre-clinical data of any relevance to the prescriber, which are additional to those already included in other sections.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize Starch
Povidone K30
Magnesium stearate

6.2 Incompatibilities

None.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Polyethylene/polypropylene and glass containers: Do not store above 25° C. Store in the original container. Keep the container tightly closed.

Blister strips: Do not store above 25° C. Store in the original container. Keep in the outer carton.

6.5 Nature and contents of container

Polypropylene or polyethylene tablet container with polypropylene or polyethylene tamper evident closure containing 100, 500 or 1000 tablets

Glass container with plastic tamper evident closure containing 100, 500 or 1000 tablets.

White opaque blister (250μm UPVC 40gsm UPVDC) sealed with 20μm tempered aluminium foil. Tablets are packed in multiples of strips of 10, 14 or 28 tablets.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Activase Pharmaceuticals Limited,

11 Boumpoulinas,

P.C. 1060

Nicosia.

Cyprus

8 MARKETING AUTHORISATION NUMBER(S)

PL 28444/0148

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