Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Glibenclamide Tablets BP 5mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glibenclamide BP 5mg.

For excipients see 6.1

3 PHARMACEUTICAL FORM

Tablets.

White oval biconvex tablets, coded ‘GLI5’ and breakline on one side, twin triangle logo on the reverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A sulphonylurea hypoglycaemic in the treatment of maturity onset diabetes which is not adequately controlled by dietary measures, and does not require insulin therapy.

4.2 Posology and method of adminstration

Adults:

The final dosage regimen depends upon the individual requirements of the patient and is at the discretion of the physician.

Initial dosage is usually 2.5 to 5mg daily with slow increments until optimal control has been achieved, generally in the dose range 2.5 to 15mg daily.

If adequate control is not achieved with diet and this product alone, biguanide therapy may be combined with it.

(i) Elderly

In elderly patients who may be more liable to hypoglycaemia, treatment should start with 2.5mg glibenclamide per day.

(ii) Children

Non-insulin-dependant diabetes is not a disease of childhood and therefore glibenclamide is not recommended for use in children, infants or neonates.

(iii) Infants and Neonates

(see (ii) above).

(iv) Special Groups

In debilitated patients, who may be more liable to hypoglycaemia, treatment should start with 2.5mg glibenclamide per day. Hepatic or renal dysfunction may require a reduction in dosage.

Route of Administration

Oral.

4.3 Contraindications

1. Use in the presence of ketoacidosis, or severe renal, hepatic, thyroid or adrenal dysfunction.

2. Use in patients with sulphonylurea or sulphonamide intolerance.

3. Use in 'brittle' or juvenile diabetes.

4. Use in pregnancy.

5. Use in children.

4.4 Special warnings and special precautions for use

1. Adjustment of dosage of hypoglycaemic agents may be required in patients suffering from intercurrent infections, trauma, shock or anaesthesia.

2. For major surgery, insulin therapy should be substituted for oral hypoglycaemics.

3. Hepatic or renal dysfunction may require reduction in dosage.

4.5 Interaction with other medicinal products and other forms of interaction

1. Potentiation of the hypoglycaemic action of the drug may occur with concomitant administration of sulphonamides, salicylates, phenylbutazone, coumarin anti-coagulants, β-adrenoceptor blocking agents, mono-amine oxidase inhibitors, ACE inhibitors, cyclophosphamide, chloramphenicol, tuberculostats.

2. Diminution of this action may occur with the concomitant administration of thiazide diuretics, ethacrynic acid, frusemide, oestrogens and corticosteroids.

4.6 Pregnancy and lactation

There is no information of the use of glibenclamide in pregnancy, but it has been in wide general use for many years without apparent ill consequence. Its use in pregnancy should only be considered after the benefits have been weighed against the risks. It is not known whether glibenclamide is excreted in breast milk but other sulphonylureas are. Glibenclamide should not be taken by mothers who are breast feeding.

4.7 Effects on ability to drive and use machines

No adverse effect on ability to drive or use machines is expected in well-controlled patients, but patients should be warned about the possible adverse effects of hypoglycaemia.

4.8 Undesirable effects

Hypoglycaemia, gastro-intestinal disturbance and allergic skin reactions. Reversible leucopenia and thrombocytopenia

have been reported, as have changes in liver function tests and enzyme levels. Fever may occur.

4.9 Overdose

Hypoglycaemia may be treated in conscious patients with oral glucose or 3 to 4 lumps of table sugar with water. This may be repeated as necessary. If the patient is comatose, glucose should be given by IV infusion. Bolus glucose injections may be given but can cause rebound hypoglycaemia. Alternatively, glucagon may be administered in a dose of 1mg SC or IM to restore consciousness. Once consciousness is restored the patient can be given glucose or a mixed carbohydrate meal (containing slowly assimilated carbohydrate).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A sulphonylurea hypoglycaemic agent rapidly absorbed and exerting its effect within 3 hours with a duration of up to 15 hours although the T½ of the drug is 5-10 hours.

5.2 Pharmacokinetic properties

The drug is metabolised extensively in the liver and excreted via bile and urine. It is strongly protein bound.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Maize Starch
Pregelatinised Starch
Talc
Colloidal Silicon Dioxide
Magnesium Stearate

6.2 Incompatibilities

None known.

6.3 Shelf Life

The shelf life expiry date of this product shall not exceed 3 years from the date of its manufacture.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

A polypropylene tubular tablet container with an open end equipped to accept a polyethylene cap, with a tamper-evident tear strip of the appropriate size to accommodate 100, 500 or 1,000 tablets.

6.6 Instructions for use and handling

None.

7 MARKETING AUTHORISATION HOLDER

McDermott Laboratories Limited
(trading as Gerard Laboratories)
Baldoyle Industrial Estate
Grange Road
Dublin 13
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 577/15/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 21st June 2001

10 DATE OF REVISION OF THE TEXT

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