Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rimatase Chlorpropamide Tablets BP 250mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorpropamide Ph. Eur. 250 mg

For excipients see 6.1

3 PHARMACEUTICAL FORM

Tablet.

Round, white biconvex embossed ‘RIMA’ on one surface and with a breakline on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an oral hypoglycaemic for use in the management of uncomplicated maturity onset diabetes which is not adequately controlled by dietary methods alone and does not require insulin therapy.

4.2 Posology and method of adminstration

For oral administration.

Adults only:

The usual initial dose is 125-250mg daily in a single dose with breakfast with subsequent increments after 5-7 days of 50 (half of 100mg tablet) to 125mg until optimal control is obtained. The usual daily maintenance dose is 100-250mg. Response is usually not improved by dosage in excess of 500mg daily.

The elderly patients should be started on lower doses of 100-125mg daily.

4.3 Contraindications

None stated.

4.4 Special warnings and special precautions for use

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

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

Hepatic and renal dysfunction may require reduction in dosage.

Chlorpropamide has a duration of up to 24 hours and begins to exert an effect 1-3 hours post dose.

Patients for whom sulphonylurea therapy is intended should be carefully selected, and limited to those who cannot be controlled on dietary measures alone, do not require insulin, and do not suffer from those disorders, the course of which might be affected by this therapy.

4.5 Interaction with other medicinal products and other forms of interaction

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

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

Alcohol should be avoided since a disulfiram-like reaction may occur.

4.6 Pregnancy and lactation

None stated.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Side effects are usually dose-related and transient, and include nausea, vomiting, epigastric pain, dizziness, weakness, paraesthesia and headache. Sensitivity reactions with fever, eosinophilia, jaundice, skin rashes and blood dyscrasias, including leucopenia, thrombocytopenia, aplastic anaemia, and agranulocytosis have occurred.

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sulphonylurea which reduces blood sugar concentration.

5.2 Pharmacokinetic properties

It is readily absorbed from the gut, reaching peak concentration 2-4 hours later. It is extensively bound to plasma proteins and has a half-life of approximately 35 hours. Excretion is predominantly through the urine.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone
Sodium starch glycollate (Type A)
Magnesium stearate
Starch (Maize)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep in the original container. Keep the container tightly closed.

6.5 Nature and contents of container

White polypropylene containers with a tamper-evident lids.
(1000), (500), (100) and (50) tablets.

6.6 Instructions for use and handling

No special precautions required.

7 MARKETING AUTHORISATION HOLDER

Ranbaxy Ireland Ltd.
Spafield
Cork Road
Cashel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 408/15/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th April 1988
Date of last renewal: 8th April 2003

10 DATE OF REVISION OF THE TEXT

April 2002