Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rimarin Chlorphenamine Tablets BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablets contains chlorphenamine maleate 4 mg.

For Excipients, see 6.1

3 PHARMACEUTICAL FORM

Tablet.

Round, yellow, biconvex tablet marked RIMA on one face and with a breakline on the reverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of allergic conditions and reactions.

4.2 Posology and method of adminstration

For oral administration only.

Adults: The usual dose is 4 mg (1 tablet) 3 to 4 times daily.

Children 6 to 12 years: 2 mg (one half tablet) 3 to 4 times daily.

4.3 Contraindications

Use in patients hypersensitive to the active ingredient.

4.4 Special warnings and special precautions for use

Use with care in epileptic patients.

4.5 Interaction with other medicinal products and other forms of interaction

The effects of anti-cholinergics, e.g. some psychotropic drugs and atropine may be potentiated by this product. The product may potentiate the effects of alcohol and other central nervous system depressants.

4.6 Pregnancy and lactation

This product should not be used during pregnancy unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

This product causes drowsiness. Patients receiving Chlorphenamine should not drive or operate machinery unless it has been shown that their physical and mental capacity remains unaffected.

4.8 Undesirable effects

This product may give rise to tachycardia, mouth dryness, gastro-intestinal disturbances e.g. colic, urinary retention and headache.

This product may act as a cerebral stimulant in children and occasionally in adults, giving rise to insomnia, nervousness, hyperpyrexia, tremors and should be used with care in epileptic patients.

4.9 Overdose

The estimated lethal dose of Chlorphenamine Maleate is 25-50 mg per kg body weight. Treatment should include gastric lavage. In the event of convulsions, sedate with intramuscular paraldehyde. Severe respiratory depression may necessitate mechanical ventilation. Severe hypotension may require fluid replacement.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorphenamine acts as an antihistamine, probably by occupying the receptor sites in the effector cells to the exclusion of histamine. It is a histamine H_1 receptor antagonist which can effectively block most of the actions of histamine in the body, but has no effect on the stimulating action of histamine on the secretion of gastric acid.

5.2 Pharmacokinetic properties

Alkylamine derivative with a plasma half life of up to 42 hours which is extensively metabolised and excreted almost exclusively in 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 200#
Maize starch
Quinoline yellow
Povidone (K30)
Purified water
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Polypropylene/polyethylene containers and tamper evident closures.
Pack sizes: 50, 100, 500 and 1000 tablets.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA 408/19/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th July 1988
Date of last renewal: 18th July 2003

10 DATE OF REVISION OF THE TEXT

June 2005