Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rimapen Penicillin VK 250 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 250 mg of phenoxymethylpenicillin as Phenoxymethylpenicillin Potassium.

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

Round white biconvex film coated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of mild to moderately severe infections due to penicillin sensitive organisms.

4.2 Posology and method of adminstration

For Oral administration.

Adults: 250mg 6 times daily.
Children 6-12 years: 125-250mg 6 times daily.

4.3 Contraindications

Use in patients with a known hypersensitivity to penicillins.

4.4 Special warnings and special precautions for use

Prolonged use of an anti-infective may lead to super-infection by resistant micro-organisms such as Proteus, Pseudomonas and Candida.

4.5 Interaction with other medicinal products and other forms of interaction

The excretion of phenoxymethylpenicillin in urine is retarded by probenecid as is the case for all penicillins.

4.6 Pregnancy and lactation

The product should not be used during pregnancy unless considered essential by the physician. The product is excreted in breast milk, presenting the risk of candidiasis and also of central nervous system toxicity due to prematurity of the blood brain barrier. There is a theoretical possibility of later sensitization.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Side effects include maculopapular rashes, urticaria and other evidence of hypersensitivity, gastrointestinal disturbances, and diarrhoea. Transient induction of liver enzymes occurs occasionally and pseudomembranous colitis has been reported in a few cases.

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Penicillin is bactericidal, interfering with cell wall synthesis.

5.2 Pharmacokinetic properties

The potassium salt is absorbed more readily from the gastrointestinal tract than the free acid resulting in higher serum concentrations. Absorption is usually rapid. 20-35% of a dose is excreted in the urine in 24 hours.

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
Povidone 30
Povidone CL
Magnesium Stearate
Starch (Maize)

Constituents of film-coat:

Talc
Titanium Dioxide
Macrogol 4000
Triethylcitrate
Eudragit RL 30D (a copolymer of acrylic and methacrylic acid esters)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Polypropylene/polyethylene containers and tamper evident closures.
1000, 500 and 100 tablets.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA 408/9/1

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 2003