Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rimadol Paracetamol Capsules 500mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 500mg of Paracetamol.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Hard capsule

Size 0 hard gelatin capsules with opaque red caps and opaque white bodies, containing white or off-white granules.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an analgesic for the treatment of mild to moderate pain. As an antipyretic.

4.2 Posology and method of adminstration

Oral administration

Adults and children over 12 years:
The usual dose is 1-2 capsules 3-4 times daily. A maximum dose of 8 capsules daily should not be exceeded.

4.3 Contraindications

Not suitable for children under 12 years of age.

4.4 Special warnings and precautions for use

Paracetamol should be given with care to patients with impaired kidney or liver function. Paracetamol should also be given with care to patients taking other drugs that affect the liver.

4.5 Interaction with other medicinal products and other forms of interaction

Where Paracetamol is taken regularly or in high doses and oral anticoagulants such as Warfarin are administered concurrently potentiation of the oral anti-coagulant may occur.

Paracetamol and Cholestyramine administered together may result in reduced absorption of the Paracetamol.
Paracetamol and Metoclopramide administered concurrently may result in potentiation of the Paracetamol.

4.6 Pregnancy and lactation

Paracetamol, like all other drugs, should be avoided if possible during pregnancy but especially during the first

trimester. Where Paracetamol is taken during pregnancy, the smallest effective dose should be used.

There is no evidence of harm where Paracetamol is or had been taken during breast-feeding. However, in cases where Paracetamol has been taken by nursing mothers, significant amounts have been found in breast milk. Therefore it should be avoided where possible, as children have less capacity for Paracetamol breakdown than adults.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Side effects of paracetamol are usually mild, though haematological reactions have been reported. Skin rashes and other allergic reactions including anaphylaxis occur occasionally. Prolonged use of Paracetamol may cause renal damage.

4.9 Overdose

Symptoms of overdose include vomiting, gastro intestinal haemorrhage, liver damage, cerebral oedema, and renal tubular necrosis. It should be noted that patients who have taken an overdose of Paracetamol may appear well for the first three days then succumb with liver damage. The hepatic changes produced by overdose with Paracetamol result from the accumulation of a highly reactive intermediate metabolite in the hepatocytes. N-Acetyl Cysteine intravenously or Methionine orally protects the liver if administered within 10-12 hours of ingesting the overdose. N-Acetyl Cysteine is effective up to and possibly beyond 24 hours but expert advice is essential.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol has analgesic and anti-pyretic effects but has only weak anti-inflammatory effects. These actions are considered to be due to inhibition of the biosynthesis of prostaglandins.

5.2 Pharmacokinetic properties

Para aminophenol derivative well absorbed from the gut, metabolised in the liver and excreted in urine as glucuronide and sulphate conjugates. Half-life is 1-4 hours.

5.3 Preclinical safety data

Paracetamol is well established for its pharmacological and toxicological properties. There are no pre-clinical issues of concern.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize, Starch
Lactose Monohydrate
Polyvidone
Sodium Starch Glycollate
Magnesium Stearate

Capsule shell body:
Titanium Dioxide (E171)

Gelatin

Capsule shell cap:
Erythrosin (E127)
Indigotine (E132)
Titanium Dioxide (E171)
Gelatin

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

12 months.

6.4 Special precautions for storage

Do not store above 25°C.
Keep the containers tightly closed (container pack only).
Store in the original package (blister pack only).
Keep all medicines out of the reach of children.

6.5 Nature and contents of container

Polypropylene tablet containers with tamper evident polyethylene caps.
Pack sizes: 25, 50, 100, 250, 500, 1000 and 5000.

Blister packs consisting of white PVC aluminium foil.
Pack size: 24

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special precautions required.

7 MARKETING AUTHORISATION HOLDER

Ranbaxy Ireland Ltd
Spafield
Cork Road
Cashel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 408/4/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 October 1992
Date of last renewal: 27 October 2002

10 DATE OF REVISION OF THE TEXT

June 2003