Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rimaprin Aspirin Tablets BP 300mg.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Acetylsalicylic Acid/Aspirin BP 300mg.

3 PHARMACEUTICAL FORM

Round, white biconvex tablets marked “RA 300” on one face and plain on the reverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of symptoms associated with headache, rheumatic, muscular or neuralgic pain, toothache, common cold, influenza, fever.

4.2 Posology and method of adminstration

Oral administration.

Adults only:
1-2 tablets every 4 hours as required, to a maximum of 10 tablets in any 24 hour period, unless specifically instructed by the physician.

Do not give to children and adolescents aged under 16 years, except on medical advice, where the benefit outweighs the risk.

4.3 Contraindications

Aspirin is contra-indicated in patients with gastro-intestinal ulceration, hypoprothrombinaemia in haemophiliacs, and in patients undergoing concurrent anti-coagulant therapy. It is also contra-indicated in the case of hypersensitivity to Aspirin or to non-steroidal anti-inflammatory drugs. Aspirin is contra-indicated for children under 12 years unless under medical advice. Extreme caution should be taken and Aspirin administration should be restricted in patients with liver disease.

4.4 Special warnings and special precautions for use

Certain individuals display intolerance to Aspirin and other non-steroidal anti-inflammatory agents, this is manifested by symptoms that range from vasomotor rhinitis with profuse watery secretions, angioneurotic oedema, generalised urticaria, and bronchial asthma to laryngeal oedema and bronchoconstriction, hypotension, shock, loss of consciousness, and complete vasomotor collapse. While rare in children, this syndrome may occur in 20 to 25% of middle aged patients with asthma, nasal polyps or chronic urticaria. Prolonged administration of large doses of Aspirin can lead to renal papillary necrosis.

There is a possible association between aspirin and Reye’s syndrome when given to children. Reye’s syndrome is a very rare disease, which affects the brain and liver, and can be fatal. For this reason aspirin should not be

given to children and adolescents aged under 16 years unless specifically indicated.

4.5 Interaction with other medicinal products and other forms of interaction

Aspirin causes potentiation of anti-coagulants, such as Warfarin, also Heparin, Phenindione, Phenytoin. The haemorrhagic effects of Aspirin on the gastric mucosa may be enhanced by anti-coagulants. Aspirin causes delayed excretion and increased toxicity of Methotrexate. It causes inhibition, diminishing the effects of Probenecid and Sulphinpyrazone. Some of the effects of Aspirin are enhanced by alcohol.

Barbiturates and other sedatives may mask the respiratory symptoms of Aspirin overdosage and have been reported to enhance its toxicity.

4.6 Pregnancy and lactation

There is no evidence that moderate therapeutic doses of salicylates cause foetal damage in human beings, although babies born in women who ingest salicylates chronically may have significantly reduced weights at birth. In addition, there is a definite increase in prenatal mortality, anaemia, ante partum and post partum haemorrhage, prolonged gestation and complicated deliveries.

Aspirin should be avoided during the last three months of pregnancy.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

The most common side effects is a propensity to induce gastric or intestinal ulceration that can sometimes be accompanied by a secondary anaemia from the resultant blood loss. Other side effects include disturbances in platelet function, increases in bleeding time and the prolongation of gestation or spontaneous labour.

4.9 Overdose

In severe poisoning, there is usually a metabolic acidosis or alkalosis with symptoms of stimulation of the central nervous system. These may progress until delirium and convulsions occur, followed later by signs of depression of the central nervous system with coma and death. There is severe pyrexia.

In the emergency treatment of salicylic acid poisoning, unabsorbed salicylate is removed from the stomach by gastric lavage. Electrolyte and acid base balance should be monitored regularly.

Adequate amounts of intravenous fluids must be given promptly. The type and amount of solutions to be employed depend on the interpretation of the laboratory data on acid base balances. If the patient presents with an acidosis, correction of the low blood pH is essential. Bicarbonate solution should be infused intravenously; if possible, in sufficient quantity to maintain alkaline diuresis.

Administration of Glucose is also essential for complete control of the metabolic acidosis.

If potassium deficiency occurs, it should be treated by the addition of the cation to the intravenous fluids once it has been established that urine formation is adequate. Plasma transfusion may be beneficial especially if the shock syndrome intervenes.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Aspirin has analgesic, anti-pyretic, and anti-inflammatory actions. It acts by acetylating a serine at the active site of the enzyme cyclo-oxygenase, and thus inhibiting the production of prostaglandins.

5.2 Pharmacokinetic properties

Aspirin is absorbed rapidly - mainly from the upper small intestine. Appreciable concentrations are found in plasma in less than 30 minutes. After a single dose, a peak value is reached in about 2 hours and then gradually declines. It is distributed throughout most body tissues and most transcellular fluids. The rate of excretion varies with the pH of the urine. Aspirin is excreted as salicylic acid and as glucuronide conjugates and as salicyluric and gentisic acids.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose (E460 (i))
Starch (maize)
Talc (E553 (b))

6.2 Incompatibilities

None stated.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Keep tightly closed.
Do not store above 25°C.

6.5 Nature and contents of container

Blister packs; PVC and aluminium foil 24 tablets.

Polypropylene tamper evident containers: 25, 50, 100, 500, 1000, 5000 tablets.

6.6 Instructions for use and handling

None stated.

7 MARKETING AUTHORISATION HOLDER

Ranbaxy Ireland Limited
Spafield

Cork Road
Cashel
Co Tipperary

8 MARKETING AUTHORISATION NUMBER

PA 408/24/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th February 1991
Date of last renewal: 11th February 2001

10 DATE OF REVISION OF THE TEXT

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