Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aspro Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Acetylsalicylic acid (Aspirin) 320 mg/tablet.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
White to creamy white biconvex circular tablets. One side is impressed with the word ‘Aspro’, the letters being radially arranged around the periphery. The other face is bisected with a breakline.

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 administration

Posology: Oral.

Adults: Adults and children over 12 years: one to two tablets every four hours as required. Do not exceed twelve tablets in 24 hours unless directed by a doctor.

Elderly: Aspirin should be used with particular caution in elderly patients who are more prone to adverse events. The lowest dose compatible with adequate safe clinical control should be employed. See also Section 4.4.

Children: Do not give to children under 12 unless your doctor tells you to.

4.3 Contraindications

Active peptic ulceration.
As aspirin can interfere with platelet function, aspirin should not be used in patients with bleeding diatheses such as haemophilia.
History of hypersensitivity reactions (bronchospasm, rhiniris and urticaria) to aspirin, other non-steroidal anti-inflammatory drugs or any of the ingredients.

4.4 Special warnings and precautions for use

Prolonged use except under medical supervision can be harmful. If symptoms persist, the physician should be consulted.

If you are taking any other medications or are under the care of a doctor you should consult the physician before using.

If symptoms persist consult your doctor**.**

In patients with renal, cardiac or hepatic impairment, caution is required since the use of non steroidal anti-inflamatory drugs (NSAIDs) may result in deterioration of renal function. Assessment of renal function should occur prior to the initiation of therapy and regularly thereafter.

Elderly patients are particularly susceptible to the adverse effects of NSAIDs. Prolonged use of NSAIDs in the elderly is not recommended. Where prolonged therapy is required, patients should be reviewed regularly.

Aspro should be used with caution in patients with a history of peptic ulceration.

Use with caution in patients with gout.

4.5 Interaction with other medicinal products and other forms of interaction

IT IS CONSIDERED UNSAFE TO TAKE NSAIDs IN COMBINATION WITH WARFARIN OR HEPARIN UNLESS UNDER DIRECT MEDICAL SUPERVISION.
Care should be taken in patients treated with any of the following drugs as interactions have been reported:

ACE (angiotensin converting enzyme) inhibitors and beta-blockers: reduced anti-hypertensive effect.

Diuretics: reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

Methotrexate: decreased elimination of methotrexate.

Other NSAIDs: avoid concomitant use of two or more NSAIDs.

Corticosteroids: increased risk of gastrointestinal bleeding.

Probenecid: reduction in metabolism and elimination of NSAID and metabolites.

Oral hypoglycemic agents: inhibition of metabolism of sulfonylurea drugs, prolonged half-life and increased risk of hypoglycaemia.

4.6 Pregnancy and lactation

There is clinical and epidemiological evidence of safety of aspirin in pregnancy, but it may prolong labour and contribute to maternal and neo-natal bleeding so it is best avoided at term. Breast feeding is contraindicated at high doses due to the theoretical risk of affecting clotting mechanisms.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Aspirin may precipitate bronchospasm and induce asthmatic attacks in susceptible subjects. It may induce gastro-intestinal haemorrhage, occasionally major.

4.9 Overdose

Gastric lavage, forced alkaline diuresis and supportive therapy may be employed. Restoration of acid-base balance may be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Aspirin - Analgesic, Anti-Pyretic, Anti-Inflammatory.

5.2 Pharmacokinetic properties

The biological half-life of Aspirin is reported at 2-3 hours after a single dose, but appears to be nearer 10 hours after multiple 1 g doses.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potato starch
Sodium lauryl sulphate
Colloidal anhydrous silica

6.2 Incompatibilities

None.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium Foil/PVC Film Blister Packs.
Pack sizes: 10 or 20 tablets.

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

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Bayer plc
Bayer House
Strawberry Hill
Newbury
Berkshire RG14 1JA
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 21/58/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1978

Date of last renewal: 01 April 2003

10 DATE OF REVISION OF THE TEXT

July 2005