

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aspirin (Acetylsalicylic acid) Tablets 300 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 300mg of Aspirin (also known as acetylsalicylic acid)

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Tablet

White, circular, biconvex plain tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of mild to moderate pain in headaches, toothache and neuralgia.

For reduction of temperature.

For reduction of inflammation in lumbago.

4.2 Posology and method of administration

Adults only: 300mg to 600mg three to four times daily.

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

Elderly: Non steroidal anti-inflammatory drugs should be used with particular caution in elderly patients who are more prone to adverse events. The lowest dose compatible with adequate clinical control should be employed. See also section 4.4.

Route of administration

Oral.

4.3 Contraindications

Hypersensitivity to any of the ingredients or to other non-steroidal anti-inflammatory drugs.

Not to be taken by children under 12 years, unless on medical advice.

4.4 Special warnings and special precautions for use

- i) Aspirin may precipitate bronchospasm and induce attacks of asthma or hypersensitivity in susceptible subjects.
- ii) If the person is taking any other medicine or is under doctor's care, he should consult the physician before using aspirin.
- iii) Prolonged use except under medical direction may be harmful.
- iv) Interference with laboratory tests: Salicylates may produce falsely increased results for blood creatinine, urate (low dose aspirin) and urea. Falsely decreased results may be obtained for blood thyroxine and urate (>4g/day aspirin) and for urinary 5-HIAA (with nitrosonaphthol method). Urinary VMA (HMMA) levels may be falsely increased or decreased depending on the method of analysis.
- v) There is 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

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.

Anti-hypertensives: reduced anti-hypertensive effect.

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

Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycoside levels.

Lithium: decreased elimination of lithium.

Methotrexate: decreased elimination of methotrexate.

Cyclosporin: increased risk of nephrotoxicity with NSAIDs.

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

Corticosteroids: increased risk of gastrointestinal bleeding.

Aminoglycosides: reduction in renal function in susceptible individuals, decreased elimination of aminoglycoside and increased plasma concentrations.

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

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

4.6 Pregnancy and lactation

Although clinical and epidemiological evidence would suggest the safety of aspirin for use during pregnancy, caution should be exercised when prescribing for pregnant patients. Aspirin may prolong labour and contribute to maternal and neonatal bleeding and it is best avoided at term.

Usage in nursing mothers: As aspirin is excreted into breast milk, aspirin should not be taken by patients who are breast feeding.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Aspirin is harmful to the gastric mucosa, increases the incidence of mucosal lesions (erosions, ulcers or both) and promotes gastric bleeding. Long-term use increases the risk of sudden massive haemorrhaging. Aspirin may also induce hypersensitivity, asthma, urate kidney stones, tinnitus, nausea and vomiting.

4.9 Overdose

Overdosage produces dizziness, tinnitus, sweating, nausea and vomiting, confusion and hyperventilation. Gross overdosage may lead to CNS depression with coma, cardiovascular collapse and respiratory depression. If overdosage is suspected, the patient should be kept under observation for at least 24 hours, as symptoms and salicylate blood levels may not become apparent for several hours. Treatment of overdosage consists of gastric lavage and forced alkaline diuresis. Haemodialysis may be necessary in severe cases.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

As an antipyretic aspirin, like many related drugs, acts on the heat-regulating centres of the brain to bring about a dissipation of body heat through cutaneous vasodilatation. The usual dose of aspirin as an analgesic and antipyretic is 0.3 to 1g which may be repeated according to clinical needs, up to a maximum of 4g daily.

Aspirin is used in the treatment of acute and chronic rheumatic states. Maximum suppression of rheumatic symptoms occurs with plasma concentrations of about 300 µg per ml. These concentrations are frequently associated with mild toxic effects such as nausea and tinnitus; adequate control of rheumatic symptoms may often be achieved with lower concentrations. In chronic rheumatic disease, 300 to 900 mg is administered every 4 hours over long periods. In acute rheumatism, 4-8 g daily in divided doses is sometimes recommended. Doses of 150 mg per kg body weight daily have been given initially.

5.2 Pharmacokinetic properties

Aspirin is readily absorbed from the gut and rapidly distributed to all body tissues, into breast milk and crosses the placenta. Protein binding is extensive. The rate of excretion varies with urinary pH, increasing as this rises.

5.3 Preclinical safety data

No information submitted.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Starch Maize

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Blister:

Do not store above 25°C.

Store in the original package.

6.5 Nature and contents of container

Blister packs consisting of clear PVC and 20µm hard temper aluminium foil contained in a carton.

Pack sizes: 10, 20, 30 and 50 tablets.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Chanelle Medical Limited

Loughrea

Co. Galway

8 MARKETING AUTHORISATION NUMBER

PA 688/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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