Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aspirin EC 300mg, gastro-resistant tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 300 mg aspirin (acetylsalicylic acid).

This product contains lactose monohydrate (60mg/tablet).

For the full list of excipients, see sections 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet.

Round, biconvex white or almost white tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Acetylsalicylic acid EC 300mg, gastro-resistant tablets have analgesic, antipyretic and anti-inflammatory actions.

Acetylsalicylic acid EC 300mg gastro-resistant tablets are furthermore indicated to reduce the risk of myocardial infarction in patients who have had a previous attack or in patients with unstable angina and to reduce the risk of occlusive stroke and recurrent cerebral transient ischaemic attacks in patients with a history of such thrombotic events.

This product is indicated wherever high and prolonged dosage of aspirin is required. The special coating resists dissolution in gastric juice but will dissolve readily in the relatively less acid environment of the duodenum. Owing to the delay that the coating imposes on the release of the active ingredient, this product is unsuitable for the short-term relief of pain.

4.2 Posology and method of administration

Method of administration
The tablets have to be swallowed whole with water.
Dosage:
Acetylsalicylic acid EC 300mg, gastro-resistant tablets are for oral administration to adults only.
Analgesic, antipyretic and anti-inflammatory actions: 300-600mg repeated three to four times daily according to clinical needs. In acute rheumatic disorders the dose is in the range of 4-8g daily, taken in divided doses.
Anti-thrombotic action: The recommended dose is 300mg daily.

The elderly: analgesic, antipyretic and anti-inflammatory actions: As for adults. 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

Treatment should be reviewed at regular intervals. Where aspirin is intended for analgesic or anti-inflammatory use, treatment should be discontinued if no benefit is seen.
Children: Acetylsalicylic acid should not be given to children under 12 years.

4.3 Contraindications

Hypersensitivity (e.g. bronchospasm, rhinitis, urticaria) to aspirin or to non-steroidal anti-inflammatory drugs, hypoprothrombinaemia, haemophilia, cerebral haemorrhage and active peptic ulceration.

4.4 Special warnings and precautions for use

Undesirable effects associated with NSAIDs may be reduced by using the minimum effective dose for the shortest possible duration. Patients treated with NSAIDs long-term should undergo regular medical supervision to monitor for adverse events.

Aspirin should not be given to children, particularly those under 12 years, unless the expected benefits outweigh the possible risks. Aspirin may be a contributory factor in the causation of Reye's syndrome in some children.

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

Aspirin should be used with caution in patients with a history of peptic ulceration or inflammatory bowel disease or coagulation abnormalities. They may also induce gastro intestinal haemorrhage, occasional major.

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

In patients with strokes, aspirin should not be given until the possibility of cerebral haemorrhage has been excluded.

Patients with hypertension should be carefully monitored.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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

Antacids: patients using enteric coated aspirin should be advised against ingesting antacids simultaneously to avoid premature drug release.

4.6 Fertility, pregnancy and lactation

Usage in pregnancy: Aspirin does not appear to have teratogenic effects. However, prolonged pregnancy and labour, with increased bleeding before and after delivery, decreased birth weight and increased rate of stillbirth were reported with high blood salicylate levels. Aspirin should be avoided during the last 3 months of pregnancy.

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

4.7 Effects on ability to drive and use machines

It is unlikely that the use of acetylsalicylic acid will influence the ability to drive and use machines.

4.8 Undesirable effects

Salicylates may induce hypersensitivity (urticaria, rash, angio-oedema, rhinitis, bronchospasm and anaphylactic shock) urate kidney stones, chronic gastro-intestinal blood loss, tinnitus, nausea and vomiting.

4.9 Overdose

Moderate overdose produces dizziness, confusion, tinnitus, sweating, headache, gastro-intestinal symptoms (nausea, vomiting, gastralgia). Severe intoxication may lead to CNS depression with coma, cardiovascular collapse and severe disturbance of the body acid/base equilibrium. This leads via hyperventilation to respiratory alkalosis. Because of the suppressant effect on the respiratory centre a metabolic acidosis can occur. The presence of salicylate causes also a metabolic acidosis. Because young children are mostly observed in a late stage of intoxication they are usually already acidotic.

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

Effect: Acetylsalicylic acid is a prostaglandin-synthetase-inhibitor and has antipyretic, analgesic and also anti-inflammatory properties. It also inhibits platelet aggregation. This anti-thrombotic effect is caused by acetylation of the enzyme cyclo-oxygenase in the platelet, inhibiting the production of the prostaglandin thromboxane A2. Because of the inhibition of platelet aggregation by acetylsalicylic acid the bleeding time is extended. The influence on platelet aggregation is present at low doses and lasts for about 4-6 days after the discontinuation of the treatment.

5.2 Pharmacokinetic properties

Absorption: After oral administration of acetylsalicylic acid it is rapidly absorbed in the proximal part of the duodenum. The maximum plasma concentration is reached after 0.5 - 2 hours. A substantial part of the dose undergoes hydrolysis in the intestinal mucosa during absorption. Simultaneous intake of food inhibits the rate of absorption (lower plasma concentration) but it does not influence the amount of acetylsalicylic acid absorbed.

Distribution: The distribution volume of acetylsalicylic acid is 0.16 1/kg bodyweight. The first degradation product of acetylsalicylic acid, the anti-inflammatory active salicylic acid, is bound more 90% to plasma-protein, mostly albumin. Salicylic acid diffuses slowly to the synovia and synovial fluid. It passes the placenta and enters breast milk.

Biotransformation: Acetylsalicylic acid is primarily metabolised by hydrolysis into salicylic acid. The t½ of acetylsalicylic acid is short, about 15-20 minutes. Salicylic acid is subsequently transferred into glycine- and glucuronic acid conjugates and traces of gentisic acid.

At higher therapeutic doses the capacity or degradation to salicylic acid becomes saturated resulting in non-linear pharmacokinetics. This results in an apparent extension of the t½ elimination of salicylic acid from several hours to about one day.

Excretion: Excretion takes place mainly through the kidneys. Tubular reabsorption of acetylsalicylic acid is pH-dependent. The amount of excreted unchanged acetylsalicylic acid in the urine can raise from about 10% to about 80% by alkalization of the urine.

5.3 Preclinical safety data

No special information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose-monohydrate
Cellulose
Silicon dioxide
Croscarmellose sodium
Stearic acid
Hypromellose
Polyethylene glycol
Triethyl citrate
Glycerin monostearate
Titanium dioxide (E171)
Polymethacrylic acid : methylmethacrylate 1:1
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

Keep the container tightly closed to protect from moisture.

6.5 Nature and contents of container

Polyethylene tablet container with a desiccant (silicagel) containing polypropylene cap, containing 100 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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

PCO Manufacturing Limited,
Unit 10, Ashbourne Business Park,
Rath,
Ashbourne,
Co Meath

8 MARKETING AUTHORISATION NUMBER

PA 465/57/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th July 2002

Date of last renewal: 17th July 2007

10 DATE OF REVISION OF THE TEXT

October 2012