SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Aspirin 300mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Aspirin 300 mg.
Excipient with known effect:
Each tablet also contains 18.0 mg of Lactose
For the full list of excipients see Section 6.1

3 PHARMACEUTICAL FORM

Tablet

White, round, uncoated tablets. They are biconvex (rounded on top and bottom) with a break line on one side and plain on the other side.

The break-line can be used to break the tablet for ease of swallowing but not to divide it into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Anti-inflammatory indications:

Symptomatic relief of sprains, strains, rheumatic pain, sciatica, lumbago, muscular aches, fibrositis, joint swelling and stiffness.

Analgesic and antipyretic indications:

Mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains, symptomatic relief of influenza and feverish colds.

4.2 Posology and method of administration

Posology

Adults & children over 16 years:
1 - 3 tablets every four hours, or as directed by a doctor.
Not more than 4 doses in 24 hours.
Elderly:
A lower dose is recommended.
Paediatric population:
Do not give to children aged under 16 years, unless Aspirin has been specifically prescribed for that child (e.g. for Kawasaki's disease).
Method of administration
The tablets to be taken orally with water.

4.3 Contraindications

Aspirin is contraindicated in patients with;

- Active peptic ulceration or a history of peptic ulceration.
- Haemophilia, haemorrhagic disease or a history of bleeding disorders. Gout or a history of gout.
- Hypersensitivity to aspirin (e.g. asthma, rhinitis, angioedema or urticaria), other NSAIDs or other tablet excipients
- Doses > 100 mg/day during the third trimester of pregnancy

4.4 Special warnings and precautions for use

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 under 16 years unless specifically indicated (e.g. for Kawasaki's disease).

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

Patients should be warned:

- not to exceed the stated dose.
- not to take aspirin if they have ever suffered from stomach ulcers.
- to keep medicines out of the reach of children.

Caution is required if administrated to patients suffering from, or with a previous history of bronchial asthma.

May produce haemolysis is some glucose-6-phoshate dehydrogenase deficient individuals.

4.5 Interaction with other medicinal products and other forms of interaction

Aspirin should not be used in combination with other NSAIDS as this may increase the risk of side-effects.
Aspirin should be used with caution in combination with:

- ACE Inhibitors and Angio-II Receptor Antagonists: due to risk of renal impairment and the hypotensive effect is antagonize
- Antacids : excretion of Aspirin is increased by alkaline urine due to some antacids.
- Anti-depressants, SSRI's: increased risk of bleeding
- Anticoagulants: the risk of bleeding is increased with Aspirin due to the antiplatelet effect.
- Corticosteroids: increased risk of gastrointestinal bleeding.
- Anti-epileptic drug (eg phenytoin, sodium valproate): will be enhanced by Aspirin.
- Diuretics: effect will be antagonised by aspirin.
- Gout treatments such as probenecid, sulphinpyrazone: will be antagonised by aspirin.
- Methotrexate: excretion can be reduced with increased risk of toxicity.
- Metoclopramide: may enhance the effect of aspirin.

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. However, the limitations of these data and the uncertainties extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use

4.6 Pregnancy and lactation

Pregnancy

Low doses (up to and100 mg/day):
Clinical studies indicate that doses up to 100 mg/day for restricted obstetrical use, which require specialised monitoring, appear safe.

Doses of above 100 mg/day- and up to 500 mg/day:
There is insufficient clinical experience regarding the use of doses above 100 mg/day up to 500 mg/day. Therefore, the recommendations below for doses of 500 mg/d and above apply also for this dose range.

Doses of 500 mg/day and above:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early

pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period. From the 20th week of pregnancy onward, acetylsalicylic acid use may cause oligohydramnios resulting from foetal renal dysfunction. This may occur shortly after treatment initiation and is usually reversible upon discontinuation. In addition, there have been reports of ductus arteriosus constriction following treatment in the second trimester, most of which resolved after treatment cessation. Therefore, during the first and second trimester of pregnancy, acetyl salicylic acid should not be given unless clearly necessary. If acetylsalicylic acid is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible. Antenatal monitoring for oligohydramnios and ductus arteriosus constriction should be considered after exposure to acetylsalicylic acid for several days from gestational week 20 onward. acetylsalicylic acid should be discontinued if oligohydramnios or ductus arteriosus constriction are found.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:
- cardiopulmonary toxicity (premature constriction/ closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction, (see above),
the mother and the neonate, at the end of pregnancy, to:
- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- inhibition of uterine contractions resulting in delayed or prolonged labour.
Consequently, acetylsalicylic acid at doses higher than 100 mg/day and contraindicated during the third trimester of pregnancy (see section 4.3). Doses up to and including 100 mg/day may only be used under strict obstetric monitoring.

Breast feeding*:*
Aspirin should not be taken when breast feeding as it impairs platelet function and increases the risk of haemorrhage to the baby, i.e. intracranial haemorrhage.

4.7 Effects on ability to drive and use machines

None Stated.

4.8 Undesirable effects

Adverse effects of aspirin treatment which have been reported include:

Blood and lymphatic system disorders	Anaemia may occur following chronic gastrointestinal blood loss or acute haemorrhage. Aspirin prolongs bleeding time, and bleeding disorders, such as epistaxis, purpura and intracranial haemorrhage have occasionally been reported.
Nervous system disorders	Mental confusion. Dizziness
Ear and labyrinth disorders	Hearing disturbances (such as tinnitus), vertigo
Respiratory, thoracic and mediastinal disorders	Aspirin may precipitate bronchospasm and induce asthma in susceptible patients. Dyspnoea also have been reported.
Gastrointestinal disorders	Gastric irritation, dyspepsia, nausea, vomiting, gastrointestinal erosions, ulcerations, gastritis. In some cases of intensive use may induce gastrointestinal haemorrhage, occasionally major, which may manifest as melaena or haematemesis.
General disorders and administration site conditions	Hypersensitivity reactions include skin rashes, urticaria and angioedema

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for the MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Salicylate poisoning is usually associated with plasma concentrations >350mg/L (2.5mmol/L). Most adult deaths occur in patients whose concentrations exceed 700mg/L (5.1 mmol/L). Single doses less than 100mg/kg are unlikely to cause serious poisoning.

Symptoms: Common features include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation. Some degree of acid-base disturbance is present in most cases. A mixed respiratory alkalosis and metabolic acidosis with normal or high arterial pH (normal or reduced hydrogen ion

concentration) is usual in adults and children over the age of four years. In children aged four years or less, a dominant metabolic acidosis with low arterial pH (raised hydrogen ion concentration) is common. Acidosis may increase salicylate transfer across the blood brain barrier.Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopenia, increased INR/PTR, intravascular coagulation, renal failure, and non-cardiac pulmonary oedema.Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.

Management: Give activated charcoal if an adult presents within one hour of ingestion of more than 250mg/kg. The plasma salicylate concentration should be measured, although the severity of poisoning cannot be determined from this alone and the clinical and biochemical features must be taken into account. Elimination is increased by urinary alkalinisation, which is achieved by the administration of 1.26% sodium bicarbonate. The urine pH should be monitored. Correct metabolic acidosis with intravenous 8.4% sodium bicarbonate (first check serum potassium). Forced diuresis should not be used since it does not enhance salicylate excretion and may cause pulmonary oedema.

Haemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations >700mg/L (5.1mmol/L), or lower concentrations associated with severe clinical or metabolic features. Patients under ten years or over 70 have an increased risk of salicylate toxicity and may require dialysis at an earlier stage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other analgesics and antipyretics -ATC Code: N02B A01
Aspirin has analgesic, anti-inflammatory and antipyretic actions due to inhibition of the biosynthesis of prostaglandins.

5.2 Pharmacokinetic properties

Absorption: Aspirin is rapidly absorbed after oral administration, with some hydrolysis to salicylate before absorption. Absorption is delayed by the presence of food and is impaired in patients suffering migraine attacks. Absorption is more rapid in patients with achlorhydria and also following administration of polysorbates and antacids.

Blood Concentration: Peak plasma concentrations of approximately 45mcg/ml are attained 1 to 2 hours after an oral dose of 650mg but stabilise at approximately 270mcg/ml after oral doses of 3g daily.

After an oral dose of about 2g, peak plasma concentrations approximately 15mcg/ml of aspirin are attained in about one hour and peak plasma concentrations of approximately 130mcg/ml of salicylate are attained in 2-4 hours.

Half life: Plasma / aspirin: approximately 17 minutes

Plasma / salicylate: low dose: 2-3 hours

high dose: up to 19 hours

Salicylates are extensively bound to plasma proteins; aspirin to a lesser degree. Aspirin and salicylates are rapidly distributed to all body tissues; they appear in milk and cross the placenta. The rate of excretion of aspirin varies with the pH of the urine, increasing as the pH rises and being greatest at pH 7.5 and above. Aspirin is excreted as salicylic acid and as glucuronide conjugate, and as salicyluric and gentisic acid.

5.3 Preclinical safety data

No data of relevance in addition to that already stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potato starch, anhydrous lactose and talc

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Vials or Securitainers of polyethylene containing 24 or 32 tablets.

Aluminium foil/PVC blisters of 24 or 32 tablets.

Not all pack sizes are marketed.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

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PL 08977/0022

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10 DATE OF REVISION OF THE TEXT

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