SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Aspirin 300mg Tablets BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains aspirin 300 mg

For excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablets

White, biconvex tablets; breakline on one side and debossed <A> on other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of mild to moderate pain, including headaches, migraine, neuralgia, toothache, sore throat, period pains, aches and pains.

For the symptomatic relief of influenza, feverishness, feverish colds.

For the symptomatic relief of sprains, strains, rheumatic pain, sciatica, lumbago, fibrositis, muscular aches and pains, joint swelling & stiffiness.

4.2 Posology and method of administration

For Oral use

Adults & children over 16 years of age:

One to three tablets.

Dose should not be repeated more frequently than 4 hour intervals and not more than 4 times in any 24 hour period.

If symptoms persist for more than 3 days, consult your doctor.

Do not give to children under 16 years, unless specifically indicated (e.g. for Kawasaki's Disease).

4.3 Contraindications

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

ii) Active peptic ulceration or a history of peptic ulceration

iii) Haemophilia, other coagulopathies or concurrent anticoagulant therapy.

iv) Hypersensitivity to aspirin, any other NSAIDs, or any of the excipients (See section 6.1)

v) Gout

4.4 Special warnings and precautions for use:

Caution should be exercised in patients-with asthma, allergic disease, impairment of hepatic or renal function (avoid if severe) and-dehydration.

The elderly may be more susceptible to the toxic effects of salicylates. Continuous, prolonged use of aspirin should be avoided in the elderly because of the risk of gastrointestinal bleeding.

Caution should be used in patients with glucose 6-phosphate dehydrogenase (G6PD) deficiency as haemolytic anaemia may occur.

Aspirin may interfere with insulin and glucagon in diabetes.

Aspirin prolongs bleeding time, mainly by inhibiting platelet aggregation and therefore it should be discontinued several days before scheduled surgical procedures.

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

Do not take if you have a stomach ulcer.

If symptoms persists for more than 3 days consult your doctor.

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

4.5 Interaction with other medicinal products and ether forms of interaction

Alcohol: Some of the effects of aspirin on the gastrointestinal tract are enhanced by alcohol.

Antacids and adsorbents: The excretion of aspirin is increased in alkaline urine; kaolin possibly reduces absorption.

Anticoagulants: Aspirin may enhance the effects of anticoagulants: concurrent use is contraindicated (see section 4.3)

Antiepileptics: May enhance the effects of phenytoin and sodium valproate.

Antimetabolites: The activity of methotrexate may be markedly enhanced and its toxicity increased.

ACE inhibitors: Aspirin may reduce the antihypertensive effect of ACE inhibitors.

Antibacterials: The toxicity of sulfonamides may be increased.

Antiemetics: Metoclopramide enhances the effects of aspirin by increasing the rate of absorption.

Corticosteroids: The risk of gastrointestinal bleeding and ulceration is increased. Corticosteroids reduce the plasma salicylate concentration.

Diuretics: Antagonism of the diuretic effect of spironolactone. Reduced excretion of acetazolamide with an increased risk of toxicity. Salicytate intoxication has occurred in patients on high dose salicylate regimens and carbonic anhydrase inhibitors.

Hypoglycaemic agents: Aspirin may enhance the effects of insulin and oral hypoglycaemic agents.

Leukotriene antagonists: The plasma concentration of zafirlukast is increased.

Mifepristone: The manufacturer of Mifepristone recommends that aspirin should be avoided until eight to twelve days after Mifepristone has been discontinued.

Other non-steroidal anti-inflammatory drugs (NSAIDS): Concurrent administration can increase side effects.

Thyroid function tests: Aspirin may interfere with thyroid function tests.

Uricosurics: Effect of probenecid and sulfinyrazone reduced.

4.6 Pregnancy and lactation

There is clinical and epidemiological evidence of the safety of aspirin in pregnancy.

Aspirin may prolong gestation, delay the onset of or prolong labour and may contribute to maternal and neonatal bleeding and is best avoided at term and during breast feeding - possible risk of Reye's syndrome.

Maternal use of aspirin prior to birth may increase the risk of intracranial haemorrhage in premature or low birth weight infants. Regular use of high doses could impair platelet function and produce hypoprothrombinaemia in the infant if neonatal Vitamin K stores are low. The use of aspirin during pregnancy may cause premature closure of the foetal ductus arteriosus and pulmonary hypertension.

4.7 Effects on ability to drive and use machines

Aspirin does not usually affect the ability to drive or operate machinery.

4.8 Undesirable effects

Side effects are generally mild and infrequent.

Blood disorders: Aspirin increases bleeding time, decreases platelet adhesiveness and, in large doses, may cause hypoprothrombinaemia. It may also cause other blood disorders including thrombocytopenia. Haemolytic anaemia can occur in patients with glucose 6-phosphate dehydrogenase deficiency (G6PD).

Immune System: Aspirin may precipitate bronchospasm, and induce asthma attacks, rhinitis, angioedema, or other hypersensitivity reaction in susceptible individuals.

Gastro-intestinal: There is a relatively high incidence of gastro-intestinal irritation with a slight asymptomatic blood loss.

Skin: Skin reactions may occur in susceptible patients.

4.9 Overdose

Salicylate poisoning is usually associated with plasma concentrations >35Omg/L (2.5mmol/L) Most adult deaths occur in patients whose concentrations exceed 700mg/L (5.1mmol/L). Single doses less than 100mg/kg are unlikely to cause serious poisoning.

a) 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.

b) Treatment

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 increased risk of salicylate toxicity and may require dialysis at an earlier stage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

N02B A01- (Nervous system- analgesics/ antipyretics)

Aspirin is an analgesic and antipyretic with anti-inflammatory properties. Aspirin inhibits prostaglandin synthetase.

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 640mg, but stabilise at approximately 270mcg/ml after oral doses of 3g daily. After an oral dose of about 2g, peak plasma concentrations of approximately l5mcg/ml of aspirin are attained in about one hour and peak plasma concentrations of approximately) 130mcg/ml of salicylate are attained in 2 to 4 hours.

Half-life

Plasma / Aspirin	Approximately 17 minutes
Plasma / Salicylate	Low doses 24 hours
	High doses up to 19 horns

Distribution

Aspirin is found in the saliva, milk, plasma and synovial fluid at concentrations less than blood and crosses the placenta.

Salicylate - extensive protein binding.

Aspirin - protein binding to a small extent.

Metabolism

In the blood, rapid hydrolysis to salicylic acid; glucuronic acid/ glycine conjugation to form glucuronides and salicyluronic acid; oxidation of a small proportion.

Excretion

Excreted in the urine mainly as salicyluronic acid, Salicylate reabsorbed by renal tubules in acid urine, and alkaline diuresis will increase the rate of excretion; 85% of dose excreted as free salicylate.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Starch

Lactose monohydrate

Purified Talc E553b

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

Blister packs: store in the original package.

6.5 Nature and contents of container

Blister Packs:

8, 10, 12 or 16 as GSL.

Blister Strips consists of a 35 gsm paper/9 µ soft tempered aluminium foil lid and 250 µ PVC film base in cartons.

6.6 Instructions for use, handling and disposal

None

7. MARKETING AUTHRISATION HOLDER

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HP41EG,

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8. MARKETING AUTHORISATION NUMER(S)

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