

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Aspirin Tablets BP 300mg

Aspirin 300 mg Tablets

Heritage Aspirin 300mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains active: Aspirin BP 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 specifically indicated (eg 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 administered to patients suffering from, or with a previous history of bronchial asthma.

May produce haemolysis in some glucose-6-phosphate 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 antagonized
- 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, sulphapyrazone: 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 Fertility, Pregnancy and lactation**

##### **Pregnancy**

Low doses (up to and including 100 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/day 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 is 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 known

## **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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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  $>350\text{mg/L}$  ( $2.5\text{mmol/L}$ ). Most adult deaths occur in patients whose concentrations exceed  $700\text{mg/L}$  ( $5.1\text{mmol/L}$ ). Single doses less than  $100\text{mg/kg}$  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  $250\text{mg/kg}$ . 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  $>700\text{mg/L}$  ( $5.1\text{mmol/L}$ ), 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 of non-ionised aspirin occurs in the stomach. Acetylsalicylates and salicylates are also readily absorbed from the intestine. Hydrolysis to salicylic acid occurs rapidly in the intestine and in the circulation. 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. Pre-clinical Safety Data**

No data of relevance in addition to that already stated.

# **6. PHARMACEUTICAL PARTICULARS**

## **6.1. List of Excipients**

Potato starch, lactose, talc.

## **6.2. Incompatibilities**

None known.

## **6.3 Shelf life**

5 years from date of manufacture

#### **6.4 Special precautions for storage**

Store below 25°C.

#### **6.5 Nature and contents of container**

Vials or Securitainers containing 8, 16, 25, 32, 50, 100, 250, 500, 1000 or 5000 tablets

Foil Blisters or paper strips of 2, 4, 8, 12, 16, 24, 32, 48, 50, 96 or 100 tablets

Not all pack sizes may be marketed.

#### **6.6 Instruction for Use, Handling and Disposal**

Not applicable.

## **7 MARKETING AUTHORISATION HOLDER**

Aspar Pharmaceuticals Ltd  
Albany House,  
Acrewood way,  
St Albans,  
AL4 0JY,  
United Kingdom

## **8. MARKETING AUTHORISATION NUMBER**

PL 08977/0002

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

First licenced: 5 February 1991

Renewed: 24 April 1996

**10 DATE OF REVISION OF THE TEXT**

04/12/2025