SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Aspirin 75mg Dispersible Tablets
Dispersible Aspirin Tablets BP 75mg
Dispersible Aspirin 75mg Tablets
POST MI® 75mg Dispersible Tablets
Boots Aspirin 75mg Dispersible tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains active: Aspirin BP 75.0 mg

Excipients with known effect
Each Aspirin Dispersible tablet contains:
27.5 mg of lactose

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Dispersible Tablets

White round, uncoated tablets with a bevelled edge. The tablets have 'aD' and '75' debossed (stamped into) one side and plain on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the secondary prevention of thrombotic cerebrovascular or cardiovascular disease and following by-pass surgery.

4.2 Posology and method of administration

The advice of a doctor should be sought before commencing therapy for the first time. The usual dosage, for long term use, is 75-150mg daily. In some circumstances, a higher dose may be appropriate, especially in the short term, and up to 300mg a day may be used on the advice of a doctor.

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

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
- During the third trimester of pregnancy
- children under 16 (except for the treatment of Still's disease),
- breast feeding,.
- concurrent anticoagulant therapy.

4.4 Special warnings and precautions for use

Before commencing long term aspirin therapy, for the management of cardiovascular and cerebrovascular disease, patients should consult their doctor who can advise on the relative benefits versus the risks for the individual patient.

Administer with caution in the presence of allergic disease, renal or hepatic impairment, dehydration.

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, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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
This medicine contains less than 1 mmol sodium (23 mg) per 75mg tablet that is to say essentially 'sodium-free'.

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.

Metamizole may reduce the effect of acetylsalicylic acid on platelet aggregation, when taken concomitantly. Therefore, this combination should be used with caution in patients taking low dose aspirin for cardioprotection.'

4.6 Pregnancy and lactation

Pregnancy:

Low doses (up to and 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 to500 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 than100 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.

Lactation:
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.

Immune system disorders:

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 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.
Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. In one study, when a single dose of ibuprofen 400mg was taken within 8 h before or within 30 min after immediate release aspirin dosing (81mg), a decreased effect of ASA on the formation of thromboxane or platelet aggregation occurred. However, the limitations of these data and the uncertainties regarding 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.

5.2 Pharmacokinetic properties

Absorption of non-ionised aspirin occurs in the stomach. Acetylsalicylates and salicylates are also readily absorbed from the intesine. 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 the milk and cross the placenta. The rate of excretion of aspirin varies as the pH rises, being greatest at pH 7.5 and above.

Aspirin is also excreted as salicylic acid and as glucuronide conjugate, and as salicyluric and gentisic acid.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Starch, sodium saccharin, lactose granules DMV, citric acid anhydrous, calcium carbonate, talc, sodium lauryl sulphate.

6.2 Incompatibilities

None known

6.3 Shelf life

PVC/Aluminum foil blister - 12 months
Tub – 12 months
PVC/PVDC/Aluminum foil blister – 18 months

6.4 Special precautions for storage

Do not store above 25°C.

Keep the product in the original container in order to protect from moisture.

6.5 Nature and contents of container

HDPE Securipac container and LDPE Tamper Evident (TE) flip top cap 25, 28, 32, 50, 56, 60, 100 tablets.

Blister pack (PVC/Aluminum or PVC/PVDC/Aluminum foil) 24, 28, 56 and 100 tablets.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Aspar Pharmaceuticals Ltd

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St Albans

AL4 0JY

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 08977/0007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/03/1990 / 14/10/2004

10 DATE OF REVISION OF THE TEXT

13/04/2026