

ACETYSALICYLIC ACID

Tablets BP 500mg

Composition:

Each Uncoated Tablet Contains:
Acetylsalicylic Acid BP.....500 mg
Excipients.....q.s.

PHARMACEUTICAL FORM

Uncoated Tablets

Therapeutic indications

Symptomatic treatment for fever and/or mild to moderate pain.

Posology and method of administration

Posology

Adults and adolescents (aged 16 and older):

1 to 2 tablets with each dose to be repeated as needed after a minimum period of 4 hours. The maximum daily dose should not exceed 6 tablets.

Elderly patients (aged 65 and older):

1 tablet with each dose to be repeated as needed after a minimum period of 4 hours. The maximum daily dose should not exceed 4 tablets.

Adolescents aged 12 – 15 years (40 - 50 kg):

1 tablet with each dose to be repeated as needed after a minimum period of 4 hours. The maximum daily dose should not exceed 4 tablets.

Acetylsalicylic acid should not be taken for more than 3 days (for fever) respectively for more than 3 - 4 days (for pain) unless directed by a physician.

Paediatric patients

This medicinal product is not suitable for children under 12 years (under 40 kg).

Hepatic impairment/ renal impairment

Acetylsalicylic acid should be used with caution in patients with impaired hepatic or renal function or cardiovascular problems

Method of administration

For oral use. The tablets should be taken with plenty of liquid.

Contraindications

- hypersensitivity to acetylsalicylic acid or other salicylates, or to any of the excipients
- history of asthma or hypersensitivity reactions (e.g. urticaria, angioedema, severe rhinitis, shock) induced by the administration of salicylates or substances with a similar action, notably non-steroidal anti-inflammatory drugs (NSAID),
- active peptic ulcer,
- haemorrhagic diathesis,
- severe renal insufficiency,
- severe hepatic insufficiency,
- severe uncontrolled cardiac insufficiency,

Special warnings and precautions for use

- In the event of combination with other medicinal products, to avoid any risk of overdose, check that acetylsalicylic acid is absent from the composition of other medicinal products.
- Reye's syndrome, a very rare life-threatening disease, has been observed in children with signs of viral infection (in particular, varicella and influenza-like episodes) with or without taking acetylsalicylic acid. Consequently, acetylsalicylic acid must only be administered to children in this situation following medical advice, when other measures have failed. In the event of persistent vomiting, disturbances of consciousness or abnormal behaviour, treatment with acetylsalicylic acid must be discontinued.
- Monitoring of treatment should be reinforced in the following cases:
 - in patients with a history of gastric or duodenal ulcer, or gastrointestinal bleeding, or gastritis
 - in patients with renal insufficiency
 - in patients with hepatic insufficiency
 - in patients with asthma: the occurrence of an asthma attack, in some patients, may be related to an allergy to non-steroidal anti-inflammatory drugs or to acetylsalicylic acid; in this case, this medicine is contraindicated (see section 4.3)
 - in patients with metrorrhagia or menorrhagia (risk of increasing the volume and duration of periods)
- Acetylsalicylic acid reduces the excretion of uric acid. This can possibly trigger gout attacks in predisposed patients.
- Use of this medicinal product is not recommended during breast-feeding

Interaction with other medicinal products and other forms of interaction

Several substances are involved in interactions, due to their platelet aggregation inhibitory properties: abaciximab, acetylsalicylic acid, cistazolol, clopidogrel, epoprostenol, eptifibatid, iloprost, iloprost trometamol, prasugrel, ticlopidine, tirofiban, ticagrelor.

The use of multiple platelet aggregation inhibitors increases the risk of bleeding, as does their combination with heparin or related molecules, oral anticoagulants or other thrombolytics, and must be taken into consideration by maintaining regular clinical monitoring.

Contraindicated combinations:

- Methotrexate at doses > 15 mg/week: Increased toxicity of methotrexate, in particular haematological toxicity (due to reduction in renal clearance of methotrexate by acetylsalicylic acid).
- Oral anticoagulants in patients with a history of gastro-duodenal ulcers: Increased risk of haemorrhage.

Combinations not recommended:

- Oral anticoagulants in patients with no history of gastro-duodenal ulcers: Increased risk of haemorrhage.
- Other non-steroidal anti-inflammatory drugs (NSAIDs): Increased risk of gastrointestinal ulcers and haemorrhage.
- Low molecular weight heparins (and related molecules) and unfractionated heparins at curative doses, or in elderly

- patients (≥ 65 years) regardless of the dose of heparin: Increased risk of haemorrhage (inhibition of platelet aggregation and aggression of the gastro-duodenal mucosa by acetylsalicylic acid). Another anti-inflammatory drug, or another analgesic or antipyretic should be used.
- Clopidogrel (beyond the approved indications for this combination in patients with acute coronary syndrome): Increased risk of haemorrhage. If co-administration cannot be avoided, clinical monitoring is recommended.
- Ticlopidine: Increased risk of haemorrhage. If co-administration cannot be avoided, clinical monitoring is recommended.
- Uricosurics (benzbromarone, probenecid): Reduction in the uricosuric effect due to competition for elimination of uric acid in renal tubules.
- Glucocorticoids (except hydrocortisone replacement therapy) for anti-inflammatory doses of acetylsalicylic acid: Increased risk of haemorrhage.
- Alcohol: Increased risk of gastrointestinal ulcers and bleeding.
- Pemetrexed in patients with mild to moderate renal impairment (creatinine clearance between 45 ml/min and 80 ml/min): Increased risk of pemetrexed toxicity (due to decreased renal clearance of pemetrexed by acetylsalicylic acid).
- Anagrelid: Increased risk of haemorrhage and decrease of the antithrombotic effect. If co-administration cannot be avoided, clinical monitoring is recommended.

Combinations requiring precautions for use:

- Diuretics, angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor antagonists: Acute renal failure may occur in dehydrated patients due to decreased glomerular filtration rate secondary to decreased synthesis of renal prostaglandins. In addition, reduction of antihypertensive effect may occur. Ensure that the patient is hydrated and renal function is monitored at the beginning of treatment.
- Methotrexate at doses ≤ 15 mg/week: Increased toxicity of methotrexate, in particular haematological toxicity (due to reduction in renal clearance of methotrexate by acetylsalicylic acid). Blood counts should be monitored weekly during the first weeks of co-administration. Close monitoring is required in patients with renal impairment (even mild) as well as in elderly patients.
- Clopidogrel (in the approved indications for this combination in patients with acute coronary syndrome): Increased risk of haemorrhage. Clinical monitoring is recommended.
- Gastrointestinal topicals, antacids: Increased renal excretion of acetylsalicylic acid due to alkalinisation of urine. Charcoal: Reduced absorption of acetylsalicylic acid due to adsorption. It is recommended to administer gastrointestinal topicals, antacids and charcoal at least 2 hours apart from acetylsalicylic acid.
- Pemetrexed in patients with normal renal function: Increased risk of pemetrexed toxicity (due to decreased renal clearance of pemetrexed by acetylsalicylic acid). Renal function should be monitored.

Combinations to be taken into account:

- Glucocorticoids (except hydrocortisone replacement therapy): Increased risk of haemorrhage.
- Deferasirox: Increased risk of gastrointestinal ulcers and haemorrhage.
- Low molecular weight heparins (and related molecules) and unfractionated heparins at preventive doses in patients under 65 years of age: Co-administration acting at different levels of haemostasis increases the risk of haemorrhage. Therefore, in patients less than 65 years of age, co-administration of heparins at preventive doses (or related molecules), and acetylsalicylic acid, should be taken into account by maintaining clinical monitoring, and laboratory monitoring as needed.
- Thrombolytics: Increased risk of haemorrhage.
- Selective Serotonin Re-uptake Inhibitors (citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline): Increased risk of haemorrhage.

Pregnancy and Lactation

Pregnancy

Inhibition of prostaglandin synthesis may adversely affect the course of pregnancy and/or the embryo-fetal development. Data from epidemiological studies suggest an increased risk of miscarriage, cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk of cardiovascular malformations was increased from less than 1% to approximately 1.5%. The risk seems to increase with dose and duration of treatment.

Lactation:

Low quantities of salicylates and their metabolites are excreted into the breast milk. Since adverse effects for the infant have not been reported up to now, incidental use of the recommended dose does not require suspending lactation. In cases of regular use and/or administration of higher doses breastfeeding should be discontinued.

Overdose

The risk of overdose is of concern in elderly subjects and particularly in young children (therapeutic overdose or, more frequently, accidental poisoning) where it can be fatal.

Storage

Store below 30°C in dry place. Protect from light. Keep the medicine out of reach of children.

Presentation

Aluminium/PVC blister pack of 10 Tablets.

Such 10 blisters are packed in a printed carton along with pack insert.

Manufactured by:

