

Asper

Enteric Coated Tablets



Composition:

Each Asper-81 Enteric Coated Tablet contains: Aspirin (Acetylsalicylic acid) 81 mg.
 Each Asper-100 Enteric Coated Tablet contains: Aspirin (Acetylsalicylic acid) 100 mg.
 Each Asper-162 Enteric Coated Tablet contains: Aspirin (Acetylsalicylic acid) 162 mg.

Mechanism of Action:

Aspirin inhibits platelet aggregation by inactivation of platelet cyclo-oxygenase. It is the enzyme responsible for the production of precursor thromboxane A₂.

Pharmacokinetics:

Following oral administration, Aspirin is absorbed rapidly and completely from the gastro-intestinal. During and after absorption Aspirin is converted into its main active metabolite, salicylic acid. Maximal plasma levels are reached after 10-20 minutes for Aspirin and after 0.3-2 hours for salicylic acid, respectively. Both Aspirin and salicylic acid are extensively bound to plasma proteins and are rapidly distributed throughout the body. Salicylic acid is excreted predominantly by hepatic metabolism. The elimination kinetics of salicylic acid is dose-dependent, as metabolism is limited by liver enzyme capacity.

The excretion half-life therefore varies from 2 to 3 hours after low doses to up to about 15 hours at high doses. Salicylic acid and its metabolites are excreted mainly via the kidneys.

Indications:

Asper is indicated for the following cardiovascular diseases:

- To reduce the risk of myocardial infarction in patients with unstable angina or in patients who have had a previous myocardial infarction.
- To reduce the risk of recurrent transient ischaemic attacks or stroke in men who have had transient ischaemia of the brain due to fibrin platelet emboli.
- To reduce the risk of graft occlusion following aortocoronary by-pass surgery.
- For reducing the risk of myocardial ischaemic events in people with cardiovascular risk factors.

Contraindications:

- Hypersensitivity to Aspirin, to other salicylates, or to any other components of the product
- A history of asthma induced by the administration of salicylates or substances with a similar action, notably non-steroidal anti-inflammatory medicines.
- Patients at risk of hemorrhagic, acute gastro-intestinal ulcer.
- Severe renal or hepatic impairment.
- Severe cardiac failure.
- Last trimester of pregnancy.

Warnings & Precautions:

- Asper should be used with particular caution in the following cases:
 - Hypersensitivity to analgesics / anti-inflammatory agents/ antirheumatic medicinal products and in the presence of other allergies.
 - History of gastro-intestinal ulcers including chronic or recurrent ulcer disease or history of gastro-intestinal bleedings.
 - Use of other anticoagulants.
 - Impairment of kidney and/or liver function.
- Asper may precipitate bronchospasm and induce asthma attacks and other hypersensitivity reactions.
- Due to its inhibitory effect on platelet aggregation which persists for several

days after administration. Asper may lead to an increased bleeding tendency during and after surgical operations (including minor surgeries, e.g. dental extractions).

- Aspirin, when taken in low doses, reduces uric acid excretion, and can trigger gout attacks in patients with hyperuricemia.
- Asper should not be used in children and adolescents for viral infections with or without fever without consulting a physician. There is a risk of Reye's syndrome, a very rare but possibly life-threatening illness requires directly medical procedures.

Pregnancy & Lactation:

Pregnancy:

Low doses (up to 100 mg/day): Clinical studies indicate that doses up to 100 mg/day for use in pregnant, which require specialised monitoring, appear safe. High doses: During the first and second trimester of pregnancy, Aspirin containing medicines are not recommended. During the third trimester of pregnancy Aspirin is contraindicated during the third trimester of pregnancy.

Lactation: Salicylates and their metabolites (the safety of which is not established in the nursing infant) may pass into breast milk in small amounts. Therefore, breastfeeding should be discontinued upon regular use of Aspirin.

Drug Interactions:

- Methotrexate: Concomitant use with Aspirin may increase the hematological toxicity of methotrexate, therefore doses greater than 15 mg/week of methotrexate are contraindicated.
- Ibuprofen: Treatment with ibuprofen in patients at increased risk of cardiovascular disease may limit of Asper the protective effects cardioprotective.
- Anticoagulants and other platelet aggregation inhibitors: Increased risk of bleeding.
- Other non-steroidal anti-inflammatory medicines with salicylates at high doses: Increased risk of ulcers and gastrointestinal bleeding due to synergistic effect.
- Selective Serotonin Reuptake Inhibitors (SSRIs): Increased risk of upper gastrointestinal - bleeding due to possibly synergistic effect.
- Digoxin: Plasma concentrations of digoxin are increased due to a decrease in renal excretion.
- Medicines used to treat diabetes such as sulfonylureas: The hypoglycemic effects are increased when used concomitantly with Aspirin in high doses.
- Diuretics in combination with Aspirin at higher doses: Decreased glomerular filtration via decreased renal prostaglandin synthesis.
- Antiepileptics: Aspirin enhances the effects of antiepileptics e.g. phenytoin and valproate.

Side Effects:

- Blood and lymphatic system disorders: Increased bleeding tendencies, thrombocytopenia, granulocytosis, aplastic anaemia.
- Immune system disorders: Hypersensitivity reactions, skin rashes, urticarial, asthma, bronchospasm, angio-oedema, allergic oedema, anaphylactic reactions including shock.
- Metabolic disorders: High concentration of uric acid in the blood.
- Nervous system disorders: Intracranial haemorrhage.
- Vascular disorders: Hemorrhagic vasculitis.
- Gastrointestinal disorders: Dyspepsia. Rare: Severe gastrointestinal haemorrhage, nausea, vomiting, gastritis.
- Renal and urinary tract disorders: Impaired renal function, salt and water retention.
- Skin and subcutaneous tissue disorders: Steven-Johnsons syndrome, purpura, erythema nodosum, erythema multiforme.

Driving & Using Machines:

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

Dosage & Administration:

Asper tablets should be taken with a sufficient amount of water. Do not chew or crush the tablets.

Adults:

- Aspirin can be used at a dose of 75-160 mg once daily in the following cases:

- Secondary prevention of myocardial infarction.
- Prevention of cardiovascular morbidity in patients suffering from stable angina pectoris.
- History of unstable angina pectoris, except during the acute phase.
- Prevention of graft occlusion after Coronary Artery Bypass Grafting (CABG).
- Coronary angioplasty, except during the acute phase.

- The recommended dose is 75 -300 mg once daily in the following cases:

Secondary prevention of Transient Ischaemic Attacks (TIA) and ischaemic Cerebrovascular Accidents (CVA), provided intracerebral haemorrhages have been ruled out.

- Acute myocardial infarction: The recommended loading dose is 150-300 mg followed by a lower dose (75-160 mg) daily thereafter.

Aspirin should not be used at higher doses unless advised by a doctor, and the dose should not exceed 300 mg a day.

Elderly people:

In general, Aspirin should be used with caution in elderly patients who are more prone to adverse events. Treatment should be reviewed at regular intervals.

Children:

Aspirin should not be administered to children and adolescents younger than 16 years, except on medical advice where the benefit outweighs the risk.

Overdose:

Caution should be exercised in the event of poisoning, especially in the elderly and in young children (therapeutic overdose or repeated accidental poisoning) that may be fatal.

Symptoms:

Moderate poisoning: Nausea, vomiting, tinnitus, hearing impairment, headache, dizziness and mental confusion have been observed in the event of an overdose. These symptoms may be controlled by reducing the dose.

Severe poisoning: fever, hyperventilation, elevated levels of ketone in the blood, metabolic acidosis, coma, cardiovascular shock, acute hypoglycemia.

Treatment:

If a toxic dose has been ingested, hospital admission is required. In the event of moderate intoxication, inducing the patient to vomit should be attempted. If this fails, gastric lavage may be attempted during the first hour after ingestion of a substantial amount of the medicine. Afterwards, active charcoal is given within one hour of poisoning and sodium sulfate (as a laxative). Alkalinisation of the urine whilst checking urine pH levels.

In the event of severe intoxication, haemodialysis is to be preferred. Other symptoms to be treated symptomatically.

The toxic dose of aspirin is about 100 mg/kg in children and about 200 mg/kg in adults.

Storage:

Keep out of reach of children. Store below 25°C, protect from heat and moisture.

Packaging:

Each Asper (81-100-162) carton box contains 20 Enteric Coated Tablets in two Alu/Alu strips.

"A medication is a product which affects your health, and it's consumption contrary to instructions is dangerous for you."
 - Follow strictly the doctors prescription, the method of use and the instructions of the pharmacist who sold the medication.
 -The doctor and the pharmacist experts in medicine, it's benefits and risks.
 -Do not repeat the same prescription without consulting your doctor.
 KEEP THE MEDICINE OUT OF REACH OF CHILDREN
 Council of Arab Health Ministers- Union of Arab Pharmacies

Reva Pharmaceutical Industry - Syria

● قد يزيد اسبير من التشنج العضلي ويسبب نوبات من الربو وتفاعلات فرط التحسس الأخرى.

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إنتاج شركة ريفال للصناعات الدوائية - سوريا

نتاج شركة ريفا للصناعات الدوائية - سوريا