

## **PACKAGE LEAFLET: Information for the patient**

### **ASPIRINE**

Tablets – 500 mg

(Acetylsalicylic acid)

#### **Read this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

#### **What is in this leaflet:**

1. What Aspirine is and what it is used for
2. What you need to know before you take Aspirine
3. How to take Aspirine
4. Possible side effects
5. How to store Aspirine
6. Other information

#### **1. WHAT ASPIRINE IS AND WHAT IT IS USED FOR**

Aspirine is a salicylic nonsteroidal anti-inflammatory drug (NSAID) which shares many common characteristics with other NSAIDs. Aspirine has analgesic, antipyretic, anti-inflammatory and antirheumatic effects. Aspirine lowers body temperature by dilating peripheral blood vessels. It has anti-inflammatory and analgesic effects through inhibition of prostaglandin synthase enzyme complex. By acetylating platelet cyclooxygenase, Aspirine inhibits synthesis of thromboxane A<sub>2</sub>, a prostaglandin derivative and potent vasoconstrictor that stimulates platelet aggregation and release. Aspirine inhibits platelet aggregation.

Aspirine 500 mg tablets are indicated in:

- pain of mild or moderate intensity such as headache, dental pain, neuralgia, myalgia, menstrual pain, postraumatic pain, postoperative pain;
- febrile patients to lower body temperature;
- inflammatory diseases such as rheumatic fever, rheumatoid arthritis, and osteoarthritis.

Your doctor may have prescribed Aspirine for other reasons. Ask your doctor if you want to know why they have prescribed Aspirine to you.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ASPIRINE**

### **Do not take Aspirine:**

- if you are allergic to acetylsalicylic acid, to other non-steroidal anti-inflammatory medicines or to any of the excipients of this medicine;
- if you have hemophilia or other blood coagulation disorders;
- if you have active peptic ulcer;
- in children under of 16 years due to risk of Reye's syndrome;
- if you have severe heart failure.

### **Take special care with Aspirine**

Ask your doctor before you take Aspirine if:

- you are prone to peptic ulcer;
- you have impairment of kidney or liver function (do not use in case of severe impairment) or you are dehydrated;
- you have asthma;
- you have allergic disease;
- you have uncontrolled hypertension and glucose-6-phosphate dehydrogenase deficiency;
- you are pregnant; it should be avoided during the last trimester;
- you are breastfeeding.

Prolonged use of aspirin should be avoided in the elderly.

It is recommended that Aspirine be discontinued 5-7 days before surgery to prevent or minimize excessive perioperative bleeding.

Aspirine should be used with caution in patients with infections, since symptoms such as fever and inflammation may be masked.

Aspirin should not be used in the treatment of gout.

### **Other medicines and Aspirine**

Use of other medicines with Aspirine could influence its effect or the other medicine's effect.

Please, contact your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines without prescription. Do not forget to inform your doctor that you are taking Aspirine if any other medicines are prescribed to you.

- Alcohol ingestion concomitantly with aspirin increases the risk for gastrointestinal ulceration.
- Concurrent administration of drugs that decrease urine pH (ammonium chloride, ascorbic acid, methionine), may decrease urinary excretion of aspirin and increase its blood levels.
- Medicines that increase urine pH, decrease aspirin's efficacy by increasing its excretion.
- Acetazolamide may increase urinary excretion for as long as urine is alkaline, and aspirin may increase acetazolamide's toxicity in central nervous system.
- Aspirin may decrease the diuretic effects of spironolactone and loop diuretics.
- Aspirin increases the anticoagulant effect and increases the risk of bleeding when given with heparin or oral anticoagulants.
- Aspirin reduces the antihypertensive effect of ACE inhibitors and beta-blockers.
- Use of aspirin with other non-steroidal anti-inflammatory drugs does not offer any therapeutic advantage and increases the risk of adverse effects.
- Use of aspirin with corticosteroids may increase the risk of gastrointestinal bleeding.
- Aspirin may increase serum concentrations of free valproic acid and thereby increase the toxicity of the anticonvulsant.
- Aspirin reduces tubular secretion of methotrexate by increasing methotrexate toxicity.
- Aspirin antagonizes the effects of uricosurics such as probenecid and sulfinpirazone.

- Metamizole (substance to decrease pain and fever) may reduce the effect of acetylsalicylic acid on platelet aggregation (blood cells sticking together and forming a blood clot), when taken concomitantly. Therefore, this combination should be used with caution in patients taking low dose aspirin for cardioprotection.

### **Taking Aspirine with food and drinks**

Aspirine should not be taken with alcoholic beverages and should be always taken after food to avoid gastric irritation.

### **Fertility, pregnancy and breastfeeding**

Fertility:

There are data that NSAIDs, aspirin included, have an effect on fertility of women who use them for a prolonged time. Women who are planning a pregnancy should avoid NSAID treatment.

Pregnancy:

Talk to your doctor or pharmacist if you are pregnant or are planning to get pregnant. Pregnancy category: C.

Aspirin should be used carefully during pregnancy and should be avoided during the last trimester of pregnancy. It may cause bleeding, delay and prolongation of labor, intrauterine closure of ductus arteriosus and kernicterus in newborns.

Breastfeeding:

Salicylates are excreted in breast milk. For this reason, they should be avoided during breastfeeding.

## **3. HOW TO TAKE ASPIRINE**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Check with your doctor if you feel that the effect of Aspirine 500 mg is too strong or too weak. The tablets should be swallowed preferably with a glass of water (250 ml) or lukewarm milk after food.

Dosage is as follows:

*Analgesic, antipyretic and anti-inflammatory dosage:* usual dose is 300 mg – 1 g, 3 – 4 times daily, as needed.

*In acute rheumatic disorders:* 4 – 8 g daily, in divided doses.

### **If you take more Aspirine than you should**

If you take more Aspirine than you should or if the children have taken this medicine by mistake, contact your doctor or the nearest hospital or call the emergency service to ask for the risks and advice on actions that should be taken. Signs of severe poisoning may develop slowly, 12 to 24 hours after ingestion of aspirin tablets. Mild intoxication with salicylates is noticed at dosages of 150 mg/kg of body weight and severe intoxication is noticed at dosages 300 mg/kg of body weight.

### **Symptoms:**

Nausea, vomiting, dizziness, hearing disorders, shaking, confusion, acid-base and electrolyte disturbances, coma and respiratory insufficiency.

### **Treatment:**

When the life of the patient is at risk due to a serious intoxication, immediate measures should be taken to prevent further absorption of the drug. The stomach should be emptied by gastric lavage and activated charcoal should be administered if not contraindicated (contraindications: reduction or absence of protective airway reflexes, low level of consciousness, risk of bleeding or gastrointestinal tract perforation or concomitant ingestion of corrosive substances).

Electrolytes should be checked and corrected, glucose and sodium bicarbonate should be administered in order to treat acidosis and favor elimination (urinary pH higher than 8). Initially, 8 grams of oral glycine are administered, then 4 g. The whole quantity should be administered within 2 to 16 hours. If needed, hemoperfusion or hemodialysis may be performed.

**If you forget to take Aspirine**

If you forget to take one or more doses, take the next dose at the next prescribed time. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody manifests them. Aspirine is well-tolerated in the recommended doses. Talk to your doctor if the side effects mentioned below appear to you:

- gastrointestinal disorders or vomiting;
- ulcer with occult blood loss (major upper gastrointestinal bleeding occurs rarely);
- other hemorrhages, e.g., subconjunctival hemorrhage;
- hearing disorders, such as tinnitus (rarely hearing loss has been reported);
- dizziness, confusion;
- hypersensitivity reactions (angioedema, bronchospasms, exanthema);
- prolonged bleeding time;
- rarely, edema;
- myocarditis;
- blood disorders including thrombocytopenia;
- hepatotoxicity in patients with juvenile idiopathic arthritis or other connective tissue disorders.

If any of the side effects gets worse or if you notice side effects not mentioned in this leaflet, please contact your doctor or pharmacist. If any of the above-mentioned side effects occurs, then discontinue Aspirine treatment and contact your doctor or pharmacist.

**5. HOW TO STORE ASPIRINE**

Keep this medicine out of the sight and reach of children!

Do not use Aspirine after the expiry date which is stated on the package!

Store below 25°C!

Keep in the original packaging to protect it from light and humidity!

## **6. OTHER INFORMATION**

### **What Aspirine 500 mg tablets contain**

**The active substance** is Acetylsalicylic acid.

Each tablet contains 500 mg acetylsalicylic acid.

**The excipients** are sodium carboxymethylcellulose, tartaric acid, microcrystalline cellulose, maize starch, sodium starch glycolate, stearic acid, talc.

**Contents of the pack:** carton box with 30 tablets.

### **Marketing Authorisation Holder (MAH) and Manufacturer**

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