

PACKAGE LEAFLET: INFORMATION FOR THE USER

ASPIRIN 500

500 mg tablet

ACETYLSALICYLIC ACID

• *This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

• *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 signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

What is in this leaflet?

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1. WHAT ASPIRIN 500 IS AND WHAT IT IS USED FOR

Aspirin 500 contains acetylsalicylic acid (aspirin). Acetylsalicylic acid is an analgesic (pain-relief) and an antipyretic (fever-reducer). It is used for the symptomatic treatment for fever and/or mild to moderate pain such as headache, menstrual pain, and minor pain caused by arthritis, muscle pain, pain and fever caused by colds, toothache. It is also used for the treatment of fever caused by flu and colds.

2. BEFORE YOU TAKE ASPIRIN 500

Do not take ASPIRIN 500

- if you are allergic (hypersensitive) to Acetylsalicylic acid or to any of the other ingredients in this medicine
- if you have had an allergic reaction to a history of the salicylates or other nonsteroidal anti-inflammatory drugs, including asthma attacks, bronchospasm, angioedema, urticaria, rhinitis
- if you have bronchial asthma
- if you suffer from diseases of the upper digestive system, such as gastritis and gastric and duodenal ulcers
- if you have increased tendency to bleed
- if you have a serious kidney or liver disease

- if you suffer from gout
- if you are in the last trimester of pregnancy
- if you are receiving methotrexate at a dose of 15 mg / week or more
- if you have severe heart failure which is not adequately treated
- if you are under 16 years

Take special care with ASPIRIN 500, so you must tell the doctor

- if you are being treated with other products containing acetylsalicylic acid (aspirin), to avoid the risk of overdose
- if you have a G6PD (Glucose-6-phosphate dehydrogenase) deficiency (a hereditary disease affecting red-blood cells), since elevated doses of acetylsalicylic acid could lead to hemolysis (destruction of red blood cells)
- if you use pain killers regularly, in particular several pain killers in combination, this may lead to reduced kidney function
- if you have a history of stomach or intestinal ulcers, stomach or intestinal hemorrhages or gastritis
- if you have impaired kidney or liver function
- if you have asthma: the occurrence of asthma attacks, in some patients, may be related to allergic reactions to non-steroidal anti-inflammatory drugs or to acetylsalicylic acid. In this case, the use of this medication is not recommended
- in case of heavy menstrual bleeding
- if gastrointestinal hemorrhage occur during the treatment (rejection of blood by mouth, blood in feces, black color of feces); you must stop the treatment and call immediately your doctor or an emergency medical service
- if you are also taking medicines to thin the blood and to prevent it clotting (anticoagulants)
- Acetylsalicylic acid increases hemorrhagic risks even in low doses and even if it is taken several days before. Tell your doctor, surgeon or anesthetist or dentist in case a surgery, even minor, is envisaged
- Acetylsalicylic acid modifies the quantity of uric acid in the blood. This has to be taken into account if you take medicines used against gout
- It is not recommended to use this medicine during breast-feeding.

Children

Reye's syndrome (a rare yet very serious disease primarily associated with neurological and liver damage) has been observed in children suffering from viral illnesses and being administered acetylsalicylic acid. As a result, in the case of a viral sickness such as the flu or chicken pox, administration of acetylsalicylic acid to a child should not be done without the prior consultation of a doctor.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Symultaneous use of Aspirin 500 and certain medications can affect the effect of the medicines.

The combination which is contraindicated (do not take Acetylsalicylic acid if you are taking the following medicine):

- Methotrexate (a medicine used in treating cancer and certain rheumatic diseases) in doses of 15 mg / week or more:

There is an increase haematological toxicity of methotrexate.

Combinations which require caution when taking:

- Methotrexate at doses of less than 15 mg / week:

There is an increase haematological toxicity of methotrexate.

- Anticoagulants, thrombolytics / other inhibitors of platelet aggregation / hemostasis:

Increased risk of bleeding.

- Other non-steroidal anti-inflammatory drugs containing high doses of salicylates

It increases the risk of ulcers and bleeding in the digestive system.

- Selective serotonin reuptake inhibitors (SSRIs = Selective Serotonin Reuptake Inhibitors)

Increased risk of bleeding in the upper gastrointestinal tract.

- Digoxin (a medicine that strengthens the heart muscle)

The concentration of digoxin in plasma is elevated due to reduced excretion by the kidneys.

- Antidiabetic medicines (medicines that lower blood sugar), for example. Insulin, sulphonylureas

High doses of aspirin increase the hypoglycaemic effect of antidiabetic agents.

- Diuretics (medicines that increase the excretion of urine) in combination with aspirin at high doses

Due to decreased production of prostaglandins in the kidneys, renal glomerular filtration is reduced.

- Systemic glucocorticoids, except hydrocortisone, applied in the replacement therapy for Addison's disease

Corticosteroids increase the excretion of salicylates, and therefore the level of salicylate in the blood during treatment with corticosteroids decreases; After stopping the treatment with corticosteroids there is a risk of salicylate overdose.

- Angiotensin converting enzyme (ACE inhibitors, medicines that lower blood pressure) in combination with high-dose acetylsalicylic acid

Glomerular filtration is reduced due to the inhibition of vasodilating prostaglandin and the antihypertensive effect is reduced.

- Valproic acid (a medicine used to treat seizures)

Increases the toxicity of valproic acid.

- Alcohol

Aspirin and alcohol act mutually, and it increases the damage to the lining of the digestive tract and prolongs the bleeding time.

- Medicines for the treatment of gout that stimulate excretion of uric acid: benzbromarone and probenecid

It reduces the excretion of uric acid

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Aspirin® 500 mg tablets should not be used during the first and second trimester of pregnancy, unless it is absolutely necessary. If you are trying to get pregnant, but are taking medicines containing acetylsalicylic acid, or if you are taking them during the first and second trimester of pregnancy, the dose administered should be the lowest possible, and duration of treatment the shortest possible.

Aspirin® 500 mg tablets should not be taken during the last trimester of pregnancy because of the increased risk of complications for mother and child before and during birth. During the last trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the fetus to cardio-pulmonary toxicity and damage to kidney function, which can lead to kidney failure with a lack of amniotic fluid. Prostaglandin synthesis inhibitors may expose the mother and child at the end of pregnancy to bleeding and protracted inhibition of uterine contractions, which can lead to delayed or prolonged labor.

Breastfeeding

Small amounts of acetylsalicylic acid and its metabolites pass into breast milk. Side effects have not been observed in infants whose mothers occasionally took acetylsalicylic acid, so it is not necessary to interrupt breastfeeding. However, mothers who take aspirin regularly or in high doses have to stop breastfeeding early.

Driving and using machines

Aspirin 500 should not affect your ability to drive and use machines.

3. HOW TO TAKE ASPIRIN 500

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Dosage

For oral use only. Take tablet(s) with plenty of liquid.

For adults and adolescents (aged 16 and older)

Single dose: 1-2 tablets (Equivalent to 500-1000 mg acetylsalicylic acid)

Daily dose: 3-8 tablets (Equivalent to 1500 mg -4000 acetylsalicylic acid)

Take Aspirin 500 mg tablets after meals with a large amount of liquid (a glass of water). This will speed up the onset of action of the medicine. To speed up the absorption of the medicine, you need to dissolve the tablet in a spoon with some water. After you swallow a pill drink plenty of fluids.

Do not take Aspirin® 500 mg tablets on an empty stomach.

Single dose may be administered at intervals of 4 to 8 hours to a maximum of 4 doses per day.

Do not take Aspirin® 500 mg tablets for longer than 3-5 days without consulting a doctor or dentist.

If you take more Aspirin 500 than you should

Poisoning by salicylates can result from chronic treatment with salicylates and due to acute toxicity which is a life-threatening (overdose), which varies from accidental intake in children to deliberate taking.

Chronic poisoning with salicylate can be seamless because the signs and symptoms are nonspecific. Mild chronic salicylate poisoning usually occurs only after repeated high doses.

Symptoms of overdose may include dizziness, vertigo, tinnitus, deafness, sweating, nausea and vomiting, headache, confusion, and can be controlled by reducing the dose.

The main sign of acute poisoning is a serious disorder of acid-base balance which can vary depending of age and degree of intoxication. The most common form in the children is metabolic acidosis. Key measures should include accelerated excretion of the medicine, as well as restoring electrolyte and acid-base metabolism.

Talk to your doctor or pharmacist if you have any additional questions.

If you forget to take Aspirin 500

If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.

Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ASPIRIN 500 can cause side effects, although not everybody gets them.

Side effects are listed according to the following categories of frequency:

Very common: more than 1 treated person of 10

Common: 1 to 10 treated persons of 100

Uncommon: 1 to 10 treated persons of 1000

Rare: 1 to 10 treated persons of 10000

Very rare: less than 1 treated person of 10000

Not known: frequency cannot be estimated from the available data

If you notice any of the following serious side effects, stop taking the medicine and consult a doctor immediately:

- sudden wheezing, swelling of the lips, face or body, rash, fainting or difficulties in swallowing (severe hypersensitivity reaction)

- redness of the skin with blistering or peeling, followed by fever and joint pain; these symptoms may indicate conditions such as polymorphic erythema, Stevens-Johnson syndrome or Lyell's syndrome
- unusual bleeding, such as coughing out blood, vomiting blood, blood in the urine or stool (dark stool).

Gastrointestinal disorders

disorders of the upper and lower gastrointestinal tract may occur, such as the common signs and symptoms of disturbed / painful indigestion, pain in the gastrointestinal tract and abdominal cavity, a rare inflammation of the digestive tract, ulcer in the digestive system which potentially in the very rare cases can lead to bleeding and perforations, with the corresponding laboratory findings and clinical signs and symptoms.

Blood and lymphatic system

Because of the inhibitory effect on platelets, acetylsalicylic acid may be associated with an increased risk of bleeding. There have been bleedings such as bleeding during surgery, hematomas, bleeding from the nose, urogenital bleeding, bleeding from the gums.

Rarely to very rarely serious bleedings were observed, such as bleeding in the gastrointestinal tract, bleeding in the central nervous system (especially in patients with uncontrolled hypertension) which in individual cases can be potentially life-threatening.

The bleeding can lead to acute and chronic anemia after bleeding / anemia due to iron deficiency (due to eg. disguised microbleeds) with the corresponding laboratory findings and clinical signs and symptoms such as weakness, paleness, decreased organ blood supply.

In patients with severe shortage of the enzyme glucose-6-phosphate dehydrogenase (G6DP), haemolysis and haemolytic anemia were observed.

Immune System

Hypersensitivity reactions with the corresponding laboratory findings and clinical manifestations include asthma syndrome, mild to moderate reaction that can affect the skin, respiratory system, digestive system and circulatory system, including symptoms such as rash, hives, swelling, itching, runny nose, nasal congestion, heart - respiratory distress and rarely severe reactions, including anaphylactic shock.

Hepatobiliary disorders

Transient liver damage with elevated liver transaminases are very rarely recorded.

Nervous system disorders

confusion and ringing in the ears were recorded which may indicate an overdose.

Renal and urinary system

renal impairment and acute renal failure were recorded.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ASPIRIN 500

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use ASPIRIN 500 after the expiry date which is stated on the label.

6. FURTHER INFORMATION

What ASPIRIN 500 contains

One tablet contains 500 mg of acetylsalicylic acid.
Other ingredients: cellulose, powder; starch, corn.

What ASPIRIN 500 looks like and contents of the pack

Aspirin 500 mg tablet is white. The pack contains 20 tablets in the the blister pack in a box.

Regime of dispensing

The medicine is issued without a doctor's prescription.

Manufactuer

Bayer Bitterfeld GmbH, Ortsteil Greppin, Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen, Germany

This leaflet was last approved in July, 2012