



# ASPIRIN<sup>®</sup> 500

## Instructions for use

Aspirin 500

Tablets with 500 mg acetylsalicylic acid

**Please read the entire patient information leaflet carefully as it contains important information on using the medicine.**

This medicine is available on a non-prescription basis. To achieve the best possible therapeutic results, you must nonetheless use Aspirin 500 as directed.

Keep the patient information leaflet - you may wish to read it again later.

If you have any further questions or need advice, please consult your pharmacist.

If your condition worsens or has not improved within 4 days, you must consult a doctor.

If any of the mentioned side effects affects you seriously or if you notice any side effects that are not listed in this patient information leaflet, inform your doctor or pharmacist.

This leaflet contains:

1. What is Aspirin 500 and what is it used for?
2. What should you be aware of before taking Aspirin 500?
3. How should Aspirin 500 be taken?
4. What side effects may occur?
5. How should Aspirin 500 be stored?
6. Further information

### **1. WHAT IS ASPIRIN 500 AND WHAT IS IT USED FOR?**

Aspirin 500 is an analgesic, antipyretic and anti-inflammatory substance (nonsteroidal anti-inflammatory /analgesic).

**Aspirin 500 is indicated for:**

- Mild to moderate pain
- Fever

Please note the instructions for children and adolescent (see section 2 “children and adolescent”).

### **2. WHAT SHOULD YOU BE AWARE OF BEFORE TAKING ASPIRIN 500?**

**Aspirin 500 must not be used:**

- if you are hypersensitive (allergic) to acetylsalicylic acid, other salicylates or any of the other ingredients of Aspirin 500;
- if you have a history of reacting hypersensitively to special drugs against pain, fever or inflammation (salicylates or other nonsteroidal anti-inflammatory drugs) with asthma attacks or the like;
- if you have acute gastric or duodenal ulcers;
- if you have a pathologically increased tendency to bleed;
- if you have liver or kidney failure;
- if you have severe, non-stabilized heart failure (cardiac insufficiency);
- if you are concurrently taking 15 mg or more methotrexate per week;
- during the last trimester of pregnancy.

**Particular caution is required when using Aspirin 500:**

- if you are hypersensitive to other analgesics / anti-inflammatory special drugs against rheumatism or inflammation (antirheumatic drugs) or other allergenic substances;
- if you have allergies (e.g. skin reactions, itching, nettle rash), asthma, hay fever, nasal polyps or chronic respiratory tract infections;
- if you are undergoing concomitant treatment with anticoagulant drugs;
- if you have gastric or duodenal ulcers or a history of gastrointestinal bleeding;

- if you have impaired liver function;
- if you have impaired kidney function or patients with impaired cardiovascular circulation (e.g. renal vascular disease, congestive heart failure, volume depletion, major surgery, sepsis or major hemorrhagic events), since acetylsalicylic acid may further increase the risk of renal impairment and acute renal failure,
- before surgery (including minor surgery such as dental extractions); increase in bleeding tendency can occur. Please inform your doctor or dentist if you have taken Aspirin 500;
- In patients suffering from severe glucose-6-phosphate dehydrogenase (G6PD) deficiency, acetylsalicylic acid may induce hemolysis or hemolytic anemia. Factors that may increase the risk of hemolysis are high dosage, fever, or acute infections, for example.

### **What other precautions must be taken?**

Long-term consumption of analgesics can cause headaches which, if treated with more analgesics, can in turn lead to perpetuation of the headache.

Habitual use of analgesics can lead to permanent kidney damage with the risk of kidney failure (analgesic nephropathy). The risk is particularly great when several different analgesics are taken concomitantly.

At low doses acetylsalicylic acid reduces the excretion of uric acid. This may cause a gout attack in predisposed patients.

### **Children and adolescent**

Aspirin 500 should not be taken by children or adolescents with feverish illnesses unless they have been instructed to do so by a doctor and other therapeutic measures have failed. Prolonged vomiting in conjunction with such illnesses could be a sign of Reye's syndrome, a very rare but life-threatening disease which requires immediate medical attention.

### **Interactions with other drugs**

Please inform your doctor or pharmacist if you are taking/using other medicines or have taken/used other medicines recently, even if they are non-prescription medicines.

The effects of the medicines or groups of substances below may be affected by concomitant treatment with Aspirin 500.

### **Enhanced effects ranging up to an increased risk of side effects:**

- Anticoagulants (e.g. coumarin, heparin) and thrombolytic medicines: acetylsalicylic acid can increase the risk of bleeding if taken before thrombolytic treatment. You must therefore pay attention to signs of external or internal bleeding (e.g. bruising) if you are undergoing such treatment;
- Drugs that inhibit the clumping together of blood platelets (platelet aggregation inhibitors), e.g. ticlopidine, clopidogrel: increases risk for bleedings;
- Other drugs against pain or inflammation (nonsteroidal analgesics / anti-inflammatory drugs) at Aspirin doses of 6 tablets per day and more: increased risk of gastrointestinal ulcers and bleedings;
- Drug products containing cortisone or cortisone-like substances (with the exception of products that are applied topically or cortisone replacement therapy for Addison's disease): increased risk of gastrointestinal side effects;
- Alcohol: elevated risk of gastrointestinal ulcers and bleeding;
- Digoxin (a drug to strengthen the heart muscle);
- Drugs to reduce blood glucose (antidiabetics): the blood glucose level can be reduced;
- Methotrexate (a drug used to treat cancer and certain rheumatic disorders);
- Valproic acid (a drug used to treat convulsions of the brain [epilepsy]);
- Selective serotonin re-uptake inhibitors (SSRIs): increased risk of gastrointestinal bleedings.

### **Weakening of effects:**

- Diuretics (drugs to increase urine excretion) at Aspirin 500 doses of 6 tablets per day and more;
- ACE inhibitors (a class of blood pressure-reducing drugs) at Aspirin 500 doses of 6 tablets per day and more;
- Gout remedies that promote the excretion of uric acid (e.g. probenecid, benzbromarone).

### **Pregnancy and Breast-feeding**

Before taking any medicines consult your doctor or pharmacist.

Aspirin 500 should not be taken during the first and second trimester of pregnancy. Necessarily consult your doctor before taking Aspirin.

Aspirin 500 must not be taken during the last trimester of pregnancy due to an increased risk of complications for mother and baby before and during the birth.

This medication is one of a group of drugs (non-steroid antiphlogistics) which could impair a woman's fertility. This effect is reversible following discontinuation of the medication.

Small quantities of acetylsalicylic acid and their metabolites pass into breast milk. Detrimental effects on the infant have not been reported to date; it is therefore not necessary to interrupt breast-feeding for occasional use at the recommended dosage. Nonetheless, in the event of extended use or consumption of high doses, the infant should be weaned.

#### **Driving and operating machinery**

No special precautions are necessary.

### **3. HOW SHOULD ASPIRIN 500 BE TAKEN?**

Always take Aspirin 500 exactly as directed in the patient information leaflet. Please ask your doctor or pharmacist if you are unsure how to take this medicine.

#### **Dosage**

Unless otherwise prescribed by your doctor, the usual dose is:

<b>Age</b>	<b>Single dose</b>	<b>Total daily dose</b>
Children* aged above 12 years	<b>1</b> tablet	<b>Up to 3</b> tablets
Adolescents* and adults	<b>1-2</b> tablets	<b>3-6</b> tablets

\* Please note the instructions for children and adolescent (see section 2 "children and adolescent").

#### **Mode of administration**

Take Aspirin 500 tablets with plenty of liquid (glass of water). This improves the onset of action. To facilitate the intake, you should disintegrate the tablet on a spoon in some water. Please drink afterwards a plenty of liquid.

You should not take Aspirin on an empty stomach.

#### **Duration of administration**

The single dose can be taken at intervals of 4 to 8 hours if necessary, up to a maximum of 3 doses a day.

The maximum daily dose must not be exceeded.

Do not take Aspirin 500 for longer than 4 days without consulting your doctor or dentist.

#### **What should you do if you take too much Aspirin 500?**

Tinnitus, feeling of impaired hearing, sweating, nausea, vomiting, headache and vertigo, particularly in children and elderly patients, may indicate serious poisoning.

Please notify your doctor if you suspect an overdosage of Aspirin 500. He will decide on the necessary measures to be taken depending on the severity.

### **4. WHAT SIDE EFFECTS MAY OCCUR?**

Like all medicines, Aspirin 500 can have side effects, which must not occur at everybody.

The following adverse effects comprise all reported side effects following treatment with acetylsalicylic acid, including those following long-term high-dose therapy in rheumatism patients.

The incidence figures for events that go beyond isolated cases are based on short-term use of daily doses of not more than 3 g acetylsalicylic acid .

The following incidence rating is used to evaluate the frequency of side effects:

Very Common:	more than 1 treated patient of 10
Common:	1 to 10 treated patients of 100
Uncommon:	1 to 10 treated patients of 1,000
Rare:	1 to 10 treated patients of 10,000
Very rare:	less than 1 treated patient of 10,000
Not known:	frequencies can not estimated from available data

Common:

Gastrointestinal disorders such as heartburn, nausea, vomiting, abdominal pain.

Uncommon:

Hypersensitivity reactions such as skin reactions.

Rare:

Serious bleedings, such as cerebral bleeding (especially in patients with uncontrolled hypertension and/or on concomitant antihemostatic agents), which in single cases may be potentially life-threatening.

Gastrointestinal bleeding which in very rare cases can lead to iron deficiency anaemia. If you pass black stools or vomit blood (signs of serious bleeding in the stomach), you must inform your doctor immediately.

Gastrointestinal ulcers which in very rare cases can lead to perforation.

Hypersensitivity reactions of the respiratory system, gastrointestinal tract and of the cardiovascular system, particular in asthmatics.

The following symptoms may occur:

a drop in blood pressure, attacks of difficult breathing, rhinitis, nasal congestion, allergic shock, swelling of the face, tongue and larynx (angioedema). Hypersensitivity reactions such severe skin reactions (up to severe feverish skin rash with mucosa involvement [erythema exudativum multiforme]).

Gastrointestinal inflammation.

Very rare:

Elevated liver values.

*Frequency not known:*

Hemolysis and hemolytic anemia in patients with severe forms of glucose-6-phosphate dehydrogenase (G6PD) deficiency have been reported.

Renal impairment and acute renal failure have been reported.

Bleeding, e.g. nosebleeds, bleeding gums, skin bleeding or urogenital bleedings, possibly with prolongation of the bleeding time. This effect can persist for 4 to 8 days after use. Headache, dizziness, impaired hearing ability, tinnitus and mental confusion can be signs of an overdose.

If you experience any of the above-mentioned side effects, do not take any more Aspirin 500.

Notify your doctor so that he can determine the severity of the side effect(s) and decide on any necessary further action.

Inform your doctor or pharmacist if you notice any side effects that are not listed in this patient information leaflet.

## **5. HOW SHOULD ASPIRIN 500 BE STORED?**

Keep medicines out of the reach of children.

The expiry date of this product is printed on the tablet strips and the cardboard box. Do not use the product after this date.

**Not to be stored above 25°C.**

## **6. FURTHER INFORMATION**

### **What contains Aspirin 500?**

The active ingredient is acetylsalicylic acid.

1 tablet contains 500 mg acetylsalicylic acid.

The other ingredients are: Cellulose powder, maize starch.

### **Dosage form and content:**

Aspirin 500 is a white tablet and available in pack containing 20 tablets.

### **Manufacturer:**

Bayer Bitterfeld GmbH - Germany  
for Bayer Consumer Care AG – Basel - Switzerland

**Date of information:** August 2011

### **This is a medicament**

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor 's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

**Keep medicament out of reach of children.**

**Council of Arab Health Ministers**

**Union of Arab Pharmacists**

Bayer