

Aspirin[®] 500

Tablets

Active ingredient

Each tablet contains:

Acetylsalicylic acid 500 mg.

For a list of inactive ingredients and allergens in this medicine see section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Take this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Consult your doctor if your symptoms of illness get worse or do not improve within 4 days.

1) What is this medicine intended for?

Aspirin 500 is intended to relieve pain, reduce fever.

Therapeutic group: Non-steroidal anti-inflammatory drugs (NSAIDs).

2) Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to acetylsalicylic acid, other salicylates or any of the other ingredients of Aspirin 500 (see section 6 'Additional information' for a list of the inactive ingredients).
- you have previously had a hypersensitivity reaction caused by exposure to certain medications for pain, fever or inflammation (salicylates or other non-steroidal anti-inflammatory drugs) with asthma attacks or other reactions that indicate hypersensitivity.
- you have an acute ulcer in your stomach or bowel.
- you have an increased tendency to bleed.
- you have liver or kidney failure.
- you have severe heart failure that is not controlled.
- you are taking at the same time 15 mg or more methotrexate per week.
- you are in the last 3 months of pregnancy.

Special warnings about using this medicine

Talk to your doctor before taking Aspirin 500 if:

- you are sensitive to pain medicines, other medicines that reduce inflammation, antirheumatics (for rheumatism), or other allergy-triggering substances.
- you have allergies (skin reactions, itching, hives [urticaria]), asthma, hay fever, swelling of the mucous lining in the nose (nasal polyps), or chronic respiratory diseases.
- you are being treated with blood-thinning medicines at the same time (see below, "Medicines that strengthen the effect of this medicine including increased risk of side effects").
- you have a history of stomach or intestinal bleeding or ulcers.
- you have impaired liver function.
- you have impaired kidney function or reduced blood flow in your heart and/or blood vessels (e.g., vascular disease in the kidneys, heart failure, reduced blood volume, major surgeries, blood poisoning, or severe bleeding events), acetylsalicylic acid may further increase the risk of impaired kidney function and acute kidney failure.
- you are before surgery, including minor procedures such as tooth extraction. There may be an increased bleeding tendency. Tell your doctor or dentist if you have taken Aspirin 500.

- you have severe glucose-6-phosphate dehydrogenase (G6PD) deficiency. Acetylsalicylic acid may cause accelerated breakdown or disintegration of red blood cells or a certain type of anaemia. This risk may be increased by factors such as high doses, fever, or acute infections.

Additional warnings

Taking painkillers **over a long period of time** can cause headaches, resulting in more painkillers being taken, which can result in continuation of the headaches.

Habitual use of painkillers can result in permanent damage to the kidneys with the risk of kidney failure (analgesic nephropathy). This risk is particularly high if you take a combination of more than one different pain medication.

At low doses, acetylsalicylic acid reduces uric acid excretion. This can trigger a gout attack under certain circumstances in predisposed patients.

Children and adolescents

This medicine is for adults. Do not use this medicine in children or in adolescents without first consulting a doctor.

Do not use Aspirin 500 in children and adolescents with fevers unless prescribed by a doctor and only if other therapeutic measures are not working. If a child or adolescent with such a condition experiences prolonged vomiting, this may be a sign of Reye's syndrome, a very rare but life-threatening disease that requires immediate medical treatment.

Interactions with other medicines

If you are taking, have recently taken or might take other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

Medicines that strengthen the effect of this medicine including increased risk of side effects

- blood thinners (e.g. heparin, coumarin) and thrombolytic medicines (that break down blood clots). Acetylsalicylic acid may increase the risk of bleeding if it is taken before thrombolytic therapy. If you are getting treatment of this type, you must watch closely for signs of external or internal bleeding (such as bruises).
- medicines that prevent the adhering and clumping of platelets in the blood such as ticlopidine, clopidogrel: there is an increased risk of bleeding.
- other painkillers and anti-inflammatory medicines (nonsteroidal analgesics/anti-inflammatory drugs) together with doses of 6 or more Aspirin 500 tablets per day: there is an increased risk of ulcers and bleeding in the gastrointestinal system.
- medicines that contain cortisone or cortisone-like substances (except for products that are applied to the skin or used in cases of cortisone replacement therapy for Addison's disease): there is an increased risk of side effects in the gastrointestinal system.
- digoxin (a medicine used to strengthen the contractions of the heart muscle).
- blood sugar-lowering medicines: blood sugar level may drop significantly.
- methotrexate (a medicine used to treat cancers and certain rheumatic conditions). See the section 'Do not use this medicine if:', above.
- valproic acid (a medicine used to treat seizures in the brain [epilepsy]).
- certain medicines for depression (selective serotonin re-uptake inhibitors [SSRIs]: there is an increased risk of bleeding in the gastrointestinal system.

Medicines that weaken the effect of this medicine

- diuretics (medicines used to increase urination) with doses of 6 or more Aspirin 500 tablets per day.
- ACE inhibitors used to treat high blood pressure with doses of 6 or more Aspirin 500 tablets per day.
- medicines used to treat gout that increase the excretion of uric acid (such as probenecid, benzbromarone).

Using this medicine and food

Do not take this medicine on an empty stomach.

Using this medicine and alcohol consumption

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

Pregnancy, breastfeeding, and fertility:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this or any other medicine.

Pregnancy

In the last trimester:

Do not take Aspirin 500 if you are in the final 3 months of pregnancy because this might harm your unborn baby or cause problems during delivery. This medicine could cause kidney and heart problems in the unborn baby, can affect mother and baby's tendency to bleed and lead to the birth process being delayed or taking longer than expected.

In the first and second trimesters:

Do not take aspirin during the first 6 months of pregnancy unless it is absolutely necessary and recommended by your doctor. If you have to be treated during this time or while you are trying to conceive, use the lowest dosage possible for the shortest possible period of time. If you take Aspirin for more than a few days, starting from week 20 of pregnancy this medicine can cause kidney problems in your unborn child, which can lead to a reduction in the amount of amniotic fluid surrounding your baby (oligohydramnios), or to narrowing of one of the blood vessels (ductus arteriosus) in your baby's heart. This effect can start soon after starting treatment with aspirin and is usually reversible after the medicine has been stopped. Stop treatment with aspirin immediately if diagnosed with reduced amount of amniotic fluid or narrowing of blood vessels in the baby's heart. If you have to be treated for more than a few days, your doctor may recommend closer monitoring (with an emphasis on amount of amniotic fluid and the blood vessels in the baby's heart).

Breast-feeding

Small quantities of the active substance, acetylsalicylic acid and its metabolites are excreted in human milk. As no adverse effects on the infant have currently been reported, interruption of breast-feeding is not necessary when the recommended dose is occasionally used. Nevertheless, do not breast-feed if using the product for extended periods or at high doses.

Fertility

This medicine belongs to a group of medicines called nonsteroidal anti-inflammatory drugs which may affect a woman's fertility. This effect is reversible after the medicine has been stopped.

Driving and using machines:

Acetylsalicylic acid has no effect on the ability to drive or use machines.

3) How to use this medicine?

Check with a doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The recommended dosage is usually:

Adults:

1-2 tablets every 4-6 hours, but no more than 8 tablets in 24 hours.

Children and adolescents:

Only use this medicine in children after consulting a doctor.

Only your doctor will determine your dose and how you should take this medicine. The recommended dosage in children aged 12 years and older is usually 1 tablet up to 3 times a day.

Please note the information for use in children and adolescents in section 2 'Children and adolescents'.

Patients with liver impairment and patients with kidney impairment:

Acetylsalicylic acid should be used with caution in patients with liver impairment and in patients with kidney impairment (see section 2 above, under 'Special warnings about using this medicine').

Do not exceed the recommended dose.

Duration of use

You may take a single dose at intervals of 4 to 6 hours, as needed, but do not take more than 8 tablets in 24 hours. Do not take Aspirin 500 for longer than 4 days without talking to a doctor/dentist.

Method of administration

Take the medicine with plenty of liquid (a glass of water). This helps its effect set in. To make the tablets easier to swallow, you can allow them to disintegrate in a spoonful of water. Drink plenty of liquids afterwards. Do not take this medicine on an empty stomach.

If you have accidentally taken a higher dose, immediately talk to your doctor who will evaluate the severity of overdose/poisoning and decide about suitable measures to be taken. You may experience: ringing in the ears, hearing problems, sweating, nausea, vomiting, headaches, and dizziness. These may be signs of severe poisoning, especially in children and elderly patients.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4) Side effects

Like with all medicines, using Aspirin 500 may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

The following list of side effects includes all known side effects reported under treatment with acetylsalicylic acid, including those under high-dose long-term therapy in rheumatoid arthritis patients. Except for individual cases, frequencies relate to short-term use of the maximum daily dose of 3 g acetylsalicylic acid.

Stop using and consult your doctor immediately if you experience:

These side effects occur rarely (may affect 1–10 in 10,000 users).

- hypersensitivity reactions of the respiratory tract, gastrointestinal system, and the heart and blood vessels, especially in asthmatic patients. The following symptoms may occur: drop in blood pressure, attacks of breathlessness, inflammation of the mucous membranes of the nose, stuffy nose, allergic shock, swelling of the face, tongue and throat (angioedema).
- hypersensitivity reactions such as severe skin reactions (including severe skin rashes with a fever and involvement of the mucous membranes [exudative erythema multiforme]).
- bleeding in the stomach and intestines, which may very rarely result in iron deficiency anaemia. If you experience black faeces or bloody vomiting (signs of severe bleeding in the stomach), **consult your doctor immediately**.

Common side effects (affect 1–10 in 100 users)

- stomach and intestinal problems such as heartburn, nausea, vomiting, abdominal pain.

Uncommon side effects (affect 1–10 in 1,000 users)

- hypersensitivity reactions such as skin reactions.

Rare side effects (affect 1–10 in 10,000 users)

- serious bleeding, such as brain haemorrhage (especially in patients with uncontrolled high blood pressure and/or those treated at the same time with medicines that prevent blood clotting) has been reported; these may be life-threatening in some cases.
- ulcers in the stomach and intestines, which may, in rare cases, result in perforation.
- gastrointestinal inflammation.

Very rare side effects (affect less than one in 10,000 users):

- increases in liver enzyme values.

Side effects of unknown frequency (frequency cannot be estimated from the available data)

- accelerated breakdown or disintegration of red blood cells, and a specific form of anaemia in patients with a severe glucose-6-phosphate dehydrogenase (G6PD) deficiency.
- impaired kidney function and acute kidney failure.
- bleeding such as nose bleeds, bleeding gums, bruising, bleeding in the genitals and urinary tract, possibly with prolonged bleeding time. This effect may persist for 4–8 days after use.
- Headache, dizziness, hearing problems, ringing in the ears, and mental confusion may be signs of an overdose.
- In the event of prior damage to the intestinal mucosa, membranes can form in the intestine, which may result in a subsequent blockage (particularly with long-term use).

If you get any of the side effects listed above, **stop taking this medicine** and contact your doctor who will determine severity and decide about your treatment. If any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il) which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

5) How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C. Protect from moisture.

6) Additional information

- **In addition to the active ingredient this medicine also contains:**
Maize starch, powdered cellulose.
- **What the medicine looks like and contents of the pack:**
White tablets; tablets are packaged in blister trays of 20 tablets.
- **Registration holder/importer's name and address:** Bayer Israel Ltd., 36 HaCharash St., Hod Hasharon 45240.
- Revised in February 2024.
- Registration number of the medicine in the Ministry of Health's National Drug Registry:
025 43 21130 00