

## Acetylsalicylic acid Powder and solvent for solution for injection 500 mg/5 ml

### What is Acetylsalicylic Injection 500 and what is it used for?

Acetylsalicylic Injection 500 has analgesic, antipyretic, and anti-inflammatory effects and is used for rheumatic conditions, lumbago, acute and chronic rheumatoid arthritis, neuralgia, and high fever.

### When should you not use this medicine or use it with extra caution?

#### When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine.
- You are allergic to a group of painkillers with anti-inflammatory and antipyretic effects (NSAIDs, nonsteroidal anti-inflammatory drugs); these are non-hormonal anti-inflammatory drugs.
- You have experienced an asthma attack in the past when using acetylsalicylic acid or other non-hormonal anti-inflammatory drugs (NSAIDs).
- You have a significant increase in mast cells (mastocytosis). The mast cell is a white blood cell that plays an important role in the immune system. They are involved in allergic reactions and fighting certain infections.
- You have an active, chronic, or recurrent stomach or duodenal ulcer or have had one in the past. Or you have had bleeding or perforation (a hole) in your stomach after treatment with aspirin (acetylsalicylic acid) or other non-hormonal anti-inflammatory drugs (NSAIDs). NSAIDs are pain relievers that reduce fever and inflammation.
- You currently have or have had a stomach ulcer/stomach bleeding.
- You have severely impaired liver function.
- You have severe renal impairment.
- You have severe heart failure.
- You are using anticoagulant medications (anticoagulants).
- You are prone to bleeding or have blood clotting disorders.
- You are pregnant from the sixth month until delivery.
- You are using methotrexate (a medication used for cancer and rheumatoid arthritis), among other applications.
- When should you use extra caution with this medicine?
- Contact your doctor or pharmacist before using this medicine.
- You have a stomach or duodenal ulcer, or you have experienced or are experiencing gastrointestinal bleeding, or you have inflammation in the stomach (gastritis).
- You have asthma.
- You have impaired liver or kidney function.
- You have high blood pressure and/or heart failure.

The active ingredient in this medicine, acetylsalicylic acid, inhibits blood clotting even at very low doses. There is a risk of bleeding during surgeries, even minor ones such as tooth extractions. Therefore, inform your dentist or doctor if you are using this medicine. Menstrual bleeding may increase slightly while using this medicine. Additionally, the intensity and duration of menstruation may increase. During the use of this medicine, gastrointestinal bleeding may occur, even if you have never experienced it before. The risk is higher in older patients and patients with low body weight. Discontinue the use of this medicine immediately if you experience gastrointestinal bleeding.

Do not use Acetylsalicylic Injection 500 together with levothyroxine (a medication used to treat thyroid disorders) (see "Are you taking any other medications?"). Acetylsalicylic Injection 500 can alter the levels of thyroid hormones in the blood. Therefore, your doctor will monitor your thyroid hormones.

If you are using Acetylsalicylic Injection 500 together with nicorandil (a medication used to prevent or relieve chest pain due to heart problems), the risk of ulcers, perforations, and bleeding in the stomach and intestines may increase (see "Are you taking any other medications?").

If you have a certain metabolic disorder (G6PD deficiency), a high dose of acetylsalicylic acid can lead to rapid breakdown of red blood cells (hemolysis). Administration of this medicine should always be done under medical supervision.

If you are using Acetylsalicylic Injection 500 in combination with other medications, make sure those other medications do not contain acetylsalicylic acid to prevent overdose.

Regular use of painkillers, especially a combination of painkillers, can lead to permanent kidney damage.

Discontinue the use of this medicine immediately and inform your doctor immediately if you experience tinnitus, dizziness, or hearing disorders.

Headache has been reported as a side effect after using the active ingredient in this medicine. In case of prolonged administration of high-dose painkillers, the occurrence of headaches should not be treated with an even higher dose of the painkiller.

### Children and adolescents under 18 years of age

Children with flu or chickenpox should only be administered this medicine on the advice of a doctor. Furthermore, this medicine should only be administered when other measures are insufficient.

Immediately contact your doctor if there is any indication of during the treatment.

- Prolonged vomiting
- Decreased consciousness or
- Behavioral disorders.
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These symptoms may indicate Reye's syndrome, a very rare but potentially life-threatening disease under certain circumstances.

Administration of this medicine to infants younger than 1 month is only allowed after consulting with a doctor.

#### **Are you taking any other medications?**

If you are taking any other medications in addition to Acetylsalicylic Injection 500, have recently taken any, or are planning to take any in the near future, please inform your doctor or pharmacist. If you regularly use acetylsalicylic acid, always consult your doctor or pharmacist before using it concurrently with other medications. This also applies to medications available without a prescription.

#### **Do not use Acetylsalicylic Injection 500 simultaneously with:**

- Anticoagulant medications, as it may prolong blood clotting time.
- Methotrexate (a medication used for cancer and rheumatoid arthritis) in doses of 15 mg methotrexate per week or more.

#### **Acetylsalicylic Injection 500 is not recommended to be used together with:**

- Other painkillers with anti-inflammatory and antipyretic effects (NSAIDs) as they increase the risk of stomach and intestinal ulcers.
- Anticoagulant medications (heparins) and medications that inhibit platelet aggregation (platelet aggregation inhibitors such as clopidogrel and ticlopidine) due to an increased risk of bleeding.
- Anti-gout medications such as probenecid or benzbromarone, as the effectiveness of gout medications may be reduced.
- Glucocorticosteroids (except hydrocortisone) (medications that reduce inflammation and allergic reactions) along with aspirin (acetylsalicylic acid) at fever and pain-relieving doses due to an increased risk of bleeding.
- Pemetrexed (used for certain types of cancer). Pemetrexed can become more harmful when combined with Acetylsalicylic Injection 500. Your doctor will monitor your health.
- Levothyroxine (used to treat thyroid problems); Acetylsalicylic Injection 500 can alter the levels of thyroid hormones in the blood. Therefore, your doctor will monitor your thyroid hormones.

#### **If used concurrently with Acetylsalicylic Injection 500, controls and dosage adjustments may be necessary for:**

- Diabetes medications, as it may cause low blood sugar levels. Extra monitoring of blood sugar levels is necessary.
- Antacids (magnesium, aluminum, and calcium-based stomach acid reducers) and activated charcoal, as they can promote the excretion of salicylic acid, reducing the effectiveness of Acetylsalicylic Injection 500.
- Diuretics and other medications that lower blood pressure (ACE inhibitors) as they increase the risk of reduced kidney function and may also reduce their effectiveness in controlling high blood pressure.
- Methotrexate, as its harmful effects (particularly on the blood) may increase.
- Corticosteroids, as they increase the risk of gastrointestinal bleeding.
- Heparins, platelet aggregation inhibitors (clopidogrel), anticoagulant medications (used to dissolve blood clots) as they may increase the risk of bleeding.
- Other nonsteroidal anti-inflammatory drugs (NSAIDs) as they increase the risk of stomach and intestinal ulcers and bleeding.
- Specific serotonin reuptake inhibitors (antidepressants (SSRIs) such as citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline) due to an increased risk of bleeding.
- Pentoxifylline (a medication used for certain circulation disorders) as it increases the risk of bleeding.

Metamizole (a medication for pain and fever) can reduce the effectiveness of aspirin (acetylsalicylic acid) in preventing blood cell aggregation and blood clot formation when used together. Therefore, your doctor advises caution when using metamizole if you use a low dose of acetylsalicylic acid for heart conditions (cardioprotection).

- Acetazolamide (for high blood pressure). When used together with Acetylsalicylic Injection 500, there is a risk of vomiting, rapid heartbeat (tachycardia), rapid and deep breathing (hyperpnea), confusion, fatigue, feeling sluggish, having low energy, and excessive sleepiness (lethargy), and metabolic acidosis with increased chloride and salt in the blood due to kidney problems.
- Valproic acid (used for the treatment of epilepsy). There may be an increased amount of valproic acid in the blood when Acetylsalicylic Injection 500 is used together with valproic acid-like medications. Therefore, your doctor will monitor the level of valproate in your blood.
- Varicella vaccine. It is not recommended to administer Acetylsalicylic Injection 500 within six weeks after receiving the varicella vaccine. Cases of Reye's syndrome have occurred after the use of Acetylsalicylic Injection 500 during varicella infections.
- Tenofovir (used in the treatment of certain viral infections). The use of Acetylsalicylic Injection 500 together with tenofovir can increase the risk of kidney problems (renal failure). Therefore, your doctor will monitor your kidney function.
- Insulin and sulfonylurea derivatives (medications that lower blood sugar levels). The use of Acetylsalicylic Injection 500 together with insulin and sulfonylurea derivatives increases the risk of low blood sugar (hypoglycemia).
- Nicorandil (for chest pain due to heart problems or to alleviate the pain). The use of Acetylsalicylic Injection 500 together with nicorandil can increase the risk of stomach or intestinal ulcers, perforation, and bleeding (see "When should you take extra care with this medication?").

#### **What should you consider regarding alcohol?**

Alcohol can increase the risk of stomach and intestinal injury when taken together with aspirin (acetylsalicylic acid). It can also affect the results of blood clotting tests (prolonged bleeding time) when taken with acetylsalicylic acid. Therefore, patients should be cautious with alcohol during and up to 36 hours after taking acetylsalicylic acid.

## **Pregnancy and breastfeeding**

Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Please consult your doctor or pharmacist before using this medication.

**Pregnancy:** You should not use this medication after the sixth month of pregnancy.

The use of this medication during pregnancy can be harmful to the unborn child. During the first 6 months of pregnancy, you should only use this medication after consulting with your doctor. If you use this medication during the first 6 months of pregnancy, you should keep the dosage as low and as short as possible.

**Breastfeeding:** The active ingredient in this medication, acetylsalicylic acid, passes into breast milk.

The use of this medication during breastfeeding is not recommended.

## **Driving and using machines**

Acetylsalicylic Injection 500 does not affect driving ability and the ability to use machinery.

## **How to use this medication?**

Always use this medication exactly as your doctor or pharmacist has instructed you. If you are unsure about the correct usage, contact your doctor or pharmacist.

## **The recommended dosage is:**

**Adults:** 1 to 2 vials per administration. Acetylsalicylic Injection 500 should be completely dissolved in injection water (glass ampoule) and injected deeply into the muscle or vein. In case of severe pain, 2 vials can be dissolved in 2 ampoules of injection water and injected into the vein simultaneously.

## **Use in children and adolescents under 18 years:**

**Children:** 5 to 25 mg of acetylsalicylic acid per kg of body weight per day.

The prepared solution should be used immediately and should not be stored.

## **What to do if you have used too much of this medication?**

Overdoses can be fatal, especially in the elderly and young children. In cases of acute or prolonged acetylsalicylic acid overdose, excessive fluid can accumulate in the lungs (non-cardiogenic pulmonary edema), which can be lethal.

The following symptoms may occur with overdose: ringing in the ears, hearing loss, headache, dizziness, and low blood sugar accompanied by hunger, sweating, dizziness, and palpitations (hypoglycemia). If you experience these symptoms, go to the emergency department of a hospital as soon as possible.

## **What if you forget to use this medication?**

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

**If you stop using this medication:** If you suddenly stop using this medication, the symptoms that existed before the start of treatment may reoccur. Do you have any other questions about the use of this medication? Contact your doctor or pharmacist.

## **Possible side effects:**

Like any medication, this medication can have side effects. Not everyone experiences them.

**Common side effects (occur in less than 1 in 100 users):** Abdominal pain, gastrointestinal bleeding leading to anemia, blood vomiting, black stool, gastrointestinal ulcers, and the formation of a hole in the stomach or intestines. These can occur at any dose of acetylsalicylic acid.

**Rare side effects (occur in less than 1 in 1000 users):** Confusion.

**Very rare side effects (occur in less than 1 in 10,000 users):** Reye's syndrome (a severe illness characterized by vomiting, confusion, and behavioral disorders).

## **Other side effects include:**

- Hypersensitivity reactions, asthma, sudden swelling of the throat (angioedema), skin and joint swelling, and shock due to an anaphylactic reaction to a specific substance.
- Visual disturbances.
- Asthma and rapid breathing, especially in young children.
- Difficulty breathing due to bronchial muscle spasms (bronchospasm) and asthma (inflammation and spasms of the bronchial muscles). Bronchi are in your lungs.
- Hives, skin rash (including allergic reactions to the medication), breathlessness.
- Kidney abnormalities in rare cases.
- Pain and local skin reactions at the injection site.
- Fluid retention (edema).

#### **How to store this medication?**

- Store below 25°C. Do not freeze. Keep in the original packaging.
- Keep out of sight and reach of children.
- The prepared solution should be used immediately and should not be stored.
- Do not use this medication after the expiry date stated on the label after "EXP" and on the box after "do not use after." The date consists of a month and a year. The last day of that month is the expiry date.
- Do not flush medications down the sink or toilet or throw them in the trash. Ask your pharmacist how to dispose of medications that are no longer needed. By disposing of medications correctly, they are disposed of properly and do not enter the environment.