

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 more 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.

ASA ZADA 100 mg gastro-resistant tablets
acetyl salicylic acid

What is in this leaflet:

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1. What ASA ZADA is and what it is used for

ASA ZADA contain acetylsalicylic acid, which in low doses belong to a group of medicines called anti-platelet agents. Platelets are tiny cells in the blood that cause

the blood to clot and are involved in thrombosis. When a blood clot occurs in an artery it stops the blood flowing and cuts off the oxygen supply. When this happens in the heart it can cause a heart attack or angina; in the brain it can cause a stroke.

ASA ZADA are taken to reduce the risk of blood clots forming and thereby prevent further:

- heart attacks
- strokes
- cardiovascular problems in patients who suffer from stable or unstable angina (a type of chest pain).

ASA ZADA are also used in the treatment of acute heart attack and to prevent the formation of blood clots after certain types of heart surgery in order to widen or to unblock the blood vessels.

This medicinal product is not suitable as a pain killer or fever reducer.

2. What you need to know before you take ASA ZADA

Do not take ASA ZADA if you:

- are allergic to acetylsalicylic acid or any of the ingredients of this medicine (listed in section 6)
- are allergic to other salicylates or non-steroidal anti-inflammatory drugs (NSAIDs).
- NSAIDs are often used for arthritis or rheumatism and pain have had an asthma attack or swelling of some parts of the body e.g. face, lips, throat or tongue (angioedema) after taking salicylates or NSAIDs
- currently have or have ever had an ulcer in your stomach or small intestine or any other type of bleeding like a stroke
- have ever had the problem of your blood not clotting properly
- have severe liver or kidney problems
- suffer from gout
- are in your last 3 months of pregnancy; you must not use higher doses than 100mg per day (see section "Pregnancy and breast-feeding")
- are taking a medicine called methotrexate (e.g. for cancer or rheumatoid arthritis) in doses higher than 15mg per week.

Warnings and precautions

Talk to your doctor or pharmacist before taking **ASA ZADA** if you:

- have trouble with your kidneys, liver or heart
- have or have ever had problems with your stomach or small intestine
- have high blood pressure
- are asthmatic, have hay fever, nasal polyps or other chronic respiratory diseases; acetylsalicylic acid may induce an asthma attack
- have ever had gout
- have heavy menstrual periods.

You must immediately seek medical advice, if your symptoms get worse or if you experience severe or unexpected side effects e.g. unusual bleeding symptoms, serious skin reactions or any other sign of serious allergy (see section "Possible sideeffects").

Inform your doctor if you are planning to have an operation (even a minor one, such as tooth extraction) since acetylsalicylic acid is blood-thinning there may be an increased risk of bleeding.

Acetylsalicylic acid may cause Reye's syndrome when given to children. Reye's syndrome is a very rare disease which affects the brain and liver and can be life threatening. For this reason, **ASA ZADA** should not be given to children aged under 16 years, unless on the advice of a doctor. You should take care not to become dehydrated (you may feel thirsty with a dry mouth) since the use of acetylsalicylic acid at the same time may result in deterioration of kidney function.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist.

Other medicines and ASA ZADA

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The effect of treatment may be influenced if acetylsalicylic acid is taken at the same time as some other medicines for:

- thinning of the blood/prevention of clots (e.g. warfarin, heparin, clopidogrel)
- rejection of organ after transplantation (ciclosporin, tacrolimus)
- high blood pressure (e.g. diuretics and ACE-inhibitors)
- regulation of the heart beat (digoxin)
- manic-depressive illness (lithium)
- pain and inflammation (e.g. NSAIDs such as ibuprofen or steroids)
- gout (e.g. probenecid)
- glaucoma (acetazolamide)
- cancer or rheumatoid arthritis (methotrexate; in doses lower than 15mg per week)
- diabetes (e.g. glibenclamide)
- depression (selective serotonin re-uptake inhibitors (SSRIs) such as sertraline or paroxetine)

use as hormone replacement therapy when the adrenal glands or pituitary gland have been destroyed or removed, or to treat inflammation, including rheumatic diseases and inflammation of the intestines (corticosteroids) -antacids (indigestion medicine).

ASA ZADA with alcohol

Drinking alcohol may possibly increase the risk of gastrointestinal bleeding and prolong bleeding time.

Pregnancy and breast-feeding

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 medicine.

Acetylsalicylic acid should not be taken during pregnancy unless advised by a doctor.

Driving and using machines

ASA ZADA should not affect your ability to drive and using machines.

3. How to take ASA ZADA

Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

The recommended dose is one tablet once daily.

Elderly (older than 65)

In general, acetylsalicylic acids should be used with caution in elderly patients who are more prone to adverse events. Use in children and adolescents

Acetylsalicylic acid should not be administered to children and adolescents younger than 16 years, unless prescribed by a doctor (see section "Warnings and precautions").

Method of administration

For oral use.

If you take more ASA ZADA than you should

If you (or someone else) accidentally take too many tablets, you should tell your doctor at once or contact immediately the nearest casualty department. Show any leftover medicines or the empty packet to the doctor.

Symptoms of overdose may include ringing in ears, hearing problems, headache, dizziness, confusion, nausea, vomiting and abdominal pain. A large overdose can lead to more rapid breathing than normal (hyperventilation), fever, excess sweating, restlessness, seizures, hallucinations, low blood sugar, coma and shock.

If you forget to take ASA ZADA

If you miss a dose, wait until it is time for your next dose, then go on as normal.

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

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

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects, stop taking Aspirin Tablets and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling and may be associated with a high fever and joint pains. This could be erythema multiforme, Stevens-Johnson syndrome or Lyell's syndrome.
- Unusual bleeding, such as coughing up blood, blood in your vomit or urine, or black stools.
- Common side effects (may affect up to 1 in 10 people):
- Indigestion.
- Increased tendency for bleeding.
- Uncommon side effects (may affect up to 1 in 100 people):
- Hives.
- Runny noses.
- Breathing difficulty.

Rare side effects (may affect up to 1 in 1000 people):

- Severe bleeding in the stomach or intestines, brain haemorrhage; altered number of blood cells.
- Nausea and vomiting.
- Cramps in the lower respiratory tract, asthma attack.
- Inflammation in the blood vessels.
- Bruising with purple spots (cutaneous bleeding).
- Severe skin reactions such as rash known as erythema multiforme and it's life threatening forms Stevens-Johnson syndrome and Lyell's syndrome.
- Hypersensitivity reactions, such as swelling of e.g. lips, face or body, or shock.
- Abnormal heavy or prolonged menstrual periods.
- Side effects with unknown frequency (frequency cannot be estimated from the available data)
- Ringing in your ears (tinnitus) or reduced hearing ability.
- Headache.
- Vertigo.
- Ulcers in stomach or small intestine and perforation.
- Prolonged bleeding time.
- Impaired kidney function.
- Salt or water retention which may cause swelling of hands, feet, legs,

stomach, breasts or face.
-Impaired liver function.
-High level of uric acid in the blood.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ASA ZADA

Do not store above 25°C. Store in the original package. Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month

6 Contents of the pack and other information

What ASA ZADA contains

The active substance is acetylsalicylic acid. Each tablet contains 100 mg of acetylsalicylic acid.

The other ingredients are: pregelatinized starch, copovidone, talc, stearic acid.

FILM: HPMC E6, methyl methacrylate copolymer, triethyl citrate, ammonium hydroxide, talc, purified water.

What ASA ZADA look like and contents of the pack

Box of 30 tablets of 100 mg acetyl salicylic acid in blister pack.

Manufacture and Marketing Authorisation Holder

ZADA Pharmaceuticals Ltd.
Donji Bistarac without number
75300 Lukavac
Bosnia and Herzegovina

Date and number of first authorisation/renewal of the authorization

ASA ZADA gastro-resistant tablets:

Number: 04-07.3-2-3343/18

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