Package leaflet: Information for the user

ASA Krka 75 mg gastro-resistant tablets
ASA Krka 100 mg gastro-resistant tablets
ASA Krka 160 mg gastro-resistant tablets

acetylsalicylic acid

Read all of this leaflet carefully before because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

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

ASA Krka contains 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 Krka is 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 Krka is also used to prevent the formation of blood clots after certain types of heart surgery in order to widen or to unblock the blood vessels.

The decision concerning initiation of the therapy and appropriate dosing should be made by a physician.

This medicinal product is not recommended for emergencies. It can only be used as a preventive treatment.

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

Do not take ASA Krka:
- if you are allergic to acetylsalicylic acid or any of the other ingredients of this medicine (listed in section 6).

- if you are allergic to other salicylates or non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs are often used for arthritis or rheumatism and pain.
- if you 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.
- if you currently have or have ever had an ulcer in your stomach or small intestine or any other type of bleeding like a stroke.
- if you have ever had the problem of your blood not clotting properly.
- if you have severe liver or kidney problems.
- if you have severe heart problems which can cause shortness of breath and ankle swelling
- if you are in your last 3 months of pregnancy; you must not use higher doses than 100 mg per day (see section "Pregnancy and breast-feeding").
- if you are taking a medicine called methotrexate (e.g. for cancer or rheumatoid arthritis) in doses higher than 15 mg per week.

Warnings and precautions
Talk to your doctor or pharmacist before taking ASA Krka.
- if you have trouble with your kidneys, liver or heart.
- if you have or have ever had problems with your stomach or small intestine.
- if you have uncontrolled high blood pressure.
- if you are asthmatic, have hay fever, nasal polyps or other chronic respiratory diseases; acetylsalicylic acid may induce an asthma attack.
- if you have ever had gout.
- if you have heavy menstrual periods.
- if you suffer from a deficiency of the enzyme glucose-6-phosphate dehydrogenase (G6PD)

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 side effects").

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.

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.

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

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

Children and adolescents
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 live threatening. For this reason, ASA Krka should not be given to children aged under 16 years, unless on the advice of a doctor.

Other medicines and ASA Krka
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 or dissolving (e.g. warfarin, heparin, clopidogrel, alteplase)
- rejection of organ after transplantation (cyclosporine, 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)
- epilepsy (valproate, phenytoin)
- glaucoma (acetazolamide)
- cancer or rheumatoid arthritis (methotrexate; in doses lower than 15 mg per week)
- diabetes (e.g. glibenclamide, insulin)
- 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)

ASA Krka with food and drink and alcohol
Drinking alcohol may possibly increase the risk of gastrointestinal bleeding and prolong bleeding time.

Pregnancy and breast-feeding 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 medicine.

Pregnant women should not take acetylsalicylic acid during pregnancy unless advised by their doctor. You should not take ASA Krka if you are in the last 3 months of pregnancy, unless you are advised to do so by your doctor and then the daily dose should not exceed 100 mg (see section "Do not take ASA Krka"). Regular or high doses of this medicinal product during late pregnancy can cause serious complications in the mother or baby.

Breast-feeding women should not take acetylsalicylic acid unless advised by their doctor.

Driving and using machines
ASA Krka should not affect your ability to drive and use machines.

ASA Krka contains lactose
If you have been told that you have an intolerance to certain sugars, please inform your doctor before taking this medicine.

ASA Krka 75 mg contains sunset-yellow (E110) which may cause allergic reaction.

ASA Krka 160 mg contains lecithin (soya) (E322)
If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take ASA Krka

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

Adults

Prevention of heart attacks:
- The recommended dose is 75-160 mg once daily.

Prevention of strokes:
- The recommended dose is 75-325 mg once daily.

Prevention of cardiovascular problems in patients who suffer from stable or unstable angina (a type of chest pain):
- The recommended dose is 75-160 mg once daily.

Prevention formation of blood clots after certain types of heart surgery:
- The recommended dose is 75-160 mg once daily.

This medicine should not be used at higher doses unless advised by a doctor, and then the dose should not exceed 325 mg a day.

Elderly
As for adults. In general, acetylsalicylic acids should be used with caution in elderly patients who are more prone to adverse events. Treatment should be reviewed at regular intervals.

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.
The tablets should be swallowed whole with sufficient fluid (1/2 glass of water). The tablets have a gastro-resistant coating which prevents irritant effects on the gut, and should therefore not be crushed, broken or chewed.

If you take more ASA Krka 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 left over 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 Krka
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 stop taking ASA Krka
Do not stop taking ASA Krka without asking your doctor.

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 ASA Krka 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.

Other side effects include:
Common (may affect up to 1 in 10 people):
- Nausea, vomiting, diarrhoea.
- Indigestion.

- Increased tendency for bleeding.

Uncommon (may affect up to 1 in 100 people):
- Hives.
- Runny noses.
- Breathing difficulty.

Rare (may affect up to 1 in 1,000 people):
- Severe bleeding in the stomach or intestines, brain haemorrhage; altered number of blood cells.
- 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.
- Reye's syndrome (a very rare disease in children which affects the brain and liver (see section 2 "Children and adolescents"))
- Abnormal heavy or prolonged menstrual periods

Not known (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, acute renal failure.
- Impaired liver function, increased liver enzymes.
- High level of uric acid or low levels of sugar in the blood.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee . By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ASA Krka

Keep this medicine out of the sight and reach of children.

ASA Krka 75 mg:
Do not store above 25°C.
Store in the original package in order to protect from light.

ASA Krka 100 mg:
Do not store above 30°C.

ASA Krka 160 mg:
Do not store above 30°C.
Store in the original package in order to protect from light.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ASA Krka contains

- The active substance is acetylsalicylic acid.
  Each gastro-resistant tablet contains 75 mg, 100 mg or 160 mg acetylsalicylic acid.

- The other ingredients are for ASA Krka 75 mg:
  Tablet core: lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, potato starch, talc, triacetin, methacrylic acid-ethylacrylate copolymer (1:1) dispersion 30%, sodium dodecyl suphate* and polysorbate 80*.
  Film-coating: polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350 (E1521), carmine (E120) and sunset yellow aluminium lake (E110).

- The other ingredients are for ASA Krka 100 mg:
  Tablet core: lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica and potato starch.
  Film-coating: talc, triacetin, methacrylic acid-ethylacrylate copolymer (1:1) dispersion 30%, sodium dodecyl suphate* and polysorbate 80*.

- The other ingredients are for ASA Krka 160 mg:
  Tablet core: lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, potato starch, talc, triacetin, methacrylic acid-ethylacrylate copolymer (1:1) dispersion 30%, sodium dodecyl suphate* and polysorbate 80*.
  Film-coating: polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350 (E1521), soy lecithin (E322) and iron oxide yellow (E172).

* It may contain sodium dodecyl sulfate and polysorbate 80

What ASA Krka looks like and contents of the pack
ASA Krka 75 mg: pink, round, biconvex film-coated tablet with a diameter of about 7.2 mm.
ASA Krka 100 mg: white, round, biconvex film-coated tablet with a diameter of about 8.1 mm.
ASA Krka 160 mg: yellow, round, biconvex film-coated tablet with a diameter of about 9.2 mm.

Pack sizes:
Blisters: 28, 30, 50, 56, 60, 84, 90, 100 and 168 (only for 100 mg) gastro-resistant tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
KRKA, d.d., Novo mesto
Šmarješka cesta 6
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