

PACKAGE LEAFLET:
Information for the patient

KARDIOSPIR

Gastro – resistant film – coated tablets – 100 mg
(Acetylsalicylic acid)

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 any further 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 symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet

1. What Kardiospir is and what it is used for
2. What you need to know before you take Kardiospir
3. How to take Kardiospir
4. Possible side effects
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1. WHAT KARDIOSPIR IS AND WHAT IT IS USED FOR

Acetylsalicylic acid (aspirine) is a non-steroidal anti-inflammatory drug (NSAID) of the salicylate group and which shares many common characteristics with other NSAIDs. It has analgesic, antipyretic, anti-inflammatory and antirheumatic effects. Acetylsalicylic acid lowers body's high temperature by dilating peripheral blood vessels. It has anti-inflammatory and analgesic effects through inhibition of prostaglandin synthase enzyme complex. By acetylating platelet cyclooxygenase, acetylsalicylic acid inhibits synthesis of thromboxane A_2 , a prostaglandin derivative and potent vasoconstrictor that stimulates platelet aggregation and their release. Acetylsalicylic acid inhibits platelet aggregation.

Kardiospir is indicated in:

- prophylaxis of cerebrovascular diseases or myocardial infarction (due to its antiplatelet effect);
- unstable angina (a special, dangerous type of coronary heart disease associated with chest pain even when at rest);
- minor brain strokes (cerebral ischemic strokes including transient ischemic attacks).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE KARDIOSPIR

Do not take Kardiospir if:

- you have hypersensitivity to acetylsalicylic acid or to any of the other ingredients (excipients) of Kardiospir;
- you have hemophilia or other blood coagulation disorders;
- the patient is under 12 years old (except in treatment of juvenile arthritis) due to the risk of Reye's syndrome.

Take special care with Kardiospir

Talk to your doctor or pharmacist before taking Kardiospir if:

- you have peptic ulcer;
- you have blood coagulation disorders;
- you have kidney or liver impairment (should not be used in severe impairment) or in dehydrated patients.
- you are going to give it to children under the age of 12, because acetylsalicylic acid may cause Reye's syndrome, and may be used only after the risks are weighed against possible therapeutic benefits (may be used in juvenile arthritis).

- you have asthma;
- you have allergic disease;
- you have uncontrolled hypertension and glucose-6-phosphate dehydrogenase deficiency;
- you are pregnant; it should be avoided during the last trimester of pregnancy;
- you are breast – feeding.

Acetylsalicylic acid should not be used in the treatment of gout.

Taking Kardiospir with food and drink

Kardiospir should not be taken with alcoholic beverages and should always be taken during or after meal.

Pregnancy

If you are pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. It should be used with caution during pregnancy and should be avoided during the last trimester. It may cause bleeding, delay and prolongation of labor, intrauterine closure of ductus arteriosus and kernicterus in neonates.

Breast-feeding

Salicylates are excreted into breast milk. Therefore, they should be cautiously used during breast – feeding.

Other medicines and Kardiospir

Use of other medicines with Kardiospir could influence Kardiospir's effect or the other medicine's effect. Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines without prescription. Inform your doctor that you are taking Kardiospir, if any other medicine is prescribed to you during treatment.

- Acetazolamide may increase urinary excretion of acetylsalicylic acid for as long the urine is alkaline, and acetylsalicylic acid may increase acetazolamide toxicity in the central nervous system.
- Acetylsalicylic acid may decrease the diuretic effect of spironolactone and loop diuretics.
- Acetylsalicylic acid increases the anticoagulant effect and thus, increases the risk of bleeding when used concomitantly with heparine or oral anticoagulants.
- Acetylsalicylic acid decreases the antihypertensive effect of ACE inhibitors and beta blockers.
- Combination of acetylsalicylic acid with other non-steroidal anti-inflammatory drugs does not offer any therapeutic advantage, while it increases the incidence of adverse effects.
- Acetylsalicylic acid may increase plasmatic concentrations of free valproic acid and thereby increase its toxicity.
- Acetylsalicylic acid inhibits the tubular secretion of methotrexate and thereby increases its toxicity.
- Kardiospir should not be taken with alcoholic beverages and should always be taken during or after meal.

3. HOW TO TAKE KARDIOSPIR

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you feel that Kardiospir's effect is too strong or too weak talk to your doctor or pharmacist. Tablets should be swallowed whole with a glass of water (200 – 250 ml) during or after meal. The tablets should not be broken, crushed, or chewed. The tablets should not be broken, crushed, or chewed because this may damage the special tablet coating which prevents the release of acetylsalicylic acid in the stomach.

Dosing is as follows:

When you use acetylsalicylic acid for the first time for the indications mentioned above, your doctor may instruct you to take two tablets of 100 mg. Afterwards, the recommended daily dose is 100 mg, however your doctor may prescribe a higher dose.

For its antiplatelet (antiaggregant) effect after myocardial infarction, transient ischemic attacks or in patients with unstable angina the recommended dose is 100 mg - 300 mg daily.

If you take more Kardiospir than you should

If you have taken more Kardiospir than you should or if children have taken this medicine by mistake contact your doctor or the nearest hospital or call the emergency service to ask for the risks and advice on actions that should be taken.

Treatment: when life of the patient is at risk due to a serious intoxication, immediate measures should be taken to prevent the further absorption of the drug. Gastric lavage should be performed, active carbon should be administered, and electrolytes should be checked and corrected. If needed, hemoperfusion or hemodialysis may be performed.

If you forget to take Kardiospir

If you forget taking one (or more doses), take the next dose at the next prescribed time. Do not take a double (or higher) dose to make up for a forgotten dose (doses). If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Kardiospir can cause side effects, although not everybody gets them. Kardiospir is well tolerated in the recommended doses. Talk to your doctor or pharmacist, if you get any side effects mentioned below:

- gastrointestinal disorders or nausea;
- ulcers with occult blood loss (major bleeding occurs rarely);
- other haemorrhages e.g., suconjunctival hemorrhage;
- hearing disorders, e.g., tinnitus (rarely may cause hearing loss);
- dizziness, confusion;
- hypersensitivity reactions (angioedema, bronchospasm and exanthema);
- prolonged bleeding time;
- rarely edema;
- myocarditis;
- blood disorders, particularly thrombocytopenia.

If any of these side effects gets worse or if you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. If any of the above side effects occurs, treatment with Kardiospir

should be discontinued and you should consult your doctor or pharmacist.

5. HOW TO STORE KARDIOSPIR

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

Do not use this medicine after the expiry date which is stated on the carton box!

Store below 25°C!

Keep in the original packaging protected from light and humidity!

6. OTHER INFORMATION

What Kardiospir contains

The active substance is acetylsalicylic acid.

Each gastro – resistant film – coated tablet contains:

The excipients are microcrystalline cellulose, carboxymethylcellulose sodium, pregelatinised starch, colloidal silicon dioxide, sodium starch glycolate, stearic acid, Acryl Eze orange (colorant) and Opadry YS.

Contents of the pack

Carton box with 20 gastro – resistant film – coated tablets.

Explanatory of the illustration icons on the packaging:



Can be taken without medical prescription.



Contents.



Warning.



Tablet shape.

Marketing Authorisation Holder and Manufacturer



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This leaflet was last revised in September 2013.