

## PACKAGE LEAFLET: Information for the patient

### KARDIOSPIR

Enteric-coated (gastro-resistant) 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. Before you take Kardiospir
3. How to take Kardiospir
4. Possible side effects
5. How to store Kardiospir
6. Other information

### 1. WHAT KARDIOSPIR IS AND WHAT IT IS USED FOR

Kardiospir contains acetylsalicylic acid as active substance. Acetylsalicylic acid (aspirin) is a nonsteroidal anti-inflammatory drug (NSAID) of the salicylate group and shares many common characteristics with other NSAIDs. It has analgesic, antipyretic, anti-inflammatory and antirheumatic effects. Acetylsalicylic acid lowers the body high temperature by dilating peripheral blood vessels. It exerts anti-inflammatory and analgesic effects through inhibition of prostaglandin-synthetase enzyme complex. By acetyloyating platelet cyclooxygenase, acetylsalicylic acid inhibits the synthesis of thromboxane A<sub>2</sub>, a prostaglandin derivative and

potent vasoconstrictor that stimulates platelet aggregation and their release. Acetylsalicylic acid inhibits platelet aggregation.

It 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 strokes in the brain (cerebral ischemic strokes including transient ischemic attacks).

Your doctor may have given Kardiospir for another reason to you. Ask your doctor if you want to know why you are given Kardiospir.

## **2. BEFORE YOU TAKE KARDIOSPIR**

**Do not take Kardiospir if:**

- you suffer from hypersensitivity to acetylsalicylic acid or to any of the other ingredients (excipients) of Kardiospir;
- you suffer from hypersensitivity to other salicylates or other nonsteroidal anti-inflammatory drugs (you have experienced: asthma, angioedema, urticaria, or rhinitis after taking acetylsalicylic acid (aspirin) or other nonsteroidal anti-inflammatory drugs);
- you have haemophilia or other blood coagulation disorders;
- the patient is under 16 years old, due to the risk of Reye's syndrome; in this case, if there is a special indication, only the doctor can decide for the use of the drug;
- you suffer from active peptic ulceration.

**Take special care with Kardiospir**

Ask your doctor before taking Kardiospir if:

- you have ever had peptic ulcer;
- you have anemia;
- you have kidney or liver impairment (it should not be used in severe impairment) or in dehydrated patients;

- you have thyrotoxicosis;
- you have asthma;
- you have allergic disease;
- you have uncontrolled hypertension and glucose-6-phosphate dehydrogenase deficiency;
- you are taking methotrexate at doses 15 mg / week or higher;
- you are pregnant; it should be avoided during the last trimester of pregnancy;
- you are still breastfeeding;
- you are elderly.

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

### **Other medicines and Kardiospir**

Concomitant use of other drugs may affect or be affected by Kardiospir. Please, tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines without prescription. Remember to 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 as the urine is alkaline, whereas 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 heparin or oral anticoagulants.
- Acetylsalicylic acid decreases the antihypertensive effect of ACE inhibitors and beta-blockers.
- The combination of acetylsalicylic acid with other nonsteroidal anti-inflammatory drugs does not offer any therapeutic advantage, while it increases the incidence of adverse effects.
- Acetylsalicylic acid may increase the plasmatic concentrations of valproic acid and thereby increase its toxicity.
- Acetylsalicylic acid inhibits the tubular secretion of methotrexate and thereby increases its toxicity.

- Acetylsalicylic acid taken concomitantly with drugs for treatment of depression (such as selective serotonin reuptake inhibitors or venlafaxine) increases the risk of haemorrhage.
- Acetylsalicylic acid should be used with caution also with these drugs: digoxin, cyclosporine, probenecid, sulfinpyrazone, sulfonylurea, corticosteroids.
- Metamizole (substance to decrease pain and fever) may reduce the effect of acetylsalicylic acid on platelet aggregation (blood cells sticking together and forming a blood clot), when taken concomitantly. Therefore, this combination should be used with caution in patients taking low dose aspirin for cardioprotection.

### **Taking Kardiospir with food and drinks**

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

### **Pregnancy**

Inform your doctor or pharmacist if you are pregnant, or are planning to have a baby. 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.

### **Breastfeeding**

Salicylates are excreted into breastmilk. Therefore, they should be cautiously used during breastfeeding.

### **Driving and using machines**

There are no data, but generally there have not been noticed symptoms that affect the ability to drive or use machines.

### **Important information about some of the excipients of Kardiospir**

This drug contains the azodye Sunset Yellow FCF (E110), which may cause allergic reactions.

### **3. HOW TO TAKE KARDIOSPIR**

Always take Kardiospir exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you feel that the effect of Kardiospir is too strong or too weak, talk to your doctor or pharmacist.

The tablets should be swallowed with a glass of water (200 – 250 ml) during or after the meal. Swallow the tablets whole and with water. Do not break, crush, or chew the tablets 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 take more Kardiospir than you should or if the 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 the 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 to take 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 medicinal 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 (sometimes even serious haemorrhage);
- other haemorrhages e.g., subconjunctival haemorrhage;
- hearing disorders, e.g., tinnitus (rarely hearing loss may be caused);
- dizziness, confusion;
- hypersensitivity reactions (angioedema, bronchospasm and exanthema);
- prolonged coagulation time;
- rarely oedema;
- myocarditis;
- blood disorders, particularly thrombocytopenia.

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. When any of the above side effects appears, the treatment with Kardiospir should be interrupted and you should ask your doctor or pharmacist for advice.

## **5. HOW TO STORE KARDIOSPIR**

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

Do not use Kardiospir after the expiry date which is stated on the carton box.

Do not store above 25°C!

Store it in the original packaging protected from light and humidity.

## **6. OTHER INFORMATION**

### **What Kardiospir contains**

**The active substance** is acetylsalicylic acid.

Each enteric-coated tablet contains 100 mg acetylsalicylic acid.

**The excipients** are microcrystalline cellulose, croscarmellose sodium, pregelatinised starch, colloidal anhydrous silica, sodium starch glycolate, stearic acid, methacrylic acid copolymer, talc, yellow iron oxide, titanium dioxide, triethyl citrate, Sunset Yellow FCF (E 110), silica, sodium bicarbonate, sodium lauryl sulfate, hypromellose, triacetin.

### **Content of the pack**

Carton box with 20 enteric-coated (gastro-resistant) tablets.

### **Marketing Authorisation Holder and Manufacturer**

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