

Package leaflet: Information for the patient

Cardiosalin Protect 75 mg gastro-resistant tablets Cardiosalin Protect 100 mg gastro-resistant tablets Acetylsalicylic acid

Read all of this leaflet carefully before you start using 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 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. See section 4.

What is in this leaflet

1. What Cardiosalin Protect is and what it is used for
2. What you need to know before you use Cardiosalin Protect
3. How to use Cardiosalin Protect
4. Possible side effects
5. How to store Cardiosalin Protect
6. Contents of the pack and other information

1. What Cardiosalin Protect is and what it is used for

Cardiosalin Protect contains acetylsalicylic acid, which in low doses belongs to a group of medicines called antithrombotic agents.

Platelets are a type of blood cell that causes blood to clot and are involved in the formation of blood clots. When a blood clot forms in an artery, blood flow is disrupted and the supply of oxygen to the tissues is interrupted, which can cause the development of paroxysmal chest pain (angina pectoris), heart attack, stroke, pulmonary embolism and others.

Applied in low doses, acetylsalicylic acid reduces the ability of platelets to stick together and adhere to the walls of blood vessels, resulting in a reduced risk of blood clots (thrombi).

Cardiosalin Protect is used to reduce the risk of blood clots and thus prevent the development of:

- heart attacks;
- strokes;
- cardiovascular problems in patients suffering from stable and unstable angina (a type of chest pain).

Cardiosalin Protect is also used to prevent the formation of blood clots (thrombi) after certain types of heart surgery, in order to dilate or unblock blood vessels.

2. What you need to know before you use Cardiosalin Protect

Do not use Cardiosalin Protect:

- If you are allergic (hypersensitive) 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 in some parts of the body, such as the face, lips, throat or tongue (angioedema) after taking salicylates or NSAIDs;

- If you have or have had a stomach or duodenal ulcer or any other type of bleeding, such as a haemorrhagic stroke;
- If you have had problems with blood clotting;
- If you have severe liver or kidney damage;
- If you are in the last 3 months of your pregnancy, you should not take doses higher than 100 mg / day (see "Pregnancy, breast-feeding and fertility").
- If you are currently being treated with a medicine called methotrexate (used to treat cancer or rheumatoid arthritis) at doses above 15 mg a week.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cardiosalin Protect:

- If you have kidney, liver or heart disease;
- If you have or have had problems with your stomach or small intestines;
- If you have high blood pressure;
- If you suffer from asthma, hay fever, nasal polyps or other chronic diseases of the respiratory system. Acetylsalicylic acid can cause an asthma attack;
- If you have suffered from gout;
- If you have a heavy menstrual cycle.

You should seek medical attention immediately if your symptoms worsen or you have severe or unexpected side effects, such as symptoms of unusual bleeding, severe skin reactions or any other sign of a serious allergy (see 'Possible side effects').

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

Acetylsalicylic acid can cause Reye's syndrome when given to children. Reye's syndrome is a very rare disease that affects the brain and liver and can be life-threatening. Therefore, Cardiosalin Protect should not be given to children under 16 years of age unless prescribed by a doctor.

Care should be taken not to dehydrate (a condition accompanied by thirst and dry mouth), as the use of acetylsalicylic acid in this condition can lead to impaired renal function.

This medicine is not suitable for use as a painkiller or for lowering the temperature.

Other medicines and Cardiosalin Protect

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 rate and supporting the pumping function of the heart (digoxin)
- manic-depressive illness (lithium)
- pain and inflammation (e.g. NSAIDs such as ibuprofen or steroids)
- metamizole (a substance used to reduce pain and fever) may reduce the effect of acetylsalicylic acid on platelet aggregation (platelet aggregation and blood clot formation) when taken at the same time. Therefore, this combination should be used with caution in patients taking low-dose acetylsalicylic acid for cardioprotection (heart protection);
- gout (eg probenecid);
- epilepsy (valproate, phenytoin);
- glaucoma (acetazolamide);
- cancer or rheumatoid arthritis (methotrexate in doses below 15 mg per week);

- diabetes (eg sulphonylureas);
- depression (selective serotonin reuptake inhibitors, such as sertraline or paroxetine);
- hormone replacement therapy, when the adrenal glands or pituitary gland are damaged or removed, or to treat inflammation, including rheumatic diseases and inflammation of the gut (corticosteroids).

Cardiosalin Protect with food, drink and alcohol

Alcohol consumption may increase the risk of gastrointestinal bleeding and prolong bleeding time.

Pregnancy, 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.

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

You should not take Cardiosalin Protect if you are in the last three months of pregnancy, unless you are advised to do so by your doctor and then the daily dose should not exceed 100mg (see section “Do not take Cardiosalin Protect”). Regular or high doses of this medicinal product during late pregnancy can cause serious complications in the mother or baby.

Women should not take acetylsalicylic acid during breast-feeding unless advised by their doctor.

Driving and using machines

Cardiosalin Protect should not affect your ability to drive and use machines.

3. How to use Cardiosalin Protect

Always use this medicine exactly 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 75-150 mg once daily.

Prevention of stroke

The recommended dose is 75-300 mg once daily.

Prevention of cardiovascular disorders in patients with stable or unstable angina (chest pain)

The recommended dose is 75-150 mg once daily.

Prevent the formation of blood clots (thrombi) after some heart surgery

The recommended dose is 75-150 mg once daily.

Elderly patients

Acetylsalicylic acid should be used with caution in elderly patients, as they are more prone to side effects. Treatment in these patients should be reviewed periodically.

Use in children and adolescents

Acetylsalicylic acid should not be used in children and adolescents under 16 years of age, unless prescribed by a doctor (see section "Warnings and precautions").

Method of administration

Cardiosalin Protect film-coated tablets are for oral use.

It is recommended that gastro-resistant tablets be taken at least 30 minutes before a meal with sufficient fluid (1/2 cup water). Gastro-resistant tablets should be swallowed whole and should not be crushed, broken or chewed.

If you use more Cardiosalin Protect than you should

If you (or anyone else) inadvertently take too many tablets, you should tell your doctor immediately or contact the nearest emergency department immediately. Show the doctor the rest of the medicine or the empty pack.

Symptoms of overdose may include tinnitus, hearing problems, headache, dizziness, confusion, nausea, vomiting, and abdominal pain. Severe overdose can cause rapid breathing, fever, excessive sweating, anxiety, convulsions, hallucinations, low blood sugar, shock and coma.

If you forget to use Cardiosalin Protect

If you miss a dose, wait until it is time for your next dose and then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Reporting of 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 Cardiosalin Protect and contact your doctor immediately:

- Sudden difficulty breathing with wheezing, swelling of the lips, face or body, rash, fainting or difficulty swallowing (severe allergic reaction);
- Reddening of the skin with blisters or scaling, which may be accompanied by fever and joint pain. These may be manifestations of severe skin reactions, such as erythema multiforme, Stevens-Johnson syndrome or Lyell's syndrome;
- Unusual bleeding, such as haemoptysis, vomiting of bloody contents, blood in the urine or black stools.

Common side effects (may affect up to 1 in 10 people)

- Indigestion
- Increased tendency to bleed

Uncommon side effects (may affect up to 1 in 100 people)

- Urticaria
- Runny nose
- Difficulty breathing

Rare side effects (may affect up to 1 in 1,000 people)

- Heavy gastrointestinal bleeding, brain haemorrhage, change in the number of blood cells
- Nausea and vomiting
- Spasms in the lower respiratory tract, asthma attacks
- Inflammation of the blood vessels
- Haemorrhage with reddish-purple spots on the skin (hemorrhagic vasculitis)
- Severe skin reactions, such as rash known as erythema multiforme and its life-threatening forms
 - Stevens-Johnson syndrome and Lyell's syndrome
- Hypersensitivity reactions with swelling of the lips, face or body or shock
- Unusually large amount or duration of menstrual bleeding

Adverse reactions of unknown frequency (cannot be estimated from the available data)

- Tinnitus or hearing loss
- Headache
- Dizziness
- Gastric or duodenal ulcer and perforation
- Prolonged bleeding time

- Impaired renal function
- Impaired liver function
- High levels of uric acid 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:

Bulgarian Drug Agency
8 Damyan Gruev Street
1303 Sofia
Tel.: +35 928903417
Website: www.bda.bg

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cardiosalin Protect

Store below 25 ° C.

Keep out of reach of children.

Blister: Store in the original package in order to protect from moisture.

Jar: Keep container tightly closed in order to protect from moisture.

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

Shelf life after first opening of the jar: 4 (four) months.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cardiosalin Protect contains

- The active substance is acetylsalicylic acid. Each gastro-resistant tablet contains 75 or 100 mg of acetylsalicylic acid.
- The other ingredients (excipients) are: tablet core - corn starch; sodium starch glycolate (type A), film coating - white, copolymer of methacrylic acid - ethyl acrylate (1: 1), talc, triethyl citrate, yellow iron oxide (E 172) (for 75 mg tablets).

What Cardiosalin Protect looks like and contents of the pack

Cardiosalin Protect 75 mg - yellow, round, biconvex, gastro-resistant tablets.

Cardiosalin Protect 100 mg - white, round, biconvex, gastro-resistant tablets.

Contents of the package

Primary packaging

- Blister of PVC / PVdC / Al foil - ten (10) tablets in a blister
- HDPE jar with PP cap and dryer, one hundred (100) tablets per jar

Secondary packaging

- 3 or 4 blisters together with a patient leaflet in a cardboard box
- One jar together with a patient leaflet in a cardboard box

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Antibiotic-Razgrad AD
Office 201, 68 “Aprilsko vastanie” Blvd.
7200 Razgrad, Bulgaria

Manufacturer

Balkanpharma-Razgrad AD
68 “Aprilsko vastanie” Blvd.
7200 Razgrad, Bulgaria

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Antibiotic-Razgrad AD
Office 201, 68 “Aprilsko vastanie” Blvd.
7200 Razgrad, Bulgaria
Tel.: +359 084 613 427
e-mail: office@antibiotic.bg

This leaflet was last revised in: January, 2022