



ASPIRIN® PROTECT 100

Patient Information Leaflet

Aspirin® Protect 100 mg

Enteric-coated tablets with 100 mg acetylsalicylic acid

Please read the entire patient information leaflet carefully as it contains important information on using the medicine.

- This medicine is available on a nonprescription basis. To achieve the best possible therapeutic results, you must nonetheless use Aspirin Protect 100mg as directed.
- Keep the patient information leaflet you may wish to read it again later.
- If you have any further questions or need advice, please consult your pharmacist.
- If your condition worsens or has not improved, in any case you must consult a doctor.

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1. WHAT IS ASPIRIN® PROTECT AND WHAT IS IT USED FOR

Aspirin Protect contains the active substance acetylsalicylic acid. It inhibits the coagulation of the blood platelets even in small concentrations. Due to an enteric coating, the tablet dissolves in the small intestine. Therefore, Aspirin Protect is gentle on the stomach lining. Aspirin Protect may only be taken if prescribed by a physician.

Aspirin Protect serves as:

- Prevention of arterial thromboses after surgeries involving the coronary vessels (bypass and elimination of a constriction of the coronary vessels).
- Prevention of strokes after preliminary stages have occurred (transitory ischemic attacks, TIA).
- Prevention of arterial thromboses (blood clots in coronary vessels) and after a myocardial infarction (reinfarction prophylaxis).
- Prevention of myocardial infarctions in patients after a high risk was determined by a physician. Comorbidities such as high blood pressure, diabetes, elevated blood lipids must be treated at the same time. Smoking should also be stopped.
- Treatment of unstable angina pectoris.
- Treatment of an acute myocardial infarction.
- Prevention of arterial thromboses after surgeries on blood vessels.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ASPIRIN® PROTECT

Aspirin Protect must not be taken for an extended period of time or in higher doses without consulting a physician.

When must Aspirin Protect not be taken?

You must not use Aspirin Protect in the following cases:

- If you have an allergic reaction to any of the ingredients, or have had breathing problems or allergy-like reactions after taking acetylsalicylic acid or other painkillers or anti-inflammatories called non-steroidal anti-inflammatory drugs.
- If you have active stomach and/or intestinal ulcers or stomach or intestinal bleeding.
- If you have a pathological increased tendency to bleed.
- If you have severe liver or kidney failure.
- If you have severe heart failure.
- If you have to take methotrexate concomitantly in a dose of more than 15 mg per week.
- In the last three months of pregnancy.

When is caution indicated during the use of Aspirin Protect?

During treatment with Aspirin Protect, ulcers can occur in the upper gastrointestinal tract. Bleeding can occur in rare cases or perforations (gastric or intestinal perforation) can occur in individual cases. These complications can occur at any time during treatment without any warning symptoms.

Contact your physician if you have stomach pain and suspect a connection to the administration of medication.

Taking Aspirin Protect can damage your kidney function, which can lead to higher blood pressure and/or build-ups of fluid (oedema). Tell your doctor if you have heart or kidney problems, if you are taking blood pressure medicines (e.g., diuretics, ACE inhibitors) or if you lose a significant amount of fluid, e.g., through extreme sweating.

The drug should be taken only in accordance with strict instructions of the physician in the event of chronic or recurring gastrointestinal disorders and asthma, urticaria, nasal polyps, hay fever or other allergies, a rare disease of the red blood cells, the so-called “glucose-6 phosphate dehydrogenase deficiency” as well as a treatment with anticoagulants (“blood thinners”) or blood pressure reducing agents (antihypertensives).

Aspirin Protect is not recommended for children and adolescents under the age of 18.

Children and adolescents with fever, flu, chicken-pox or other viral diseases may use Aspirin Protect only as instructed by the physician and only as a second choice agent. Consult the physician immediately if disturbances of consciousness with vomiting occur during these illnesses or after they subsided.

Taking Aspirin Protect and antidiabetic drugs (e.g. insulin, sulphonylureas) at the same time may lower the blood sugar level.

You should talk to your physician if you are taking Aspirin Protect concurrently with any pain or anti-inflammatory medication (such as, for example, the active pharmaceutical ingredients ibuprofen or naproxen), as these may weaken the effect of Aspirin Protect.

If Metamizole (medicinal product for the treatment of pain and fever) is taken at the same time as Aspirin Protect, it may reduce the effect of acetylsalicylic acid on platelet aggregation (clumping of blood platelets and clot formation). This combination should therefore be used with caution in patients who are taking low-dose acetylsalicylic acid for cardio protection.

The effect of gout medications (probenecid and sulfinpyrazone), diuretics and medications against high blood pressure may be reduced. If antirheumatic agents or methotrexate (which is e.g. taken to treat chronic polyarthritis; see also section “Do not take Aspirin Protect”) are used, then the adverse effects may intensify.

In the event of the concomitant and prolonged use of Aspirin Protect, the effect of cortisone products, anticonvulsants (anti-epileptics), blood thinners, digoxin and lithium preparations against depression may be increased. The adverse effect of these medicinal products may be increased.

If taken concomitantly with cortisone products, alcohol or medicinal products from the group of the so-called serotonin reuptake inhibitors against depression, Aspirin Protect may increase the risk for bleeding. The concomitant use of Aspirin Protect and cortisone products or alcohol may increase the risk for gastrointestinal ulcers.

The tendency to bleed may be increased even after minor interventions such as tooth extractions. Acetylsalicylic acid reduces the excretion of uric acid even in small dosages. This can induce gout in patients who already exhibit a low uric acid excretion.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

Tell your doctor or pharmacist if you

- suffer from other illnesses
- have any allergies or
- are taking or outwardly applying any other medicines (including those bought over the counter).

Ask or inform the physician or dentist about the use of the medication prior to surgical interventions.

May Aspirin Protect be taken during pregnancy and breastfeeding?

Pregnancy

You should not use medicinal products during pregnancy as a precaution.

If you become pregnant or are planning a pregnancy, you should talk to your doctor

before you take Aspirin Protect. If you continue or start treatment with Aspirin Protect during pregnancy per instruction of the physician, then this may occur only under strict compliance with his or her instructions and only during the first six months of pregnancy. Aspirin Protect must not be taken during the last three months of pregnancy due to a possible risk to the unborn child, the risk for bleeding and a possible delay of the date of the birth.

If you take Aspirin Protect from 20 weeks of pregnancy, it may cause narrowing of a blood vessel (ductus arteriosus) in your child's heart. If you need to take Aspirin Protect, your doctor may recommend additional monitoring.

Breastfeeding

Aspirin Protect should not be taken while breast-feeding unless your doctor has explicitly told you to.

3. HOW TO TAKE ASPIRIN® PROTECT

If not prescribed otherwise by the physician:

Prevention of arterial thromboses without bypass surgery on the coronary vessels and after dilation (balloon dilation) of constricted coronary vessels:

100 mg/day.

Prevention of arterial thromboses after bypass surgery on the coronary vessels and after dilation (balloon dilation) of constricted coronary vessels:

100 – 300 mg/day.

Prevention of strokes:

1 x 100 mg/daily.

Prevention of thromboses after myocardial infarction and treatment of unstable angina pectoris:

1 x 100 mg/day.

Prevention of heart attacks in patients after a high risk was determined by a physician:

1 x 100 mg/day.

It is recommended to take the tablets with a small amount of fluid at least half an hour before a meal. Drink approximately ½ -1 glass of liquid afterward. The tablets should not be crushed, broken or chewed.

In the event of an acute heart attack:

If you suffer an acute heart attack, at hospital, you will be administered 200-300 mg of acetylsalicylic acid intravenously. Alternatively, you may be administered a rapidly absorbed acetylsalicylic acid preparation (non-enteric-coated form), which you may take by mouth, either crushed or chewed, in order for the active pharmaceutical ingredient to be absorbed more quickly. From the second day onwards, the dose is 100 mg of Aspirin Protect daily.

The physician in charge will decide on the dose and duration of use.

Do not deviate from the prescribed dosage. If you believe that the effect of the medicine is too weak or too strong, talk to your doctor or pharmacist.

Consult a physician immediately in the event of uncontrolled administration (overdose). Tinnitus and/or sweating may indicate an overdose.

Aspirin Protect should not be used in children and adolescents under the age of 18.

4. POSSIBLE SIDE EFFECTS

Common (affects 1 to 10 out of 100 users)

Stomach problems are a common side effect.

Uncommon (affects 1 to 10 out of 1,000 users)

Asthma, digestive problems, nausea, vomiting and diarrhoea were reported occasionally.

Rare (affects 1 to 10 out of 10,000 users)

Hypersensitivity reactions (such as swelling of the skin and mucous membranes (e.g. stuffy nose), skin rashes, shortness of breath, drop in blood pressure up to shock) as well as gastrointestinal bleeding and gastrointestinal ulcers, which very rarely may lead to perforations may occur in rare cases.

Headaches, dizziness, tinnitus, visual impairment, hearing impairment, states of confusion, anemia due to iron deficiency as well as renal and hepatic dysfunctions rarely occur.

In rare to very rare cases, serious bleeding, especially in patients with unbalanced hypertension and/or treated concomitantly with “blood thinners” (anticoagulants) were reported, and

these can in single cases be potentially life-threatening.

Very rare (affects less than 1 out of 10,000 users)

Very rare side effects may include severe skin reactions including exudative erythema multiform, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), drug-induced hypersensitivity syndrome, drug rash with eosinophilia and systemic symptoms (DRESS), low blood sugar, disturbances of the acid base balance as well as Reye's syndrome in children.

Contusions, nose bleeds, bleeding gums, urogenital bleeding and bleeding after surgical interventions were observed. A prolongation of the bleeding time is possible.

Frequency not known (cannot be estimated from the available data)

Sudden renal failure was reported.

Changes in the intestinal wall have been reported, especially with long-term use.

The medicinal product must be discontinued and the physician must be consulted if signs of a hypersensitivity reaction occur.

If black stool or bloody vomiting occur during the treatment, then the medicinal product should be discontinued and the physician should be consulted immediately.

If you get any side effects, talk to your doctor or pharmacist. This particularly includes any possible side effects not listed in this leaflet.

To report any side effect

Jordan	Rational drug use and pharmacovigilance department-JFDA Phone: 06-4602000 Fax: 06-5626325 E-mail: jpc@jfda.jo Website: http://www.jfda.jo/
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5. HOW TO STORE ASPIRIN® PROTECT

Keep out of the reach and sight of children. Not to be stored above 25°C.

Do not use this medicine after the expiry date which is stated on the container after “EXP”. Your doctor or pharmacist will provide you with more detailed information. They have the detailed information for healthcare professionals.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Aspirin Protect contains

1 film-coated tablet Aspirin Protect 100 with enteric coating contains:

Active ingredient: 100 mg acetylsalicylic acid.

Other ingredients: Maize starch, cellulose powder, methacrylic acid – ethyl acrylate copolymer (1:1), polysorbate 80, sodium laurilsulfate (E 487) equiv. sodium max. 0.01 mg, talc (E 553b), triethyl citrate.

Which pack sizes are available

100 mg Enteric-coated tablets: 20 , 30, 60 and 90.

Not all pack sizes may be marketed.

Bulk Manufacturer:

Bayer AG, Leverkusen, Germany.

Manufacturer:

Manufactured by Bayer Bitterfeld GmbH, Germany for Bayer Consumer Care AG, Basel, Switzerland.

This leaflet was last reviewed in August 2023.

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists