In leaflet
1. What is Aspirin Protect and when is it used

Aspirin Protect contains the active pharmaceutical ingredient 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 (transient ischaemic attacks).
- 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 asymptomatic coronary atherosclerotic plaques.
- Prevention of gouty arthritis (probenecid and sulfapyrazone), diuretics and medications against high blood pressure may be reduced. If antiphlogistics or methotrexate (which is e.g. taken to treat chronic polyarthritis; see also section "What Must Aspirin Protect not be used") are used, then the adverse effects may be intensified.
- The effect of gout medications (probenecid and sulfapyrazone), diuretics and medications against high blood pressure may be reduced. If antiphlogistics or methotrexate (which is e.g. taken to treat chronic polyarthritis; see also section "What Must Aspirin Protect not be used") are used, then the adverse effects may be intensified.
- In the event of the concomitant and prolonged use of Aspirin Protect, the effect of contraceptives, anticonvulsants (anti-epileptic), 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.

Inform your physician or pharmacist if you are suffering from other diseases,
- have allergies or
- are using other medicinal products (even over-the-counter medications!).

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 lactation?
You should not use medicinal products during pregnancy and lactation as a precaution. 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 being female and a possible delay of the date of the birth. If higher doses are taken regularly during lactation, then the infant should be weaned.

3. HOW TO USE 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: 3 × 100 mg/day.
- Prevention of thromboses after myocardial infarction and treatment of unstable angina pectoris: 1 × 100 mg/day.
- Prevention of heart attacks in patients after a high risk was determined by a physician: 1 × 100 mg/day.

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

In the event of acute myocardial infarction:
If you suffer of an acute myocardial infarction, at hospital, you will be administered 200-250 mg acetylsalicylic acid intravenously. Alternatively, you may be administered a rapidly absorbed acetylsalicylic acid preparation (non-enteric-coated form), which may be taken 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 treating physician decides on the dosage and the duration of use.

Do not change the prescribed dose by yourself. Talk to your physician or pharmacist if you believe that the medicine acts too mildly or too strongly.

Consult a physician immediately in the event of an 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

Stomach problems are a common side effect. Asthma, digestive problems, nausea, vomiting and diarrhoea were reported occasionally. 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 gastro-intestinal ulcers, which very rarely may lead to perforations may occur in rare cases.

Headaches, dizziness, tinnitus, visual impairment, hearing impairment, states of confusion, anaemia due to iron deficiency as well as renal and hepatic dysfunction 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 side effects may include severe skin reactions, low blood sugar, disturbances of the acid base balance as well as Reye's syndrome in children.

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

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.

You should inform your physician or pharmacist if you notice side effects that are not described here.

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
- Iron oxide, red iron oxide, ferric oxide.
- Titanium dioxide, talc, 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: Bayer Consumer Care AG, Basel, Switzerland.

This leaflet was last reviewed in November 2017.

This is a medicinal 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 medicine.

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 medicinal out of reach of children.