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1. WHAT ASPIRIN PROTECT IS AND WHAT IT IS USED FOR
Aspirin Protect contains the active substance acetylsalicylic acid. Even low amounts of this active substance can affect the clotting of blood platelets. Since it has a stomach acid-resistant coating, the tablet does not dissolve until it reaches the small intestine. In this way, Aspirin Protect protects the stomach lining.

Take Aspirin Protect only if it has been prescribed to you by a doctor.

Aspirin Protect is used to:
• Prevent arterial thromboses after coronary vessel operations (bypasses and corrections of narrowing of the coronary vessels);
• Prevent strokes after the onset of precursor stages (transient ischaemic attacks, TIA);
• Prevent arterial thromboses (blood clots in coronary vessels) after heart attacks (reinfarction prevention);
• Prevent heart attacks in patients with a medically confirmed high risk. At the same time, accompanying diseases such as high blood pressure, diabetes or increased blood fat levels need to be treated. Smoking should also stop;
• Treat unstable angina pectoris;
• Treat acute heart attacks;
• Prevent arterial thromboses after operations on blood vessels.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ASPIRIN PROTECT
Do not take Aspirin Protect for a prolonged period of time or in relatively high doses without consulting your doctor.

When Aspirin Protect should not be used
Do not use Aspirin Protect in the following cases:
• If you have a stomach or duodenal ulcer.
• If you have an abnormally high bleeding tendency.
• If you are hypersensitive (allergic) to the active substance acetylsalicylic acid or another anti-inflammatory (antirheumatic) drugs or painkillers and fever medicines. This type of hypersensitivity shows for instance as asthma, difficulty breathing, circulatory disorders, swelling of the skin and mucous membranes or skin rashes (hives).
• If you have a severe heart, kidney or liver condition.
• If you need to take methotrexate doses of more than 15 mg per week at the same time.
• In the last three months of pregnancy.

When to take special care with Aspirin Protect
• If you have pre-existing coronary artery disease, or a cerebrovascular function is impaired, e.g. by volume depletion, major operations, blood poisoning or major bleeding, careful monitoring is required.
• If you have chronic or recurrent gastrointestinal disorders or asthma, hives, nasal polyps, hay fever or other allergies, the rare hereditary red blood cell disease called “glucose-6-phosphate dehydrogenase deficiency” or if you are being treated with anticoagulant drugs (“blood thinners”), you should take Aspirin Protect only in strict compliance with your doctor's instructions.
• Children and adolescents with fever, influenza, chickenpox or other viral diseases may take Aspirin Protect only in accordance with the doctor’s instructions and only as a second-choice treatment. If impaired consciousness in association with being sick occurs during or after these illnesses, a doctor must be consulted immediately.
• When taken at the same time or for a prolonged time, Aspirin Protect may increase the effects of cortisone products, anticoagulant drugs (antiepileptic drugs, blood thinners, digoxin, lithium drugs for depression and tablets which lower blood sugar levels. The side effects of these medicines may be increased.
• You should consult your doctor if you are taking a painkiller with the active substance ibuprofen at the same time as Aspirin Protect.
• The effects of gut medicines (probenecid and sulfinpyrazone) and medicines for high blood pressure may be decreased.
• If you use antirheumatic drugs or methotrexate (which is for example used in rheumatoid arthritis), the side effects may be enhanced.
• Even small doses of acetylsalicylic acid decrease the excretion of uric acid. In patients who already have low uric acid excretion, this may cause gout.
• When taken at the same time as cortisone products, alcohol or drugs in the group called serotonin reuptake inhibitors for depression, Aspirin Protect may increase the risk of gastrointestinal bleeding.
• The tendency to bleed may also be increased after minor procedures such as tooth extractions.
• Tell your doctor or pharmacist if you have any other illnesses, have allergies or are taking any other medicines (including ones you bought yourself). You should ask / inform your doctor or dentist about use before surgical procedures.

Taking Aspirin Protect during pregnancy / when breast-feeding
As a precautionary measure, you should not take any medicines during pregnancy and when breast-feeding. If you continue or begin treatment with Aspirin Protect during pregnancy on your doctor's instructions, you must follow your doctor's instructions closely and take it only during the first 6 months of pregnancy. Due to possible harm to the unborn child, the risk of bleeding and a possible delay in the delivery date, Aspirin Protect must not be taken during the last three months of pregnancy. If you regularly take relatively high doses, breast-feeding should be discontinued.

3. HOW TO TAKE ASPIRIN PROTECT
Unless prescribed otherwise by your doctor:
• Prevention of arterial thromboses without bypass surgery on the coronary vessels and after balloon dilatation of narrowed coronary vessels: 100 mg/day.
• Prevention of arterial thromboses after bypass surgery on the coronary vessels and after balloon dilatation of narrowed coronary vessels: 100–300 mg/day.
• Stroke prevention: 3 × 100 mg/day.
• Prevention of thromboses after heart attack and treatment of unstable angina pectoris: 1 × 100 mg/day.
• Acute heart attack: If you have an acute heart attack, you will be given 200–300 mg acetylsalicylic acid intravenously in the hospital. As an alternative, you may be given a rapidly absorbed acetylsalicylic acid product which can be taken orally. From the second day, the dose is 100 mg Aspirin Protect daily.
• The treating doctor will decide about the dose and duration of administration.
• Prevention of heart attacks in patients with a medically confirmed high risk: 1 × 100 mg/day. It is recommended to take the tablets with some liquid, if possible after meals. Drink ½–1 glass of liquid after swallowing the tablets. Do not change the prescribed dose on your own. Please consult your doctor or pharmacist if you think that the effect of the medicine is too strong or too weak.

4. POSSIBLE SIDE EFFECTS
Stomach discomfort can be a possible side effect. In rare cases, hypersensitivity (allergic) reactions such as swollen skin and mucous membranes (e.g. blocked nose) or skin rash or asthma, difficulty breathing and stomach ulcers and bleeding of the stomach lining, bruises, nose bleeds or bleeding gums may occur. Dizziness, headaches, visual disturbances or states of confusion also occur rarely.
• If signs of a hypersensitivity (allergic) reaction occur, you should discontinue the medicine and consult your doctor. If you notice blackening of your stools or if you vomit blood during treatment, you should discontinue the medicine and see a doctor immediately.
• If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ASPIRIN PROTECT
Keep out of the reach and sight of children.
• Immediately consult a doctor after uncontrolled ingestion (overdose). Rinsing in the ears and/or sweating outbreaks may be signs of an overdose.
• Not to be stored above 25°C.
• Do not use this medicine after the expiry date which is stated on the container “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
• 5 film-coated tablet of Aspirin Protect 100 mg with a stomach acid-resistant coating contains 100 mg acetylsalicylic acid.
• The other ingredients are: Maize starch, cellulose powder, methacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30%, polysorbate 80, sodium dodecylsulphate, talc, triethyl citrate.

Which pack sizes are available
100 mg Enteric-coated tablets: 20, 30 and 90
Not all pack sizes may be marketed.

Bulk Manufacturer:
Bayer Pharma AG,
Leverkusen, Germany.

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

This leaflet was last reviewed in May 2012

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