



Aspirin[®] PROTECT 100mg

Active ingredient: acetylsalicylic acid

Instructions for use.

Information for the patient

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 non-prescription basis.
- To achieve the best possible therapeutic results, you must nonetheless use Aspirin protect 100 mg 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.

This patient information leaflet concerns the following:

- What is Aspirin protect 100 mg and what is it used for?
- What should you be aware of before taking Aspirin protect 100 mg?
- How should Aspirin protect 100 mg be taken?
- What side effects may occur?
- How should Aspirin protect 100 mg be stored?
- Further information

1. WHAT IS ASPIRIN PROTECT 100 MG AND WHAT IS IT USED FOR?

Aspirin protect 100 mg inhibits the adhesion and clumping of blood platelets (thrombocytes) and in this way prevents blood clots (thrombi) from developing (inhibition of platelet aggregation).

Aspirin protect 100 mg is used for:

- Unstable angina pectoris (chest pain due to impaired circulation in the coronary heart vessels) - as part of the standard treatment;
- Acute myocardial infarction - as part of the standard treatment;
- Prevention of a repeat myocardial infarction after an initial myocardial infarction (reinfarction prophylaxis);
- Following surgery or other interventions in arterial blood vessels (e.g. after an aortocoronary venous bypass [ACVB], in percutaneous transluminal coronary angioplasty [PTCA]);
- Prevention of transient ischaemic attacks (TIA) and cerebral infarction following manifestation of the precursor stages (e.g. transient signs of paralysis in the face or arm muscles or transient loss of vision).

Kawasaki-Syndrome, (a rare, acute febrile disease in children, that can affect amongst other the skin and the lymph nodes):

- To reduce inflammation for the duration of febrile phase.
- For prophylaxis of blood clot case of modification of the coronary vessels (for prophylactic inhibition of platelet aggregation in coronary aneurysms).

Note: Aspirin protect 100 mg is not suitable for the treatment of pain.

2. WHAT SHOULD YOU BE AWARE OF BEFORE TAKING ASPIRIN PROTECT 100 MG?

Aspirin protect 100 mg must not be used:

- if you are hypersensitive (allergic) to acetylsalicylic acid, salicylates or any of the other ingredients of Aspirin protect 100 mg;
- if you have a history of reacting to certain drugs against pain, fever or inflammation (salicylates or other nonsteroidal anti-inflammatory drugs) with asthma attacks or other hypersensitive (allergic) reactions;
- if you have acute gastric or duodenal ulcers;
- if you have a pathologically increased tendency to bleed (haemorrhagic diathesis);
- if you have liver or kidney failure;
- if you have severe heart failure for which you are not receiving adequate treatment;
- If you are concurrently taking 15 mg or more methotrexate per week;
- In the last trimester of pregnancy at dosages above 150 mg acetylsalicylic acid/day (see "Pregnancy").

Particular caution is required when using Aspirin protect 100 mg

- if you are hypersensitive (allergic) to other analgesic, anti-inflammatory or antirheumatic medicines or other allergy-triggering substances;
- if you have other allergies (e.g. with symptoms like skin reactions, itching, nettle rash);
- if you have bronchial asthma, hay fever, swelling of the nasal mucosa (nasal polyps) or chronic respiratory tract diseases;
- If you are undergoing concomitant treatment with anticoagulant drugs (e.g. coumarin derivatives, heparin – with the exception of low-dose heparin therapy)
- if you have gastric or duodenal ulcers or a history of gastrointestinal bleeding;
- if you have impaired liver function;
- in patients with impaired renal function or patients with impaired cardiovascular circulation (e.g. renal vascular disease, congestive heart failure, volume depletion, major surgery, sepsis or major hemorrhagic events), since acetylsalicylic acid may further increase the risk of renal impairment and acute renal failure;
- before surgery (including minor surgery such as dental extractions): increase in bleeding tendency can occur. Please inform your doctor or dentist if you have taken Aspirin protect 100 mg;
- in patients suffering from severe glucose-6-phosphate dehydrogenase (G6PD) deficiency, acetylsalicylic acid may induce hemolysis or hemolytic anemia. Factors that may increase the risk of hemolysis are e.g. high dosage, fever or acute infections.

What other precautions must be taken?

At low doses acetylsalicylic acid reduces the excretion of uric acid. This may cause a gout attack in predisposed patients.

If you cut or injure yourself, it may take longer than usual for the bleeding to stop. This has to do with the action of Aspirin protect 100 mg. Minor cuts and injuries (e.g. when shaving) are generally not significant. If you experience unusual bleeding (at an unusual place or for an unusual length of time), consult your doctor. Drugs containing acetylsalicylic acid should not be taken for prolonged periods or at high doses without consulting a doctor.

Children and adolescents

Aspirin protect 100 mg should not be taken by children or adolescents with febrile illnesses unless they have been instructed to do so by a doctor and other therapeutic measures have failed.

Prolonged vomiting in conjunction with such illnesses could be a sign of Reye's syndrome, a very rare but life-threatening disease which requires immediate medical attention.

Interactions with other drugs

The effects of the medicines or groups of substances below may be affected by concomitant treatment with Aspirin protect 100 mg.

Enhanced effects ranging up to an increased risk of side effects:

- Anticoagulants (e.g. coumarin, heparin) and thrombolytic drugs: acetylsalicylic acid can increase the risk of bleeding if taken before anticoagulant treatment. You must therefore pay attention to signs of external or internal bleeding (e.g. bruising) if you are undergoing such treatment.
- Other platelet aggregation inhibitors (drugs that inhibit the clumping together of blood platelets), e.g. ticlopidine, Clopidogrel: increased bleeding risk.
- Drug product containing cortisone or cortisone-like substances (with the exception of products that are applied topically or cortisone replacement therapy for Addison's disease): increased risk for gastrointestinal side effects.
- Alcohol: increased risk of gastrointestinal ulcers and bleeding.
- Other analgesics and anti-inflammatory medicines (nonsteroidal anti-inflammatory drugs) and other antirheumatic medicines in general: increased risk for gastrointestinal ulcers and bleeding.
- Antidiabetics: the blood glucose level can be reduced.
- Digoxin (a drug to strengthen the heart muscle contraction).
- Methotrexate (a drug used to treat cancer and certain rheumatic disorders).
- Valproic acid (a drug used to treat convulsions of the brain [epilepsy]).
- Selective Serotonin Re-uptake inhibitors (certain medicines for treatment of depression): increased risk for gastrointestinal bleeding.

Weakening of effects:

- Certain medicines that increase the excretion of urine (diuretics so-called aldosterone antagonists, e.g. spironolactone and canrenoate, and loop diuretics, e.g. furosemide).
- Certain antihypertension drugs (in particular ACE inhibitors).
- Gout remedies that promote the excretion of uric acid (e.g. probenecid, benzbromarone).

Before using acetylsalicylic acid inform your doctor about the medicines you are taking. If you are using acetylsalicylic acid regularly seek advice of your doctor before taking any other medicine (including OTC medicines).

Accordingly, patients should not take Aspirin protect 100 mg in conjunction with any of the above-mentioned substances unless expressly instructed to do so by a doctor.

Pregnancy and breast feeding

If you are discover that you are pregnant during treatment with Aspirin protect 100 mg, please notify your doctor without delay.

In the first and second trimester of pregnancy, Aspirin protect 100 mg may only be taken if prescribed by your doctor.

In the last trimester of pregnancy, acetylsalicylic acid, the active ingredient of Aspirin protect 100 mg, must not be taken at a dosage of more than 150 mg per day due to an increased risk of complications for the mother and child before and during the birth (see also "... must not be used").

During the last trimester of pregnancy, doses of up to 150 mg acetylsalicylic acid per day may only be taken if prescribed by your doctor.

Small quantities of the active ingredient acetylsalicylic acid and its metabolites pass into breast milk.

Detrimental effects on the infant have not been reported to date, it is therefore not necessary to

interrupt breast-feeding if the daily dose does not exceed 150 mg. If higher doses are taken (more than 150 mg daily), the patient should stop breast-feeding.

Driving and operating machinery

No special precautions are necessary.

What foods and drinks should you avoid?

Please note that acetylsalicylic acid should not be taken with alcohol.

3. HOW SHOULD ASPIRIN PROTECT 100 MG BE TAKEN?

Always take Aspirin protect 100 mg exactly as directed in this patient information leaflet.

Please ask your doctor or pharmacist if you are unsure how to take this medicine.

Dosage: Unless otherwise prescribed by your doctor, the usual dose is:

- For unstable angina pectoris (chest pain caused by impaired circulation in the coronary heart vessels), A daily dose of one Aspirin protect 100 mg enteric-coated tablet (equivalent to 100 mg acetylsalicylic acid per day) is recommended.
- For acute myocardial infarction, A daily dose of one Aspirin protect 100 mg enteric-coated tablet (equivalent to 100 mg acetylsalicylic acid per day) is recommended.
- Prevention of a repeat myocardial infarction after an initial myocardial infarction (reinfarction prophylaxis), A daily dose of three Aspirin protect 100 mg enteric-coated tablets (equivalent to 300 mg acetylsalicylic acid per day) is recommended.
- Following operations or other interventions in arterial blood vessels (e.g. after ACVB, in PTCA), A daily dose of one Aspirin protect 100 mg enteric-coated tablet (equivalent to 100 mg acetylsalicylic acid per day) is recommended. The most favourable time for starting treatment with Aspirin protect 100 mg after an aortocoronary venous bypass (ACVB) would appear to be 24 hours after the operation.
- To prevent transient ischaemic attacks (TIA) and cerebral infarction following manifestation of the precursor stages, A daily dose of one Aspirin protect 100 mg enteric-coated tablet (equivalent to 100 mg acetylsalicylic acid per day) is recommended.

Kawasaki-Syndrome

- At the febrile phase the treatment should start initially with acetylsalicylic acid in a dose of 80-100 mg/kg body weight per day in 4 single doses combined with immunoglobulins.
- For prophylaxis of blood clot in case of modification of the coronary vessels (for prophylactic inhibition of platelet aggregation in coronary aneurysms), later (as of the 2nd-3rd disease week) the treatment should maintain in a dose of 3-5 mg/kg body weight per day.

Type of administration:

Swallow the tablets whole with plenty of liquid, preferably before a meal (e.g. a glass of water).

For treatment of acute myocardial infarction, the first tablet should be bitten or chewed.

Duration of treatment:

Aspirin protect 100 mg is intended for long-term use. The attending doctor must decide on the length of the treatment.

What should you do if you have taken too much Aspirin protect 100 mg?

Dizziness and ringing in the ears, particularly in children and elderly patients, may indicate serious poisoning.

Please notify your doctor if you suspect an overdose of Aspirin protect 100 mg.

He will decide on the necessary measures to be taken depending on the severity of over dosage/intoxication.

If you have forgotten to take Aspirin protect 100 mg or have taken too little:

If you have taken too little Aspirin protect 100 mg or have forgotten to take a dose, do not, for example, take a double dose the next time;

simply continue taking the medicine as described in the dosage instructions or as prescribed by your doctor.

Effects of discontinuing treatment with Aspirin protect 100 mg enteric-coated tablets:

Please do not interrupt or discontinue this treatment with Aspirin protect 100 mg without first consulting your doctor.

If you have any more questions about using this medicinal product, consult your doctor or pharmacist.

4. WHAT SIDE EFFECTS MAY OCCUR?

Like all medicines, Aspirin protect 100 mg can have side effects.

The following incidence rating is used to evaluate the frequency of side effects:

- Very common:** more than 1 treated patient of 10
- Common:** 1 to 10 treated patients of 100
- Uncommon:** 1 to 10 treated patients of 1,000
- Rare:** 1 to 10 treated patients of 10,000
- Very rare:** less than 1 treated patient of 10,000
- Not known:** frequency cannot be estimated from the available data

Gastrointestinal tract:

Common:

- Gastrointestinal disorders such as heartburn, nausea, vomiting, abdominal pain and diarrhoea.
- Minor blood loss from the gastrointestinal tract (microhaemorrhaging)

Uncommon:

- Gastrointestinal bleeding.
- Long-term use of Aspirin protect 100 mg may cause iron deficiency anaemia due to occult blood loss from the gastrointestinal tract.
- Gastrointestinal ulcers which in very rare cases can lead to perforation.
- Gastrointestinal inflammation.

If you pass black stools or vomit blood (signs of serious bleeding in the stomach), you must inform your doctor immediately (see also "Countermeasures").

Skin:

Uncommon:

- Skin reactions (very rare up to severe febrile eczema at skin and mucosa (erythema exudativum multiforme)).

Hypersensitivity reactions:

Rare:

- Hypersensitivity reactions of the skin, the respiratory tracts, the gastrointestinal tract and the cardiovascular system, in particular in asthmatics. Symptoms could be: drop in blood pressure, attacks of difficult breathing, inflammation of nasal mucosa, stuffy nose, allergic reactions, swelling of the face, tongue and larynx (angioedema).

Nervous system:

- Headache, dizziness, confusion, impaired hearing ability or tinnitus can be signs of an overdose (see also "What should you do if you have taken too much Aspirin protect 100 mg?").

Blood:

- Bleeding, e.g. nosebleeds, bleeding gums, skin bleeding or bleedings of the urinary tract and the genitals, possibly with prolongation of the bleeding time. This effect can persist for 4 to 8 days after use. Hemolysis and hemolytic anemia in patients with severe forms of glucose-6-phosphate dehydrogenase (G6PD) deficiency have been reported. Rare to very rare serious bleeding, such as cerebral bleeding, (especially in patients with uncontrolled hypertension and/or concomitant treatment with anticoagulants), which in single cases may be potentially life-threatening, have been reported.

Liver:

Very rare:

- Elevated liver values.

Kidneys:

Very rare:

- Renal impairment and acute renal failure.

Metabolism:

Very rare:

- Reduced blood glucose levels (hypoglycaemia).
- At low doses acetylsalicylic acid reduces the excretion of uric acid. This may cause a gout attack in predisposed patients.

Countermeasures

If you experience any of the above-mentioned side effects, do not take any more Aspirin protect 100 mg. Notify your doctor so that he can determine the severity of the side effect(s) and decide on any necessary further action.

Use of Aspirin protect 100 mg should be stopped at the first signs of hypersensitivity. Inform your doctor or pharmacist if you notice any side effects that are not listed in this patient information leaflet.

5. HOW SHOULD ASPIRIN PROTECT 100 MG BE STORED?

Keep medicines out of the reach of children.

The expiry date of this product is printed on the tablet strips and the cardboard box. Do not use the product after this date.

Storage instruction: "Not to be stored above 25°C"

6. FURTHER INFORMATION

Composition:

The active ingredient is acetylsalicylic acid. 1 enteric-coated tablet 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 dodecylsulfate, talc, triethyl citrate.

Dosage form and content:

Aspirin protect 100 mg is available in packs containing 20,30 &90 enteric-coated tablets.

Manufacturer:

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

Date of preparation: October 2010

- 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

Bayer

