

PACKAGE LEAFLET: INFORMATION FOR THE USER

ASPIRIN PROTECT 100

100 mg, gastro-resistant tablets

ACETYLSALICYLIC ACID

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

What is in this leaflet?

1. What ASPIRIN PROTECT 100 is and what it is used for
2. Before you take ASPIRIN PROTECT 100
3. How to take use ASPIRIN PROTECT 100
4. Possible side effects
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1. WHAT ASPIRIN PROTECT 100 IS AND WHAT IT IS USED FOR

ASPIRIN PROTECT 100 gastro-resistant tablets contain acetylsalicylic acid which, in lower doses, belongs to a group of medicines known as antithrombotics that prevent the accumulation and adhesion of platelets and thereby prevent formation of blood clots.

Aspirin protect 100 mg is used in the treatment of:

- acute heart attack - as part of the standard treatment;
- for the prevention of heart attack after the initial attack;
- for the reduction of the risk of recurrent transient ischaemic attacks or stroke in men who have had transient ischaemia of the brain due to fibrin platelet emboli;
- after surgery or other procedures on the arteries (after aorto-coronary venous bypass [ACVB], percutaneous transluminal coronary angioplasty [PTCA]);
- for the treatment of unstable angina (chest pain due to damaged circulatory coronary blood vessels) - as a part of the standard treatment;
- for the prevention of deep vein thrombosis and pulmonary embolism after prolonged immobilization (after major surgery);
- reduction of the risk of first heart attack in people with cardiovascular risk factors (diabetes, hyperlipidemia, hypertension, obesity, smoking, age).

2. BEFORE YOU TAKE ASPIRIN PROTECT 100

Do not take ASPIRIN PROTECT 100

- if you are allergic to acetylsalicylic acid or to any of the ingredients of ASPIRIN PROTECT 100 (see section 6. "Further information"),
- if you are allergic (hypersensitive) to Acetylsalicylic acid or to any of the other ingredients in this medicine
- if you had an allergic reaction to other non-steroidal anti-inflammatory medicine
- if you have bronchial asthma
- if you suffer from diseases of the upper digestive system, such as gastritis and gastric and duodenal ulcers
- if you have increased tendency to bleed
- if you have a serious kidney or liver disease
- if you suffer from gout
- if you are in the last trimester of pregnancy
- if you are receiving methotrexate at a dose of 15 mg / week or more
- if you have severe heart failure which is not adequately treated

Take special care with ASPIRIN PROTECT 100, so you must tell the doctor if you

- are pregnant, trying to get pregnant or breast-feeding
- are taking other anticoagulant medicines
- have liver or kidney problems
- are suffering from diseases of the digestive system, such as gastritis and gastric and duodenal ulcers
- suffer from bronchial asthma, hay fever, swelling of the nasal mucosa (nasal polyps) or chronic respiratory disease
- are taking anticoagulant medicines (eg, coumarin derivatives, heparin - except the treatment with low doses of heparin);
- have a stomach ulcer or duodenum or gastrointestinal bleeding in anamnesis of the disease;
- have a scheduled surgery (including minor surgery such as, tooth extraction): may cause increased tendency to bleed. Please tell your doctor or dentist if you have taken Aspirin protect 100 mg
- are diagnosed with a lack of glucose-6-phosphate dehydrogenase (congenital or acquired metabolic disorder), please inform your doctor before you start taking Aspirin protect 100 mg

What other precautions you should take?

In low doses, acetylsalicylic acid reduces the excretion of uric acid. In predisposed patients it can lead to gout attacks.

If you cut yourself or injure yourself, it may take longer to stop bleeding. Minor cuts and injuries (eg, shaving) are generally not significant. In case of abnormal bleeding (in a strange place or during the unusually long period of time), consult a doctor.

Medicines containing acetylsalicylic acid should not be taken for extended periods of time or in high doses without consulting a doctor.

Due to the risk of Reye's syndrome Aspirin protect 100 is not recommended for the use in children under 16. If any of the abovementioned applies to you or if you are not sure, consult your doctor or pharmacist.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Symultaneous use of ASPIRIN PROTECT 100 and certain medications can affect the treatment effect.

Aspirin protect 100 mg can increase the effectiveness of:

- anticoagulants (eg, coumarin, heparin) and thrombolytic medicines: aspirin may increase the risk of bleeding if the medicine is taken before the anticoagulant treatment. You should therefore carefully follow the signs of external and internal bleeding (eg, bruises) if you are taking this medication;
 - other platelet aggregation inhibitors (medicines that prevent the accumulation of platelets), for example. ticlopidine, clopidogrel: increased risk of bleeding;
 - medicines containing cortisone or cortisone-like substances (with the exception of products which are applied topically or in the replacement therapy with cortisone for Addison's disease: increased risk of side effect by the digestive tract);
 - Alcohol: Increased risk of damage to the digestive tract and bleeding;
 - other analgesics and anti-inflammatory drugs (NSAIDs) and other anti-rheumatic drugs generally: increased risk of damage to the digestive tract and bleeding;
 - antidiabetic medicines: the concentration of glucose in the blood can be reduced;
 - digoxin (medicine that increases the contractions of the heart muscle);
 - methotrexate (medicine used to treat cancer and other rheumatic diseases);
 - valproic acid (medicine used to treat brain seizures (epilepsy));
 - selective serotonin reuptake inhibitors (medicine used to treat depression): increased risk of bleeding in the digestive tract.
- Aspirin protect 100 mg can reduce the effectiveness of:
- medicines that increase the excretion of urine (diuretics; Aldosterone antagonists, eg. Spironolactone and canrenoate, Furosemide);
 - some antihypertensive agents (particularly ACE inhibitors);
 - medicines for the treatment of gout, which stimulate secretion of uric acid in urine (e.g., probenecid, benzbromarone).

Taking ASPIRIN PROTECT 100 with food and drink

Acetylsalicylic acid should not be taken with alcohol.

Pregnancy and breastfeeding

If you find that you are pregnant and you are taking Aspirin protect 100 mg, please immediately inform your doctor.

During the first and second trimester of pregnancy Aspirin protect 100 mg can be taken only if it is prescribed by a doctor. Pregnant women should not take acetylsalicylic acid, unless they have been advised by a doctor.

Aspirin protect 100 should not be taken during the last trimester of pregnancy because of the increased risk of complications for mother and child before and during birth. During the last trimester of pregnancy, doses up to 150 mg of acetylsalicylic acid can be taken only if it is prescribed by a doctor.

Small amounts of acetylsalicylic acid and its metabolites pass into breast milk. Side effects have not been observed in infants whose mothers occasionally took acetylsalicylic acid, so it is not necessary to interrupt breastfeeding. However, mothers who take aspirin regularly or in high doses have to stop breastfeeding early.

Driving and using machines

ASPIRIN PROTECT 100 should not affect your ability to drive and use machines.

3. HOW TO TAKE ASPIRIN PROTECT 100

If you are not sure how to take the medicine, ask your doctor or pharmacist for advice.

Take your medicine according to these instructions (unless your doctor tells you otherwise).

In acute heart attack

Recommended daily dose is 1 to 2 Aspirin protect 100 mg gastro-resistant tablets (corresponding to 100 to 200 mg of acetylsalicylic acid daily) or three Aspirin protect 100 mg gastro-resistant tablets every other day (corresponding to 300 mg of acetylsalicylic acid every other day).

For prevention of repeat heart attack after the initial heart attack

Recommended daily dose is 1 to 3 Aspirin protect 100 mg gastro-resistant tablets (corresponding to 100 to 300 mg of acetylsalicylic acid per day).

For prevention of repeated stroke after the initial stroke

Recommended daily dose is 1 to 3 Aspirin protect 100 mg gastro-resistant tablets (corresponding to 100 to 300 mg of acetylsalicylic acid per day).

For prevention of recurrent transient ischaemic attacks and stroke

Recommended daily dose is 1 to 3 Aspirin protect 100 mg gastro-resistant tablets (corresponding to 100 to 300 mg of acetylsalicylic acid per day).

After surgery or other procedures on the arteries

Recommended daily dose is 1 to 3 Aspirin protect 100 mg gastro-resistant tablets (corresponding to 100 to 300 mg of acetylsalicylic acid per day).

For treatment of unstable angina (chest pain due to damaged circulatory coronary blood vessels)

Recommended daily dose is 1 to 3 Aspirin protect 100 mg gastro-resistant tablets (corresponding to 100 to 300 mg of acetylsalicylic acid per day).

For prevention of deep vein thrombosis and pulmonary embolism after prolonged immobilization (after major surgery)

Recommended daily dose is 1 to 2 Aspirin protect 100 mg gastro-resistant tablets (corresponding to 100 to 200 mg of acetylsalicylic acid daily) or three Aspirin protect 100 mg gastro-resistant tablets every other day (corresponding to 300 mg of acetylsalicylic acid every other day).

For reduction of the risk of first heart attack in people with cardiovascular risk factors (diabetes, hyperlipidemia, hypertension, obesity, smoking, age)

Recommended daily dose is 1 Aspirin protect 100 mg gastro-resistant tablet (corresponding to 100 to 200 mg of acetylsalicylic acid daily) or three Aspirin protect 100 mg gastro-resistant tablets every other day (corresponding to 300 mg of acetylsalicylic acid every other day).

If you take more ASPIRIN PROTECT 100 than you should

Dizziness and noises in the ears, especially in children and the elderly may be indicative of serious poisoning. Please inform your doctor if you suspect an overdose of Aspirin protect 100 mg. the doctor will decide on the measures that should be implemented depending on the severity of overdose / intoxication.

If you forget to take ASPIRIN PROTECT 100

If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.

Do not take a double dose to make up for a forgotten dose.

If you stop taking ASPIRIN PROTECT 100 mg

Please do not stop your treatment with Aspirin protect 100 mg without consulting your doctor first.

If you have any further questions, contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ASPIRIN PROTECT 100 can cause side effects, although not everybody gets them.

Side effects are listed according to the following categories of frequency:

Very common: more than 1 treated person of 10

Common: 1 to 10 treated persons of 100

Uncommon: 1 to 10 treated persons of 1000

Rare: 1 to 10 treated persons of 10000

Very rare: less than 1 treated person of 10000

Not known: frequency cannot be estimated from the available data

Digestive system

Common:

- Digestive disorders as heartburn, nausea, vomiting, abdominal pain and diarrhea.
- Insignificant blood loss from the digestive tract

Uncommon:

- Bleeding from the digestive tract. Prolonged taking of Aspirin protect 100 mg can cause anemia due to iron deficiency caused by occult bleeding from the digestive tract.
- Damage to the digestive tract, which in rare cases can lead to perforation.
- Inflammation of the digestive tract.

If you have dark stool or if you vomit blood (signs of serious bleeding in the stomach), you should immediately inform the doctor (see also "Countermeasures").

Skin

Uncommon:

- Skin reactions (rarely can cause severe eczema on the skin and mucous membrane (erythema multiforme exudativum)).

Hypersensitivity reactions

Rare:

- Hypersensitivity reactions of the skin, respiratory tract, digestive tract and the cardiovascular system, particularly in asthmatic patients.

Symptoms may include low blood pressure, difficulty breathing, inflammation of the nasal mucosa, nasal congestion, allergic reactions, swelling of the face, tongue and throat (angioedema).

The nervous system

Headache, dizziness, confusion, hearing loss and noise in the ears can be signs of an overdose (see also section "If you take more Aspirin protect 100 mg than you should").

Blood

There have been bleedings such as bleeding during surgery, hematomas, bleeding from the nose, urogenital bleeding, bleeding from the gums.

Rarely to very rarely serious bleedings were observed, such as bleeding in the gastrointestinal tract, bleeding in the central nervous system (especially in patients with uncontrolled hypertension) which in individual cases can be potentially life-threatening.

Liver

Very rare: Increased liver enzymes.

Kidneys

Very rare: Impaired renal function.

Metabolism

Very rare:

- The reduced concentration of blood glucose (hypoglycemia).
- In small doses acetylsalicylic acid reduces the excretion of uric acid. This can cause gout attack in susceptible patients.

Countermeasures

If you have any of the above mentioned side effects, stop taking Aspirin protect 100 mg. Tell your doctor in order to determine the severity of side effects and decided on the necessary measures.

Taking Aspirin protect 100 mg should be discontinued at the first sign of hypersensitivity.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ASPIRIN PROTECT 100

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use ASPIRIN PROTECT 100 after the expiry date which is stated on the label.

6. FURTHER INFORMATION

What ASPIRIN PROTECT 100 contains

One tablet contains 100 mg of acetylsalicylic acid.

Other ingredients: cellulose powder, starch, corn, methacrylic acid and ethyl acrylate copolymer 1: 1, polysorbate 80, sodium lauryl sulfate, talc, triethyl citrate.

What ASPIRIN PROTECT 100 looks like and contents of the pack

Aspirin protect 100 mg gastro-resistant tablets: 30 (3x10) tablets in a blister in a box.

Regime of dispensing

The medicine is issued without a doctor's prescription.

Manufacturer

Bayer Schering Pharma AG
13342, Berlin, Germany

Manufacturer of the medicinal product

Bayer Bitterfeld GmbH, Ortsteil Greppin, Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen, Germany