

Aspetax Protect Adipharm 100 mg gastro-resistant tablets

Acetylsalicylic acid



aspipharm

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 or nurse.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse after a few days.

What is in this leaflet

1. What Aspetax Protect Adipharm is and what it is used for
2. What you need to know before you take Aspetax Protect Adipharm
3. How to take Aspetax Protect Adipharm
4. Possible side effects
5. How to store Aspetax Protect Adipharm
6. Contents of the pack and other information

1. What Aspetax Protect Adipharm is and what it is used for
Aspetax Protect Adipharm 100 mg belongs to a group of medicines inhibiting aggregation (adhesion) of a type of blood cells (platelets) to prevent the formation of a blood clot. Aspetax Protect Adipharm 100 mg has a protective effect on the heart.

It is used for:

- Treatment of unstable angina pectoris (chest pain caused by impaired blood flow through the coronary arteries of the heart);
- Acute myocardial infarction, as part of standard therapy;
- Secondary prevention following a myocardial infarction;
- Following arterial vascular surgery or intervention (after aorto-coronary bypass surgery, in percutaneous transluminal coronary angioplasty);
- For prevention of transient ischemic attacks due to insufficient blood supply to the brain, and brain infarctions when warning symptoms are observed.

2. What you need to know before you take Aspetax Protect Adipharm

Do not take Aspetax Protect Adipharm:

- if you are allergic to Acetylsalicylic acid or any of the other ingredients of this medicine (listed in section 6).
- if you have an abnormally increased tendency to bleed;
- if you suffer from indigestion, peptic gastric and/or duodenal ulcer;

This product should not be used during the first and the third trimestre of pregnancy as it may seriously harm the fetus, delay or extend the delivery, and prolong bleeding.

This medicinal product should not be used during the second trimestre of pregnancy unless absolutely inevitable. In the presence of serious reasons to use the product in women expecting pregnancy or women in the second trimestre of pregnancy, the lowest possible dose should be used for the shortest possible time.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Aspetax Protect Adipharm.

Caution is required in administering the product to the following groups of patients: patients with asthma and nasal polyps; diseases of the hemopoietic system; liver or kidney diseases; uncontrolled hypertension; diabetes; patients consuming concentrated alcohol in amounts exceeding 75 ml daily.

Children and adolescents

Aspetax Protect Adipharm 100 mg should not be given to children and adolescents under 18 years of age, to patients with chicken pox and other viral diseases due to a risk of Reye's Syndrome. Aspetax Protect Adipharm 100 mg can be given to children under 18 years of age only if expressly prescribed by the doctor, and if no other effective drugs are available.

Other medicines and Aspetax Protect Adipharm

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Aspetax Protect Adipharm may interact with alcohol, anti-inflammatory agents, anti-blood clotting drugs, hormones, antidiabetic agents, antiepileptics, probenecid, ginkgo biloba.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Use of Aspetax Protect Adipharm during pregnancy is not recommended unless expressly directed by a doctor.

Driving and using machines

No special requirements.

Aspetax Protect Adipharm contains lactose. If the doctor has told you that you are suffering from intolerance to some sugars, please consult your doctor before taking this medicine.

3. How to take Aspetax Protect Adipharm

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Unless the doctor directed otherwise, you should follow the instructions for use of Aspetax Protect Adipharm 100 mg. Follow the instructions because otherwise Aspetax Protect Adipharm 100 mg may not show satisfactory results.

The gastro-resistant tablets should be taken once daily, always at the same time of the day if possible, before meals with a sufficient amount of liquid.

Aspetax Protect Adipharm 100 mg is intended for long-term use. The duration of treatment should be determined by your doctor. Following an aortocoronary bypass surgery, therapy with Aspetax Protect Adipharm 100 mg should start within 24 hours of surgery. The recommended dose is:

For treatment of unstable angina pectoris (chest pain caused by impaired blood flow through the coronary arteries of the heart): The daily dose is between 75 and 300 mg acetylsalicylic acid. For better tolerance, the recommended daily dose is 1 tablet of

Aspetax Protect Adipharm 100 mg (equivalent to 100 mg acetylsalicylic acid).

In the event of an acute myocardial infarction:

The daily dose is from 100 to 160 mg acetylsalicylic acid. The recommended daily dose is 1 tablet of Aspetax Protect Adipharm 100 mg (equivalent to 100 mg acetylsalicylic acid).

For prevention of myocardial infarction in patients who have had a previous myocardial infarction (secondary prevention of myocardial infarction):

The recommended daily dose is 3 tablets Aspetax Protect Adipharm 100 mg (equivalent to 300 mg acetylsalicylic acid).

Following surgery or other interventions performed on arteries (after arterial vascular surgery or intervention, e.g. aortocoronary bypass surgery, percutaneous transluminal coronary angioplasty):

The daily dose is between 100 and 300 mg of acetylsalicylic acid. For better tolerance, the recommended daily dose is 1 tablet of Aspetax Protect Adipharm.

Prevention of transient ischemic attacks due to insufficient blood supply to the brain, and brain infarction when warning symptoms are observed:

The daily dose varies between 30 mg and 300 mg of acetylsalicylic acid. For better tolerance, a daily dose of 1 tablet of Aspetax Protect Adipharm 100 mg is recommended.

If you take more Aspetax Protect Adipharm than you should

Seek medical help immediately in case of suspected overdose of Aspetax Protect Adipharm tablets. The doctor will decide on the measures that should be undertaken depending on the severity of overdosing (intoxication). Overdosing may lead to dizziness and ringing in the ears, particularly in children and elderly patients. *If symptoms of overdosing should appear, call your doctor immediately.*

If you forget to take Aspetax Protect Adipharm

If you missed a dose, take your next dose at the normal time without increasing the dose.

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

If you stop taking Aspetax Protect Adipharm

Do not stop taking Aspetax Protect Adipharm without first consulting your doctor

If you have any further questions on the use of this medicine, ask your doctor, or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Frequency categories are defined according to the following convention:

Very common (affect more than 1 in 10 patients)

Common (affect up to 1 in 10 patients)

Uncommon (affect up to 1 in 100 patients)

Rare (affect up to 1 in 1000 patients)

Very rare (affect up to 1 in 10 000 patients)

Unknown (cannot be estimated from the available data)

Common:

- increased tendency to bleeding, as well as problems with the stomach and intestines (e.g. gastric pain) and insignificant blood loss in the area of stomach and intestines (mild bleeding)
- indigestion

Uncommon:

- rhinitis
- difficulty breathing
- rash

Rare:

- nausea, vomiting and diarrhea
- spasms in the lower respiratory tract
- brain haemorrhage

Adverse reactions of unknown frequency:

- impairment of liver and kidney functions, reduction of blood sugar (hypoglycaemia), and extremely severe skin reactions.
- bleeding and ulcers in the stomach, as well as hypersensitivity reactions, mostly in asthmatic patients (e.g. apnea attacks, skin reactions)
- acetylsalicylic acid in low doses inhibits the excretion of uric acid. This may precipitate a gout attack in predisposed patients.
- prolonged use of Aspetax Protect Adipharm may result in the development of anemia (reduced red blood cell count which may lead to paleness, weakness or shortness of breath) due to hidden loss of blood from the stomach or intestines.
- Dizziness and ringing in the ears in children and elderly patients.

If any of the side effects get serious or if you notice any side effects not listed in this leaflet, talk to your doctor or pharmacist.

5. How to store Aspetax Protect Adipharm

Store below 30°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Aspetax Protect Adipharm contains

- The active substance is acetylsalicylic acid. Each gastro resistant tablet contains 100 mg acetylsalicylic acid.
- The other ingredients are (excipients): lactose, silicified microcrystalline cellulose, sodium stearyl fumarate, croscarmellose sodium, hypromellose (E464), titanium dioxide (E171), triethyl citrate, of methacrylic acid copolymer – ethyl acrylate, talc and silica - colloidal, anhydrous.

What Aspetax Protect Adipharm looks like and contents of the pack

Aspetax Protect Adipharm is supplied as gastric resistant tablets. The tablets are white to off-white, round, and biconvex.

Aspetax Protect Adipharm is supplied in packs of 30 or 100 tablets. 3 and/or 10 blisters of 10 tablets each in a carton box.

2 blisters of 15 tablets each in a carton box.

Marketing Authorisation Holder and Manufacturer

ADIPHARM EAD, 130, Simeonovsko shosse Blvd.
Sofia 1700, Bulgaria

This leaflet was last revised in

January 2013