

## Aspetax Protect Adipharma 75 mg gastro-resistant tablets

### Acetylsalicylic acid

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor, or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- If you do not feel better or your condition gets worse, you should seek medical attention.

#### What is in this leaflet:

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

#### 1. What **Aspetax Protect Adipharma** is and what it is used for

Aspetax Protect Adipharma contains acetylsalicylic acid, which in low doses belongs to a group of medicines called antithrombotic agents (preventing blood clots). Platelets are small blood cells that cause clotting of the blood and participate in the formation of blood clots. When an artery forms a blood clot (thrombus), it stops the blood supply and stops the oxygen supply. When this happens in the heart, it can cause a heart attack or angina pectoris (chest pain); in the brain this thrombus can cause stroke.

Aspetax Protect Adipharma is taken to reduce the risk of blood clots formation and thereby prevent:

- heart attacks
- strokes
- cardiovascular problems in patients suffering from stable or unstable angina (a type of chest pain)

Aspetax Protect Adipharma is also used to prevent the formation of blood clots after some types of cardiac surgery to enlarge or unblock blood vessels.

This medicinal product is not recommended for use in emergency situations. It can only be used as a prophylactic treatment.

#### 2. What you need to know before you take **Aspetax Protect Adipharma**

##### Do not take **Aspetax Protect Adipharma**:

- if you are allergic to Acetylsalicylic acid or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to other salicylates or non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs are often used in arthritis or rheumatism and pain;
- if you have had an asthma attack or swelling of some parts of the body, such as the face, lips, throat or tongue (angioedema) after taking salicylates or NSAIDs;
- if you have or have had a stomach or small intestine ulcer, or other bleeding such as a stroke;
- if you have had problems with blood clotting;
- if you have severe liver or kidney problems;
- if you are pregnant in the last 3 months of pregnancy; You should not take higher doses of 100 mg daily (see section «Pregnancy and breast-feeding»);
- if you are taking a medicine called methotrexate (for example, in cancer or rheumatoid arthritis) at doses above 15 mg per week.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking **Aspetax Protect Adipharma**.

- if you have kidney, liver or heart disease;
- if you have or have had problems with your stomach or small intestine;

- if you have high blood pressure;
- if you suffer from asthma, hay fever, nasal polyps or other chronic respiratory diseases; acetylsalicylic acid may cause an asthma attack;
- if you have suffered from gout;
- if you have a heavy menstrual cycle.

You should seek medical advice immediately if your symptoms get worse or have severe or unexpected side effects such as symptoms of abnormal bleeding; serious skin reactions or any other sign of serious allergy (see section "Possible side effects").

Tell your doctor if you are planning a surgery (even a small one, for example tooth extraction) as acetylsalicylic acid dilutes the blood and may increase the risk of bleeding.

#### Children and adolescents

Acetylsalicylic acid can cause Reye's syndrome when given to children. Reye's syndrome is a very rare disease that affects the brain and the liver and can be life-threatening. Therefore, **Aspetax Protect Adipharma** should not be given to children under 16 years of age except as prescribed by a physician.

You should be careful not to get dehydrated (you may feel thirst and dry mouth), as in dehydration the use of acetylsalicylic acid may lead to deterioration of renal function.

This is a medicinal product that is not suitable as an analgesic agent or to lower the temperature.

If any of the above applies to you or you are not sure about anything, talk to your doctor or pharmacist.

#### Other medicines and **Aspetax Protect Adipharma**

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

The effect of treatment may be affected if acetylsalicylic acid is taken concomitantly with other medicines for:

- blood thinning / prevention of blood clots (e.g. warfarin, heparin, clopidogrel)
- Organ rejection after transplantation (cyclosporin, tacrolimus);
- high blood pressure (e.g. diuretics and ACE inhibitors);
- regulation of heart rhythm (digoxin);
- manic-depressive illness (lithium);
- pain and inflammation (e.g. NSAIDs such as ibuprofen or steroids);
- gout (for example, probenecid);
- epilepsy (valproate, phenytoin);
- glaucoma (acetazolamide);
- cancer or rheumatoid arthritis (methotrexate at doses less than 15 mg per week);
- diabetes (e.g., glibenclamide);
- depression (selective serotonin reuptake inhibitors such as sertraline or paroxetine);
- use as hormone replacement therapy when the adrenal glands or pituitary are damaged or removed, or for the treatment of inflammation, including rheumatic diseases and inflammation of the intestines (corticosteroids).

#### **Aspetax Protect Adipharma with Alcohol**

Drinking alcohol may increase the risk of bleeding from the gastrointestinal tract and prolong bleeding time.

#### **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.

Pregnant women should not take acetylsalicylic acid during pregnancy except on the advice of their physician. You should not take **Aspetax Protect Adipharma** if you are in the last 3 months of pregnancy unless your doctor advises that the daily dose should not exceed 100 mg (see section "Do not take **Aspetax Protect Adipharma**"). Regularly taking or taking high doses of this medicine during late pregnancy can lead to

serious complications for the mother or baby.

Nursing mothers should not take acetylsalicylic acid unless it has been prescribed by their doctor.

### Driving and using machines

Aspetax Protect Adipharm has no influence on the ability to drive and use machines.

Aspetax Protect Adipharm contains lactose. If you know that you suffer from intolerance to some sugars please tell 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.*

The recommended dose is:

#### Adults

*For heart attack prophylaxis:*

75 - 160 mg once daily.

*For stroke prevention:*

75 - 325 mg once daily.

*For prevention of cardiovascular disorders in patients suffering from stable or unstable angina pectoris (type of chest pain):*

75 - 160 mg once daily.

*To prevent the formation of blood clots after some cardiac surgery:*

75 - 160 mg once daily.

#### Elderly

As with adults. In general, acetylsalicylic acid should be used with caution in elderly patients who are more susceptible to side effects. Treatment should be reviewed regularly.

#### Use in children and adolescents

Acetylsalicylic acid should not be taken by children and adolescents under 16 years of age unless prescribed by a doctor (see section "Warnings and Precautions").

#### Mode of administration

Oral use

The tablets should be swallowed whole with enough liquid (1/2 cup of water). The tablets have a gastro-resistant coating that prevents stomach irritation and should not be crushed, broken or chewed.

#### **If you take more Aspetax Protect Adipharm than you should**

If you (or someone else) have inadvertently taken too many tablets, you should immediately inform your doctor or contact your nearest emergency department immediately. Show the rest of the medicine or the empty pack to the doctor.

Symptoms of overdose may include: tinnitus, hearing problems, headache, dizziness, confusion, nausea, vomiting and abdominal pain. Severe overdose can cause rapid breathing (hyperventilation), fever, excessive sweating, anxiety, convulsions, hallucinations, low blood sugar, coma, and shock.

#### **If you forget to take Aspetax Protect Adipharm**

If you miss a dose, wait for the next dose, then continue with the usual scheme.

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

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

### 4. Possible side effects

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

*If you notice any of the following serious side effects, stop taking Aspetax Protect Adipharm and contact a doctor immediately:*

- Sudden wheezing, swelling of the lips, face or body, rash, fainting or difficulty in swallowing (severe allergic reaction);
- Reddening of the skin with blisters or peeling, which may be accompanied by fever and joint pain. This may be erythema multiforme or Lyell syndrome; Severe illness, accompanied by blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome);
- Unusual bleeding, such as expectoration of blood, blood in the vomiting or urine, or black stools.

**Common side effects** (affect up to 1 in 10 patients):

- increased tendency to bleeding,
- indigestion

**Uncommon side effects** (affect up to 1 in 100 patients):

- rhinitis
- difficulty breathing
- rash

**Rare side effects** (affect up to 1 in 1000 patients):

- severe bleeding from the stomach or intestine, brain haemorrhage; change in the number of blood cells
- nausea and vomiting
- spasms in the lower respiratory tract, asthma attacks
- inflammation of the blood vessels
- bruising with red-purple spots on the skin (skin bleeding) severe skin reactions such as rash, known as erythema multiforme and its life-threatening forms, Stevens-Johnson syndrome and Lyell syndrome
- hypersensitivity reactions, such as swelling of the lips, face or body, or shock
- an unusually heavy or prolonged menstrual cycle

**Adverse reactions of unknown frequency** (cannot be estimated from the available data):

- Tinnitus or reduced hearing
- Headache
- Vertigo
- Stomach or small intestine ulcers and perforation
- Prolonged bleeding time
- Impaired renal function
- Damaged hepatic function
- High blood uric acid level

#### *Reporting of side effects*

If any of the side effects gets serious, tell your doctor or pharmacist. This includes all possible side effects not listed in this leaflet.

### 5. How to store Aspetax Protect Adipharm

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

Store in the original package at temperatures below 30 °C.

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 tablets contains 75 mg acetylsalicylic acid.
- The other ingredients (excipients) are: *tablet core:* lactose monohydrate, silicified microcrystalline cellulose, sodium stearyl fumarate, croscarmellose sodium, hypromellose (E464), *film coating:* titanium dioxide (E171), triethyl citrate, copolymer of methacrylic acid-ethyl acrylate, talc and silica colloidal, anhydrous.

**What Aspetax Protect Adipharm looks like and contents of the pack**  
Aspetax Protect Adipharm gastro-resistant tablets: white to almost white, round, and biconvex film coated tablets with a diameter of 6 mm.

The blister contains 20 tablets.

1, 2, 3, 4 or 5 blisters of 20 tablets with a leaflet in a cardboard box

The blister contains 15 tablets.

1, 2, 3, 4, 5 or 6 blisters of 15 tablets with a leaflet in a cardboard box

Not all packs may be placed on the market.

#### **Marketing Authorisation Holder and Manufacturer**

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

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