

Package leaflet: Information for the patient

Aspicot 100 mg Enteric-Coated Tablets

Acetylsalicylic Acid

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

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2. What you need to know before you take Aspicot
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1. What Aspicot is and what it is used for

Aspicot contains the active pharmaceutical ingredient acetylsalicylic acid. It inhibits the coagulation of the blood platelets even in small concentrations. Due to an enteric coating, the tablet dissolves in the small intestine. Therefore, Aspicot is gentle on the stomach lining. Aspicot may only be taken if prescribed by a physician.

Aspicot serves as:

- Prevention of arterial thromboses after surgeries involving the coronary vessels (bypass and elimination of a constriction of the coronary vessels).
- Prevention of strokes after preliminary stages have occurred (transient ischaemic attacks, TIA).
- Prevention of arterial thromboses (blood clots in coronary vessels) and after a myocardial infarction (reinfarction prophylaxis).
- Prevention of myocardial infarctions in patients after a high risk was determined by a physician. Comorbidities such as high blood pressure, diabetes, elevated blood lipids must be treated at the same time. Smoking should also be stopped.
- Treatment of unstable angina pectoris.
- Treatment of an acute myocardial infarction.
- Prevention of arterial thromboses after surgeries on blood vessels.

2. What you need to know before you take Aspicot

Aspicot must not be taken for an extended period of time or in higher doses without consulting a physician.

Do not take Aspicot

You must not take Aspicot in the following cases:

- If you are suffering from a gastric or duodenal ulcer;
- If you have a pathological increased tendency to bleed;
- If you are hypersensitive to the active pharmaceutical ingredient acetylsalicylic acid or other anti-inflammatory drugs (antirheumatic agents) or pain and fever medication. Such a hypersensitivity manifests e.g. in the form of asthma, shortness of breath, circulatory problems, swelling of the skin and mucus membranes or skin rashes (urticaria).
- In the event of serious heart, kidney and liver diseases.
- If you have to take methotrexate concomitantly in a dose of more than 15 mg per week.
- In the last three months of pregnancy

Warnings and precautions:

• During treatment with Aspicot, ulcers can occur in the upper gastrointestinal tract. Bleeding can occur in rare cases or perforations (gastric or intestinal perforation) can occur in individual cases.

These complications can occur at any time during treatment without any warning symptoms. Contact your physician if you have stomach pain and suspect a connection to the administration of medication.

- Careful monitoring is indicated in the event of a limited renal or cardiovascular function such as volume deficiencies, major surgeries, blood poisoning or major bleeding.

- The drug should be taken only in accordance with strict instructions of the physician in the event of chronic or recurring gastrointestinal disorders and asthma, urticaria, nasal polyps, hay fever or other allergies, a rare disease of the red blood cells, the so-called “glucose-6 phosphate dehydrogenase deficiency” as well as a treatment with anticoagulants (“blood thinners”) or blood pressure reducing agents (antihypertensives).
- The tendency to bleed may be increased even after minor interventions such as tooth extractions.
- Acetylsalicylic acid reduces the excretion of uric acid even in small dosages. This can induce gout in patients who already exhibit a low uric acid excretion.

Inform your physician or pharmacist if

- you are suffering from other diseases,
 - have allergies or
 - are using other medicinal products (even over-the-counter medications!).
- Ask or inform the physician or dentist about the use of the medication prior to surgical interventions.

Other medicines and Aspicot:

- Taking Aspicot and antidiabetic drugs (e.g. insulin, sulphonylureas) at the same time may lower the blood sugar level.
- You should talk to your physician if you are taking Aspicot concurrently with any pain or anti-inflammatory medication (such as, for example, the active pharmaceutical ingredients ibuprofen or naproxen), as these may weaken the effect of Aspicot.
- The effect of gout medications (probenecid and sulfinpyrazone), diuretics and medications against high blood pressure may be reduced. If antirheumatic agents or methotrexate (which is e.g. taken to treat chronic polyarthritis; see also section “Do not take Aspicot”) are used, then the adverse effects may intensified.
- In the event of the concomitant and prolonged use of Aspicot, the effect of cortisone products, anticonvulsants (antiepileptics), blood thinners, digoxin and lithium preparations against depression may be increased. The adverse effect of these medicinal products may be increased.
- If taken concomitantly with cortisone products, alcohol or medicinal products from the group of the so-called serotonin reuptake inhibitors against depression, Aspicot may increase the risk for bleeding. The concomitant use of Aspicot and cortisone products or alcohol may increase the risk for gastrointestinal ulcers.

Children and adolescents:

- Aspicot is not recommended for children and adolescents under the age of 18.
- Children and adolescents with fever, flu, chickenpox or other viral diseases may use Aspicot only as instructed by the physician and only as a second choice agent. Consult the physician immediately if disturbances of consciousness with vomiting occur during these illnesses or after they subsided.

Pregnancy and breast-feeding:

You should not use medicinal products during pregnancy and lactation as a precaution. If you continue or start treatment with Aspicot during pregnancy per instruction of the physician, then this may occur only under strict compliance with his or her instructions and only during the first six months of pregnancy. Aspicot must not be taken during the last three months of pregnancy due to a possible risk to the unborn child, the risk for bleeding and a possible delay of the date of the birth.

If higher doses are taken regularly during lactation, then the infant should be weaned.

Driving and using machines:

This medicine has no influence on your ability to drive or use machines.

3. How to take Aspicot

If not prescribed otherwise by the physician:

- Prevention of arterial thromboses without bypass surgery on the coronary vessels and after dilation (balloon dilation) of constricted coronary vessels: 100 mg/day.
- Prevention of arterial thromboses after bypass surgery on the coronary vessels and after dilation (balloon dilation) of constricted coronary vessels: 100–300 mg/day.
- Prevention of strokes: 3 × 100 mg/day.
- Prevention of thromboses after myocardial infarction and treatment of unstable angina pectoris: 1 × 100 mg/day.
- Prevention of heart attacks in patients after a high risk was determined by a physician: 1 × 100 mg/day.

It is recommended to take the tablets with a bit of fluid at least half an hour before a meal. Drink approximately ½ -1 glass of liquid afterward. The tablets should not be crushed, broken or chewed.

In the event of acute myocardial infarction: If you suffer of an acute myocardial infarction, at hospital, you will be administered 200-300 mg of acetylsalicylic acid intravenously. Alternatively, you may be administered a rapidly absorbed acetylsalicylic acid preparation (non-enteric-coated form), which you may take by mouth, either crushed or chewed, in order for the active pharmaceutical ingredient to be absorbed more quickly. From the second day onwards, the dose is 100 mg of Aspicot daily. The treating physician decides on the dosage and the duration of use.

Do not change the prescribed dose by yourself. Talk to your physician or pharmacist if you believe that the medicine acts too mildly or too strongly. Consult a physician immediately in the event of an uncontrolled administration (overdose). Tinnitus and/or sweating may indicate an overdose. Aspicot should not be used in children and adolescents under the age of 18.

4. Possible side effects

Stomach problems are a common side effect. Asthma, digestive problems, nausea, vomiting and diarrhoea were reported occasionally. Hypersensitivity reactions (such as swelling of the skin and mucous membranes (e.g. stuffy nose), skin rashes, shortness of breath, drop in blood pressure up to shock) as well as gastrointestinal bleeding and gastrointestinal ulcers, which very rarely may lead to perforations may occur in rare cases.

Headaches, dizziness, tinnitus, visual impairment, hearing impairment, states of confusion, anaemia due to iron deficiency as well as renal and hepatic dysfunctions rarely occur.

In rare to very rare cases, serious bleeding, especially in patients with unbalanced hypertension and/or treated concomitantly with “blood thinners” (anticoagulants) were reported, and these can in single cases be potentially lifethreatening. Very rare side effects may include severe skin reactions, low blood sugar, disturbances of the acid base balance as well as Reye's syndrome in children.

Contusions, nose bleeds, bleeding gums, urogenital bleeding and bleeding after surgical interventions were observed. A prolongation of the bleeding time is possible.

Sudden renal failure was reported. The medicinal product must be discontinued and the physician must be consulted if signs of a hypersensitivity reaction occur.

If black stool or bloody vomiting occur during the treatment, then the medicinal product should be discontinued and the physician should be consulted immediately. You should inform your physician or pharmacist if you notice side effects that are not described here.

5. How to store Aspicot

- 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 blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. 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 Aspicot contains

- The active substance is acetylsalicylic acid.
- Each enteric-coated tablet contains 100 mg of acetylsalicylic acid.
- The other ingredients are colloidal anhydrous silica, maize starch, microcrystalline cellulose, stearic acid, talc, simethicone emulsion, triethyl citrate, methacrylic acid-ethyl acrylate copolymer.

What Aspicot looks like and contents of the pack

White, round, enteric-coated tablets.

Aspicot 100 mg is available in boxes containing 30/100 tablets with leaflet.

Marketing Authorisation Holder and Manufacturer

Pharmaline, sal – Lebanon
P.O. Box 90201 Jdeidet-El-Metn, Lebanon
Contact us: pharmaline@maliagroup.com
Website: www.pharmaline.com.lb

Reg. No. in Lebanon for Aspicot 100 mg 30 Enteric-Coated Tablet: 261088/97

Reg. No. in Lebanon for Aspicot 100 mg 100 Enteric-Coated Tablets: 261087/97

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 for you.
- Do not repeat the same prescription without consulting your doctor.

Council of Arab Health Ministers

Union of Arab Pharmacists

This leaflet was last revised in October 2021.