

PACKAGE LEAFLET: INFORMATION FOR THE USER

ASK LEK

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?

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1. WHAT ASK LEK IS AND WHAT IT IS USED FOR

ASK Lek contains acetylsalicylic acid which in a lower dose belongs to a group of medicines called antithrombotics.

Thrombocytes (platelets) are blood cells that cause blood clotting, and participate in the creation of a blood clot. When the blood clot is created in the artery, blood flow stops and there is a disruption in the oxygen supply. This phenomenon in the heart may lead to heart attack or angina pectoris (chest pain), and to the brain stroke.

ASK Lek is used to mitigate the risk of thrombosis, and thus prevents:

- heart attack
- stroke
- cardiovascular problems in patients with stable or unstable angina (a type of chest pain).

ASK Lek is used to prevent blood clots after surgery on a heart with the aim of expanding the blood vessels or remove the clot.

The use of this medicine is not recommended in emergency medical conditions, but only as a preventive treatment.

Acetylsalicylic acid, which is an integral part of the ASK Lek can also be used to treat other diseases that are not listed in this leaflet. For any questions, consult a doctor or medical personnel and always follow their instructions.

2. BEFORE YOU TAKE ASK LEK

Do not take ASK LEK

- If you are hypersensitive (allergic) to acetylsalicylic acid or any other substance of ASK Lek (see section 6 "Further information").
- If you are allergic to salicylates or other nonsteroidal anti-inflammatory drugs (NSAIDs). NSAIDs are often used to treat arthritis or rheumatism and pain relief.
- If you have had an asthma attack or the appearance of swelling on a part of the body, for example, on the face, lips, throat or tongue (angioedema) after taking salicylates or NSAIDs,
- If you have or have had stomach ulcers or duodenum or any type of bleeding like a stroke.
- If you have ever had problems with blood clotting.
- If you have serious problems with your liver or kidneys.
- If you are in the third trimester of pregnancy you should not take doses higher than 100 mg per day (see section "Pregnancy and lactation").
- If you are taking methotrexate (a drug for the treatment of cancer or arthritis) at doses higher than 15 mg per week.

Take special care with ASK LEK if you

Before you take ASK Lek, tell your doctor or pharmacist if:

- you have kidney, liver or heart problems
- have or have had gastrointestinal problems
- you have high blood pressure
- If you have asthma, hay fever, nasal polyps or other chronic diseases of the respiratory tract because acetylsalicylic acid can trigger an asthma attack
- you have ever had an attack of gout
- have heavy menstrual bleeding.

Immediately consult a doctor for advice if your symptoms get worse or you experience serious or unexpected side effects such as abnormal bleeding, serious skin reactions or other symptoms of severe allergic reactions (see section "Possible side effects").

Tell your doctor if you are planning to undergo a surgical procedure (even a minor procedure such as tooth extraction) because acetylsalicylic acid thins the blood and thereby increase the risk of bleeding.

Acetylsalicylic acid can cause Reye's syndrome in children. This is a very rare disease that affects the brain and liver, and can be life-threatening. Therefore, acetylsalicylic acid should not be given to children under 16 years of age without a doctor's prescription.

You must ensure that you do not dehydrate (sensation of thirst and dry mouth) because application of acetylsalicylic acid can impair kidney function.

This medicine is not suitable for pain relief or lowering the fever.

If any of the above applies to you or if you are not sure, ask your doctor or pharmacist.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription.

The effect of treatment can be influenced by concomitant use of ASK Lek and certain medications such as medicines for:

- blood-thinning / prevention of blood clots (warfarin, heparin, clopidogrel)
- prevention of organ rejection after transplantation (cyclosporine, tacrolimus)
- High blood pressure (diuretics and angiotensin-converting)
- regulation of heart rate (digoxin)
- manic depression (lithium),
- relief of pain and inflammation (non-steroidal anti-inflammatory drugs such as ibuprofen or steroids),
- treatment of gout (probenecid)
- epilepsy (valproate, phenytoin)
- treatment of glaucoma (acetazolamide),
- treatment of cancer or arthritis (methotrexate; at doses less than 15 mg per week)
- diabetes (glibenclamide)
- depression (selective serotonin reuptake inhibitors such as sertraline, or paroxetine),
- use in hormone replacement therapy following failure or removal of the pituitary or adrenal gland or in the treatment of inflammation, including rheumatic diseases, and inflammatory bowel disease (corticosteroids).

Taking ASK Lek with food and drink

Alcohol may increase the risk of bleeding in the digestive tract and prolong the bleeding time.

Pregnancy and breast-feeding

Consult your doctor or pharmacist before taking any medicine.

Pregnant women should not take acetylsalicylic acid, unless prescribed by a doctor. ASK Lek should not be taken if you are in the third trimester of pregnancy unless you have been prescribed by a doctor, and even then the daily dose should not exceed 100 mg (see section "Do not take ASK Lek"). The use of normal or high doses of this medicine in late pregnancy can cause serious complications for the mother and child. Breastfeeding mothers should not take acetylsalicylic acid, unless prescribed by a doctor.

Driving and using machines

ASK LEK should not affect your ability to drive and use machines.

3. HOW TO TAKE ASK LEK

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults

Preventing heart attack:

The recommended dose is 100 mg once daily.

Preventing stroke:

The recommended dose is 100 mg once daily.

Preventing cardiovascular problems in patients with stable or unstable angina (a type of chest pain):
The recommended dose is 100 mg once daily.

Preventing blood clots after certain surgical procedures on the heart:

The recommended dose is 100 mg once daily.

The usual dose for longer treatment is 100 mg once daily. Do not take ASK Lek in higher doses unless recommended by a doctor. The prescribed dosage should not be higher than 300 mg.

Elderly

The dosage is the same as in adults. Generally, the ASK should be used with caution in elderly patients who are more likely to get side effects. The course of treatment should be monitored at regular intervals.

Children

ASK LEK should not be given to children and adolescents under 16 years old unless prescribed by a doctor (see section "Take special care with ASK Lek").

Method of administration

Swallow the tablets whole with plenty of fluid (1/2 glass of water). The tablets have a gastro-resistant coating that prevents irritation of the stomach, and are therefore you should not crush, break or chew them.

If you take more ASK LEK than you should

If you have taken more medicine than you should, talk to your doctor or pharmacist.

Symptoms of overdose may be noise in the ears, hearing problems, headaches, dizziness, confusion, nausea, vomiting and abdominal pain. Serious overdose can cause shortness of breath, fever, sweating, restlessness, convulsions, hallucinations, a drop in blood sugar levels, coma and shock.

If you forget to take ASK LEK

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

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

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ASK LEK can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects, stop taking ASK Lek and immediately contact your doctor.

- sudden wheezing (breathing), swelling of the lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction)
- redness of the skin with blistering or peeling, along with fever and joint pain; These symptoms may indicate conditions such as erythema multiforme, Stevens-Johnson syndrome or Lyell's syndrome,
- unusual bleeding, such as coughing up blood, vomiting blood, blood in the urine or stool (dark stool).

Common side effects (affects 1 to 10 per 100 persons):

- indigestion,
- increased bleeding tendency.

Less common side effects (affects 1 to 100 per 1,000 people)

- rash (hives)

- runny nose,
- difficulty breathing.

Rare side effects (affects 1 to 10 in 10,000 people)

- heavy bleeding in the stomach or intestines, bleeding in the brain, altered blood counts,
- nausea and vomiting,
- cramps in the lower respiratory tract infections, asthma attacks,
- inflammation of blood vessels,
- bruising or purple stain (skin bleeding)
- severe skin reactions such as rash known as erythema multiforme and its life-threatening forms; Stevens-Johnson syndrome and Lyell's syndrome,
- hypersensitivity reactions such as swelling of lips, face or body, or shock,
- unusually abundant or prolonged menstrual bleeding.

Side effects of unknown frequency

- noise in the ears (tinnitus) or hearing problems,
- headache,
- dizziness,
- ulceration and perforation of the stomach and small intestine,
- prolonged bleeding time,
- impaired renal function,
- impaired liver function,
- High levels of uric acid in the blood.

If there is a deterioration of some of the side effects or if you notice any side effects not listed in this leaflet, you should inform your doctor or pharmacist.

5. HOW TO STORE ASK LEK

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use ASK LEK after the expiry date which is stated on the label.

Shelf life: 2 years.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What ASK LEK contains

The active substance is acetylsalicylic acid.

One gastroresistant tablet contains 100 mg of acetylsalicylic acid.

The other ingredients are: microcrystalline cellulose, maize starch, colloidal silica, anhydrous, stearic acid, methacrylic acid, ethyl acrylate copolymer (1: 1), polysorbate 80, sodium lauryl sulfate, triethyl citrate, talc.

What ASK LEK looks like and contents of the pack

ASK Lek contains white round biconvex gastro-resistant tablets.
They are available in packs of 100 gastroresistant tablets.

Regime of dispensing

The medicine is issued without doctor`s prescription.

Manufacturer

Lek farmacevtska družba dd, Verovškova 57, Ljubljana, Slovenia

Manufacturer of the medicinal product

Actavis ehf., Reykjavikuvegur 79, IS-220 Hafnarfjordur, Iceland
Actavis Ltd. BLB 010, Bulebel Industrial Estate, Zejtun DRR 3000, Malta
Balkanpharma Dupnitsa AD, 3 Samokovsko Shosse Str., Dupnitsa