

Package leaflet: Information for the user

Acetylsalicylsyra G.L. Pharma 75 mg tablets

acetylsalicylic acid

[For medicines available only on prescription:]

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. See section 4.

[For medicines available without a prescription:]

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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

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

1. What Acetylsalicylsyra G.L. Pharma is and what it is used for

Acetylsalicylsyra G.L. Pharma contains acetylsalicylic acid, which in low doses belong to a group of medicines called anti-platelet agents. Platelets are tiny cells in the blood that cause the blood to clot and are involved in thrombosis. When a blood clot occurs in an artery it stops the blood flowing and cuts off the oxygen supply. When this happens in the heart it can cause a heart attack or angina; in the brain it can cause a stroke.

Acetylsalicylsyra G.L. Pharma is taken to reduce the risk of blood clots forming and thereby prevent further:

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

Acetylsalicylsyra G.L. Pharma is also used to prevent the formation of blood clots after certain types of heart surgery in order to widen or to unblock the blood vessels.

Acetylsalicylsyra G.L. Pharma is also used for the treatment of acute myocardial infarction.

[For medicines available without a prescription:]

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Acetylsalicylsyra G.L. Pharma

Do not take Acetylsalicylsyra G.L. Pharma

- if you are allergic to acetylsalicylic acid, to other salicylates or non-steroidal anti-inflammatory drugs (NSAIDs; NSAIDs are often used for arthritis or rheumatism and pain), or to any of the ingredients in Acetylsalicylsyra G.L. Pharma (listed in section 6)
- if you have had an asthma attack or swelling of some parts of the body e.g. face, lips, throat or tongue (angioedema) after taking salicylates or NSAIDs.
- if you have or have had stomach ulcers or bleeding in your stomach/ intestines caused by previous NSAID treatment
- if you have or have had recurrent ulcers in your stomach/intestines or any other type of bleeding like a stroke.
- if you have ever had the problem of your blood not clotting properly.
- have severe liver or kidney problems
- if you have severe heart problems which can cause shortness of breath and ankle swelling
- if you are in the last 3 months of your pregnancy; you must not use higher doses than 100 mg per day (see section “Pregnancy and breast-feeding”).
- if you are taking a medicine called methotrexate (e.g. for cancer or rheumatoid arthritis) in doses higher than 15 mg per week.

Warnings and precautions

Talk to your doctor or pharmacist before taking Acetylsalicylsyra G.L. Pharma if you:

- have trouble with your kidneys, liver or heart.
- have or have ever had ulcers or bleedings (e.g. in your stomach or small intestine).
- have uncontrolled high blood pressure.
- are asthmatic, have hay fever, nasal polyps or other chronic respiratory diseases; acetylsalicylic acid may induce an asthma attack.
- have ever had gout.
- have severe menstrual periods.
- suffer from a deficiency of the enzyme glucose-6-phosphate dehydrogenase (G6PD).

You must immediately seek medical advice, if your symptoms get worse or if you experience severe or unexpected side effects e.g. unusual bleeding symptoms, serious skin reactions or any other sign of serious allergy (see section “Possible side effects”).

Inform your doctor if you are planning to have an operation (even a minor one, such as tooth extraction) since acetylsalicylic acid is blood-thinning there may be an increased risk of bleeding.

You should take care not to become dehydrated (you may feel thirsty with a dry mouth) since the use of acetylsalicylic acid at the same time may result in deterioration of kidney function.

This medicinal product is not suitable as a pain killer or fever reducer.

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

Children and adolescents

Acetylsalicylic acid may cause Reye’s syndrome when given to children. Reye’s syndrome is a very rare disease which affects the brain and liver and can be life threatening. For this reason, Acetylsalicylsyra G.L. Pharma should not be given to children aged under 16 years, unless on the advice of a doctor.

Other medicines and Acetylsalicylsyra G.L. Pharma

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

The effect of treatment may be influenced if acetylsalicylic acid is taken at the same time as some other medicines e.g.:

- medicines for thinning of the blood/prevention of clots or dissolving (e.g. warfarin, heparin, clopidogrel, alteplase)
- medicines which counteract organ rejection after transplantation (cyclosporine, tacrolimus)

- medicines for high blood pressure (e.g. diuretics and ACE-inhibitors)
- medicines for regulation of the heartbeat (digoxin)
- medicines for manic-depressive illness (lithium)
- medicines for pain and inflammation (e.g. NSAIDs (such as ibuprofen), or steroids)
- metamizole (a substance that reduces pain and fever) can reduce the effect of acetylsalicylic acid on platelet aggregation (blood cells that attach together and form a blood clot) when taken at the same time. Therefore, this combination should be used with caution in patients taking a low dose of acetylsalicylic acid for cardiac protection
- medicines for gout (e.g. probenecid)
- medicines for epilepsy (valproate, phenytoin)
- medicines for glaucoma ie increased pressure in the eye (acetazolamide) when used with high doses of acetylsalicylic acid (at least 500 mg)
- medicines for cancer or rheumatoid arthritis (methotrexate; in doses lower than 15 mg per week)
- medicines for diabetes (e.g. glibenclamide, insulin)
- medicines for depression (selective serotonin re-uptake inhibitors (SSRIs) such as sertraline or paroxetine).
- medicines for use in hormone replacement therapy when the adrenal glands or pituitary gland have been destroyed or removed, or to treat inflammation, including rheumatic diseases and inflammation of the intestines (corticosteroids)

Acetylsalicylsyra G.L. Pharma with alcohol

Drinking alcohol may possibly increase the risk of gastrointestinal bleeding 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.

If you continue or start treatment with Acetylsalicylsyra G.L. Pharma during pregnancy per instruction of the physician, then use Acetylsalicylsyra G.L. Pharma as advised by your doctor and do not use a higher dose than is recommended.

Pregnancy - last trimester (the last three month of the pregnancy)

Do not take Acetylsalicylsyra G.L. Pharma higher than 100 mg per day if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

If you take Acetylsalicylsyra G.L. Pharma at low doses (up to and including 100 mg per day), you need strict obstetric monitoring as advised by your doctor.

Pregnancy - first and second trimester (the first six month of the pregnancy)

You should not take Acetylsalicylsyra G.L. Pharma during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Acetylsalicylsyra G.L. Pharma can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breast-feeding

Breast-feeding women should not take acetylsalicylic acid unless advised by their doctor.

Fertility

Acetylsalicylic acid can affect female fertility in women. This affect is temporary and will cease if the medication is discontinued.

Driving and using machines

Acetylsalicylsyra G.L. Pharma should not affect your ability to drive and use machines.

Acetylsalicylsyra G.L. Pharma contains lactose

If you have been told that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

3. How to take Acetylsalicylsyra G.L. Pharma

[For medicines available only on prescription:]

Always take this medicine exactly as your doctor or pharmacist has told you.

[For medicines available without a prescription:]

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

Check with your doctor or pharmacist if you are not sure.

Adults

Prevention of heart attacks:

- The recommended dose is 75-160 mg once daily.

Prevention of strokes:

- The recommended dose is 75-300 mg once daily.

Prevention of cardiovascular problems in patients who suffer from stable or unstable angina (a type of chest pain):

- The recommended dose is 75-160 mg once daily.

Prevention formation of blood clots after certain types of heart surgery:

- The recommended dose is 75-160 mg once daily.

Treatment of acute myocardial infarction:

- The recommended initial dose is 150-300 mg followed by a lower dose (75-160 mg) thereafter.

This medicine should not be used at higher doses unless advised by a doctor.

Elderly patients

As for adults. In general, acetylsalicylic acids should be used with caution in elderly patients who are more prone to adverse events. Treatment should be reviewed at regular intervals.

Children and adolescents

Acetylsalicylic acid should not be administered to children and adolescents younger than 16 years, unless prescribed by a doctor (see section "Warnings and precautions").

Duration of treatment

Long-term treatment with the lowest possible dose.

The tablets should be swallowed with sufficient fluid (1/2 glass of water).

If you take more Acetylsalicylsyra G.L. Pharma than you should

If you (or e.g. a child) accidentally take too many tablets, you should immediately contact your doctor, hospital for risk assessment and treatment advice. Show any leftover medicines or the empty packet to the doctor.

Symptoms of overdose may include ringing in ears, hearing problems, headache, dizziness, confusion, nausea, vomiting and abdominal pain. A large overdose can lead to more rapid breathing than normal (hyperventilation), fever, excess sweating, restlessness, seizures, hallucinations, low blood sugar, pulmonary oedema, coma and shock.

If you forget to take Acetylsalicylsyra G.L. Pharma

If you miss a dose, wait until it is time for your next dose, then go on as normal.

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

If you stop taking Acetylsalicylsyra G.L. Pharma

Do not stop taking Acetylsalicylsyra G.L. Pharma without asking your doctor.

If you have any further questions on the use of this product, 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 Acetylsalicylsyra G.L. Pharma and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling and may be associated with a high fever and joint pains. This could be erythema multiforme, Stevens-Johnson syndrome or Lyell's syndrome.
- Unusual bleeding, such as coughing up blood, blood in your vomit or urine, or black stools.

Other side effects include:

Common (may affect up to 1 in 10 people)

- Nausea, vomiting, diarrhoea
- Indigestion.
- Increased tendency for bleeding.

Uncommon (may affect up to 1 in 100 people)

- Hives.
- Runny noses.
- Breathing difficulty.

Rare (may affect up to 1 in 1,000 people)

- Severe bleeding in the stomach or intestines, brain haemorrhage; altered number of blood cells.
- Cramps in the lower respiratory tract, asthma attack.
- Inflammation in the blood vessels.
- Bruising with purple spots (cutaneous 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 e.g. lips, face or body, or shock.
- Reye's syndrome (a very rare disease in children which affects the brain and liver (see section 2 "Children and adolescents".))
- Abnormal heavy or prolonged menstrual periods

Not known (frequency cannot be estimated from the available data)

- Ringing in your ears (tinnitus) or reduced hearing ability.
- Headache.
- Vertigo.
- Ulcers in stomach or small intestine and perforation.
- Prolonged bleeding time.

- Impaired kidney function, acute renal failure.
- Impaired liver function, increased liver enzymes.
- High level of uric acid or low levels of sugar in the blood.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Acetylsalicylsyra G.L. Pharma

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

Do not store above 30°C.

Keep the blister in the original package in order to protect from moisture.

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

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. Contents of the pack and other information

What Acetylsalicylsyra G.L. Pharma contains

- The active substance is acetylsalicylic acid. Each tablet contains 75 mg of acetylsalicylic acid.
- The other ingredients are:
Lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, potato starch.

What Acetylsalicylsyra G.L. Pharma looks like and contents of the pack

White, round, biconvex tablet with a diameter of about 7.0 mm.

Pack sizes:

10, 20, 28, 30, 50, 56, 60, 90, 100, 105, 110 and 200 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

G.L. Pharma GmbH,
Schlossplatz 1
8502 Lannach,
Austria

This medicinal product is authorised in the Member States of the European Economic Area under the following names:

Denmark: Acetylsalicylsyre G.L. Pharma

Sweden: Acetylsalicylsyra G.L. Pharma

This leaflet was last approved in
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