Package leaflet: Information for the user

Aspirin 75 mg 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. See section 4.

What is in this leaflet:

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

1. What Aspirin is and what it is used for

Aspirin 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.

Aspirin 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).

Aspirin 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.
Aspirin is also used for the treatment of acute myocardial infarction.

2. What you need to know before you take Aspirin

Do not take Aspirin
- if you are allergic to aspirin, to other salicylates or non-steroidal anti-inflammatory drugs (NSAIDs; NSAIDs are often used for arthritis or rheumatism and pain), or any of the ingredients in Aspirin (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), a runny nose, or hives after taking salicylates or NSAIDs.
- if you currently have or have ever had an ulcer in your stomach or small intestine.
- if you have a history of gastrointestinal bleeding or perforation (gastric or intestinal failure) caused by previous NSAID therapy.
- if you have a history of recurrent gastric and duodenal ulcer/hemorrhage with episodes of ulceration or bleeding, 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 your last 3 months of 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 before taking Aspirin:
- if you have trouble with your kidneys, liver or heart.
- if you have or have ever had ulcers or bleedings (e.g. in your stomach or small intestine).
- if you have uncontrolled high blood pressure.
- if you are asthmatic, have hay fever, nasal polyps or other chronic respiratory diseases; aspirin may induce an asthma attack.
- if you have ever had gout.
- if you have severe menstrual periods.
- If you 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").

When taking acetylsalicylic acid, serious allergic reactions which may include chest pain and even heart attack (Kounis syndrome) have been reported (see section 4). Seek medical care immediately when you notice chest pain with allergic reactions (such as skin rashes, shortness of breath).

Inform your doctor if you are planning to have an operation (even a minor one, such as tooth extraction) since aspirin 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 aspirin 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
Aspirin 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 live threatening. For this reason, Aspirin should not be given to children aged under 16 years, unless on the advice of a doctor.

Other medicines and Aspirin
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 aspirin is taken at the same time as some other medicines for:
- thinning of the blood/prevention of clots (e.g. warfarin, heparin, clopidogrel, alteplase)
- rejection of organ after transplantation (cyclosporine, tacrolimus)
- high blood pressure (e.g. diuretics and ACE-inhibitors)
- regulation of the heart beat (digoxin)
- manic-depressive illness (lithium)
- pain and inflammation (e.g. NSAIDs such as ibuprofen, metamizole or steroids)
- gout (e.g. probenecid)
- epilepsy (valproate, phenytoin)
- glaucoma (acetazolamide)
- cancer or rheumatoid arthritis (methotrexate; in doses lower than 15 mg per week)
- diabetes (e.g. glibenclamide, insulin)
- depression (selective serotonin re-uptake inhibitors (SSRIs) such as sertraline or paroxetine).

- use as 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)

Aspirin with food, drink and 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.

Pregnant women should not take aspirin during pregnancy unless advised by their doctor.
You should not take Aspirin if you are in the last 3 months of pregnancy, unless you are advised to do so by your doctor and then the daily dose should not exceed 100 mg (see section "Do not take Aspirin"). Regular or high doses of this medicinal product during late pregnancy can cause serious complications in the mother or baby.

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

For aspirin ≥ 500 mg/day and equipotent derivates
Aspirin may affect female fertility via an effect on ovulation. This effect is reversible after discontinuation of treatment.

Driving and using machines
Aspirin should not affect your ability to drive and use machines.

Aspirin 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 Aspirin

Always take this medicine exactly 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 150-500 mg followed by a lower dose (75-160 mg) thereafter.

This medicine should not be used at higher doses unless advised by a doctor. The dose should not exceed 300 mg a day.

Elderly patients
As for adults. In general, aspirins 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
Aspirin should not be administered to children and adolescents younger than 16 years, unless prescribed by a doctor (see section "Warnings and precautions").

Method of administration
For oral use.
The tablets should be swallowed with sufficient fluid (1/2 glass of water).

If you take more Aspirin than you should
If you (or someone else) accidentally take too many tablets, you should tell your doctor at once or contact immediately the nearest casualty department. 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 Aspirin
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 Aspirin
Do not stop taking Aspirin 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 Aspirin 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 it's 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.
- Acute myocardial ischemia (painful heart condition caused by lack of blood flow to the heart) with or without myocardial infarction (heart attack) occurring as part of an allergic reaction (Kounis syndrome).

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.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aspirin

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

Do not store above 30°C.

Keep the blister in the outer carton in order to protect from moisture.

Do not use Aspirin after the expiry date which is stated on the carton or blister 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 Aspirin 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 Aspirin looks like and contents of the pack

White to off white coloured tablets, round and biconvex, with whithout break score.
Diameter: 7.0 ± 0.2 mm; Thickness: 3.5 ± 0.3 mm

Pack sizes:
Blisters: 10, 20, 28, 30, 50, 56, 60, 90 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

This leaflet was last revised in August 2026