

Summary Public Assessment Report

Acetylsalicylsyra G.L. Pharma (acetylsalicylic acid)

SE/H/1511/004/MR

Summary Public Assessment Report

Acetylsalicylsyra G.L. Pharma
acetylsalicylic acid

Tablet, 75 mg

This is a summary of the public assessment report (PAR) for Acetylsalicylsyra G.L. Pharma. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

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

The product is a medicine with 'well-established use'. This means that the medicinal use of the active substance of the product is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

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.

How does Acetylsalicylsyra G.L. Pharma work?

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.

How is Acetylsalicylsyra G.L. Pharma used?

The pharmaceutical form is tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Acetylsalicylsyra G.L. Pharma have been shown in studies?

As acetylsalicylic acid is a well-known substance, and its use in the treatment of;

Acute myocardial infarction.

- Secondary prevention of myocardial infarction.
- Prevention of cardiovascular morbidity in patients suffering from stable angina pectoris.
- History of unstable angina pectoris, except during the acute phase.
- Prevention of graft occlusion after Coronary Artery Bypass Grafting (CABG).
- Coronary angioplasty, except during the acute phase.
- Secondary prevention of transient ischaemic attacks (TIA) and ischaemic cerebrovascular accidents (CVA), provided intracerebral haemorrhages have been ruled out,

is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of acetylsalicylic acid in the treatment of the above-mentioned indication.

What are the possible side effects from Acetylsalicylsyra G.L. Pharma?

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Acetylsalicylsyra G.L. Pharma approved?

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Acetylsalicylsyra G.L. Pharma?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Acetylsalicylsyra G.L. Pharma

The full PAR for Acetylsalicylsyra G.L. Pharma can be found on the following website: [MRI - Home](#). For more information about treatment with Acetylsalicylsyra G.L. Pharma, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-03.