

Summary Public Assessment Report

Acetylsalicylsyra Evolan (acetylsalicylic acid)

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Acetylsalicylsyra Evolan
acetylsalicylic acid

Film-coated tablet, 75 mg

This is a summary of the public assessment report (PAR) for Acetylsalicylsyra Evolan. 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 Evolan and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Tromblyl.

The product is used 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).

The product is also used in the treatment of acute heart attack and to prevent the formation of blood clots after certain types of heart surgery in order to widen or to unblock the blood vessels.

How does Acetylsalicylsyra Evolan work?

The product 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. When a blood clot occurs in an artery it stops the blood flowing and cuts off the oxygen supply. The product works by reducing the risk of blood clots forming.

How is Acetylsalicylsyra Evolan used?

The pharmaceutical form is film-coated tablets 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 Evolan have been shown in studies?

No additional studies were needed as the product is a generic medicine considered to be bioequivalent to the reference medicine, Tromblyl. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Acetylsalicylsyra Evolan?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

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 Evolan approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Tromblyl, 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 Evolan?

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 Evolan

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

This summary was last updated in 2025-12.