

Summary Public Assessment Report

Thromboass (acetylsalicylic acid)

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(acetylsalicylic acid)

gastro-resistant tablets, 75, 100, 160 mg

This is a summary of the public assessment report (PAR) for Thromboass. It explains how Thromboass was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Thromboass.

For practical information about using Thromboass, patients should read the package leaflet or contact their doctor or pharmacist.

What is Thromboass and what is it used for?

Thromboass 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).

Thromboass 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.

This medicinal product is not recommended for emergencies. It can only be used as a preventive treatment.

How does Thromboass work?

Thromboass 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 Thromboass used?

The pharmaceutical form of Thromboass is gastro-resistant 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.

What benefits of Thromboass have been shown in studies?

As acetylsalicylic acid is a well-known substance, and its use in the treatment of the proposed indication are 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 proposed indications.

What are the possible side effects of Thromboass?

For the full list of all side effects reported with Thromboass, see section 4 of the package leaflet.

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

Why is Thromboass approved?

The use of Thromboass in the treatment of the proposed indication is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Thromboass's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Thromboass?

A risk management plan has been developed to ensure that Thromboass 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 for Thromboass, 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 Thromboass

The marketing authorisation for Thromboass was granted on 2015-12-10 in Sweden.

The full PAR for Thromboass can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Thromboass, please read the [[package leaflet](#)] or contact your doctor or pharmacist.

This summary was last updated in 2015-12-21.