

Summary Public Assessment Report

Acetylsalicylsyra Teva (acetylsalicylic acid)

SE/H/1593/01-03/DC

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(acetylsalicylic acid)

Tablet, 75 mg, 150 mg and 160 mg

This is a summary of the public assessment report (PAR) for Acetylsalicylsyra Teva. It explains how Acetylsalicylsyra Teva 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 Acetylsalicylsyra Teva.

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

What is Acetylsalicylsyra Teva and what is it used for?

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

Acetylsalicylsyra Actavis 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 Actavis 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 Teva work?

Acetylsalicylsyra Actavis 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 Teva used?

The pharmaceutical form of Acetylsalicylsyra Teva 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.

What benefits of Acetylsalicylsyra Teva have been shown in studies?

As acetylsalicylic acid is a well-known substance, and its use:

- in order to reduce the risk of blood clots forming and thereby prevent further:
 - o heart attacks
 - o strokes
 - o cardiovascular problems in patients who suffer from stable or unstable angina (a type of chest pain).
- 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.

, 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 conditions.

What are the possible side effects of Acetylsalicylsyra Teva?

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

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

Why is Acetylsalicylsyra Teva approved?

The use of Acetylsalicylsyra Teva:

- in order to reduce the risk of blood clots forming and thereby prevent further:
 - o heart attacks
 - o strokes
 - o cardiovascular problems in patients who suffer from stable or unstable angina (a type of chest pain).
- 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.

, 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 Acetylsalicylsyra Teva'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 Acetylsalicylsyra Teva?

A risk management plan has been developed to ensure that Acetylsalicylsyra Teva 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 Acetylsalicylsyra Teva, 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 Teva

The marketing authorisation for Acetylsalicylsyra Teva was granted on 2016-10-27 in Sweden.

The full PAR for Acetylsalicylsyra Teva can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Acetylsalicylsyra Teva, please read the [[package leaflet](#)] or contact your doctor or pharmacist.

This summary was last updated in 2016-10-27.