

Summary Public Assessment Report

Acetylsalicylic acid Krka (acetylsalicylic acid)

SE/H/1604/01-03/DC

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Acetylsalicylic acid Krka
(acetylsalicylic acid)

Gastro-resistant tablet, 75 mg, 100 mg and 160 mg

This is a summary of the public assessment report (PAR) for Acetylsalicylic acid Krka. It explains how Acetylsalicylic acid Krka 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 Acetylsalicylic acid Krka.

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

What is Acetylsalicylic acid Krka and what is it used for?

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

Acetylsalicylic acid Krka 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).

Acetylsalicylic acid Krka 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.

How does Acetylsalicylic acid Krka work?

Acetylsalicylic acid Krka 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 Acetylsalicylic acid Krka used?

The pharmaceutical form of Acetylsalicylic acid Krka is gastro-resistant 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 Acetylsalicylic acid Krka have been shown in studies?

As acetylsalicylic acid is a well-known substance, and its use 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)
- 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 its use 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)
- prevent the formation of blood clots after certain types of heart surgery in order to widen or to unblock the blood vessels

What are the possible side effects of Acetylsalicylic acid Krka?

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

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

Why is Acetylsalicylic acid Krka approved?

The use of acetylsalicylic acid 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)
- 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 Acetylsalicylic acid Krka'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 Acetylsalicylic acid Krka?

A risk management plan has been developed to ensure that Acetylsalicylic acid Krka 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 Acetylsalicylic acid Krka, 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 Acetylsalicylic acid Krka

The marketing authorisation for Acetylsalicylic acid Krka was granted on 2017-02-10 in Sweden.

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

This summary was last updated in 2017-02-10.