

Summary Public Assessment Report

Acetylsalicylic acid Bluefish (acetylsalicylic acid)

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Tablet, 75 mg, 160 mg

This is a summary of the public assessment report (PAR) for Acetylsalicylic acid Bluefish. 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 Acetylsalicylic acid Bluefish 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 Trombyl .

Acetylsalicylic acid Bluefish is used by patients who have severe angina in the heart (unstable angina pectoris) or who have a history of cardiac or cerebral infarction (stroke). Acetylsalicylic acid Bluefish helps reduce the risk of relapse of a new infarction, by preventing clots forming in the heart and the brain's blood vessels.

How does Acetylsalicylic acid Bluefish work?

Acetylsalicylic acid Bluefish is a so-called blood thinner agent, which reduces the risk of blood clotting by preventing the blood platelets clumping together.

How is Acetylsalicylic acid Bluefish 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 Acetylsalicylic acid Bluefish have been shown in studies?

Because the product is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Trombyl. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Acetylsalicylic acid Bluefish?

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 Acetylsalicylic acid Bluefish approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Trombyl, 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 Acetylsalicylic acid Bluefish?

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.

For more details, please see the full PAR for Acetylsalicylic acid Bluefish on the following website: [MRI - Home](#).

Other information about Acetylsalicylic acid Bluefish

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

This summary was last updated in 2025-11.