LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Raxeva,
(acetylsalicylic acid, rivaroxaban)

SE/H/2763/001/DC

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Capsule, hard, 2,5 mg/50 mg

This is a summary of the public assessment report (PAR) for Raxeva. 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 Raxeva and what is it used for?
Raxeva contains the active substances rivaroxaban and acetylsalicylic acid and belongs to a group of medicines called antithrombotic agents.

The product can be used by patients who

- have been diagnosed with an acute coronary syndrome (a group of conditions that includes heart attack and unstable angina, a severe type of chest pain) and have been shown to have had an increase in certain cardiac blood tests.
  Raxeva reduces the risk in adults of having another heart attack or reduces the risk of dying from a disease related to your heart or your blood vessels.
  Raxeva may be given to you on its own or your doctor might also tell you to take either clopidogrel or ticlopidine.

or

- have been diagnosed with a high risk of getting a blood clot due to a coronary artery disease or peripheral artery disease which causes symptoms.
  Raxeva reduces the risk in adults of getting blot clots (atherothrombotic events).
  In some cases, if you get Raxeva after a procedure to open a narrowed or closed artery of your leg to restore blood flow, your doctor may also prescribe clopidogrel for you to take for a short while.

How does Raxeva work?
Both active substances Rivaroxaban/Acetylsalicylic acid reduce the risk of blood clots forming, rivaroxaban works by blocking a blood clotting factor (factor Xa) and acetylsalicylic acid works by preventing platelets (a type of blood cell) in the blood from sticking together and forming clumps.

How is Raxeva used?
The pharmaceutical form is capsule, hard, 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 Raxeva have been shown in studies?
The company provided its own data on efficacy and safety studies. These studies have shown that the product is effective for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers and for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events.

What are the possible side effects from Raxeva?
For the full list of restrictions, see the package leaflet.

Why is Raxeva approved?
The Swedish Medical Products Agency decided that 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 Raxeva?
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.

Additional risk minimisation measures (including educational material)
The MAH shall provide an educational pack prior to launch, targeting all physicians who are expected to prescribe/use Raxeva. The educational pack is aimed at increasing awareness about the potential risk of bleeding during treatment with rivaroxaban/acetylsalicylic acid and providing guidance on how to manage that risk. The physician educational pack should contain:
• The Summary of Product Characteristics
• Prescriber Guide
• Patient Cards

The Prescriber Guide should contain the following key safety messages:
• Details of populations potentially at higher risk of bleeding
• Recommendations for dose reduction in at risk populations
• Guidance regarding switching from or to rivaroxaban/acetylsalicylic acid treatment
• Management of overdose situations
• The use of coagulation tests and their interpretation
• That all patients should be counselled about:
  ➢ Signs or symptoms of bleeding and when to seek attention from a health care provider.
  ➢ Importance of treatment compliance
  ➢ Necessity to carry the Patient Card that is included in each pack, with them at all times
  ➢ The need to inform Health Care Professionals that they are taking rivaroxaban/acetylsalicylic acid if they need to have any surgery or invasive procedure. For more details, please see the full PAR for Raxeva on the following website: MRI - Home.

Other information about Raxeva
The full PAR for Raxeva can be found on the following website: MRI - Home. For more information about treatment with Raxeva, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-06.