LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Arxebo
(edoxaban tosilate monohydrate)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

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Arxebo
edoxaban tosilate monohydrate

Film-coated tablet, 15 mg, 30 mg, 60 mg

This is a summary of the public assessment report (PAR) for Arxebo. 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 Arxebo 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 Lixiana.

Arxebo is used in adults to:
- prevent blood clots in the brain (stroke) and other blood vessels in the body if you have a form of irregular heart rhythm called nonvalvular atrial fibrillation and at least one additional risk factor, such as heart failure, previous stroke or high blood pressure;
- treat blood clots in the veins of the legs (deep vein thrombosis) and in the blood vessels in the lungs (pulmonary embolism), and to prevent blood clots from re-occurring in the blood vessels in the legs and/or lungs.

How does Arxebo work?
Arxebo contains the active substance edoxaban and belongs to a group of medicines called anticoagulants. This medicine helps to prevent blood clots from forming. It works by blocking the activity of factor Xa, which is an important component of blood clotting.

How is Arxebo used?

The pharmaceutical form is film-coated 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 Arxebo 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, Lixiana. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Arxebo?
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 restrictions, see the package leaflet.

Why is Arxebo 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 Lixiana, 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 Arxebo?
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.

The MAH shall ensure that in each Member State where Arxebo is marketed, all healthcare professionals who are expected to use Arxebo are provided with the following educational material:

- The Summary of Product Characteristics (SmPC)
- Prescriber guide for healthcare professionals
- Patient alert card

The prescriber guide for healthcare professionals shall contain the following key elements:

- Relevant information on the risk of bleeding
- Details of the population potentially at higher risk of bleeding
- Contraindications
- Recommendations for dose adjustment in at risk populations, including patients with renal or hepatic impairment, low body weight and concomitant use of some P-gp inhibitors
- Guidance on switching from or to Nabaxo treatment
- Guidance regarding surgery or invasive procedure, and temporary discontinuation
- Management of overdose situations and haemorrhage
- Use of coagulation tests and their interpretation
- That all patients should be provided with a patient alert card and be counselled about:
  - The signs or symptoms of bleeding and when to seek attention from a healthcare provider ➢ Importance of treatment compliance
  - Necessity to carry the patient alert card with them at all times
  - The need to inform health care professionals that they are taking Nabaxo if they need to have any surgery or invasive procedure

The patient alert card should contain the following key safety messages:

- The signs or symptoms of bleeding and when to seek attention
- Importance of treatment compliance
- Necessity to carry the patient alert card with them at all times
- The need to inform health care professionals that they are taking Arxebo if they need to have any surgery or invasive procedure

For more details, please see the full PAR for Arxebo on the following website: MRI - Home.

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

This summary was last updated in 2026-07.