LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Erjulizam
(edoxaban tosilate monohydrate, edoxaban)

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Summary Public Assessment Report

Erjulizam
edoxaban tosilate monohydrate, edoxaban

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

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

Erjulizam 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 Erjulizam work?

Erjulizam 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 Erjulizam 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 Erjulizam have been shown in studies?

Because the product is a generic medicine, studies in patients 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 Erjulizam?

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 Erjulizam 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 Erjulizam?

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.

Prior to launch of Erjulizam in each Member State, the MAH must agree the content and format of the educational programme, including communication media, distribution modalities, and any other aspects of the programme, with the national competent authority (NCA).

The educational programme is aimed at mitigating the risk of serious bleeds or haemorrhage in patients treated with Erjulizam by ensuring prescriber awareness and providing guidance on appropriate patient selection, correct dosing as well as management of the risk. The programme is also aimed at ensuring that the healthcare professionals who intend to prescribe Erjulizam are aware of the patient alert card and that the card is to be given to and reviewed with all patients treated with Erjulizam.

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

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

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

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

This summary was last updated in 2025-11.