LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Edoxaban Sandoz
(edoxaban tosilate monohydrate)

SE/H/2475/01-03/DC

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edoxaban tosilate monohydrate

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

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

The product contains the active substance edoxaban and belongs to a group of medicines called anticoagulants. This medicine helps to prevent blood clots from forming.

How does Edoxaban Sandoz work?
It works by blocking the activity of factor Xa, which is an important component of blood clotting.

How is Edoxaban Sandoz 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 Edoxaban Sandoz have been shown in studies?
Because the product is a generic medicine, studies in humans 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 Edoxaban Sandoz?
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 Edoxaban Sandoz 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.

The product has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below "What measures are being taken to ensure the safe and effective use of Edoxaban Sandoz?"

What measures are being taken to ensure the safe and effective use of Edoxaban Sandoz?
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 Edoxaban Sandoz in each Member State, the Marketing Authorisation Holder (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.

The educational programme is aimed at mitigating the risk of serious bleeds or haemorrhage in patients treated with Edoxaban Sandoz 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 Edoxaban Sandoz are aware of the patient alert card and that the card is to be given to and reviewed with all patients treated with Edoxaban Sandoz.

The MAH shall ensure that in each Member State where Edoxaban Sandoz is marketed, all healthcare professionals who are expected to use Edoxaban Sandoz 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 Edoxaban Sandoz on the following website: https://mri.cts-mrp.eu/portal/home.

Other information about Edoxaban Sandoz
The full PAR for Edoxaban Sandoz can be found on the following website: https://mri.cts-mrp.eu/portal/home. For more information about treatment with Edoxaban Sandoz, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-06.