LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Rivaroxaban STADA
# (rivaroxaban)

# SE/H/2173/01-02/DC

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

# Summary Public Assessment Report

Rivaroxaban STADA
rivaroxaban

capsule, hard, 15 mg, 20 mg

This is a summary of the public assessment report (PAR) for Rivaroxaban STADA. 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 Rivaroxaban STADA 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 Xarelto.

The product is used in the treatment of adults to prevent blood clots in brain (stroke) and other blood vessels in the body if they have a form of irregular heart rhythm called non-valvular atrial fibrillation. It is also used in adults to treat blood clots in the veins of the legs (deep vein thrombosis) and in the blood vessels of the lungs (pulmonary embolism), as well as to prevent blood clots from re-occurring in these areas of the body.

The product is also used in the treatment of children and adolescents below 18 years and with a body weight of 30 kg or more, to treat blood clots and prevent re-occurrence of blood clots in the veins or in the blood vessels of the lungs, following initial treatment of at least 5 days with injectable medicines used to treat blood clots.

**How does Rivaroxaban STADA work?**

Rivaroxaban STADA belongs to a group of medicines called antithrombotic agents. It blocks a specific blood clotting factor (factor Xa) and thus reduces the tendency of the blood to form clots. It does not affect the blood cells themselves.

**How is Rivaroxaban STADA 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 Rivaroxaban STADA 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, Xarelto. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

**What are the possible side effects from Rivaroxaban STADA?**

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 Rivaroxaban STADA approved?**

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Xarelto, 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 Rivaroxaban STADA?".

**What measures are being taken to ensure the safe and effective use of Rivaroxaban STADA?**

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 educational material should contain the following key elements:

The MAH shall provide an educational pack, targeting all physicians who are expected to prescribe/use Rivaroxaban. The educational pack is aimed at increasing awareness about the potential risk of haemorrhage during treatment with Rivaroxaban and providing guidance on how to manage that risk. The physician educational pack should contain:

- The Summary of Product Characteristics
- Prescriber Guide
- Patient Alert Cards

The MAH must agree on the content and format of the Prescriber Guide together with a communication plan, with the national competent authority prior to distribution of the educational pack. 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 treatment
- The need for intake of the 15 mg and 20 mg capsules with food
- 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
  - The need for intake of the 15 mg and 20 mg capsules with food
  - Necessity to carry the Patient Alert Card with them at all times
  - The need to inform Health Care Professionals that they are taking Rivaroxaban if they need to have any surgery or invasive procedure.

Patient Alert Card is made directly accessible to the patient. The exact form of distribution channel will be discussed with each national competent authority.

**Other information about Rivaroxaban STADA**

The full PAR for Rivaroxaban STADA can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Rivaroxaban STADA, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2023-04.