LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Rivaroxaban STADA Arzneimittel AG (rivaroxaban)

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rivaroxaban

Film-coated tablet, 2,5 mg, 10 mg, 15 mg, 20 mg, 15 mg + 20 mg

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

Rivaroxaban STADA Arzneimittel AG contains the active substance rivaroxaban and belongs to a group of medicines called antithrombotic agents.

2.5 mg
The doctor will prescribe Rivaroxaban STADA Arzneimittel AG in combination with (an)other drug(s) to patients 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. The product reduces the risk in adults of having another heart attack or reduces the risk of dying from a disease related to the patient´s heart or blood vessels.
or
- a high risk of getting a blood clot due to a coronary artery disease or peripheral artery disease which causes symptoms. The product reduces the risk in adults of getting blot clots (atherothrombotic events).

10 mg
Rivaroxaban STADA Arzneimittel AG can be used in adult patients to prevent blood clots in the veins after a hip or knee replacement operation.

15 mg, 20 mg
Rivaroxaban STADA Arzneimittel AG can be used in adult patients to prevent blood clots in brain (stroke) and other blood vessels in the body if the patient has a form of irregular heart rhythm called non-valvular atrial fibrillation.
The product can also be used in 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.

10 mg, 15 mg, 20 mg, 15 mg + 20 mg (Treatment Initiation Pack)
Rivaroxaban STADA Arzneimittel AG can be used in adult patients to treat blood clots in the veins of the legs (deep vein thrombosis) and in the blood vessels of the lungs (pulmonary embolism), and to prevent blood clots from re-occurring in the blood vessels of the legs and/or lungs.

How does Rivaroxaban STADA Arzneimittel AG work?

Rivaroxaban STADA Arzneimittel AG works by blocking a blood clotting factor (factor Xa) and thus reducing the tendency of the blood to form clots.

How is Rivaroxaban STADA Arzneimittel AG 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 Rivaroxaban STADA Arzneimittel AG 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 Arzneimittel AG?

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 Arzneimittel AG 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 Arzneimittel AG?”

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

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.

<u>Additional risk minimisation measures (including educational material):</u>

The MAH shall provide an educational pack prior to launch, targeting all physicians who are expected to prescribe/use rivaroxaban. The educational pack is aimed at increasing awareness about the potential risk of bleeding 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 the content and format of the Prescriber Guide together with a communication plan, with the national competent authority in each Member State prior to distribution of the educational pack in their territory.

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 tablets with food
- Management of overdose situations
- The use of coagulation tests and their interpretation
- That all patients should be provided with a Patient alert card and 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 tablets 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.

- The Patient alert card should contain the following key safety messages:
  - 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 tablets 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.

Other information about Rivaroxaban STADA Arzneimittel AG

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

This summary was last updated in 2024-01-23.