LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Rivaroxaban Bluefish (rivaroxaban)

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Summary Public Assessment Report

Rivaroxaban Bluefish
rivaroxaban

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

This is a summary of the public assessment report (PAR) for Rivaroxaban Bluefish. 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 Bluefish 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 Bluefish contains the active substance rivaroxaban.

Rivaroxaban Bluefish 10 mg is used in adults to:
- prevent blood clots in the veins after a hip or knee replacement operation.
- 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.

Rivaroxaban Bluefish 15 mg and Rivaroxaban Bluefish 20 mg are used in adults 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.
- 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.

Rivaroxaban Bluefish 15 mg and Rivaroxaban Bluefish 20 mg are 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.

Rivaroxaban Bluefish 15 mg + 20 mg (Treatment initiation pack) is 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), and to prevent blood clots from re-occurring in the blood vessels of the legs and/or lungs.

How does Rivaroxaban Bluefish work?

Rivaroxaban Bluefish belongs to a group of medicines called antithrombotic agents. It works by blocking a blood clotting factor (factor Xa) and thus reducing the tendency of the blood to form clots.

How is Rivaroxaban Bluefish 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 Bluefish 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 Bluefish?

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 Bluefish 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 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 Bluefish?”

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

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 Marketing Authorisation Holder shall provide an educational pack prior to marketing the product, 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

Other information about Rivaroxaban Bluefish

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

This summary was last updated in 2024-02.