Summary of risk management plan for Rivaroxaban Bluefish (rivaroxaban)

This is a summary of the risk management plan (RMP) for Rivaroxaban Bluefish. The RMP details important risks of Rivaroxaban Bluefish, which can be minimized through routine pharmacovigilance activities.

Rivaroxaban Bluefish's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Rivaroxaban Bluefish should be used.

Important new concerns or changes to the current ones will be included in updates of Rivaroxaban Bluefish's RMP.

I. The medicine and what it is used for

Rivaroxaban Bluefish 10 mg is authorised for prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. (See section 4.4 for haemodynamically unstable PE patients.)

Rivaroxaban Bluefish 15 mg and Rivaroxaban Bluefish 20 mg are authorised for:
Adults:
Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack.

Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. (See section 4.4 for haemodynamically unstable PE patients.)

Paediatric population:
Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing more than 50 kg after at least 5 days of initial parenteral anticoagulation treatment.

Rivaroxaban Bluefish 15 mg + 20 mg is authorised for treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. (See section 4.4 for haemodynamically unstable PE patients.) (See SmPC for the full indication).

It contains rivaroxaban as the active substance and it is given orally as 10 mg, 15 mg, 20 mg and 15 mg + 20 mg film-coated tablets.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Rivaroxaban Bluefish, together with measures to minimise such risks and the proposed studies for learning more about Rivaroxaban Bluefish's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals.
- Important advice on the medicine's packaging.
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly.
- The medicine's legal status — the way a medicine is supplied to the patient (e.g., with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In the case of Rivaroxaban Bluefish, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risk, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Rivaroxaban Bluefish is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Rivaroxaban Bluefish are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Rivaroxaban Bluefish. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g., on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	• Haemorrhage
Important potential risks	• Embryo-fetal toxicity
Missing information	• Remedial pro-coagulant therapy for excessive haemorrhage • Patients with atrial fibrillation (AF) and a prosthetic heart valve

II.B Summary of important risks

Important identified risks	
Haemorrhage	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> Information is included in Sections 4.3, 4.4, 4.5**,** 4.8, and 4.9 of the EU SmPC**.** PL sections 2, 3 and 4. Limited package supply Prescription only medicine <u>Additional risk minimisation measures:</u>

	Educational material for prescribers Patient alert card
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None
Important potential risks	
Embryo-fetal toxicity	
Risk minimisation measures	Routine risk minimisation measures: Information is included in Sections 4.3, 4.6 and 5.3 of the EU SmPC Limited package supply Prescription only medicine Additional risk minimisation measures: None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None
Missing information:	
Remedial pro-coagulant therapy for excessive haemorrhage	
Risk minimisation measures	Routine risk minimisation measures: Information is included in Section 4.9 of the EU SmPC Limited package supply Prescription only medicine Additional risk minimisation measures: None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None
Patients with atrial fibrillation (AF) and a prosthetic heart valve	
Risk minimisation measures	Routine risk minimisation measures: Information is included in Section 4.4 of the EU SmPC Limited package supply Prescription only medicine Additional risk minimisation measures: None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Rivaroxaban Bluefish.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Rivaroxaban Bluefish.