Part VI: Summary of the risk management plan for Rivaroxaban Pharmazac

This is a summary of the risk management plan (RMP) for Rivaroxaban Pharmazac 2.5 mg, 10 mg, 15 mg & 20 mg film-coated tablet (Rivaroxaban). The RMP details important risks of Rivaroxaban Pharmazac, how these risks can be minimised, and how more information will be obtained about Rivaroxaban Pharmazac risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Rivaroxaban Pharmazac 2.5 mg is indicated for:

- Co-administered with acetylsalicylic acid (ASA) alone or with ASA plus clopidogrel or ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers.
- Co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events.

Rivaroxaban Pharmazac 10 mg is indicated 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.

Rivaroxaban Pharmazac 15 mg is indicated 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.

Paediatric population

- Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing from 30 kg to 50 kg after at least 5 days of initial parenteral anticoagulation treatment.

Rivaroxaban Pharmazac 20 mg is indicated 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.

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.

It contains Rivaroxaban as the active substance and it is given orally by 2.5 mg, 10 mg, 15 mg & 20 mg film-coated tablet.

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

Important risks of Rivaroxaban Pharmazac together with measures to minimise such risks and the proposed studies for learning more about Rivaroxaban Pharmazac, 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 public (with prescription) can help to minimises its risks.

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

In the case of Rivaroxaban Pharmazac, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, 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 Pharmazac is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Rivaroxaban Pharmazac 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 Pharmazac. 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-foetal 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 risk: Haemorrhage	
Risk minimisation measures	**Routine risk minimisation measures** **Proposed text in PL, section 2 and 4** Section 2. What you need to know before you take Rivaroxaban Pharmazac Section 4 Possible side effects **Proposed text in SmPC, section 4.3, 4.4 and 4.8** Section 4.3 Contraindications Section 4.4 Special warnings and precautions for use Section 4.8 Undesirable effects **Routine risk minimisation activities recommending specific clinical measures to address the risk:** None **Other routine risk minimisation measures** Pack size: Limited pack sizes. Legal status: Prescription only medicine.

	Additional risk minimisation measure(s) Educational material for prescribers Patient alert card

Important potential risk: Embryo-foetal toxicity	
Risk minimisation measures	**Routine risk minimisation measures** **Proposed text in PL, section 2** Section 2. What you need to know before you take Rivarobaxan Pharmazac **Proposed text in SmPC, section 4.3, 4.6 and 5.3** Section 4.3 Contraindications Section 4.6 Fertility, pregnancy and breast-feeding Section 5.3 Preclinical safety data **Routine risk minimisation activities recommending specific clinical measures to address the risk:** None **Other routine risk minimisation measures** Pack size: Limited pack sizes. Legal status: Prescription only medicine. **Additional risk minimisation measure(s)** None

Missing information: Remedial pro-coagulant therapy for excessive haemorrhage	
Risk minimisation measures	**Routine risk minimisation measures** **Proposed text in PL, section 2 and 4** Section 2. What you need to know before you take Rivarobaxan Pharmazac Section 4 Possible side effects **Proposed text in SmPC, section 4.9** Section 4.9 Overdose **Routine risk minimisation activities recommending specific clinical measures to address the risk:**

	None **<u>Other routine risk minimisation measures</u>** Pack size: Limited pack sizes. Legal status: Prescription only medicine. **<u>Additional risk minimisation measure(s)</u>** None

Missing information: Patients with atrial fibrillation (AF) and a prosthetic heart valve	
Risk minimisation measures	**<u>Routine risk minimisation measures</u>** **Proposed text in PL, section 2 and 4** Section 2. What you need to know before you take Rivarobaxan Pharmazac Section 4 Possible side effects **Proposed text in SmPC, section 4.4** Section 4.4 Special warnings and precautions for use **<u>Routine risk minimisation activities recommending specific clinical measures to address the risk:</u>** None **<u>Other routine risk minimisation measures</u>** Pack size: Limited pack sizes. Legal status: Prescription only medicine. **<u>Additional risk minimisation measure(s)</u>** None

II.C Post-authorisation development plan

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

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

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

There are no studies required for Rivaroxaban Pharmazac.