Part VI: Summary of the risk management plan

Summary of risk management plan for Rivaroxaban/ Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules (rivaroxaban/acetylsalicylic acid)

This is a summary of the risk management plan (RMP) for Rivaroxaban/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules. The RMP details important risks of Rivaroxaban/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules, how these risks can be minimised, and how more information will be obtained about Rivaroxaban/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules risks and uncertainties (missing information).

Rivaroxaban/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Rivaroxaban/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules should be used.

Important new concerns or changes to the current ones will be included in updates of Rivaroxaban/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules' RMP.

I. The medicine and what it is used for

Rivaroxaban/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules, alone or with clopidogrel or ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers.

Rivaroxaban/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules 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.

It contains rivaroxaban/acetylsalicylic acid as the active substances, and it is given by oral route.

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

Important risks of Rivaroxaban/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules, together with measures to minimise such risks and the proposed studies for learning more about Rivaroxaban/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules' 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/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules 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/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Rivaroxaban/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules. 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 a prosthetic heart valve

II.B Summary of important risks

Haemorrhage **Important identified risk**	
Risk minimisation measures	Routine risk minimisation measures: SmPC (sections 4.3, 4.4, 4.5 and 4.8) PIL (section "What you need to know before you take rivaroxaban Do not take rivaroxaban", "Possible side effects"). – Prescription only medicine. – Limited pack sizes Additional risk minimisation measures:

	• *Educational material for prescribers (Prescriber guide)* • *Patient cards*

Embryo-fetal toxicity **Important potential risk**	
Risk minimisation measures	Routine risk minimisation measures: SmPC (sections 4.3, 4.6 and 5.3) – Prescription only medicine. – Limited pack sizes Additional risk minimisation measures: *None*

Remedial pro-coagulant therapy for excessive haemorrhage **Missing information**	
Risk minimisation measures	Routine risk minimisation measures: SmPC (section 4.9) – Prescription only medicine. – Limited pack sizes Additional risk minimisation measures: *None*

Patients with a prosthetic heart valve **Missing information**	
Risk minimisation measures	Routine risk minimisation measures: SmPC (section 4.4) – Prescription only medicine. – Limited pack sizes Additional risk minimisation measures: *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/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules.

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

There are no studies required for Rivaroxaban/Acetylsalicylic acid PharOS 2.5 mg/50 mg hard capsules.