Summary of risk management plan for Rivaroxaban Accord film coated tablets (2.5 mg, 10 mg, 15 mg and 20 mg) (Rivaroxaban)

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

Rivaroxaban Accord film coated tablets (2.5 mg, 10 mg, 15 mg and 20 mg)'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Rivaroxaban Accord film coated tablets (2.5 mg, 10 mg, 15 mg and 20 mg) should be used.

This summary of the RMP for Rivaroxaban Accord film coated tablets (2.5 mg, 10 mg, 15 mg and 20 mg) should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Rivaroxaban Accord film coated tablets (2.5 mg, 10 mg, 15 mg and 20 mg)’s RMP.

I. The medicine and what it is used for

Rivaroxaban Accord 2.5 mg film coated tablets co administered with acetylsalicylic acid (ASA) alone or with ASA plus ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers. Rivaroxaban Accord, 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 Accord 10 mg film coated tablets is used 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 Accord 15 mg and 20 mg film coated tablets are used for 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.

It contains Rivaroxaban as the active substance and it is given by oral route.

Further information about the evaluation of Rivaroxaban Accord 15 mg and 20 mg film coated tablets benefits can be found in < Rivaroxaban Accord 15 mg and 20 mg film coated tablets EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

https://www.ema.europa.eu/en/medicines/human/EPAR/rivaroxaban-accord

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

Important risks of Rivaroxaban Accord film coated tablets (2.5 mg, 10 mg, 15 mg and 20 mg), together with measures to minimise such risks and the proposed studies for learning more about Rivaroxaban Accord film coated tablets (2.5 mg, 10 mg, 15 mg and 20 mg)'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 Accord film coated tablets (2.5 mg, 10 mg, 15 mg and 20 mg), 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, including PSUR assessment and signal management activity, 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 Accord film coated tablets (2.5 mg, 10 mg, 15 mg and 20 mg) is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Rivaroxaban Accord film coated tablets (2.5 mg, 10 mg, 15 mg and 20 mg) 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 Accord film coated tablets (2.5 mg, 10 mg, 15 mg and 20 mg). 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);

Important identified risks	• Haemorrhage
Important potential risks	• Embryo-fetal toxicity
Missing information	• Patients with severe renal impairment (CrCl < 30 mL/min) • Patients receiving concomitant systemic inhibitors of CYP 3A4 or P-gp other than azole antimycotics (e.g.

	ketoconazole) and HIV-protease inhibitors (e.g. ritonavir) • Remedial pro-coagulant therapy for excessive haemorrhage • Pregnant or breast-feeding women • Patients with atrial fibrillation (AF) and a prosthetic heart valve • Long-term therapy with rivaroxaban in treatment of DVT, PE, SPAF and ACS in real-life setting • Patients with significant liver diseases (severe hepatic impairment/Child Pugh C) • Patients < 18 years

II.B Summary of important risks

Important Identified Risks: **Haemorrhage**	
Risk minimisation measures	Routine risk minimisation measures: Section 4.2, 4.3, 4.4, 4.6 4.8, 4.9 and 5.3 of Rivaroxaban SmPC and corresponding section of PIL has information on this safety concern. Other routine risk minimisation measures include the prescription only status of the product. Limited pack sizes Additional risk minimisation measures: • Educational material for prescribers • Patient alert cards

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 Accord film coated tablets (2.5 mg, 10 mg, 15 mg and 20 mg).

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

There are no studies required for Rivaroxaban Accord film coated tablets (2.5 mg, 10 mg, 15 mg and 20 mg).