Part VI: Summary of the risk management plan

Summary of risk management plan for Rivaroxaban Aristo 2.5 mg, 10 mg, 15 mg, 20 mg, 15 mg+20 mg film-coated tablets (rivaroxaban)

This is a summary of the risk management plan (RMP) for Rivaroxaban Aristo 2.5 mg, 10 mg, 15 mg, 20 mg, 15 mg+20 mg film-coated tablets. The RMP details important risks of Rivaroxaban Aristo 2.5 mg, 10 mg, 15 mg, 20 mg , 15 mg+20 mg film-coated tablets, how these risks can be

minimised, and how more information will be obtained about Rivaroxaban Aristo 2.5 mg, 10 mg, 15 mg, 20 mg film-coated tablets 's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Rivaroxaban Aristo 2.5 mg, 10 mg, 15 mg, 20, 15 mg+20 mg mg film-coated tablets is authorised prevention of prevention of atherothrombotic events (see SmPC for the full indication). It contains rivaroxaban as the active substance and it is given by oral use.

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

Important risks of Rivaroxaban Aristo 2.5 mg, 10 mg, 15 mg, 20 mg, 15 mg+20 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Rivaroxaban Aristo 2.5 mg, 10 mg, 15 mg, 20 mg, 15 mg+20 mg film-coated tablets '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 Aristo 2.5 mg, 10 mg, 15 mg, 20 mg, 15 mg+20 mg film-coated tablets, 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 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 Aristo 2.5 mg, 10 mg, 15 mg, 20 mg, 15 mg+20 mg film-coated tablets is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Rivaroxaban Aristo 2.5 mg, 10 mg, 15 mg, 20 mg, 15 mg+20 mg film-coated tablets 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 Aristo 2.5 mg, 10 mg, 15 mg, 20 mg, 15 mg+20 mg film-coated tablets.

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	• Patients with severe renal impairment (CrCl < 30 mL/min) • Remedial pro-coagulant therapy for excessive haemorrhage • Patients receiving concomitant systemic inhibitors of CYP3A4 or P gp other than azole antimycotics (e.g. ketoconazole) and HIV-protease inhibitors (e.g. ritonavir) • 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, and Systemic embolism in adult patients with non-valvular atrial fibrillation (SPAF) in real-life setting • Patients with significant liver diseases (severe hepatic impairment/Child Pugh C) • Patients <18 years

II.B Summary of important risks

Haemorrhage	
Risk minimisation measures	**Reference to this safety concern is made in the following section**: 4.4 Special warnings and precautions for use 4.5 Interaction with other medicinal products and other forms of interaction 4.8 Undesirable effects **Routine risk minimisation activities recommending specific clinical measures to address the risk**: As with other anticoagulants, patients taking rivaroxaban are to be carefully observed for signs of bleeding. It is recommended to be used with caution in conditions with increased risk of haemorrhage. rivaroxaban administration should be discontinued if severe haemorrhage occurs.

Haemorrhage	
	Other routine risk minimisation measures beyond the Product Information: Prescription only medicine **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

Not applicable.

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

Not applicable.