Part VI: Summary of the risk management plan

Summary of risk management plan for Rivaroxaban OPKO (Rivaroxaban).

This is a summary of the risk management plan (RMP) Rivaroxaban OPKO. The RMP details important risks of Rivaroxaban OPKO and how more information will be obtained about Rivaroxaban OPKO risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Rivaroxaban OPKO is authorised for the prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery and as 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 for oral use.

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

Important risks of Rivaroxaban OPKO, together with measures to minimise such risks and the proposed studies for learning more about Rivaroxaban OPKO'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 OPKO, 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 OPKO is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Rivaroxaban OPKO 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 OPKO. 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 risk: Haemorrhage	
Risk minimisation measures	**Routine risk minimisation measures:** SmPC sections 4.3, 4.4, 4.5, 4.8 and 4.9 PL section 2 Prescription-only medicine Limited pack sizes **Additional risk minimisation measures:** Educational material for prescribers Patient alert cards

Important potential risk: Embryo-fetal toxicity

Risk minimisation measures	**Routine risk minimisation measures:** SmPC sections 4.3, 4.6, 5.3. PL section 2. Prescription-only medicine Limited pack sizes **Additional risk minimisation measures:** None.

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

Missing information: Patients with atrial fibrillation (AF) and a prosthetic heart valve.	
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 OPKO.

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

There are no studies required for Rivaroxaban OPKO.