Part VI: Summary of the risk management plan

Summary of risk management plan for rivaroxaban by Krka

This is a summary of the risk management plan (RMP) for rivaroxaban by Krka. The RMP details important risks of rivaroxaban by Krka, how these risks can be minimised, and how more information will be obtained about rivaroxaban by Krka's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Rivaroxaban 2.5 mg film-coated tablets by Krka is authorised for the prevention of atherothrombotic events in adult patients (see SmPC for the full indication).

Rivaroxaban 10 mg film-coated tablets by Krka is authorised for the prevention of venous thromboembolism, deep vein thrombosis (DVT), pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults (see SmPC for the full indication).

Rivaroxaban 15 mg and 20 mg film-coated tablets by Krka are authorised for the prevention of stroke and systemic embolism, for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), prevention of recurrent DVT and PE in adults. Rivaroxaban 15 mg and 20 mg film-coated tablets are also authorised for the treatment of venous thromboembolism (VTE), prevention of VTE recurrence in children and adolescents aged less than 18 years (see SmPC for the full indication).

It contains rivaroxaban as the active substance and it is given orally.

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

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

II.A List of important risks and missing information

Important risks of rivaroxaban by Krka 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 by Krka. 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 measure: SmPC section: 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9 PL section: 2, 3 and 4 Additional risk minimisation measures: Educational materials: - Prescriber guide - Patient alert card

Important potential risk <Embryo-fetal toxicity>	
Risk minimisation measures	Routine risk minimisation measure: SmPC section: 4.3, 4.6 and 5.3 PL section: 2 Additional risk minimisation measures: Educational materials: None

Missing information <Remedial pro-coagulant therapy for excessive haemorrhage>	
Risk minimisation measures	Routine risk minimisation measure: SmPC section: 4.9 PL section: 3 Additional risk minimisation measures: Educational materials: None

Missing information <Patients with atrial fibrillation (AF) and a prosthetic heart valve>	
Risk minimisation measures	Routine risk minimisation measure: SmPC section: 4.4 PL section: 2 Additional risk minimisation measures:

	Educational materials: 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 by Krka.

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

There are no studies required for rivaroxaban by Krka.