Part VI: Summary of the risk management plan

Summary of risk management plan for dabigatran by Krka

This is a summary of the risk management plan (RMP) for dabigatran by Krka. The RMP details important risks of dabigatran by Krka, how these risks can be minimised, and how more information will be obtained about dabigatran by Krka's risks and uncertainties (missing information).
Dabigatran by Krka's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how dabigatran by Krka should be used.
Important new concerns or changes to the current ones will be included in updates of dabigatran by Krka's RMP.

I. The medicine and what it is used for

Dabigatran by Krka is authorised for primary prevention of venous thromboembolic events, prevention of stroke and systemic embolism and treatment of deep vein thrombosis and pulmonary embolism (see SmPC for the full indication). It contains dabigatran 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 dabigatran by Krka, together with measures to minimise such risks and the proposed studies for learning more about dabigatran 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 dabigatran 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, 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 dabigatran 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 dabigatran 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 dabigatran 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	None
Missing information	Patients aged 0 to 2 years who were born prematurely[1]
	Paediatric patients with renal dysfunction (eGFR < 50 ml/min)[1]

[1] these safety concerns are only valid in countries where the paediatric indication is approved.

II.B Summary of important risks

Haemorrhage	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.2, 4.3, 4.4, 4.5, 4.8, 4.9, 5.1* *SmPC section 4.4 where information on using the specific reversal agent for situations of life-threatening or uncontrolled bleeding, recommendation on close observation for signs of bleeding, guidance on actions taken when severe bleeding occur and guidance on using dabigatran before/during/after surgery.* *PL sections 2* *PL section 3 where recommendation to contact doctor if patient takes too many tablets* *PL section 4 where recommendation to contact doctor if patient experiences bleeding.* *Prescription only medicine* Additional risk minimisation measures: *Prescriber guides* *Prescriber guide for paediatric population* *Patient alert card*

Patients aged 0 to 2 years who were born prematurely[1]	
Risk minimisation measures	Routine risk minimisation measures: *No risk minimisation measures* *Prescription only medicine* Additional risk minimisation measures: *None*

[1] these safety concerns are only valid in countries where the paediatric indication is approved.

Paediatric patients with renal dysfunction (eGFR < 50 ml/min)[1]	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.2, 4.4* *PL section 2* *Prescription only medicine* Additional risk minimisation measures: *None*

[1] these safety concerns are only valid in countries where the paediatric indication is approved.

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 dabigatran by Krka.

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

There are no studies required for dabigatran by Krka.