Part VI: Summary of the risk management plan

Summary of risk management plan for Dabigatran Reddy 75 mg, 110 mg and 150 mg Hartkapseln (dabigatran etexilate)

This is a summary of the risk management plan (RMP) for Dabigatran Reddy 75 mg, 110 mg and 150 mg Hartkapseln. The RMP details important risks of Dabigatran Reddy 75 mg, 110 mg and 150 mg Hartkapseln, how these risks can be minimised, and how more information will be obtained about Dabigatran Reddy 75 mg, 110 mg and 150 mg Hartkapseln's risks and uncertainties (missing information).

Dabigatran Reddy 75 mg, 110 mg and 150 mg Hartkapseln's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Dabigatran Reddy 75 mg, 110 mg and 150 mg Hartkapseln should be used.

Important new concerns or changes to the current ones will be included in updates of Dabigatran Reddy 75 mg, 110 mg and 150 mg Hartkapseln's RMP.

I. The medicine and what it is used for

Dabigatran Reddy 75 mg, 110 mg and 150 mg Hartkapseln are indicated for (see SmPC for the full indication):

- Primary prevention of venous thromboembolic events (VTE) in adult patients undergoing elective total hip or knee replacement or knee replacement surgery, programmed in both cases

    - For the same indications capsules can be used in adults and paediatric patients aged 8 years or older who are able to swallow the capsules whole.

Dabigatran Reddy 110 mg and 150 mg Hartkapseln are also indicated for (see SmPC for the full indication):

- Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischemic attack (TIA); age ≥ 75 years; heart failure (NYHA Class ≥ II); diabetes mellitus; hypertension.

- Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

- Treatment of VTE and prevention of recurrent VTE in paediatric patients from birth to less than 18 years of age.

It contains dabigatran etexilate as the active substance and it is given by oral administration.

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

Important risks of Dabigatran Reddy 75 mg, 110 mg and 150 mg Hartkapseln, together with measures to minimise such risks and the proposed studies for learning more about Dabigatran Reddy 75 mg, 110 mg and 150 mg Hartkapseln’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 Reddy 75 mg, 110 mg and 150 mg Hartkapseln, 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 Reddy 75 mg, 110 mg and 150 mg Hartkapseln is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Dabigatran Reddy 75 mg, 110 mg and 150 mg Hartkapseln 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 Reddy 75 mg, 110 mg and 150 mg Hartkapseln. 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 • Paediatric patients with renal dysfunction (eGFR <50ml/min)

II.B Summary of important risks

The safety information in the proposed product is aligned with the reference medicinal product innovator Pradaxa®.

Important identified risk: Haemorrhage	
Risk minimisation measures	**Routine risk communication:** • SmPC sections 4.2, 4.3, 4.4, 4.5, 4.8 and 4.9

	• PL sections 2, 3, and 4 **Additional risk minimisation measures:** • *Prescriber guide* • *Patient alert card*

Missing information: patients aged 0 to 2 years who born prematurely	
Risk minimisation measures	**Routine risk communication:** • *None* **Additional risk minimisation measures:** • *None*

Missing information: Paediatric patients with renal dysfunction (eGFR <50ml/min)	
Risk minimisation measures	**Routine risk communication:** • SmPC sections 4.2, and 4.4 • PL sections 2 **Additional risk minimisation measures:** • *None*

II.C Post-authorisation development plan

There are no post-authorisation development plans of Dabigatran Reddy 75 mg, 110 mg and 150 mg Hartkapseln.

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 Reddy 75 mg, 110 mg and 150 mg Hartkapseln.

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

There are no studies required for Dabigatran Reddy 75 mg, 110 mg and 150 mg Hartkapseln.