PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Dabigatran Etexilate Vale (dabigatran)

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

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

Important new concerns or changes to the current ones will be included in updates of Dabigatran Etexilate Vale's RMP.

I. The Medicine and What it is Used For

Dabigatran Etexilate Vale 75 mg, 110 mg, and 150 mg Hard Capsules is authorised for:

- Primary prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery.
- 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 via the oral route.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Dabigatran Etexilate Vale, together with measures to minimise such 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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events 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 Etexilate Vale is not yet available, it is listed under 'missing information' below.

In the case of Dabigatran Etexilate Vale, these routine measures are supplemented with additional risk minimisation measures, mentioned under relevant risks below.

II.A List of Important Risks and Missing Information

Important risks of Dabigatran Etexilate Vale are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by patients. 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 Etexilate Vale. 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/use in special patient populations etc.);

Table 6: Part VI.1- Summary of safety concerns

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

Important identified risks: Haemorrhage	
Risk minimisation measures	***Routine risk minimisation measures*** SmPC Sections 4.2, 4.3, 4.4, 4.5, 4.8, and 4.9 PL Sections 2, 3, and 4 ***Other risk minimisation measures:*** Idarucizumab has been approved in adult patients as a specific reversal agent for rapid reversal of the anticoagulation effect of dabigatran in case of emergency surgery or urgent procedures for situations of life threatening or uncontrolled bleeding. For paediatric patients, haemodialysis can remove dabigatran. ***Additional risk minimisation measures:*** Prescriber guide and patient alert card

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 Etexilate Vale.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Dabigatran Etexilate Vale.