**Part VI: Summary of the risk management plan**

## Summary of risk management plan for Dabikaste 75, 110 & 150 hard capsules (Dabigatran etexilate)

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

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

### I. The medicine and what it is used for

Dabikaste is indicated for (see SmPC for the full indication):

- Primary prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery. (only only for Dabikaste 75 mg and 110 mg hard capsules)
- 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. (only for Dabikaste 110 mg and 150mg hard capsules)
- Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. (only for Dabikaste 110 mg and 150mg hard capsules)
- Treatment of VTE and prevention of recurrent VTE in paediatric patients from 8 years 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 Dabikaste, together with measures to minimise such risks and the proposed studies for learning more about Dabikaste'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 Dabikaste these measures are supplemented with additional risk minimization measures mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Periodic Safety Update Report (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 Dabikaste is not yet available, it is listed under 'missing information' below.

### II.A List of important risks and missing information

Important risks of Dabikaste 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 Dabikaste. 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).

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| **Important identified risks** | Haemorrhage |
| | Gastrointestinal disorders |
| | Hypersensitivity |
| | Off-label use in patients with prosthetic heart valves |
| | Off-label use in patients with severe renal impairment |
| **Important potential risks** | Hepatotoxicity |
| | Myocardial infarction (adult patients only) |
| | Pulmonary embolism |
| **Missing information** | Patients with liver impairment (liver enzymes >2x upper limit of normal) |
| | Pregnant and lactating women |
| | Paediatric patients with renal dysfunction (eGFR <50ml/min) |

### II.B Summary of important risks

| **Important identified Risk: Haemorrhage** | |
|---|---|
| **Risk minimisation measures** | *Routine risk communication:*<br>SmPC sections 4.2, 4.3, 4.4, 4.5, 4.8 and 4.9<br><br>*Additional risk minimization measures:*<br>-Prescriber guide<br>-Patient/Parent/Caregiver alert card |

## II.C Post-authorisation development plan

Not applicable.