Summary of risk management plan for *Misbadi 75 mg, 110 mg and 150 mg capsules* (Dabigatran etexilate)

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

Misbadi 75 mg, 110 mg and 150 mg capsules summary of product characteristics (SmPC) and its package leaflets give essential information to healthcare professionals and patients on how *Misbadi 75 mg, 110 mg and 150 mg capsules* should be used.

I. The medicine and what it is used for

Misbadi 75 mg, 110 mg and 150 mg capsules 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
- Treatment of VTE and prevention of recurrent VTE in paediatric patients from 8 years to less than 18 years of age.

Misbadi 110 mg and 150 mg capsules 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 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 *Misbadi 75 mg, 110 mg and 150 mg capsules*, together with measures to minimise such risks and the proposed studies for learning more about *Misbadi 75 mg, 110 mg and 150 mg capsules* 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 *Misbadi 75 mg, 110 mg and 150 mg capsules* 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 *Misbadi 75 mg, 110 mg and 150 mg capsules* are not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of *Misbadi 75 mg, 110 mg and 150 mg capsules* 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 *Misbadi 75 mg, 110 mg and 150 mg capsules*. 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 • 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

The safety information in the proposed product is going to be 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* *Additional risk minimization measures:* • *-Prescriber guide* • *Patient/Parent/Caregiver alert card*

II.C Post-authorisation development plan

There are no post-authorisation development plan of *Misbadi 75 mg, 110 mg and 150 mg capsules.*

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 *Misbadi 75 mg, 110 mg and 150 mg capsules.*

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

There are no studies required for Misbadi 75 mg, 110 mg and 150 mg capsules.