13 Part VI: Summary of the risk management plan for Dabigatran etexilate mesilate*, 75 mg, 110 mg and 150 mg, Hard capsules

* In Austria (AT)

Dabigatranetexilat Sandoz 75 mg;110 mg and 150 mg Hartkapseln for procedure AT/H/1156/001-003/DC

Gribero 75 mg;110 mg and 150 mg Hartkapseln for procedure AT/H/1157/001-003/DC

Dabigatranetexilat 1A Pharma 75 mg;110 mg and 150 mg Hartkapseln for procedure AT/H/1158/001-003/DC

Dabigatranetexilat Hexal 75 mg;110 mg and 150 mg Hartkapseln for procedure AT/H/1159/001-003/DC

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

Dabigatran etexilate mesilate, hard capsules' summaries of product characteristics (SmPC) and its package leaflets give essential information to healthcare professionals and patients on how dabigatran etexilate mesilate, hard capsules should be used.

Important new concerns or changes to the current ones will be included in updates of the dabigatran etexilate mesilate, hard capsules' RMP.

13.1 Part VI: I. The medicine and what it is used for

Dabigatran etexilate mesilate, hard capsules are authorized for:

75 mg and 110 mg, Hard capsules:

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

110 mg and 150 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 (New York Heart Association, 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.

75 mg, 110 mg and 150 mg, Hard capsules:

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

It contains dabigatran as an active substance and is given orally as hard capsules (75 mg, 110 mg and 150 mg).

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of dabigatran etexilate mesilate, hard capsules, together with measures to minimize such risks, and the proposed studies for learning more about dabigatran etexilate mesilate, hard capsules' are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflets and SmPCs addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In the case of dabigatran etexilate mesilate hard 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 analyzed 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 mesilate, hard capsules is not yet available, it is listed under 'missing information' below.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of dabigatran etexilate mesilate, hard capsules are risks that need special risk management activities to further investigate or minimize 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 etexilate mesilate, hard 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).

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	Hemorrhage
Important potential risks	None
Missing information	Patients aged 0 to 2 years who were born prematurely[1]
	Pediatric patients with renal dysfunction (eGFR <50ml/ min)[1]

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

13.2.2 Part VI – II.B: Summary of important risks

Table 13-2 Important identified risk: Hemorrhage

Risk minimization measures	**Routine risk minimization measures:** SmPC sections 4.2, 4.3, 4.4, 4.5, 4.8, and 4.9 PL sections 2, 3 and 4 Legal status: Prescription only **Additional risk minimization measures:** Education materials: Prescriber Guide and Patient Alert Card

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of dabigatran etexilate mesilate, hard capsules.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for dabigatran etexilate mesilate, hard capsules.