EU Risk Management Plan
for
Dabigatran etexilate Accord 75 mg hard capsules
Dabigatran etexilate Accord 110 mg hard capsules
Dabigatran etexilate Accord 150 mg hard capsules
(Dabigatran etexilate)

RMP version to be assessed as part of this application:

RMP Version number	3.0
Data lock point for this RMP	02-Jan-2026
Date of final sign off	26-Mar-2026

Rationale for submitting an updated RMP: This RMP has been updated in line with EPAR Risk management plan of Pradaxa (Dabigatran Etexilate) (version 42.0, dated 16-Jun-2025) published by EMA on 16-Dec-2025.

Summary of significant changes in this RMP: Significant changes have been made to the following sections of RMP: Part I, Part II (Module SVII and Module SVIII), Part V (V.1 and V.3), Part VI and Part VII (Annex 7 and Annex 8).

Other RMP versions under evaluation: Not applicable

Details of the currently approved RMP:

RMP Version	Procedure	Approval date
2.0	EMEA/H/C/005639	09-Oct-2023

[redacted]

QPPV Name: Dr. Arletta Werynska

QPPV Signature: [redacted]

[redacted]

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[redacted]

Part I: Products Overview

Table 1: Product Overview

Active substance (INN or common name)	Dabigatran etexilate
Pharmacotherapeutic group(s)(ATC Code)	**Pharmacotherapeutic group(s):** Antithrombotic agents, direct thrombin inhibitors **ATC code:** B01AE07
Marketing Authorisation Holder	Accord Healthcare S.L.U., Spain
Medicinal products to which this RMP refers	03
Invented names in the European Economic Area (EEA)	Dabigatran etexilate Accord 75 mg hard capsules Dabigatran etexilate Accord 110 mg hard capsules Dabigatran etexilate Accord 150 mg hard capsules
Marketing authorisation procedure	Centralised Procedure (EMEA/H/C/005639)
Brief description of the product	Chemical class: Dabigatran is an aromatic amide and is a direct inhibitor of thrombin and anticoagulant.
	Summary of mode of action: Dabigatran etexilate is a small molecule prodrug which does not exhibit any pharmacological activity. After oral administration, dabigatran etexilate is rapidly absorbed and converted to dabigatran by esterase-catalysed hydrolysis in plasma and in the liver. Dabigatran is a potent, competitive, reversible direct thrombin inhibitor and is the main active principle in plasma.

	Since thrombin (serine protease) enables the conversion of fibrinogen into fibrin during the coagulation cascade, its inhibition prevents the development of thrombus. Dabigatran inhibits free thrombin, fibrin bound thrombin and thrombin-induced platelet aggregation.
	Important information about its composition Each hard capsule contains dabigatran etexilate mesilate equivalent to 75 mg, 110 mg and 150 mg of dabigatran etexilate. in their respective formulation.
Hyperlink to the Product Information	Refer Module 1.3.1 for Product Information
Indication(s) in the EEA	***Current:*** Dabigatran etexilate Accord 75 mg hard capsules: • Primary prevention of venous thromboembolic (VTE) events in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery. • Treatment of VTE and prevention of recurrent VTE in paediatric patients from the time the child is able to swallow soft food to less than 18 years of age. • 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.

Dosage in the EEA

Current:

Posology

Dabigatran etexilate Accord hard capsules can be used in adults and paediatric patients aged 8 years or older who are able to swallow the capsules whole.

When changing between the formulations, the prescribed dose may need to be altered. The dose stated in the relevant dosing table of a formulation should be prescribed for the age and weight of the child.

Primary prevention of VTE in orthopaedic surgery

The recommended doses of Dabigatran etexilate Accord and the duration of therapy for primary prevention of VTE in orthopaedic surgery are shown in below table.

Table: Dose recommendations and duration of therapy for primary prevention of VTE in orthopaedic surgery

	Treatment initiation on the day of surgery 1-4 hours after completed surgery	**Maintenance dose starting on the first day after surgery**	**Duration of maintenance dose**
Patients following elective knee replacement surgery	single capsule of 110 mg Dabigatran etexilate	220 mg Dabigatran etexilate once daily taken as 2 capsules of 110 mg	10 days
Patients following elective hip replacement surgery			28-35 days
Dose reduction recommended			

[redacted]

Patients with moderate renal impairment (creatinine clearance (CrCL 30-50 mL/min)	single capsule of 75 mg Dabigatran etexilate	150 mg Dabigatran etexilate once daily taken as 2 capsules of 75 mg	10 days (knee replacement surgery) or 28-35 days (hip replacement surgery)
Patients who receive concomitant verapamil, amiodarone, quinidine			
Patients aged 75 or above			

For both surgeries, if haemostasis is not secured, initiation of treatment should be delayed. If treatment is not started on the day of surgery then treatment should be initiated with 2 capsules once daily.

Prevention of stroke and systemic embolism in adult patients with NVAF with one or more risk factors (SPAF)

Treatment of DVT and PE, and prevention of recurrent DVT, and PE in adults (DVT/PE)

The recommended doses of Dabigatran etexilate Accord in the indications SPAF, DVT and PE are shown in below below table.

Table : Dose recommendations for SPAF, DVT and PE

	Dose recommendation
Prevention of stroke and systemic embolism in adult patients with NVAF with one or more risk factors (SPAF)	300 mg Dabigatran etexilate Accord taken as one 150 mg capsule twice daily
Treatment of DVT and PE, and prevention of recurrent DVT, and PE in adults (DVT/PE)	300 mg Dabigatran etexilate Accord taken as one 150 mg capsule twice daily following

	treatment with a parenteral anticoagulant for at least 5 days
Dose reduction recommended	
Patients aged ≥80 years	daily dose of 220 mg Dabigatran etexilate taken as one 110 mg capsule twice daily
Patients who receive concomitant verapamil	
Dose reduction for consideration	
Patients between 75-80 years	daily dose of dabigatran etexilate of 300 mg or 220 mg should be selected based on an individual assessment of the thromboembolic risk and the risk of bleeding
Patients with moderate renal impairment (CrCL 30-50 mL/min)	
Patients with gastritis, esophagitis or gastroesophageal reflux	
Other patients at increased risk of bleeding	

For DVT/PE the recommendation for the use of 220 mg dabigatran etexilate taken as one 110 mg capsule twice daily is based on pharmacokinetic and pharmacodynamic analyses and has not been studied in this clinical setting.

In case of intolerability to dabigatran etexilate, patients should be instructed to immediately consult their treating physician in order to be switched to alternate acceptable treatment options for prevention of stroke and systemic embolism associated with atrial fibrillation or for DVT/PE.

Treatment of VTE and prevention of recurrent VTE in paediatric patients

For the treatment of VTE in paediatric patients, treatment should be initiated following treatment with a parenteral anticoagulant for at least 5 days. For prevention of recurrent VTE, treatment should be initiated following previous treatment.

[redacted]

	Dabigatran etexilate capsules should be taken twice daily, one dose in the morning and one dose in the evening, at approximately the same time every day. The dosing interval should be as close to 12 hours as possible. The recommended dose of dabigatran etexilate capsules is based on the patient's age and weight. **Method of administration:** Dabigatran etexilate Accord is for oral use. The capsules can be taken with or without food. The capsules should be swallowed as a whole with a glass of water, to facilitate delivery to the stomach.
Pharmaceutical form(s) and strengths	***Current***: **Pharmaceutical form:** Hard capsules **Strengths:** 75 mg, 110 mg and 150 mg
Is the product subject to additional monitoring in EU?	No

[redacted]

Part II: Safety specification

Part II: Module SI – Epidemiology of the indication(s) and target population(s)

Not applicable

Part II: Module SII – Non-clinical part of the safety specification

Not applicable

Part II: Module SIII – Clinical trial exposure

Not applicable

Part II: Module SIV – Populations not studied in clinical trials

SIV.1 Exclusion criteria in pivotal clinical studies within the development programme

Not applicable

SIV.2 Limitations to detect adverse reactions in clinical trial development programmes

Not applicable

SIV.3 Limitations in respect to populations typically under-represented in clinical trial development programmes

Not applicable

Part II: Module SV – Post-authorisation experience

SV.1 Post-authorisation exposure

Not applicable

Part II: Module SVI – Additional EU requirements for the safety specification

SVI.1 Potential for misuse for illegal purposes

Not applicable

[redacted]

Part II: Module SVII - Identified and potential risks

The safety concerns of this RMP have been updated as per European Public Assessment Report (EPAR) – RMP of reference product Pradaxa (Dabigatran) (version 42.0, dated 16-Jun-2025) published by EMA on 16-Dec-2025. There is no change proposed by MAH in these safety concerns mentioned in Module SVIII.

Hence this section remains "Not applicable".

SVII.1 Identification of safety concerns in the initial RMP submission

SVII.1.1. Risks not considered important for inclusion in the list of safety concerns in the RMP

Not applicable

SVII.1.2. Risks considered important for inclusion in the list of safety concerns in the RMP

Not applicable

SVII.2 New safety concerns and reclassification with a submission of an updated RMP

Not applicable

SVII.3 Details of important identified risks, important potential risks, and missing information

SVII.3.1. Presentation of important identified risks and important potential risks

Not applicable

SVII.3.2. Presentation of the missing information

Not Applicable

[redacted]

Part II: Module SVIII - Summary of the safety concerns

Table 2: Summary of safety concerns

Important identified risks	• Haemorrhage
Important potential risks	• None
Missing Information	• Paediatric patients with renal dysfunction (eGFR<50 ml/min)

[redacted]

Part III: Pharmacovigilance Plan (including post-authorisation safety studies)

III.1 Routine pharmacovigilance activities

Routine pharmacovigilance activities including collection and reporting of adverse reactions and signal detection as stated in pharmacovigilance system master file are sufficient for the mentioned safety concerns.

In addition, MAH has proposed specific adverse drug reaction follow-up forms for following risk concerning use of dabigatran and they are appended in Annex 4 of this RMP.

- Haemorrhage

Purpose: For collection and reporting of safety information while use of dabigatran.

Other forms of routine pharmacovigilance activities:

None

III.2 Additional pharmacovigilance activities

None proposed

III.3 Summary Table of additional Pharmacovigilance activities

Not applicable

[redacted]

Part IV: Plans for post-authorisation efficacy studies

Not applicable

[redacted]

Part V: Risk minimisation measures (including evaluation of the effectiveness of risk minimisation activities)

Risk Minimisation Plan

V.1. Routine Risk Minimisation Measures

Table 3: Description of routine risk minimisation measures by safety concern

Safety concern	Routine risk minimisation activities
Important Identified Risks	
Haemorrhage	*Routine risk communication:* • SmPC sections: 4.2, 4.3, 4.4, 4.5, 4.8, 4.9 and 5.1 • PIL sections: 2, 3 and 4 *Routine risk minimisation activities recommending specific clinical measures to address the risk:* • Recommended precautions and contraindications related to Haemorrhage with dabigatran are included in sections 4.2, 4.3 and 4.4 of SmPC • Treatment management of Haemorrhage is included in SmPC section 4.9 • Advise to not use dabigatran if patient is at risk of bleeding or injury or having bleeding is included in PIL sections 2, 3 and 4 *Other routine risk minimisation measures beyond the Product Information:* • The prescription only status of the product
Missing Information	
Paediatric patients with renal dysfunction (eGFR<50 ml/min)	*Routine risk communication:* SmPC sections: 4.2, 4.3 and 4.4 PIL sections: 2 and 3

[redacted]

Safety concern	Routine risk minimisation activities
	Routine risk minimisation activities recommending specific clinical measures to address the risk: • Contraindicated to use dabigatran in paediatric patients with eGFR < 50 mL/min/1.73 m^2, included in SmPC sections 4.2 and 4.3 *Other routine risk minimisation measures beyond the Product Information:* • The prescription only status of the product

[redacted]

V.2. Additional Risk Minimisation Measures

Additional Risk Minimisation Measures have been proposed for important identified risk "Haemorrhage".

Proposed additional risk minimisation measures are listed below and are detailed summarised in Annex 6

Prescriber guide

Objectives:

To increase an awareness of healthcare professionals regarding risk of haemorrhage with use of Dabigatran.

Rationale for the additional risk minimisation activity:

To minimise the reporting frequency of ADR related with this risk by increasing an awareness of healthcare professionals.

Target audience and planned distribution path:

Physician and other healthcare professionals who may prescribe Dabigatran.

The MAH may distribute the 'Prescriber guide' to the above-mentioned target audience as per national requirement.

Plans to evaluate the effectiveness of the interventions and criteria for success:

Routine pharmacovigilance including analysis of ADR reports to assess compliance with SmPC recommendations will allow assessing and judging the success of the risk minimisation measures. Effectiveness of the educational material for prescribers will be analysed by MAH as per the requirements for submission of periodic safety update reports (PSUR) for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c (7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

[redacted]

Patient alert cards

Objectives:

To increase an awareness of patients regarding risk of haemorrhage with use of Dabigatran.

Rationale for the additional risk minimisation activity:

To minimise the reporting frequency of ADR related with haemorrhage risk by increasing an awareness of patients.

Target audience and planned distribution path:

Patients or care taker of patients.

The MAH may distribute 'Patient alert cards" to the above-mentioned target audience as per national requirement.

Plans to evaluate the effectiveness of the interventions and criteria for success:

Routine pharmacovigilance including analysis of ADR reports to assess compliance with SmPC recommendations will allow assessing and judging the success of the risk minimisation measures. Effectiveness of the programme will be analysed by MAH as per the requirements for submission of periodic safety update reports (PSUR) for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines' web-portal.

[redacted]

V.3. Summary of risk minimisation measures

Table 4: Summary table of pharmacovigilance activities and risk minimisation activities by safety concern

Safety concern	Risk minimisation measures	Pharmacovigilance activities
Important Identified Risks		
Haemorrhage	Routine risk minimisation measures: • SmPC sections: 4.2, 4.3, 4.4, 4.5, 4.8, 4.9 and 5.1. • PIL sections: 2, 3 and 4. • Recommended precautions and contraindications related to Haemorrhage with dabigatran are included in sections 4.2, 4.3 and 4.4 of SmPC • Treatment management of Haemorrhage is included in SmPC section 4.9 • Advise to not use dabigatran if patient is at risk of bleeding or injury or having bleeding is included in PIL sections 2, 3 and 4 • The prescription only status of the product. Additional risk minimisation measures: • Prescriber guide • Patient alert card	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • Specific adverse reaction follow-up questionnaire has been proposed for 'Haemorrhage'. Additional pharmacovigilance activities: • None
Missing information		
Paediatric patients with renal dysfunction	Routine risk minimisation measures:	Routine pharmacovigilance activities beyond adverse

[redacted]

Safety concern	**Risk minimisation measures**	**Pharmacovigilance activities**
(eGFR<50 ml/min)	• SmPC sections: 4.2, 4.3 and 4.4 • PIL sections 2 and 3 • Contraindicated to use dabigatran in paediatric patients with eGFR < 50 mL/min/1.73 m^2, included in SmPC section 4.2 and 4.3 • The prescription only status of the product. Additional risk minimisation measures: • None	reactions reporting and signal detection: • None Additional pharmacovigilance activity: • None

[redacted]

Part VI: Summary of the risk management plan

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

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

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

This summary of the RMP for Dabigatran etexilate Accord 75 mg, 110 mg and 150 mg hard capsules should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Dabigatran etexilate Accord 75 mg, 110 mg and 150 mg hard capsules' RMP.

I. The medicine and what it is used for

Dabigatran etexilate Accord is indicated for following indications:

- Primary prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery.
- Treatment of VTE and prevention of recurrent VTE in paediatric patients from the time the child is able to swallow soft food to less than 18 years of age.
- 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.

[redacted]

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

It contains Dabigatran etexilate as the active substance and it is given orally.

Further information about the evaluation of Dabigatran etexilate Accord 75 mg, 110 mg and 150 mg hard capsules' benefits can be found in Dabigatran etexilate Accord 75 mg, 110 mg and 150 mg hard capsules' EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage. https://www.ema.europa.eu/en/medicines/human/EPAR/dabigatran-etexilate-accord

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

Important risks of Dabigatran etexilate Accord 75 mg, 110 mg and 150 mg hard capsules, together with measures to minimise such risks and the proposed studies for learning more about Dabigatran etexilate Accord 75 mg, 110 mg and 150 mg hard 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 Dabigatran etexilate Accord 75 mg, 110 mg and 150 mg hard capsules, 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*.

[redacted]

If important information that may affect the safe use of Dabigatran etexilate Accord 75 mg, 110 mg and 150 mg hard capsules is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Dabigatran etexilate Accord 75 mg, 110 mg and 150 mg hard 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 Dabigatran etexilate Accord 75 mg, 110 mg and 150 mg 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).

Important identified risks	• Haemorrhage
Important potential risks	• None
Missing Information	• Paediatric patients with renal dysfunction (eGFR<50 ml/min)

II.B Summary of important risks

Important Identified Risk: Haemorrhage	
Risk minimisation measures	Routine risk minimisation measures: • SmPC sections: 4.2, 4.3, 4.4, 4.5, 4.8, 4.9 and 5.1 • PIL sections: 2, 3 and 4. • Recommended precaution and contraindications related to Haemorrhage with dabigatran are included in SmPC sections 4.2, 4.3 and 4.4.

[redacted]

	• Treatment management of Haemorrhage is included in SmPC section 4.9 • Advise to not use dabigatran if patient is at risk of bleeding or injury or having bleeding is included in PIL section 2, 3 and 4 • The prescription only status of the product Additional risk minimisation measures: • Prescriber guide • 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 Accord 75 mg, 110 mg and 150 mg hard capsules.

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

There are no studies required Dabigatran etexilate Accord 75 mg, 110 mg and 150 mg hard capsules as post-authorisation development plan.

[redacted]

Annex 4 - Specific adverse drug reaction follow-up forms

MAH has developed targeted follow-up questionnaire for the following risk:

- Haemorrhage

[redacted]

Targeted follow up questionnaire for 'Haemorrhage'

***PLEASE DO NOT LEAVE ANY FIELD BLANK. STRIKE IT OUT IF INFORMATION IS 'NOT AVAILABLE' OR 'NOT APPLICABLE'.**

PATIENT DETAILS:

Initials	Age	Gender:	Weight	Height	Date of Birth	Hospital Ref.

If female, is the patient pregnant? **Yes / No**	If yes, Date of Last Menstrual Period:	Expected Delivery Date:

SUSPECTED DRUG(S):

Drug/Brand Name	Manufacturer & Batch No.	Route of Admin	Daily Dosage	Indication	Date Started	Date Stopped
1.						
2.						

DETAILS OF SUSPECTED ADVERSE REACTION(S):

Date reaction started: 1) 2)	Date reaction stopped: 1) 2)

Please describe the reaction and details of any treatment given or investigation performed.	Outcome: ○ Recovered ○ Not Recovered ○ Recovered with Sequel ○ Recovering ○ Fatal ○ Unknown

SERIOUSNESS OF ADVERSE REACTION(S):

Do you consider the reaction to be serious?	○ Yes	○ No
If Yes, Reason for Seriousness: ○ Patient Died ○ Involved/Prolonged Hospitalisation	○ Life Threatening ○ Disability/Incapacity	○ Congenital Abnormality ○ Medically Significant

ACTION TAKEN WITH SUSPECTED DRUGS:

○ Dose Decreased	○ Dose Increased	○ Drug withdrawn	○ Dose not changed
○ Unknown			

[redacted]

CONCOMITANT MEDICATION (incl. herbal or self-medication):

Drug/Brand Name	Route of Admin	Daily Dosage	Indication	Date Started	Date Stopped
1.					
2.					
3.					

SPECIFIC QUESTIONNAIRES FOR EVENT – HAEMORRHAGE

1) What was the gastrointestinal location of the reported bleeding?
   - ☐ Haemoptysis: coughing up blood
   - ☐ Epistaxis: nose bleed
   - ☐ Gastrointestinal haemorrhage
   - ☐ Haematemesis: red blood or coffee grounds material
   - ☐ Melena: black, tarry, foul-smelling stool
   - ☐ Haematochezia: bright red or maroon blood from rectum
   - ☐ Occult GI bleeding: blood in stool in the absence of overt

2) What was the location of the reported bleeding?
   - ☐ Intracranial haemorrhage
   - ☐ Skin bleeding
   - ☐ Blood in urine
   - ☐ Genital haemorrhage
   - ☐ Wound haemorrhage /procedural site haemorrhage
   - ☐ Other site (specify)_____
   - ☐ No location identified

3) When did the first signs or symptoms of the reported bleeding event occur?
   - ☐ Prior to start of treatment with Dabigatran, please specify: _____days/weeks
   - ☐ After start of treatment with Dabigatran, please specify: _____days/weeks.
   - ☐ Not known

4) Does the patient have any episodes of bleeding in the medical history?
   - ☐ Yes (If Yes, please specify_____)
   - ☐ No

5) Was there an alternative explanation, other than Dabigatran, for the bleeding event?

[redacted]

If Yes, please specify_____

6) Did the patient suffer from liver diseases that might have influenced the bleeding event?

If Yes, please specify_____

7) Did the patient suffer from an injury (e.g. fall, trauma, accident) that might have influenced the bleeding event?

If Yes, please specify_____

8) Did the patient suffer from renal impairment prior to or at the event onset of the bleeding event?

Please specify: Renal function decreased prior to start with dabigatran or renal function decreased prior to bleeding event.

_____

9) Please provide date, value, and unit for

Creatinine_____

CrCl_____

GFR_____

10) Which treatment for the bleeding event was initiated?

No treatment was initiated

Surgical procedure (please specify)_____

Blood transfusion; please specify units_____

Other drugs (please specify)_____

REPORTER DETAILS:

Title, Name & Surname	Occupation	Signature	Date
Postal Address: Postcode:	Email:	Tel No.	

[redacted]

Annex 6 - Details of proposed additional risk minimisation activities (if applicable)

The MAH shall provide an educational pack for each therapeutic indication, targeting all physicians who are expected to prescribe/use Dabigatran etexilate Accord. This educational pack is aimed at increasing awareness about the potential risk of bleeding during treatment with Dabigatran etexilate Accord and providing guidance on how to manage that risk.

The MAH must agree the content and format of the educational material, together with a communication plan, with the national competent authority prior to distribution of the educational pack. The educational pack must be available for distribution for all therapeutic indications prior to launch in the Member State.

The physician educational pack should contain:

- The Summary of Product Characteristics
- Prescriber Guide
- Patient Alert Cards

The Prescriber Guide should contain the following key safety messages:

- Details of populations potentially at higher risk of bleeding
- Information on medicinal products that are contraindicated or which should be used with caution due to an increased risk of bleeding and/or increased dabigatran exposure
- Contraindication for patients with prosthetic heart valves requiring anticoagulant treatment
- Recommendation for kidney function measurement
- Recommendations for dose reduction in at risk populations
- Management of overdose situations
- The use of coagulation tests and their interpretation
- That all patients should be provided with a Patient alert card and be counselled about:
    - Signs or symptoms of bleeding and when to seek attention from a health care provider.
    - Importance of treatment compliance

[redacted]

- Necessity to carry the Patient alert card with them at all times
- The need to inform Health Care Professionals about all medicines they are currently taking
- The need to inform Health Care Professionals that they are taking Dabigatran etexilate Accord if they need to have any surgery or invasive procedure.
- An instruction how to take Dabigatran etexilate Accord

[redacted]