

Part VI: Summary of the risk management plan

Summary of risk management plan for DABIGATRAN GEDEON RICHTER and TELEXER 110 mg, 150 mg, capsule, hard (dabigatran etexilate)

This is a summary of the risk management plan (RMP) for DABIGATRAN GEDEON RICHTER and TELEXER 110 mg, 150 mg, capsule, hard. The RMP details important risks of DABIGATRAN GEDEON RICHTER and TELEXER 110 mg, 150 mg, capsule, hard, how these risks can be minimised, and how more information will be obtained about DABIGATRAN GEDEON RICHTER and TELEXER 110 mg, 150 mg, capsule, hard's risks and uncertainties (missing information).

DABIGATRAN GEDEON RICHTER and TELEXER 110 mg, 150 mg, capsule, hard's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how DABIGATRAN GEDEON RICHTER and TELEXER 110 mg, 150 mg, capsule, hard should be used.

Important new concerns or changes to the current ones will be included in updates of DABIGATRAN GEDEON RICHTER and TELEXER 110 mg, 150 mg, capsule, hard's RMP.

I. The medicine and what it is used for

DABIGATRAN GEDEON RICHTER and TELEXER 110 mg, 150 mg, capsule, hard are 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 (110 mg only), 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 \geq 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 the time the child is able to swallow soft food to less than 18 years of age. It contains dabigatran etexilate as the active substance and it is given orally as 110 mg, 150 mg, capsule, hard.

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

Important risks of DABIGATRAN GEDEON RICHTER and TELEXER 110 mg, 150 mg, capsule, hard, together with measures to minimise such risks and the proposed studies for learning more about DABIGATRAN GEDEON RICHTER and TELEXER 110 mg, 150 mg, capsule, hard'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 DABIGATRAN GEDEON RICHTER and TELEXER 110 mg, 150 mg, capsule, hard, 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, including 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 DABIGATRAN GEDEON RICHTER and TELEXER 110 mg, 150 mg, capsule, hard is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of DABIGATRAN GEDEON RICHTER and TELEXER 110 mg, 150 mg, capsule, hard 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 GEDEON RICHTER and TELEXER 110 mg, 150 mg, capsule, hard. 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).

Summary of safety concerns	
Important identified risks	#1. Haemorrhage
Important potential risks	None.
Missing information	#2. Patient aged 0 to 2 years who were born prematurely #3. Paediatric patients with renal dysfunction (eGFR <50 ml/min)

II.B Summary of important risks

Important identified risk: Haemorrhage	
Risk minimisation measures	<p>Routine risk minimisation measures</p> <p>References to this safety concern are made in the following sections:</p> <ul style="list-style-type: none"> • SmPC sections 4.2, 4.3, 4.4, 4.5, 4.8, 4.9, 5.1, 5.3 • PL sections 2, 3, 4 <p>Additional risk minimisation measures</p> <ul style="list-style-type: none"> • Educational material for prescribers:

	<p>Prescriber guide for primary prevention of venous thromboembolic events (VTE) following elective hip or knee replacement surgery</p> <p>Prescriber guide for stroke prevention in non-valvular atrial fibrillation (NVAf) and for the treatment and secondary prevention of deep vein thrombosis (DVT) and pulmonary embolism (PE).</p> <ul style="list-style-type: none"> • Patient card (PC).
Missing information: Patient aged 0 to 2 years who were born prematurely	
Risk minimisation measures	<p>Routine risk minimisation measures</p> <ul style="list-style-type: none"> • No risk minimisation measures <p>Additional risk minimisation measures</p> <ul style="list-style-type: none"> • None
Missing information: Paediatric patients with renal dysfunction (eGFR<50 ml/min)	
Risk minimisation measures	<p>Routine risk minimisation measures</p> <p>References to this safety concern are made in the following sections:</p> <ul style="list-style-type: none"> • SmPC sections 4.2, 4.3 and 4.4 • PL sections 2 <p>Additional risk minimisation measures</p> <ul style="list-style-type: none"> • None

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 GEDEON RICHTER 110 mg, 150 mg, capsule, hard.

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

There are no studies required for DABIGATRAN GEDEON RICHTER and TELEXER 110 mg, 150 mg, capsule, hard.