Part VI: Summary of the risk management plan

Summary of risk management plan for Dabigatran etexilate Liconsa, Dabigatran etexilate DOC, Dabigatran etexilate and Dabiras 75, 110 and 150 mg hårda kapslar (dabigatran)

This is a summary of the risk management plan (RMP) for Dabigatran etexilate Liconsa, Dabigatran etexilate DOC, Dabigatran etexilate and Dabiras 75, 110 and 150 mg hårda kapslar. The RMP details important risks of Dabigatran etexilate Liconsa, Dabigatran etexilate DOC, Dabigatran etexilate and Dabiras 75, 110 and 150 mg hårda kapslar, how these risks can be minimised and how more information will be obtained about Dabigatran etexilate Liconsa, Dabigatran etexilate DOC, Dabigatran etexilate and Dabiras 75, 110 and 150 mg hårda kapslar's risks and uncertainties (missing information).

Dabigatran etexilate Liconsa, Dabigatran etexilate DOC, Dabigatran etexilate and Dabiras 75, 110 and 150 mg hårda kapslar's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Dabigatran etexilate Liconsa, Dabigatran etexilate DOC, Dabigatran etexilate and Dabiras 75, 110 and 150 mg hårda kapslar should be used.

Important new concerns or changes to the current ones will be included in updates of Dabigatran etexilate Liconsa, Dabigatran etexilate DOC, Dabigatran etexilate and Dabiras 75, 110 and 150 mg hårda kapslar's RMP.

I. The medicine and what it is used for

Dabigatran etexilate Liconsa, Dabigatran etexilate DOC, Dabigatran etexilate and Dabiras 75, 110 and 150 mg hårda kapslar is authorized in adults for (see SmPC for the full indications):

- Prevent the formation of blood clots in the veins after knee or hip replacement surgery
- Prevent blood clots in the brain (stroke) and other blood vessels in the body if you have a form of irregular heart rhythm called nonvalvular atrial fibrillation and at least one additional risk factor
- Trear blood clots in the veins of your legs and lungs and to prevent blood clots from re-occurring in the vein of your legs and lungs

Dabigatran etexilate Liconsa, Dabigatran etexilate DOC, Dabigatran etexilate and Dabiras 75, 110 and 150 mg hårda kapslar is authorized in children from the time they are able to swallow to (see SmPC for the full indications):

- Treat blood clots and prevent blood clots from reoccurring

It contains dabigatran etexilate as the active substance and it is given via the oral route.

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

Important risks of Dabigatran etexilate Liconsa, Dabigatran etexilate DOC, Dabigatran etexilate and Dabiras 75, 110 and 150 mg hårda kapslar, together with measures to minimise such 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 Liconsa, Dabigatran etexilate DOC, Dabigatran etexilate and Dabiras 75, 110 and 150 mg hårda kapslar, 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*.

II.A List of important risks and missing information

Important risks of Dabigatran etexilate Liconsa, Dabigatran etexilate DOC, Dabigatran etexilate and Dabiras 75, 110 and 150 mg hårda kapslar 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 Liconsa, Dabigatran etexilate DOC, Dabigatran etexilate and Dabiras 75, 110 and 150 mg hårda kapslar. 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

List of important risks and missing information	
Important potential risks	• None
Missing information	• Paediatric patients with renal dysfunction (eGFR <50ml/min)

II.B Summary of important risks

Important identified risks: Haemorrhage	
Risk minimisation measures	Routine risk minimisation measures: • SmPC Sections 4.2, 4.3, 4.4, 4.5, 4.8, and 4.9 • PL Sections 2, 3, and 4 Other risk minimisation measures: Praxbind (idarucizumab) has been approved in adult patients as a specific reversal agent for rapid reversal of the anticoagulation effect of dabigatran in case of emergency surgery or urgent procedures for situations of life threatening or uncontrolled bleeding. For paediatric patients, haemodialysis can remove dabigatran. Additional risk minimisation measures: Prescriber guide and patient alert card
Missing information: Patients with renal dysfunction (eGFR<50ml/min)	
Risk minimisation measures	Routine risk minimisation measures: • SmPC Sections 4.2 and 4.4 • PL Section 2

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 Liconsa, Dabigatran etexilate DOC, Dabigatran etexilate and Dabiras 75, 110 and 150 mg hårda kapslar.

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

There are no studies required for Dabigatran etexilate Liconsa, Dabigatran etexilate DOC, Dabigatran etexilate and Dabiras 75, 110 and 150 mg hårda kapslar.