Summary of risk management plan for Dabigatran Etexilate Alembic Capsules 75 mg, 110 mg and 150 mg

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

Dabigatran Etexilate Alembic Capsules 75 mg, 110 mg and 150 mg summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Dabigatran Etexilate Alembic Capsules 75 mg, 110 mg and 150 mg should be used.

Important new concerns or changes to the current ones will be included in updates of Dabigatran Etexilate Alembic Capsules 75 mg, 110 mg and 150 mg RMP.

I. The medicine and what it is used for

Dabigatran belongs to a group of medicines called anticoagulants. It works by blocking the activity of a substance in the body which is involved in blood clot formation.

Dabigatran is used in Adults to (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
- Treat 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 is used in children from the time they are able to swallow to (see SmPC for the full indication)

- Treat blood clots and prevent blood clots from reoccurring

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

Dabigatran Etexilate Alembic Capsules 75 mg, 110 mg and 150 mg together with measures to minimise such risks and the proposed studies for learning more about Dabigatran Etexilate Alembic Capsules 75 mg, 110 mg and 150 mg 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, 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 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 Alembic Capsules 75 mg, 110 mg and 150 mg 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 Alembic Capsules 75 mg, 110 mg and 150 mg. 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
Important Potential Risks	• None

Missing Information	• Paediatric patients with renal dysfunction (eGFR <50ml/min)*

*This safety concern is only valid in countries where the paediatric indication is approved.

II.B Summary of important risks

Important Identified Risks: Haemorrhage	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.3 Contraindication, 4.8 Undesirable effects, 4.4 Special warning and precaution for use, 4.9 Overdose, 5.1 Pharmacodynamics properties. PL Sections 2 Dosage and administration, 3 Dosage forms and strengths, and 4 Contraindications. Additional risk minimisation measures: • patient alert card • Prescriber guide
Important potential risks: None	
Missing information : Paediatric patients with renal dysfunction (eGFR <50ml/min)	
Risk minimisation measures	Routine risk minimisation measures: SmPC Sections 4.2 Posology and method of administration and 4.4 Special warning and precaution for use PL Section 2 Dosage and administration Additional risk minimisation measures: 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 for Dabigatran Etexilate Alembic Capsules 75 mg, 110 mg and 150 mg.

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

There are no studies required for Dabigatran Etexilate Alembic Capsules 75 mg, 110 mg and 150 mg.