Part VI: Summary of the risk management plan

Summary of risk management plan for Daroxomb/ Dabigatran Etexilate Zentiva k.s./ Dabigatran Etexilate Zentiva 75/110/150 mg hard capsules (dabigatran)

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

Dabigatran, summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Dabigatran, should be used.

Important new concerns or changes to the current ones will be included in updates of Daroxomb/ Dabigatran Etexilate Zentiva k.s./ Dabigatran Etexilate Zentiva 75/110/150 mg hard capsules' RMP.

I. The medicine and what it is used for

Daroxomb/ Dabigatran Etexilate Zentiva k.s./ Dabigatran Etexilate Zentiva 75/110/150 mg hard capsules, is an authorised active substance for prevention of venous thromboembolic events in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery; prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors; treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults; and treatment of VTE and prevention of recurrent VTE in paediatric patients from birth to less than 18 years of age (see SmPC for the full indication).

It contains dabigatran as the active substance, and it is given oral route of administration through a capsule.

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

Important risks of Daroxomb/ Dabigatran Etexilate Zentiva k.s./ Dabigatran Etexilate Zentiva 75/110/150 mg hard capsules, together with measures to minimise such risks and the proposed studies for learning more about Dabigatran´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 Daroxomb/ Dabigatran Etexilate Zentiva k.s./ Dabigatran Etexilate Zentiva 75/110/150 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 rutine 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 Daroxomb/ Dabigatran Etexilate Zentiva k.s./ Dabigatran Etexilate Zentiva 75/110/150 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 applied. 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 Daroxomb/ Dabigatran Etexilate Zentiva k.s./ Dabigatran Etexilate Zentiva 75/110/150 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).

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

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, and 4.9 PL Sections 2, 3, and 4 Additional risk minimisation measures: Prescriber guide and patient alert card

Missing information **Paediatric patients with renal dysfunction (eGFR <50ml/min)** **Patients aged 0 to 2 years who were born prematurely**	
Risk minimisation measures	Routine risk minimisation measures SmPC Sections 4.2 and 4.4 PL Sections 2

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which conditions of the marketing authorisation or specific obligation of Daroxomb/ Dabigatran Etexilate Zentiva k.s./ Dabigatran Etexilate Zentiva 75/110/150 mg hard capsules are necessary.

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

There are no studies required for Daroxomb/ Dabigatran Etexilate Zentiva k.s./ Dabigatran Etexilate Zentiva 75/110/150 mg hard capsules.