Part VI: Summary of the Risk Management Plan

As the safety concerns and their management are identical for all products covered by this RMP, the information in Part VI is presented only once together for all products.

Summary of risk management plan for Rivaroxaban Zentiva/Xanirva (Rivaroxaban)
This is a summary of the risk management plan (RMP) for Rivaroxaban Zentiva/Xanirva. The RMP details important risks of Rivaroxaban Zentiva/Xanirva, how these risks can be minimised, and how more information will be obtained about Rivaroxaban Zentiva/Xanirva's risks and uncertainties (missing information).
Rivaroxaban Zentiva/Xanirva's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Rivaroxaban Zentiva/Xanirva should be used.

Important new concerns or changes to the current ones will be included in updates of Rivaroxaban Zentiva/Xanirva's RMP.

I. The medicine and what it is used for

Rivaroxaban Zentiva/Xanirva is authorised for:

- 2.5 mg film-coated tablets: prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers. In combination with ASA, prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events.
- 10 mg film-coated tablets/hard capsules: prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery, treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE.
- 15 mg film-coated tablets/hard capsules: prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing from 30 kg to 50 kg after at least 5 days of initial parenteral anticoagulation treatment.
- 20 mg film-coated tablets/hard capsules: prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing more than 50 kg after at least 5 days of initial parenteral anticoagulation treatment.

Products contain rivaroxaban as the active substance and are given by oral route of administration.

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

Important risks of Rivaroxaban Zentiva/Xanirva, together with measures to minimise such risks and the proposed studies for learning more about Rivaroxaban Zentiva/Xanirva'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 Rivaroxaban Zentiva/Xanirva, 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.
If important information that may affect the safe use of Rivaroxaban Zentiva/Xanirva is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Rivaroxaban Zentiva/Xanirva 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 Rivaroxaban Zentiva/Xanirva. 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	• Embryo-foetal toxicity
Missing information	• Remedial pro-coagulant therapy for excessive haemorrhage • Patients with atrial fibrillation (AF) and a prosthetic heart valve

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

Haemorrhage	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.3, 4.4, 4.8, 4.9, 5.1 PL sections 2, 3, 4 Additional risk minimisation measures: Physician educational pack 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 Rivaroxaban Zentiva/Xanirva.

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

There are no studies required for Rivaroxaban Zentiva/Xanirva.