Part VI: Summary of the Risk Management Plan

Summary of risk management plan for Rivaxa (Rivaroxaban)

This is a summary of the risk management plan (RMP) for Rivaxa. The RMP details important risks of Rivaxa, how these risks can be minimised, and how more information will be obtained about Rivaxa risks and uncertainties (missing information).

Rivaxa summary of product characteristics (SmPC) and its patient information leaflet (PIL) give essential information to healthcare professionals (HCPs) and patients on how Rivaxa should be used.

I. The medicine and what it is used for

Rivaxa is authorised for the following –

- Co-administered with acetylsalicylic acid (ASA) alone or with ASA plus clopidogrel or ticlopidine, it is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome with elevated cardiac biomarkers
- Co-administered with ASA, is indicated for the prevention of atherothrombotic events in adult patients with coronary artery disease or symptomatic peripheral artery disease at high risk of ischaemic events.
- Prevention of venous thromboembolism 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 in adults.
- 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

It contains rivaroxaban as the active substance and it is taken orally.

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

Important risks of Rivaxa, together with measures to minimise such risks and the proposed studies for learning more about Rivaxa 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 HCPs;
- 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 Rivaxa, 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 Rivaxa is not yet available, it is listed under 'missing information' below.

II.A. List of important risks and missing information

Important risks of Rivaxa starter pack 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 Rivaxa 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 risk(s)	• Haemorrhage
Important potential risk(s)	• Embryo-foetal toxicity
Missing information	• Remedial pro-coagulant therapy for excessive haemorrhage • Patients with atrial fibrillation and a prosthetic heart valve

II.B. Summary of important risk

Important Identified Risk – Haemorrhage	
Risk minimisation measures	**<u>Routine risk minimisation measures:</u>** The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.3: Contraindications • Section 4.4: Special warnings and precautions for use • Section 4.8: Undesirable effects **Patient Information Leaflet:** • Section 2: What you need to know before you take rivaroxaban • Section 3: How to take rivaroxaban • Section 4: Possible side effects **<u>Additional risk minimisation measures:</u>** • Prescriber Guide • Patient Alert Cards

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 Rivaxa.

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

There are no studies required for Rivaxa.