PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Apixaban 2.5 mg and 5 mg film-coated tablets

This is a summary of the risk management plan (RMP) for Apixaban 2.5 mg/ 5 mg film-coated tablets. The RMP details important risks of Apixaban 2.5 mg/ 5 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about Apixaban 2.5 mg/ 5 mg film-coated tablets' risks and uncertainties (missing information).

Apixaban 2.5 mg/ 5 mg film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Apixaban 2.5 mg/ 5 mg film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Apixaban 2.5 mg/ 5 mg film-coated tablets RMP

I. The medicine and what it is used for

Apixaban 2.5 mg film-coated tablets are indicated for:

Adults

Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery.

Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥ 75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥ II). Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

It contains Apixaban as the active substance and it is given by oral route.

Paediatric population

Treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in pediatric patients from 28 days to less than 18 years of age.

Apixaban 5 mg film-coated tablets are indicated for:

Adults

Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischaemic

attack (TIA); age ≥ 75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥ II).

Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

It contains Apixaban as the active substance and it is given by oral route.

Paediatric population

Treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in pediatric patients from 28 days to less than 18 years of age.

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

Apixaban 2.5 mg/ 5 mg film-coated tablets together with measures to minimise such risks and the proposed studies for learning more about Apixaban 2.5 mg/ 5 mg film-coated tablets 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 case of Apixaban 2.5 mg/ 5 mg film-coated tablets, 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 (if applicable) and signal management activity, 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 Apixaban 2.5 mg/ 5 mg film-coated tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Apixaban 2.5 mg/ 5 mg film-coated tablets 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 Apixaban 2.5 mg/ 5 mg film-coated tablets. 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	• Bleeding
Important Potential Risks	• Liver injury • Potential risk of bleeding or thrombosis due to overdose or underdose
Missing Information	• Use in patients with severe renal impairment

II.B Summary of important risks

Important Identified Risks: Bleeding	
Risk minimisation measures	Routine risk minimisation measures: SmPC Section 4.3 Contraindications, 4.4 Special warnings and precautions for use, 4.5 Interaction with other medicinal products and other forms of interaction, 4.8 Undesirable effects and 4.9 Overdose Additional risk minimisation measures: • Patient card
Important potential risks: Liver injury	
Risk minimisation measures	Routine risk minimisation measures: SmPC Section 4.3 Contraindications, 4.4 Special warnings and precautions for use Additional risk minimisation measures: None
Important potential risks: Potential risk of bleeding or thrombosis due to overdose or underdose	

Risk minimisation measures	Routine risk minimisation measures: SmPC Section 4.3 Contraindications, 4.4 Special warnings and precautions for use, 4.5 Interaction with other medicinal products and other forms of interaction, 4.8 Undesirable effects and 4.9 Overdose Additional risk minimisation measures: None
Missing information: Use in patients with severe renal impairment	
Risk minimisation measures	Routine risk minimisation measures: SmPC Section 4.4 Special warnings and precautions for use, 4.8 Undesirable effects and 4.9 Overdose. 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 Apixaban 2.5 mg and 5 mg film-coated tablets.

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

There are no studies required for Apixaban 2.5 mg and 5 mg film-coated tablets.