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 and 5 mg film-coated tablets. The RMP details important risks of [Apixaban] 2.5 and 5 mg film-coated tablets, how these risks can be minimised and how more information will be obtained about [Apixaban] 2.5 mg and 5 mg film-coated tablets risks and uncertainties (missing information).

[Apixaban] 2.5 mg and 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 and 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 and 5 mg film-coated tablets' RMP.

I. The medicine and what it is used for

[Apixaban] 2.5 mg film-coated tablets is authorized for the prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery; for the 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) & for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

[Apixaban] 5 mg film-coated tablets is authorized for the 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), as well as for 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.

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

Important risks of [Apixaban] 2.5 mg and 5 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about [Apixaban] 2.5 mg and 5 mg film-coated tablets'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.

Risk minimisation measures	*Routine Risk minimization measures:* SmPC sections 4.2 and 4.9 Pack size: 28, 30, 56 ,60 film-coated tablets *Additional risk minimization measures:* Educational materials for physicians: • Prescriber Guide
Missing information: Use in patients with severe renal impairment	
Risk minimisation measures	*Routine Risk minimization measures:* SmPC sections 4.2, 4.4 and 5.2 PIL sections 2 and 3. Pack size: 28, 30, 56 ,60 film-coated tablets *Additional risk minimization 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 of [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.