Part VI: Summary of the risk management plan

Summary of risk management plan for

Apixaban Grindeks 2.5 mg film-coated tablets
Apixaban Grindeks 5 mg film-coated tablets

(apixaban)

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

Apixaban Grindeks's summary of product characteristics (SPC) and its package leaflet give essential information to healthcare professionals and patients on how Apixaban Grindeks should be used.

Important new concerns or changes to the current ones will be included in updates of Apixaban Grindeks's RMP.

I. The medicine and what it is used for

Apixaban Grindeks is indicated for 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; treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from 28 days to less than 18 years of age
It contains apixaban as the active substance and it is given by oral route of administration in concentration of 2.5 mg or 5 mg per film-coated tablets.

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

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

II.A List of important risks and missing information

Important risks of Apixaban Grindeks are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Grindeks. 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).

Summary of safety concerns	
Important identified risks	*Bleeding*
Important potential risks	*Liver Injury* *Potential risk of bleeding or thrombosis to overdose or underdose*
Missing information	*Use in patient with severe renal impairment*

II.B Summary of important risks

Important identified risk - *Bleeding*	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.2, 4.3, 4.4, 4.5, 4.8 and 4.9. Prescription only medicine. Additional risk minimization measures: Educational material: *Prescriber Guide,* *Patient Card.*
Important potential risk – *Liver Injury*	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.2, 4.3, 4.4 and 4.8. Prescription only medicine. Additional risk minimization measures: None.
Important potential risk - *Potential risk of bleeding or thrombosis due to overdose or underdose*	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.2 and 4.9. Prescription only medicine. Additional risk minimization measures: Educational material: *Prescriber Guide.*
Missing information - *Use in patient with severe renal impairment*	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.2, 4.4 and 5.2. Prescription only medicine. 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 Grindeks.

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

There are no studies required for Apixaban Grindeks.