Part VI: Summary of the risk management plan

Summary of risk management plan for Apixlets (apixaban)

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

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

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

I. The medicine and what it is used for

Apixlets is authorised for (see SmPC for the full indication):

- 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 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.

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

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

II.A List of important risks and missing information

Important risks of Apixlets 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 Apixlets. 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 risk: Bleeding	
Risk minimisation measures	**Routine risk minimisation measures:** SmPC sections 4.2,4.3, 4.4, 4.5, 4.8 and 4.9 PL sections 2, 3 and 4 **Additional risk minimisation measures:** Patient Card
Important potential risk: Liver injury	
Risk minimisation measures	**Routine risk minimisation measures:** SmPC sections 4.2, 4.3, 4.4, and 4.8 PL sections 2 and 4 **Additional risk minimisation measures:** None

Important potential risk: Potential risk of bleeding or thrombosis due to overdose or underdose	
Risk minimisation measures	**Routine risk minimisation measures:** SmPC sections 4.2 and 4.9 PL section 3 **Additional risk minimisation measures:** None
Missing information: Use in patients with severe renal impairment	
Risk minimisation measures	**Routine risk minimisation measures:** SmPC sections 4.2, 4.4 and 5.2 PL sections 2 and 3 **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 of Apixlets.

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

There are no studies required for Apixlets.