

## **Part VI: Summary of the risk management plan**

### **Summary of risk management plan for Apixaban Liconsa and Medical Valley (apixaban)**

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

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

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

#### **I. The medicine and what it is used for**

Apixaban Liconsa and Medical Valley is authorised for:

##### Apixaban 2.5 mg film-coated tablets

- 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  $\geq$  75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class  $\geq$  II).
- 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

- 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  $\geq$  75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class  $\geq$  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 orally.

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

Important risks of Apixaban Liconsa and Medical Valley, together with measures to minimise such 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 the case of Apixaban Liconsa and Medical Valley, 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 Liconsa and Medical Valley is not yet available, it is listed under ‘missing information’ below.

## **II.A List of important risks and missing information**

Important risks of Apixaban Liconsa and Medical Valley 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 Liconsa and Medical Valley. 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).

<b>List of important risks and missing information</b>	
Important identified risks	<ul style="list-style-type: none"> <li>• Bleeding</li> </ul>
Important potential risks	<ul style="list-style-type: none"> <li>• Liver Injury</li> <li>• Potential risk of bleeding or thrombosis due to overdose or underdose</li> </ul>
Missing information	<ul style="list-style-type: none"> <li>• Use in patients with severe renal impairment</li> </ul>

## **II.B Summary of important risks**

<b>Important identified risk: Bleeding</b>	
Risk minimisation measures	Routine risk minimisation measures: <i>SmPC Section 4.2, 4.3, 4.4, 4.5, 4.8 and 4.9</i> <i>PL Section 2, 3 and 4</i>  Additional risk minimisation measures: <i>Prescriber Guide and Patient Alert Card</i>

<b>Important potential risk: Liver injury</b>	
	Routine risk minimisation measures: <i>SmPC Section 4.2, 4.3, 4.4, 4.8</i> <i>PL Section 2 and 4</i>  Additional risk minimisation measures: None
<b>Important potential risks: Potential risk of bleeding or thrombosis due to overdose or underdose</b>	
Risk minimisation measures	Routine risk minimisation measures: <i>SmPC Section 4.2 and 4.9</i> <i>PIL Section 3</i>  Additional risk minimisation measures: <i>Prescriber Guide</i>
<b>Missing information: Use in patients with severe renal impairment</b>	
Use in patients with severe renal impairment	Routine risk minimisation measures: <i>SmPC Section 4.2, 4.4 and 5.2</i> <i>PIL Section 2 and 3</i>  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 Apixaban Liconsa and Medical Valley.

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

There are no studies required for Apixaban Liconsa and Medical Valley.