

## Part VI: Summary of the Risk Management Plan

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

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

Apixaban Glenmark 2.5 mg and 5 mg film-coated tablets' summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Apixaban Glenmark 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 Glenmark 2.5 mg and 5 mg film-coated tablets RMP.

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

Apixaban Glenmark 2.5 mg and 5 mg film-coated tablets is authorised for the following indications:

- 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 {(New York Heart Association (NYHA) Class  $\geq$  II)}.
- Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults (see section 4.4 for haemodynamically unstable pulmonary embolism (PE) patients).

Paediatric population

- 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 Apixaban Glenmark 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 Glenmark 2.5 mg and 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 PL 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 Glenmark 2.5 mg and 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 Periodic Safety Update Report (PSUR) assessment if PSUR is required by Health Authority, 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 Glenmark 2.5 mg and 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 Glenmark 2.5 mg and 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 Glenmark 2.5 mg and 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).

<b>List of Important Risks and Missing Information</b>	
Important identified risk(s)	<ul style="list-style-type: none"> <li>• Bleeding</li> </ul>
Important potential risk(s)	<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 risk***

<b>Important Identified Risk – Bleeding</b>	
<b>Risk minimisation measures</b>	<u>Routine risk minimisation measures:</u> <b>SmPC:</b> <ul style="list-style-type: none"> <li>• Section 4.2: Posology and method of administration</li> <li>• Section 4.3: Contraindications</li> <li>• Section 4.4: Special warnings and precautions for use</li> </ul>

<b>Important Identified Risk – Bleeding</b>	
	<ul style="list-style-type: none"><li>• Section 4.5: Interaction with other medicinal products and other forms of interaction</li><li>• Section 4.8: Undesirable effects</li><li>• Section 4.9: Overdose</li><li>• Section 5.1: Pharmacodynamic properties</li><li>• Section 5.3: Preclinical safety data</li></ul> <p><b>PL:</b></p> <ul style="list-style-type: none"><li>• Section 2: What you need to know before you take Apixaban Glenmark</li><li>• Section 3: How to take Apixaban Glenmark</li><li>• Section 4: Possible side effects</li></ul> <p><u>Additional risk minimisation measures:</u></p> <ul style="list-style-type: none"><li>• Patient Card</li></ul>

### ***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 Glenmark 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 Glenmark 2.5 mg and 5 mg film-coated tablets.