

Part VI: Summary of the risk management plan

Summary of risk management plan for [Product Name] 2.5 mg/5 mg/7.5 mg/10 mg/15 mg/ 20 mg/25 mg hard capsules (lenalidomide)

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

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

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

I. The medicine and what it is used for

Lenalidomide is authorised for multiple myeloma (see SmPC for the full indication). It contains lenalidomide 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 Lenalidomide, together with measures to minimise such risks and the proposed studies for learning more about Lenalidomide'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.

In the case of Lenalidomide, 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 PSUR assessment, 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 Lenalidomide is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Lenalidomide 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 Lenalidomide. 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	<ul style="list-style-type: none"> • Teratogenicity • Serious infection due to neutropenia • SPM (Second primary malignancies) • Important Identified Risk related to indication/target population <p>For MCL (mantle cell lymphoma)* and FL (follicular lymphoma): TFR (Tumor Flare Reaction)</p> <p>* this indication will be carved-out from the marketed SmPC/PIL until the expiry of the respective indication patent</p>
Important potential risks	<ul style="list-style-type: none"> • Cardiac failure • Cardiac arrhythmias • Ischaemic heart disease (including myocardial infarction) • Off-label use
Missing information	<ul style="list-style-type: none"> • None

II.B Summary of important risks

Important identified risk: Teratogenicity	
Risk minimisation measures	<p>Routine risk minimisation measures:</p> <p>Covered under the following section of SmPC: 4.3, 4.4, 4.6, 4.8, 5.3.</p> <p>Advice to patients in PL.</p> <p>Other routine risk minimisation measures:</p> <p>Prescription only medicine.</p> <p><u>Additional risk minimisation measure(s):</u></p> <p><u>Main Additional Risk Minimisation Measures:</u></p> <ul style="list-style-type: none"> • <u>Educational Programme for HCPs (physicians and pharmacists) and patients</u> • <u>Therapy management</u> • <u>Prescribing controls</u> • <u>Dispensing controls</u> • <u>Assessment</u>

Important identified risk: Teratogenicity	
	<p>PPP (Pregnancy Prevention Programme)</p> <p>Educational Programme: (HCP kit, Treatment algorithm, pregnancy reporting form, patient card, patient brochure and checklists)</p> <ul style="list-style-type: none"> ➤ Brochure for male patients. <p>Therapy management (Criteria for determining women of childbearing potential, Contraceptive measures and pregnancy testing for women of childbearing potential, Advice in SmPC & Package Leaflet, and educational materials).</p> <p>Patient Card (to document childbearing status, counselling and pregnancy testing).</p>
Additional pharmacovigilance activities	<p>Additional pharmacovigilance activities:</p> <p>In respect to pregnancy, a specific pregnancy report form is provided with each HCP Kit to optimise data collection and reporting of pregnancies.</p>

Important Identified risk: SPM (Second primary malignancies)	
Risk minimisation measures	<p>Routine risk minimisation measures:</p> <p>Covered under the following section of SmPC: 4.4, 4.8.</p> <p>Advice to patients provided in PL.</p> <p>Other routine risk minimisation measures:</p> <p>Prescription only medicine.</p> <p>Additional risk minimisation measure(s):</p> <p>HCP Kit (HCP Brochure).</p>

Important Identified risk related to indication/target population: For MCL (mantle cell lymphoma)* and FL (follicular lymphoma): TFR (Tumor Flare Reaction)	
* this indication will be carved-out from the marketed SmPC/PIL until the expiry of the respective indication patent	
Risk minimisation measures	<p>Routine risk minimisation measures:</p> <p>Covered under the following section of SmPC: 4.4, 4.8.</p> <p>Advice to patients provided in PL.</p>

Important Identified risk related to indication/target population: For MCL (mantle cell lymphoma)* and FL (follicular lymphoma): TFR (Tumor Flare Reaction)	
* this indication will be carved-out from the marketed SmPC/PIL until the expiry of the respective indication patent	
	Other routine risk minimisation measures: Prescription only medicine.
	Additional risk minimisation measure(s): HCP Kit (HCP Guide).

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 Lenalidomide.

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

There are no studies required for Lenalidomide.