13 Part VI: Summary of the risk management plan (RMP) – Lenalidomide, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg, hard capsules

This is a summary of the RMP for Lenalidomide, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg, hard capsules. The RMP details important risks of Lenalidomide hard capsules, how these risks can be minimized, and how more information will be obtained about Lenalidomide hard capsules' risks and uncertainties (missing information).

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

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

13.1 Part VI: I. The medicine and what it is used for

Multiple myeloma

Lenalidomide as monotherapy is indicated for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation (ASCT).

Lenalidomide as combination therapy with dexamethasone, or bortezomib and dexamethasone, or melphalan and prednisone is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.

Lenalidomide in combination with dexamethasone is indicated for the treatment of multiple myeloma in adult patients who have received at least one prior therapy.

Follicular lymphoma (FL)

Lenalidomide in combination with rituximab (anti-CD20 antibody) is indicated for the treatment of adult patients with previously treatment FL (grade 1 - 3a).

It contains Lenalidomide as the active substance and is taken orally as hard capsules (2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg).

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Lenalidomide hard capsules, together with measures to minimize such risks are outlined below.

Measures to minimize 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 HCPs;
- Important advice on the medicine’s packaging;

- The authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In the case of Lenalidomide hard capsules, these measures are supplemented with *additional risk minimization measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report (PSUR) assessment (if applicable) so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks for Lenalidomide hard capsules are risks that need special risk management activities to further investigate or minimize 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 hard capsules. 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).

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	Second primary malignancies
	Serious infection due to neutropenia
	Teratogenicity
	Tumor flare reaction*
Important potential risks	Cardiac arrhythmias
	Cardiac failure
	Ischemic heart disease (including Myocardial infarction)
	Off label use
Missing information	None

* Applicable for FL indication only

13.2.2 Part VI – II.B: Summary of important risks

The safety information in the proposed Product Information is aligned to the originator product.

Table 13-4 Important identified risk: Tumor flare reaction*

Risk minimization measures	**Routine risk minimization measures:** SmPC section 4.2, 4.4 and 4.8 Legal status: Prescription only

	Additional risk minimization measures: • HCP's kit * Applicable for FL indication only

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Lenalidomide hard capsules.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for Lenalidomide hard capsules.