PART VI Summary of the risk management plan

Summary of risk management plan for Lenalidomide-Grindeks (lenalidomide)

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

Summary of product characteristics (SPC) of **Lenalidomide-Grindeks** and its package leaflet give essential information to healthcare professionals and patients on how **Lenalidomide-Grindeks** should be used.

I. The medicine and what it is used for

Lenalidomide-Grindeks is authorised for treatment of multiple myeloma (see SPC for the full indication). It contains lenalidomide as the active substance and it is given orally as hard capsules; each capsule may contain 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg or 25 mg of lenalidomide.

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

Important risks of **Lenalidomide-Grindeks**, together with measures to minimise such risks and the proposed studies for learning more about risks of **Lenalidomide-Grindeks**, 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 SPC 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-Grindeks**, 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-Grindeks** is not yet available, it is listed under 'missing information' below.

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

Important risks of **Lenalidomide-Grindeks** are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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-Grindeks**. 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	Teratogenicity Serious Infecton due to Neutropenia SPM
Important potential risks	Cardiac failure Cardiac arrhythmias Ischaemic heart disease (including myocardial infarction) Off-label use
Missing information	None

II.B *Summary of important risks*

Important identified risks

Important identified risk - Teratogenicity	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.4, 4.6, 4.8 and 5.3. Specific pregnancy reporting form. Medicinal product subject to restricted medical prescription. Additional risk minimisation measures: Pregnancy Prevention Program (PPP). Educational material o HCP kit o Patient card, patient brochure and checklists. Therapy management o Criteria for determining women of childbearing potential, contraceptive measures and pregnancy testing for women of childbearing potential o Advice in SPC, educational materials. Patient card to document childbearing status, counselling and pregnancy testing.
Additional pharmacovigilance activities	Additional pharmacovigilance activities: Additional monitoring of implementation of Pregnancy Prevention Programme on a country specific basis in accordance with local legal framework and with agreement of the relevant NCA.
Important identified risk - Neutropenia and Infection	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.2, 4.4 and 4.8; PIL part 2 and 4. Medicinal product subject to restricted medical prescription. Additional risk minimisation measures: None.
Important identified risk - SPM	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.4 and 4.8; PIL part 4. Medicinal product subject to restricted medical prescription. Additional risk minimisation measures: HCP Brochure.

Important potential risks	**Important potential risk - Cardiac Failure and Cardiac Arrhythmias**
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.8; PIL part 2 and 4. Medicinal product subject to restricted medical prescription. Additional risk minimisation measures: None.
Important potential risk - Ischaemic Heart Disease (including myocardial infarction)	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.4 and 4.8. Medicinal product subject to restricted medical prescription. Additional risk minimisation measures: None.
Important potential risk - Off-label Use	
Risk minimisation measures	Routine risk minimisation measures: SPC section 4.4 Medicinal product subject to restricted medical prescription. Additional risk minimisation measures: None.
Additional pharmacovigilance activities	Additional pharmacovigilance activities: Off-label use will be tracked as part of evaluation of the effectiveness of Pregnancy Prevention Pogramme.

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 the Applicant's Lenalidomide.

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

There are no studies required for Lenalidomide-Grindeks.