# Part VI: Summary of the risk management plan

## Summary of risk management plan for

Pomalidomide Grindeks

(pomalidomide)

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

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

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

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

Pomalidomide Grindeks in combination with bortezomib and dexamethasone is indicated in the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide and in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.
It contains pomalidomide as the active substance and it is given by oral route of administration in concentration of 1 mg, 2 mg, 3 mg or 4 mg per hard capsule.

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

Important risks of Pomalidomide Grindeks, together with measures to minimise such risks and the proposed studies for learning more about risks of Pomalidomide 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 Pomalidomide 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*.

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

Important risks of Pomalidomide 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 Pomalidomide 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).

| **Summary of safety concerns** | |
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| **Important identified risks** | *Teratogenicity*<br>*Serious Infection due to neutropenia and pancytopenia*<br>*Thrombocytopenia and bleeding*<br>*Cardiac failure*<br>*Non-melanoma skin cancer* |
| **Important potential risks** | *Other second primary malignancies*<br>*Cardiac arrhythmia* |
| **Missing information** | *None* |

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

| **Important identified risk - Teratogenicity** | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>SPC section 4.3, 4.4, 4.6, 4.8 and 5.3.<br>PL 2 and 4.<br>Medicinal product subject to restricted medical prescription.<br>Pack size.<br>Additional risk minimisation measures:<br>Pregnancy Prevention Program (PPP);<br><br>Educational Programme<br>• HCP's kit which includes educational HCP brochure, educational brochures for patients, patient card, risk awareness forms, and information on where to find latest SmPC.<br><br>Therapy management:<br>• Criteria for determining women of childbearing potential, contraceptive measures and pregnancy testing for women of childbearing potential;<br>• Advice in SPC and educational materials.<br><br>System to ensure appropriate measures have been completed:<br>• Patient card to document childbearing status, counselling and pregnancy testing. |
| Additional pharmacovigilance activities | Additional pharmacovigilance activities:<br>The monitoring of the PPP will be implemented as Category 3 study. |
| **Important identified risk - Serious Infection due to neutropenia and pancytropenia** | |
| Risk minimisation measures | Routine risk minimisation measures:<br>SPC section 4.2, 4.4 and 4.8.<br>PL part 2 and 4.<br>Medicinal product subject to restricted medical prescription.<br>Pack size.<br>Additional risk minimisation measures:<br>None. |
| **Important identified risk – Thrombocytopenia and Bleeding** | |
| Risk minimisation measures | Routine risk minimisation measures:<br>SPC section 4.2, 4.4 and 4.8.<br>PL part 4.<br>Medicinal product subject to restricted medical prescription. |

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| | Pack size.<br>Additional risk minimisation measures:<br>HCP Brochure.<br>Patient brochure. |
| **Important identified risk - Cardiac Failure** | |
| Risk minimisation measures | Routine risk minimisation measures:<br>SPC section 4.4 and 4.8.<br>PL part 2 and 4.<br>Medicinal product subject to restricted medical prescription.<br>Pack size.<br>Additional risk minimisation measures:<br>HCP brochure. |
| **Important identified risk - Non-melanoma Skin Cancer** | |
| Risk minimisation measures | Routine risk minimisation measures:<br>SPC section 4.4 and 4.8.<br>PL part 4.<br>Medicinal product subject to restricted medical prescription.<br>Pack size.<br>Additional risk minimisation measures:<br>None. |
| **Important potential risk - Other Second Primary Malignancies** | |
| Risk minimisation measures | Routine risk minimisation measures:<br>SPC section 4.4<br>PL part 4.<br>Medicinal product subject to restricted medical prescription.<br>Pack size.<br>Additional risk minimisation measures:<br>None. |
| **Important potential risk - Cardiac Arrhythmia** | |
| Risk minimisation measures | Routine risk minimisation measures:<br>SPC section 4.8.<br>PL part 4.<br>Medicinal product subject to restricted medical prescription.<br>Pack size.<br>Additional risk minimisation measures:<br>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 Pomalidomide Grindeks.

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

**Study short name:** Pregnancy Prevention Programme Implementation.

**Purpose of the study**: to evaluate the effectiveness of the PPP in order to ensure that all reasonable steps are being taken to reduce the risk of pregnancy in patients treated with Pomalidomide Grindeks.