Swiss Summary of the Risk Management Plan (RMP) for Ixazomib citrate [Ninlaro®]

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Based on EU RMP version 7

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risk as well as to prevent or minimize them.

The RMP summary of NINLARO® is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of NINLARO® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. Takeda Pharma AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of NINLARO®.

Summary of risk management plan and what it is used for

This is a summary of the RMP for NINLARO®. The RMP details important risks of NINLARO® and how more information will be obtained about NINLARO®'s risks and uncertainties (missing information).

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

This summary of the RMP for NINLARO® should be read in context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones are included in updates of NINLARO®'s RMP.

Currently, there are no important risks and missing information for NINLARO®.

I. The medicine and what it is used for

NINLARO® in combination with lenalidomide and dexamethasone is authorized for the treatment of adult patients with multiple myeloma (MM) who have received at least one prior therapy (see SmPC for the full indication). It contains ixazomib citrate as the active substance. The recommended dose of 4 mg is administered orally once a week on days 1, 8, and 15 of a 28-day treatment cycle in combination with lenalidomide and dexamethasone.

Further information about the evaluation of NINLARO®'s benefits can be found in NINLARO® EPAR, including in its plain-language summary, available on the EMA website under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/ninlaro#overview-section .

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Measures to minimize 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 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 addition to these measures, information about adverse reactions is collected continuously and regularly analyzed including Periodic Safety Update Report (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 NINLARO® is not yet available, it is listed under "missing information" below.

II.A. List of Important Risks and Missing Information

Important risks of NINLARO® are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be taken safely. 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 NINLARO®. 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).

Currently, there are no important risks or missing information for NINLARO®.

II.B. Summary of important risks

No important risks or missing information.

II.C Post – authorization development plan

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

C16019
Purpose of the study: To continue to follow for OS/PFS2 – time from the date of randomization to the date of first documentation of disease progression on subsequent line of anticancer therapy or death from any cause, whichever occurs first (efficacy objective)

NSMM-5001
Purpose of the study: To provide real life-descriptive data on patterns of treatment and outcomes (efficacy objective)

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

There are no other studies required for NINLARO®.