Part VI: Summary of the risk management plan

Summary of risk management plan for NINLARO (ixazomib citrate)

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 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 the 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 MM who have received at least one prior therapy (see SmPC for the full indication). It contains ixazomib citrate as the active substance and it is given in 4 mg doses, 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's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003844/human_med_001998.jsp&mid=WC0b01ac058001d124.

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 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 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

Not applicable.

II.C. Post-authorization development plan

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

There are no studies which are conditions of the marketing authorisation or specific obligation of ixazomib.

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

There are no other studies required for NINLARO.