Swiss Summary of the Risk Management Plan (RMP)

for NEMLUVIO (Nemolizumab)

Based on the EU-RMP NEMLUVIO® (Nemolizumab) version 2.0
dated 18-Dec-2024, with Data Lock Point 21-Jul-2023

Active substance(s) (INN or common name):	Nemolizumab
Product(s) concerned (brand name(s)):	NEMLUVIO®
Name of Marketing Authorisation Holder or Applicant:	GALDERMA SA Zählerweg 10, 6300 Zug, Switzerland
Swiss Summary RMP Version	1.0
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Disclaimer:

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 risks as well as to prevent or minimise them. The Swiss RMP summary of NEMLUVIO® (nemolizumab) 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 NEMLUVIO® (nemolizumab) in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. Galderma SA is fully responsible for the accuracy and correctness of the content of the published summary RMP of NEMLUVIO®.

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Part VI: Summary of the Risk Management Plan

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

NEMLUVIO's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how NEMLUVIO should be used.

This summary of the RMP for NEMLUVIO 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), which can be found on the EMA website:

https://www.ema.europa.eu/en/medicines/human/EPAR/nemluvio

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

I. The Medicine and What it is used for

NEMLUVIO is indicated for the:

- Treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older who are candidates for systemic therapy.
- Treatment of adults with moderate-to-severe prurigo nodularis who are candidates for systemic therapy.

Atopic Dermatitis

Atopic Dermatitis (AD) is a chronic disease of skin barrier dysfunction and immune responses to bacterial and environmental antigens and allergens, with principal features of eczematous lesions and pruritus characterized by recurring cycles of exacerbation and remission.

Prurigo Nodularis

Prurigo Nodularis (PN) is an under-recognized inflammatory skin condition characterized by intensely itchy nodules. This condition is characterized by the presence of multiple (up to hundreds), symmetrically distributed, highly pruritic, hyperkeratotic, erosive or crusted nodules and papules. Chronic itching is believed to induce and maintain the characteristic PN skin lesions through an itch-scratch cycle. This leads to an impaired Quality of Life (QOL) due to severe itch and chronic skin lesions with a lack of treatment options.

See SmPC for the full indications.

NEMLUVIO contains nemolizumab as the active substance and it is given by subcutaneous (SC) injection.

Further information about the evaluation of NEMLUVIO's benefits can be found in NEMLUVIO's 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/nemluvio.

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

Important risks of NEMLUVIO together with measures to minimize such risks and the proposed studies for learning more about NEMLUVIO's 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 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.

If important information that may affect the safe use of NEMLUVIO is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of NEMLUVIO are risks that need special risk management activities to further investigate or minimize 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 NEMLUVIO.

- Potential risks are concerns for which an association with the use of NEMLUVIO 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 NEMLUVIO 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	None
Important potential risks	None
Missing information	Use in pregnancy Long term safety beyond 1 year of treatment with nemolizumab

II.B Summary of important risks

Important identified risks: None	
Evidence for linking the risk to the medicine	Not applicable
Risk minimisation measures	Not applicable
Additional pharmacovigilance activities	Not applicable

Important potential risks: None	
Evidence for linking the risk to the medicine	Not applicable
Risk minimisation measures	Not applicable
Additional pharmacovigilance activities	Not applicable

Missing Information: Use in Pregnancy	
Risk Minimization Measures	**Routine Risk Minimization Measures:** SmPC sections 4.6 and 5.3 PIL section 2 Prescription only medicine **Additional Risk Minimization Measures:** None
Additional Pharmacovigilance Activities	**Additional Pharmacovigilance Activities:** Observational PASS in Pregnancy: A Study of Pregnancy and Infant Outcomes in Patients Exposed to Nemolizumab During

	Pregnancy: A Retrospective Observational Study Based on Healthcare Database(s) See Section II.C of this summary for an overview of the post-authorisation development plan.
Missing Information: Long-term Safety beyond 1 year of treatment with nemolizumab	
Risk Minimization Measures	**Routine Risk Minimization Measures:** None **Additional Risk Minimization Measures:** None
Additional Pharmacovigilance Activities	**Additional Pharmacovigilance Activities:** A Phase 3, Prospective, Multicenter, Long-Term Study to Assess the Safety and Efficacy of Nemolizumab (CD14152) in Subjects with Moderate-to-Severe Atopic Dermatitis – ARCADIA LTE (RD.06.SPR.118163) and A Phase 3, Prospective, Multicenter, Long-Term Study to Assess the Safety and Efficacy of Nemolizumab (CD14152) in Subjects with Prurigo Nodularis – OLYMPIA LTE (RD.06.SPR.202699)

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 NEMLUVIO.

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

One PASS is currently planned. Its details are included below.

Planned PASS

Study short name:

Observational PASS of nemolizumab use in pregnancy.

A Study of Pregnancy and Infant Outcomes in Patients Exposed to Nemolizumab During Pregnancy: A Retrospective Observational Study Based on Healthcare Database(s).

Purpose of the study:

No experimental data indicate reproductive toxicity of nemolizumab, but the available evidence is currently insufficient to draw conclusions about the safety of using nemolizumab during pregnancy.

The study will investigate whether maternal exposure to nemolizumab during pregnancy is associated with an increased risk of major congenital malformations, preterm births, infants born small for gestational age, spontaneous abortion, or stillbirths.