Nemluvio

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type II / EMA/VR/0000309230	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the	23/04/2026	28/05/2026	SmPC	This variation concerned the update of sections 4.2 and 5.1 of the SmPC based on final results from study SPR.203890; this was a double-blind, placebo

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

	Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.2 and 5.1 of the SmPC based on final results from study SPR.203890; this was a double-blind, placebo controlled, randomized study to assess the durability of effect and safety of nemolizumab for 24 weeks in subjects with prurigo nodularis.				controlled, randomized study to assess the durability of effect and safety of nemolizumab for 24 weeks in subjects with prurigo nodularis. Section 4.2 of the SmPC states that nemolizumab treatment can be continued to maintain a therapeutic response, and section 5.1 of the SmPC briefly describes the key results of this durability study, namely that the subjects who continued nemolizumab had a lower risk of relapse than those randomised to placebo at week 24, respectively 16.7% (3 out of 18 subjects) and 75.0% (12 out of 16 subjects). For more information, please refer to the Summary of Product Characteristics.
Variation type II / EMA/VR/0000307084	Outcome: This was an application for a group of variations. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Grouping of 2 type II variations, as follows: C.I.4: Update of sections 4.4 and 4.5 of the	10/04/2026	28/05/2026	SmPC	The MAH submitted a full Drug-Drug Interaction (DDI) study CSR results, which evaluated the effect of Nemluvio on the PK of several drugs representative of cytochrome P450 (CYP450) substrates in adult subjects with moderate-to-severe atopic dermatitis. This study was already considered as part of the initial submission with initial results; the current submission did not result in PI update. The second part of the variation relates to an update of Nemluvio SmPC pertaining to the concurrent administration of inactivated or non-live vaccines. Results of the final analysis of data from a clinical study with vaccines were provided. A statement regarding the concomitant administration of inactivated or non-live vaccines during nemolizumab treatment was included in the SmPC section 4.4. Section 4.5 was updated with a short description of this study, performed in adult

	SmPC in order to update warning regarding concurrent use of non-live vaccines, based on results from the vaccine study (SPR.118380): this is a Phase 2 randomized, double-blind, placebo-controlled study to assess immunization responses in adult and adolescent subjects with moderate-to-severe atopic dermatitis treated with nemolizumab. C.I.13: Submission of DDI study CSR (SPR.201593): this is a Phase 2 open-label drug-drug interaction study to assess the effects of nemolizumab on cytochrome P450 substrates in subjects with moderate-to severe atopic dermatitis.				and adolescent patients with atopic dermatitis. For more information, please refer to the Summary of Product Characteristics.
Variation type IA / EMA/VR/0000322349	Outcome: A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted	20/01/2026			
PSUR / EMA/PSUR/0000282252	EURD: PSUSA/00011111/202503 Active substance: nemolizumab Outcome: Variation In view of available data on Bullous Pemphigoid (BP) from the literature, spontaneous reports and clinical trial(s), including • at least 12 possible cases of	13/11/2025	08/01/2026	SmPC and PL	Variation

	BP with close temporal relationship, confirmed BP diagnosis and recovery (with treatment) following withdrawal; •and 2 probable literature cases with a close temporal relationship, confirmed BP diagnosis and recovery (with treatment) following withdrawal, without reoccurrence of BP after withdrawal, supportive anti-BP 180 data and excluding the influence of most confounding factors; • although the potential mechanism of the AE remains to be elucidated; the PRAC considers a causal relationship between nemolizumab and Bullous Pemphigoid is at least a reasonable possibility. The PRAC concluded that the product information of products containing nemolizumab should be amended accordingly.				
Variation type IA_IN / EMA/VR/0000310765	Outcome: B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted	10/11/2025	08/01/2026	Annex II and PL	
Variation type IA / EMA/VR/0000306885	Outcome: This was an application for a group of variations. B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished	20/10/2025			

	product - B.II.b.1.a Secondary packaging site - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted				
Variation type IB / EMA/VR/0000296279	Outcome: This was an application for a group of variations. B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.c Deletion of a non-significant in-process test - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted	16/10/2025			
Variation type IB / EMA/VR/0000281966	Outcome: B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological	29/07/2025	08/01/2026	SmPC	

	medicinal product in accordance with an approved stability protocol - Accepted				
Variation type IA / EMA/VR/0000288003	Outcome: A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted	25/07/2025			
Variation type IB / EMA/VR/0000278836	Outcome: C.I.7 Deletion of: - C.I.7.a a pharmaceutical form - Accepted C.I.7.a - To delete the pharmaceutical form powder and solvent for solution for injection in pre-filled syringe from the Nemluvio marketing authorisation (EU/1/24/1901/004). The Annexes are updated accordingly. Additionally, the MAH took the opportunity to amend section 4.8 of the SmPC with information on worsening of asthma and superficial fungal infections, as requested by the Rapporteur, and made editorial changes to the PI in DK, DE, FI, IT, NO, PL, and SE to implement changes that were not implemented during previous linguistic review and to correct for typographical errors. Furthermore, the MAH	17/07/2025	08/01/2026	SmPC, Labelling and PL	

	took the opportunity to update the list of local representatives for BG, CZ, EE, GR, FR, HR, CY, LV, LT, HU, MT, RO, SI and SK in section 6 of the PL.				
Variation type IA_IN / EMA/VR/0000253858	Outcome: B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted	05/03/2025			
PSUR / EMA/PSUR/0000321530	EURD: PSUSA/00011111/202509 Active substance: nemolizumab Outcome: Maintenance	07/05/2026			Maintenance