Neupro

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
Article 61(3) /	- Notification acc. Article 61(3) - Accepted	07/04/2026		PL	

[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).

EMA/N/0000339937	Update of the package leaflet with revised contact details of local representatives.				
Variation type IA / EMA/VR/0000323972	B.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.b Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State - Accepted	02/02/2026			
Variation type IB / EMA/VR/0000264952	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.c) Control of excipients - B.II.c.z Other variation - Accepted	26/06/2025			
Variation type IA / EMA/VR/0000274188	This was an application for a group of variations. B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the	23/05/2025			

	manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted				
Article 61(3) / EMA/N/0000268621	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representative.	08/05/2025		PL	
Variation type IB / EMA/VR/0000246291	B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted	27/02/2025			
Variation type IA_IN / EMA/VR/0000252587	This was an application for a group of variations. B.II.a.3.a Changes in components of the flavouring or colouring system - B.II.a.3.a.1 Addition , deletion or replacement - Accepted B.II.a.3.a Changes in components of the flavouring or colouring system - B.II.a.3.a.1 Addition , deletion or replacement - Accepted	18/02/2025		SmPC, Labelling and PL	