



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Nerlynx

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, please 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 IB / | C.I HUMAN AND VETERINARY MEDICINAL | 22/05/2025 | | SmPC and 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/VR/0000265110 | <p>PRODUCTS - C.I.z Other variation - Accepted</p> <p>C.I.z – To update sections 1, 2, 3 and 4 of the PL to ensure alignment of the information with the approved sections of the SmPC, as well as to add some key information to improve understanding by the patients. In addition, some linguistic improvements have been included in the French translation of the PI and the date of latest renewal has been included in section 9 of the SmPC.</p> | | | | |
|-------------------|--|--|--|--|--|