



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Lacosamide UCB

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 IA_IN /	B.IV.1.a Addition or replacement of a device	16/05/2025	N/A		

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/0000265278	which is not an integrated part of the primary packaging - B.IV.1.a.1 Device with CE marking - Accepted				
Variation type IB / EMA/VR/0000266348	<p>C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted</p> <p>C.I.z - to align the English Product Information with latest QRD templates (10.3 and 10.4). Thus, section 9 and 10 of the SmPC were updated. Minor editing errors were amended in Annex II and in the Labelling and minor inaccurate information was removed from the Package Leaflet. The MAH took the opportunity to update the contact details of the local representative for Iceland in section 6 of the Package Leaflet. According to QRD 10.4, contact details for UK (NI) were deleted. Furthermore, updates in all EU languages were performed with additional minor linguistic adjustments in BG, HR, CS, NL, ET, FR, DE, HU, IT, LV, LT, MT, PL, SK, SL, ES and SV annexes.</p>	12/05/2025		SmPC, Annex II, Labelling and PL	
Variation type IA / EMA/VR/0000248925	<p>B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted</p> <p>B.I.b.2 Change in test procedure for active</p>	07/03/2025	N/A		

	<p>substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted</p> <p>A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Refused</p> <p>A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted</p>				
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