



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Lacosamide UCB

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
R/0020	Renewal of the marketing authorisation.	22/02/2024	05/04/2024		
IB/0019	B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking	19/01/2024	05/04/2024	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).



IA/0021	A.7 - Administrative change - Deletion of manufacturing sites	08/12/2023	n/a		
WS/2515	<p>This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>Submission of an updated RMP version 17.0 in order to introduce new updates including the removal of category 3 study EP0158 due to study closure by lack of enrolment, and the removal of category 3 studies (SP848 and EP0034).</p> <p>C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required</p>	26/10/2023	n/a		
IB/0017/G	<p>This was an application for a group of variations.</p> <p>B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size</p> <p>B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate</p>	08/02/2023	n/a		

	B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer				
N/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/12/2022	05/04/2024	Labelling and PL	
IB/0015/G	This was an application for a group of variations. B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition) B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	06/10/2022	n/a		
PSUSA/1816/202108	Periodic Safety Update EU Single assessment - lacosamide	22/04/2022	14/06/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s) for PSUSA/1816/202108.
WS/2049/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening	27/01/2022	24/02/2022	SmPC, Labelling and PL	

	(supported by real time data) C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IB/0013	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	01/12/2021	n/a		
IG/1447/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	18/10/2021	n/a		
IG/1416	B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	11/08/2021	n/a		
WS/2066	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of section 4.8 of the SmPC in order to add dyskinesia to the list of adverse drug reactions	10/06/2021	24/02/2022	SmPC, Labelling and PL	The available data indicate a possible association between dyskinesia and treatment with lacosamide although the number of assessable cases is low. Section 4.8 of the SmPC is being updated to add dyskinesia as an uncommon adverse reaction. For more information, please refer to the Summary of

	<p>(ADRs) with frequency uncommon following the outcome of continuous safety signal assessments of the relevant reported clinical and post-marketing cases. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in the PI, to bring it in line with the latest QRD template version 10.2 and relevant guidelines and to update the details of the UK local representative in the PL.</p> <p>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data</p>				Product Characteristics.
WS/1782	<p>This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>Extension of Indication to include the treatment as adjunctive therapy of primary generalised tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalised epilepsy for Lacosamide UCB and Vimpat.</p> <p>Consequently sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. The RMP version 15.1 has also been submitted.</p> <p>Furthermore, the PI is brought in line with the latest QRD template version 10.1. The MAH also takes the opportunity to align the PI of Lacosamide UCB with the PI of Vimpat.</p>	15/10/2020	24/11/2020	SmPC and PL	Please refer to Scientific Discussion Vimpat-H-C-WS1782 and Lacosamide UCB-H-C-WS1782

	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IG/1251	A.7 - Administrative change - Deletion of manufacturing sites	07/05/2020	n/a		
IB/0007	B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test	30/04/2020	n/a		
WS/1748	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	16/01/2020	n/a		
IB/0005/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.z - Change in the specification parameters	13/01/2020	n/a		

	and/or limits of an AS, starting material/intermediate/reagent - Other variation				
IG/1177	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	17/12/2019	n/a		
IG/1162	B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	13/11/2019	n/a		
IG/1151	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	29/10/2019	n/a		