Pregabalin Accord

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.11 Introduction of, or change(s) to, the	27/01/2025	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/0000238644	obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.11.z (IB) - To provide a revised RMP version to remove the important identified risk "Abuse and drug dependence" in line with the reference product.				
Variation type IA / EMA/VR/0000245344	B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.a Up to 10-fold compared to the originally approved batch size - Accepted	21/01/2025			
Variation type IA_IN / EMA/VR/0000234970	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 product - B.II.b.1.a Secondary packaging site - Accepted B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.2 Including batch control/testing - Accepted	31/10/2024		Annex II and PL	
Variation type IA_IN / EMA/VR/0000229762	This was an application for a group of variations.	08/10/2024	N/A		

	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.b Primary packaging site - Refused 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 - Refused				
Variation type IB / EMA/VR/0000221271	C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted To update the SmPC sections 4.4 and 4.8 and section 3 in the PIL with "suicidal ideation" as part of the observed withdrawal symptoms.	28/08/2024		SmPC and PL	
Variation type IB / EMA/VR/0000174437	C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template	20/05/2024	N/A		

	change) - Accepted To provide an updated RMP to align with the EPAR RMP summary available for the reference product Lyrica; in particular, to remove 'Pregnancy and Lactating women' from the missing information in the Summary of safety concerns. In addition, the marketing authorization holder has taken the opportunity to implement minor editorial changes in Annex IV.				
Variation type IA / EMA/VR/0000165859	This was an application for a group of variations. B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted	24/01/2024	N/A		