Levetiracetam SUN

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
Variation type IA_IN /	C.I.3 Change(s) in the Summary of Product	22/12/2025		SmPC and PL	To update Section 4.6 of the SmPC and Section 2 of

[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/0000317912	Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.a Implementation of wording agreed by the competent authority - Accepted				the PL to implement the wording agreed by the PRAC following the outcome of the PSUR procedure EMA/PSUR/0000257824 with more recent information on the risk of neurodevelopmental disorders in children exposed prenatally to levetiracetam.
Variation type IB / EMA/VR/0000265264	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 C.I.2.a - To update section 4.8 of the SmPC to include additional information on signs and symptoms of Drug Reactions with Eosinophilia and Systemic Symptoms (DRESS), based on a safety review, following assessment of the same change for the reference product Keppra (EMEA/H/C/WS2722). Section 4 of the PL is updated accordingly. In addition, the MAH made linguistic corrections to the SmPC in Polish language, to align with approved changes in the reference product.	02/05/2025		SmPC and PL	To update section 4.8 of the SmPC to include additional information on signs and symptoms of Drug Reactions with Eosinophilia and Systemic Symptoms (DRESS), based on a safety review, following assessment of the same change for the reference product Keppra (EMEA/H/C/WS2722). Section 4 of the PL is updated accordingly

Article 61(3) / EMA/N/0000239226	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised details of local representatives, and to delete United Kingdom (Northern Ireland) from the list of local representatives to comply with the Windsor Framework for labelling and packaging of medicines (QRD template 10.4). Additionally, the MAH took the opportunity to include minor editorial and formatting changes in some of the translations to align with the EN PI and QRD template 10.4.	18/12/2024		PL	
Variation type IA_IN / EMA/VR/0000231943	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	22/10/2024	N/A		
Variation type IA / EMA/VR/0000228680	This was an application for a group of variations. 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	19/09/2024	N/A		

	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Refused				