Levetiracetam Hospira

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 IB /	C.I.2 Change(s) in the Summary of Product	12/12/2025		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/0000315806	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 (Type IB) – To update Section 4.6 of the SmPC and Section 2 of the Package Leaflet to include the risk of neurodevelopmental disorders in children exposed prenatally to levetiracetam based on data from observational population-based registry studies. The change follows approval of the same change for the reference product Keppra. In addition, the MAH took the opportunity to implement editorial changes by updating the contact details of the local representative for MT in the Package Leaflet and correcting typographical errors in the EN and HR Product Information in alignment with the reference product.				the Package Leaflet to include the risk of neurodevelopmental disorders in children exposed prenatally to levetiracetam based on data from observational population-based registry studies. The change follows approval of the same change for the reference product Keppra.
Variation type IB / EMA/VR/0000307337	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	31/10/2025		SmPC and PL	

	C.I.2.a - to update section 4.4 of the SmPC and section 2 of the Package Leaflet the existing information on sodium content to add the sodium quantity expressed as 'mmol' per maximum single dose and per vial and other minor rewording of the statements in alignment with the Keppra innovator label 100 mg/ml concentrate for solution for infusion. In addition, in section 4.8 of the SmPC, The MAH corrected the order of the existing 'Renal and urinary disorders' SOC with ADR 'Acute kidney injury' within the ADR table following assessment of the same change for the innovator product Keppra. Furthermore, editorial changes are proposed for DE and EL Product Information to correct typographical errors.				
Variation type IA_IN / EMA/VR/0000278463	B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted	11/09/2025		Annex II and PL	
Variation type IB / EMA/VR/0000265760	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	12/05/2025		SmPC and PL	To update section 4.8 of the SmPC and section 4 of the package leaflet to include additional information on signs and symptoms of Drug reactions with Eosinophilia and Systemic Symptoms (DRESS), following assessment of the same change for the reference product Keppra.

	submitted by the MAH - Accepted C.I.2.a - To update section 4.8 of the SmPC and section 4 of the package leaflet to include additional information on signs and symptoms of Drug reactions with Eosinophilia and Systemic Symptoms (DRESS), following assessment of the same change for the reference product Keppra. Additionally, editorial changes have been made to the SK annexes to align with the EDQM and local innovator annex, as well as to the PL annexes in line with the local innovator annex. The MAH has also taken the opportunity to update the list of local representatives in the Package Leaflet for IE and DK, remove the UK (Northern Ireland), and align the PI with the latest QRD template version.				
Variation type IA_IN / EMA/VR/0000248565	This was an application for a group of variations. B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Other changes - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished	12/02/2025	N/A		

	product - B.II.b.1.a Secondary packaging site - Accepted				