Keppra

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
PSUR / EMA/PSUR/0000257824	- -	24/07/2025	13/10/2025	SmPC and PL	Variation

[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).

	In view of the available data from the observational population-based registry studies with more recent information on the risk of neurodevelopmental disorders in children exposed prenatally to levetiracetam, the PRAC concluded that the product information of products containing levetiracetam should be amended accordingly.				
Variation type IB / EMA/VR/0000267866	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.a Minor changes to an approved test procedure - Accepted	17/07/2025	N/A		
Variation type IB / EMA/VR/0000258385	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority ,	26/06/2025	13/10/2025	SmPC, Labelling and PL	

	e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon. - Accepted Type IB C.I.z - To update the Product Information in section 4.4 of the Summary of Product Characteristics and subsequent sections of the Package Leaflet and Labelling, to include additional information about the sodium content in line with European Commission guideline on "Excipients in the labelling and package leaflet of medicinal products for human use" and its Annex Rev.4. Furthermore, the MAH took the opportunity to implement editorial changes to the Product Information in alignment to the latest QRD template, and to update the list of local representatives in the Keppra Package Leaflet.				