Levetiracetam ratiopharm

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 /	This was an application for a variation	26/06/2025		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).

EMA/VR/0000256234	following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 Type IB C.I.2.a - Update of section 4.8 of the SmPC and section 4 of the PIL 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 (EMEA/H/C/WS2722). In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to introduce minor changes to the PI (also including a statement that "this medicine does not require any special storage conditions"), and to align with the latest QRD template.				
Variation type IB / EMA/VR/0000264411	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC)	19/06/2025	N/A		

	No 1234/2008. 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				
Variation type IA / EMA/VR/0000279708	B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted	17/06/2025	N/A		
Variation type IA / EMA/VR/0000261469	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.a Minor change in the manufacturing process - Accepted	25/03/2025	N/A		