



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Blitzima

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 group of	25/09/2025		SmPC	

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/0000290253	variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.3 After dilution or reconstitution (supported by real time data) - Accepted				
Variation type IB / EMA/VR/0000278117	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.z Other changes - Accepted	04/09/2025	N/A		
Variation type IA / EMA/VR/0000284450	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	11/07/2025	N/A		

	A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted				
Variation type IB / EMA/VR/0000244743	This was an application for a group of variations 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 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	19/06/2025		SmPC, Labelling and PL	To update sections 4.1, 4.2, 4.3, 4.8, 5.1, 6.2, 6.4 and 6.5 of the SmPC in order to introduce several structural and editorial changes to align with the current SmPC guideline and to remove the educational materials for HCPs and patients, following the request by the PRAC in the AR for the PSUSA procedure EMA/PRAC/257005/2023. The Annex II, Labelling and Package Leaflet are updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI in line with the same changes to the reference product. To update the RMP following the assessment of PSUR EMA/H/C/PSUSA/00002652/202311.

	change) - Accepted C.I.2.a To update sections 4.1, 4.2, 4.3, 4.8, 5.1, 6.2, 6.4 and 6.5 of the SmPC in order to introduce several structural and editorial changes to align with the current SmPC guideline and to remove the educational materials for HCPs and patients, following the request by the PRAC in the AR for the PSUSA procedure EMA/PRAC/257005/2023. The Annex II, Labelling and Package Leaflet are updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI in line with the same changes to the reference product. C.I.11.z To update the RMP following the assessment of PSUR EMEA/H/C/PSUSA/00002652/202311.				
Variation type IB / EMA/VR/0000258415	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.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted	22/05/2025		SmPC, Labelling and PL	
Variation type IA / EMA/VR/0000245595	A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active	03/02/2025		Annex II and	

	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			PL	
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