ANDEMBRY

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 II /	Outcome:	09/07/2026		SmPC and PL	Summary of SmPC amended sections: Section 4.4

[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/0000332416	C. Safety, efficacy, pharmacovigilance changes - C.4 Change(s) in the summary of product characteristics, labelling or package leaflet due to new quality, preclinical, clinical or pharmacovigilance data. - Accepted Update of sections 4.4 and 4.8 of the SmPC in order to update the existing warning on hypersensitivity reactions adding anaphylaxis and to add 'hypersensitivity' to the list of adverse drug reactions (ADRs) with frequency not known, based on a cumulative safety review and a signal evaluation. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI.				"Hypersensitivity reactions have been observed (see section 4.8). In case of severe hypersensitivity reactions, including anaphylaxis administration of garadacimab should be discontinued immediately, and appropriate treatment instituted." Section 4.8 Addition of hypersensitivity, frequency not known. For more information, please refer to the Summary of Product Characteristics.
Variation type IA / EMA/VR/0000314773	Outcome: B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - Accepted	01/12/2025			
Variation type IB / EMA/VR/0000265732	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used	04/09/2025			

	in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted				
PSUR / EMA/PSUR/0000305046	EURD: PSUSA/00011109/202507 Active substance: garadacimab Outcome: Maintenance	12/02/2026			Maintenance