Tevimbra

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 /	This was an application for a group of	18/09/2025	24/10/2025	SmPC and PL	The recommended dose of Tevimbra is either

[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/0000269879	variations. B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted A grouped application consisting of: C.I.4: Update of sections 4.2, 5.1, 5.2, and 6.6 of the SmPC in order to introduce an alternative dosing regimen of 400 mg every 6 weeks (Q6W) based on POP-PK and exposure-response analyses, and observed clinical data, and update safety information based on data collected in studies BGB-A317-315 and BGB-A317-212 (400 mg Q6W), and study BGB-A317-001; the Package Leaflet is updated accordingly. The RMP version 4.1 has also been submitted. B.I.a.4.z: Minor change to the impurity evaluation analytical procedure for the impurity in-process test to reevaluate impurities for higher clinical doses of 400mg Q6W.				200 mg once every 3 weeks or 400 mg once every 6 weeks administered by intravenous infusion.

Variation type IA_IN / EMA/VR/0000285978	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.a The activities for which the manufacturer/importer is responsible include batch release - Accepted	14/07/2025		Annex II and PL	
Variation type IB / EMA/VR/0000272164	This was an application for a group of variations. B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted 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.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted B.II.h.1.b Replacement of obsolete studies related to manufacturing steps and adventitious agents already reported in the dossier - B.II.h.1.b.2 without modification of risk assessment - Accepted	03/06/2025	N/A		

Variation type IB / EMA/VR/0000269138	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	02/06/2025		SmPC and PL	
Variation type IB / EMA/VR/0000266115	This was an application for a group of variations. B.I.d.1.a Re-test period/storage period - B.I.d.1.a.4 Extension or introduction of a re-test period/storage period supported by real time data - Accepted B.I.d.1 Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - B.I.d.1.z Other variation - Accepted	28/05/2025	N/A		
Variation type IA_IN / EMA/VR/0000271889	A. ADMINISTRATIVE CHANGES - A.1 Change in the name and/or address of the marketing authorisation holder - Accepted	13/05/2025		SmPC, Labelling and PL	
Variation type IA_IN / EMA/VR/0000255439	B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted	19/03/2025	N/A		
