Beyfortus

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 /	B.II.f.1 Change in the shelf-life or storage	12/03/2026		SmPC and PL	The SmPC section 6.3. has been updated as follows:

[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/0000319983	conditions of the finished product - B.II.f.1.c Change in storage conditions for biological medicinal products, when the stability studies have not been performed in accordance with an approved stability protocol - Accepted				Beyfortus may be kept at room temperature (20°C - 25°C) when protected from light for a maximum of 48 hours.
Variation type IB / EMA/VR/0000324927	Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted	20/02/2026		SmPC	
Variation type IA / EMA/VR/0000323322	This was an application for a group of variations. 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.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted 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.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted	20/01/2026			

Variation type IA / EMA/VR/0000303696	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.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted	09/10/2025			
Variation type IB / EMA/VR/0000291218	This was an application for a group of variations. 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.z Other changes - Accepted 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 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	19/09/2025			

	specified in the technical dossier) - Accepted				
Variation type IB / EMA/VR/0000292475	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	11/09/2025			
Variation type IB / EMA/VR/0000256455	This was an application for a group of variations. B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.c Implementation of a change for a biological/immunological medicinal product - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used 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 B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control	02/05/2025	04/08/2025	Annex II	

	testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.z Other variation - Accepted				
Variation type IB / EMA/VR/0000255557	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.z Other changes - Accepted	20/03/2025			
Variation type IA_IN / EMA/VR/0000246848	B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted	14/02/2025	04/08/2025	Annex II and PL	
PSUR / EMA/PSUR/0000248497					Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing nirsevimab remains unchanged and therefore recommends the maintenance of the marketing authorisation(s).
PSUR / EMA/PSUR/0000288237					Maintenance