Besremi

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	24/04/2026		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/0000334453	variations. Q.IV.1 Changes to a device co-packaged with the medicinal product or referenced in the product information - Q.IV.1.a) Addition or replacement of a co-packaged device or referenced device - Accepted Q.IV.1 Changes to a device co-packaged with the medicinal product or referenced in the product information - Q.IV.1.a) Addition or replacement of a co-packaged device or referenced device - Accepted				
Variation type IB / EMA/VR/0000322691	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.z Other changes - Accepted	13/03/2026			
Variation type IB / EMA/VR/0000314219	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z - To update the 'Instructions for use' in the Package Leaflet to more precisely adapt the presentation of the dosing scheme including the 5µg increment steps, implemented in procedure EMEA/H/C/004128/II/0033/G, for the Besremi 250 µg / 0.5 mL pen presentations.	09/01/2026		PL	

	In addition, The MAH took the opportunity to delete the reference to a potential pack size including six co-packed needles from English and Lithuanian 'Instructions for use' in the Package Leaflet text for the Besremi 500 µg / 0.5 mL pen. Finally, correction of a typographical error in the Norwegian 'Instructions for use' in the Package Leaflet text for the Besremi 250 µg / 0.5 mL pen was implemented.				
Variation type IB / EMA/VR/0000295474	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 Change in due date for category 1, 2 or 3 studies in the RMP and/or Annex II - Accepted C.I.11.z – to update the RMP to revise the Post-Authorisation Safety Study (PASS, category 3) milestone dates. The proposal date for the Final report has changed from 'Q4 2025' to 'Q1 2026.'	21/10/2025			
Variation type II / EMA/VR/0000277854	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 Update of section 4.8 of the SmPC in order	04/09/2025		SmPC	Not applicable.

	to correct Table 1 in Section 4.8 Undesirable effects due to an error in the statistical report. In addition, the MAH took the opportunity to introduce editorial changes to the PI, and DE, DK, NL PIs.				
Variation type II / EMA/VR/0000269531	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.c Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.a Tightening of specification limits - Accepted	04/09/2025			
Variation type IB / EMA/VR/0000246850	This was an application for a group of variations. B.IV.1.a Addition or replacement of a device which is not an integrated part of the primary packaging - B.IV.1.a.1 Device with CE marking - Accepted	29/03/2025		PL	

Variation type IA / EMA/VR/0000261647	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	25/03/2025			
Variation type IB / EMA/VR/0000258987	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted	25/03/2025			