Myalepta

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 /	C.I.11 Introduction of, or change(s) to, the	03/11/2025		Annex II	To extend the submission deadline of the SOB003

[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/0000304056	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 (Type IB) – To extend the submission deadline of the SOB003 Year 4 interim report from by end of 2025 to by end of 2026. In addition, Annex IIE of the Product Information has been updated to include the revised due date for the submission of the final report (Year 6) by the end of 2028 which was approved during a PAM assessment (EMEA/H/C/004218/SOB/003.13) on 27 Jun 2024. Furthermore, the MAH took the opportunity to implement editorial changes to Annex IIE of the Product Information to delete the sentences relative to the submission of the draft protocols for SOB001 and SOB003, which are not applicable anymore as they are already submitted to the EMA.				Year 4 interim report from by end of 2025 to by end of 2026. In addition, Annex IIE of the Product Information has been updated to include the revised due date for the submission of the final report (Year 6) by the end of 2028 which was approved during a PAM assessment (EMEA/H/C/004218/SOB/003.13) on 27 Jun 2024.
Variation type IB / EMA/VR/0000280601	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted To amend the reference to the administration kit in annex IID.	20/08/2025		Annex II	

Variation type IB / EMA/VR/0000269336	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z To replace the 2.5 mL syringes, used in the administration of the medicinal product, with a 3.0 mL syringe, due to the currently listed syringe being discontinued.	17/06/2025		SmPC and PL	To replace the 2.5 mL syringes, used in the administration of the medicinal product, with a 3.0 mL syringe, due to the currently listed syringe being discontinued.
Variation type IA / EMA/VR/0000264608	This was an application for a group of variations. 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.a Minor changes to an approved test procedure - 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	09/04/2025	N/A		
Variation type IA_IN / EMA/VR/0000245799	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	27/01/2025		SmPC, Annex II and PL	

PSUR / EMA/PSUR/0000269015	- -				Maintenance