EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Sugammadex Amomed

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 IA_IN /	B.II.b.2.c Replacement or addition of a	02/02/2026		Annex II and	

[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/0000323967	manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted			PL	
Variation type IB / EMA/VR/0000284375	B.II.d.2 Change in test procedure for the finished product - B.II.d.2.z Other changes - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - 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 B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes	25/09/2025	N/A		

	to a test procedure (including replacement or addition) - Accepted B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.z Other changes, including change from single batch size to a range of batch sizes - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Other changes - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - 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 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.f Site where any manufacturing operation(s) take place,				

	except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products - Accepted				
Variation type II / EMA/VR/0000248398	B.I ACTIVE SUBSTANCE - B.I.z Substantial updates to Mod. 3.2.S or the ASMF - Accepted	24/07/2025			N/A
Variation type IB / EMA/VR/0000267132	This was an application for a group of variations. C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted 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 Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.2.a - To extend the indication to include	03/06/2025	23/06/2025	SmPC, Labelling and PL	To extend the indication to include the treatment of paediatric patients from birth up to less than 2 years of age, based on the final results of the paediatric study PN169 (MK-8616-P169). As a result, sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the SmPC have been updated accordingly. The Package Leaflet has also been revised to reflect these changes. The changes follow assessment of the same changes for the reference product Bridion. To update part I and VI of the RMP to include all paediatric patients, in line with the RMP of the reference product, and to add the table regarding 'Summary of changes to the risk management plan over time' to Annex 8 of Part VII.

	the treatment of paediatric patients from birth up to less than 2 years of age, based on the final results of the paediatric study PN169 (MK-8616-P169). As a result, sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the SmPC have been updated accordingly. The Package Leaflet has also been revised to reflect these changes. The changes follow assessment of the same changes for the reference product Bridion. In addition, the MAH took the opportunity to introduce editorial changes to the PI in CZ, DA, DE, EL, ES, EE, FI, FR, HR, HU, LT, LV and RO to align with the PI of the reference product, to correct for abbreviations, spelling and grammar mistakes, and to align with the QRD template. C.I.11.z - To update part I and VI of the RMP to include all paediatric patients, in line with the RMP of the reference product, and to add the table regarding 'Summary of changes to the risk management plan over time' to Annex 8 of Part VII.				
Variation type IB / EMA/VR/0000254268	C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted	24/03/2025	23/06/2025	SmPC and PL	

	C.I.2.a (IB) - To update section 4.8 of the SmPC in order to include information on hypersensitivity reactions associated with the sugammadex-rocuronium complex. Furthermore, editorial changes to the Product Information involve the correction of obvious mistakes, typographical errors and minor editorial adjustments for the following languages: CS, DE, EL, EN, ES, ET, FI, FR, HR, IS, IT, LT, MT, NO, PL, PT, RO, SK, SL and SV. Finally, section 6 of the PL has been updated with new phone number for Spanish and Portuguese local representatives.				