Zilbrysq

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 /	C.3 Change(s) in the summary of product	09/07/2026		SmPC, Annex	For more information, please refer to the Summary

[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/0000343399	characteristics, labelling or package leaflet intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Article 45 or 46 of Regulation (EC) No 1901/2006, or the outcome of a PRAC signal recommendation, or to adapt to a joint recommendation of EU competent authorities (e.g. a Core SmPC, or following the assessment of an Urgent Safety Restriction etc.) - C.3.z Other variation - Accepted Update of Annex IID of the PI in order to implement the outcome of PSUR procedure, PSUSA/00000169/202509, recommending to remove the Controlled Access Program linked to the safety concern 'meningococcal infection' from the RMP. The RMP version 1.1 has also been submitted along with updated educational materials, as per PRAC recommendation.			II and PL	of Product Characteristics.
Variation type II / EMA/VR/0000314736	This was an application for a group of variations. 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	19/03/2026		SmPC, Labelling and PL	The SmPC has been updated with relevant sections to include information regarding the pre-filled pen presentations (EU/1/23/1764/007-012). The Labelling & PL have been updated accordingly.

	B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted B.IV.1 Change of a measuring or administration device - B.IV.1.c Addition or replacement of a device which is an integrated part of the primary packaging - Accepted				
Variation type IB / EMA/VR/0000320540	B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.z Other changes - Accepted	02/02/2026			

Variation type IA / EMA/VR/0000316745	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.c Other changes to a test procedure (including replacement or addition) for a reagent, which does not have a significant effect on the overall quality of the active substance - Accepted 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.d Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted 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	16/12/2025			
Variation type IB / EMA/VR/0000310131	B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted	26/11/2025		SmPC	

PSUR / EMA/PSUR/0000282282	EURD: PSUSA/00000169/202503 Active substance: zilucoplan Outcome: Maintenance	30/10/2025			Maintenance
Variation type IA / EMA/VR/0000289601	This was an application for a group of variations. 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 specified in the technical dossier) - Accepted A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted	12/08/2025			
Variation type IB / EMA/VR/0000263963	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted	05/05/2025			

Article 61(3) / EMA/N/0000267743	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representative and deletion of 'United Kingdom (Northern Ireland)' from the list of local representatives in line with the QRD template v10.4.	28/04/2025		PL	
Variation type IA / EMA/VR/0000256406	A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted	03/03/2025			
PSUR / EMA/PSUR/0000317635	EURD: PSUSA/00000169/202509 Active substance: zilucoplan Outcome: Maintenance	10/04/2026			Maintenance