Epysqli

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
Article 61(3) /	Outcome:	07/08/2026		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/N/0000365662	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with the addition of contact details of local representatives.				
PSUR / EMA/PSUR/0000327869	EURD: PSUSA/00001198/202510 Active substance: eculizumab Outcome: Maintenance	11/06/2026			
Variation type IB / EMA/VR/0000324351	Outcome: C.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.2.a) Implementation of change(s) for which no new additional data is required to be submitted by the holder - Accepted C.2.a (IB) - To update section 4.8 of the SmPC by including "liver injury" under the SOC Hepatobiliary disorders in the table of adverse reactions with unknown frequency, and section 4 of the package leaflet by adding "liver injury" with frequency "not known", and to move the PTs ("increased alanine aminotransferase," "increased aspartate aminotransferase," and "increased gamma-glutamyltransferase") listed in the table in section 4.8 to the SOC Hepatobiliary	16/02/2026	04/05/2026	SmPC and PL	

	disorders to better reflect the most appropriate system organ class for the affected target organ, to align the PI with the same changes approved for the reference product Soliris. Furthermore, the MAH has taken the opportunity to correct the numbering of the tables throughout the SmPC to align with the reference product.				
Variation type IB / EMA/VR/0000287199	Outcome: 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.2.a (Type IB) - To update Section 4.4 of the SmPC, Annex IID, and section 2 of the PL to update safety information including changes in terminology due to the lift of the controlled distribution requirement, inclusion of updated Meningococcal Serogroups A, C, Y, W 135 and B in vaccine, and reinforcement of the need for (re-)vaccination against all available serotypes. The change follows assessment of the same change for the reference product, Soliris (EMEA/H/C/000791/WS2125/0133). The RMP is updated accordingly.	19/09/2025	04/05/2026	SmPC, Annex II and PL	To update Section 4.4 of the SmPC, Annex IID, and section 2 of the PL to update safety information including changes in terminology due to the lift of the controlled distribution requirement, inclusion of updated Meningococcal Serogroups A, C, Y, W 135 and B in vaccine, and reinforcement of the need for (re-)vaccination against all available serotypes. The change follows assessment of the same change for the reference product, Soliris (EMEA/H/C/000791/WS2125/0133). The RMP is updated accordingly.

Variation type IB / EMA/VR/0000295589	Outcome: This was an application for a group of variations. 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.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.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	17/09/2025			
Variation type IA / EMA/VR/0000278784	Outcome: B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted	12/06/2025			
Variation type IB / EMA/VR/0000264625	Outcome: 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	13/05/2025			

	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				
Variation type IB / EMA/VR/0000262966	Outcome: 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.2.a - To update sections 5.1 and 5.2 of the SmPC following assessment of the same change for the reference product, in order to update efficacy and pharmacokinetic information based on final results from study ECU-MG-303; this is a Phase 3, open-label, multicenter study to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of eculizumab in pediatric patients with refractory generalized myasthenia gravis (gMG). - To introduce a sentence regarding polysorbate in line with QRD template. - The MAH has taken the opportunity to implement editorial changes in all languages for alignment with the reference product, to correct for	16/04/2025	04/05/2026	SmPC, Labelling and PL	- To update sections 5.1 and 5.2 of the SmPC following assessment of the same change for the reference product, in order to update efficacy and pharmacokinetic information based on final results from study ECU-MG-303; this is a Phase 3, open-label, multicenter study to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of eculizumab in pediatric patients with refractory generalized myasthenia gravis (gMG). - To introduce a sentence regarding polysorbate in line with QRD template.

	typographical errors, and for alignment with QRD.				
Variation type II / EMA/VR/0000245113	Outcome: 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.e The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product - Accepted	27/03/2025			