Soliris

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.3 Change(s) in the Summary of Product	17/07/2025		SmPC, Annex	To update section 4.8 of the SmPC by including

[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/0000279366	Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.z Implementation of wording agreed by the competent authority + QRD update - Accepted C.I.3.z (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 PL 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 disorders to better reflect the most appropriate system organ class for the affected target organ, following the Post-Authorisation Measure resulting from PSUSA procedure EMEA/H/C/PSUSA/00001198/202310. In addition, the MAH also amended section 3 of the SmPC to include information on osmolality, and updated section 6.1 of the SmPC and section 6 of the PL to include the			II, Labelling and PL	"liver injury" under the SOC Hepatobiliary disorders in the table of adverse reactions with unknown frequency, and section 4 of the PL 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 disorders to better reflect the most appropriate system organ class for the affected target organ, following the Post-Authorisation Measure resulting from PSUSA procedure EMEA/H/C/PSUSA/00001198/202310. In addition, the MAH also amended section 3 of the SmPC to include information on osmolality, and updated section 6.1 of the SmPC and section 6 of the PL to include the corresponding E-numbers for the excipients, as requested (EMEA/H/C/000791/II/131).

	corresponding E-numbers for the excipients, as requested (EMEA/H/C/000791/II/131). Furthermore, the MAH took the opportunity to implement editorial changes to update the contact information for the local representative for ES in the PL, to correct typographical errors throughout the PI for EN, BG and FR, and to correct a typographical error in Annex II concerning the address of one of the manufacturers, in all languages.				