



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SARCLISA

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
Extension of marketing	Outcome:	26/03/2026	04/06/2026	SmPC, Annex	

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).



<p>authorisation / EMA/X/0000281242</p>	<p>This was an application for a group of variations.</p> <p>2. Changes to strength, pharmaceutical form and route of administration - (c) change or addition of a new strength/potency - Accepted</p> <p>2. Changes to strength, pharmaceutical form and route of administration - (d) change or addition of a new pharmaceutical form - Accepted</p> <p>2. Changes to strength, pharmaceutical form and route of administration - (e) change or addition of a new route of administration - Accepted</p> <p>Extension application to introduce a new pharmaceutical form (solution for injection), a new strength (1400 mg) and a new route of administration (subcutaneous use). The RMP (version 3.0) is updated in accordance.</p>			<p>II, Labelling and PL</p>	
<p>Variation type II / EMA/VR/0000317918</p>	<p>Outcome: This was an application for a group of variations.</p> <p>B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.b Substantial change to the manufacturing process of the active substance which may have a significant impact on the quality, safety or efficacy of the medicinal product -</p>	<p>12/03/2026</p>			

	<p>Accepted</p> <p>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</p> <p>Accepted</p> <p>B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.d Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the active substance - Accepted</p>				
Variation type II / EMA/VR/0000325758	<p>Outcome:</p> <p>C. Safety, efficacy, pharmacovigilance changes - C.4 Change(s) in the summary of product characteristics, labelling or package leaflet due to new quality, preclinical, clinical or pharmacovigilance data. - Accepted</p> <p>Update of sections 4.4 and 4.8 of the SmPC in order to update information regarding anaphylactic reactions including fatal events, based on recent post-marketing surveillance data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to include minor editorial changes and to update the list of local representatives in the Package Leaflet.</p>	12/03/2026	04/06/2026	SmPC and PL	
PSUR / EMA/PSUR/0000282274	EURD: PSUSA/00010851/202503 Active substance: isatuximab Outcome:	30/10/2025			Maintenance

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