



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Enspryng

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
PSUSA/10944 /202405	Periodic Safety Update EU Single assessment - satralizumab (for centrally authorised products)	16/01/2025	n/a		PRAC Recommendation - maintenance
IB/0014	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved	27/09/2024		SmPC and Labelling	

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).



	stability protocol				
PSUSA/10944/202311	Periodic Safety Update EU Single assessment - satralizumab (for centrally authorised products)	13/06/2024	n/a		PRAC Recommendation - maintenance
PSUSA/10944/202305	Periodic Safety Update EU Single assessment - satralizumab (for centrally authorised products)	11/01/2024	n/a		PRAC Recommendation - maintenance
IB/0011/G	<p>This was an application for a group of variations.</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p> <p>B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits</p> <p>B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate</p>	24/10/2023	n/a		
IB/0009	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	08/08/2023	n/a		
PSUSA/10944/202211	Periodic Safety Update EU Single assessment - satralizumab (for centrally authorised products)	06/07/2023	n/a		PRAC Recommendation - maintenance
IB/0006	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process	20/04/2023	n/a		

	of the AS				
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/03/2023		PL	
PSUSA/10944 /202205	Periodic Safety Update EU Single assessment - satralizumab (for centrally authorised products)	12/01/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10944 /202111	Periodic Safety Update EU Single assessment - satralizumab (for centrally authorised products)	07/07/2022	n/a		PRAC Recommendation - maintenance
IB/0003/G	<p>This was an application for a group of variations.</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p> <p>B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p>	24/02/2022	n/a		
IB/0002	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	11/08/2021	n/a		
IB/0001	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	26/07/2021	30/06/2022	SmPC, Labelling and PL	