



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Kisunla

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 HUMAN AND VETERINARY MEDICINAL	09/01/2026		SmPC and 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/VR/0000316533	<p>PRODUCTS - C.I.z Other variation - Accepted</p> <p>C.I.z - to update the Package Leaflet by removing the tear-off section containing the patient card. In addition, the MAH took the opportunity to add the date of authorisation in section 9 of the SmPC. Finally, the MAH took the opportunity to make some minor editorial corrections in the Spanish and Finnish annexes.</p>				
Variation type IB / EMA/VR/0000309139	<p>B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Other changes - Accepted</p>	24/11/2025	N/A		