Eksunbi

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, please 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 Y	C.I.2 Change(s) in the Summary of Product	23/05/2025		SmPC and PL	To update section 4.5 and 5.2 of the SmPC in order

[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/0000267789	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 section 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information based on results from study CNTO1275CRD100, and sections 4.8 and 5.1 to include patient exposure numbers based on results from study CNTO1275UCO3001. The change follows assessment of the same change to the reference product, Stelara. Furthermore, the MAH took the opportunity to add a warning for Polysorbate 80 to section 4.4 of the SmPC in line with the reference product and the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'				to add drug-drug interaction information based on results from study CNTO1275CRD100, and sections 4.8 and 5.1 to include patient exposure numbers based on results from study CNTO1275UCO3001. The change follows assessment of the same change to the reference product, Stelara.