Osvyrti

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 /	This was an application for a group of	17/12/2025		SmPC,	

[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/0000302844	variations. C.I.2 Change(s) in the Summary of Product 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 Change(s) in the Summary of Product 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 Change(s) in the Summary of Product 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 amend SmPC section 4.2 Renal impairment section, to update to "No data is available in patients with long-term systemic			Labelling and PL	

	glucocorticoid therapy and severe renal impairment (Glomerular filtration rate GFR < 30 mL/min)" in place of "In Renal impairment section it is given that "No data is available in patients with long-term systemic glucocorticoid therapy and severe renal impairment Glomerular filtration rate (GFR < 30 mL/min). In section 5.1 in one multicentre, randomised, double-blind, placebo-controlled, parallel-group study conducted in 24 paediatric patients with glucocorticoid-induced osteoporosis, aged 5 to 17 years, evaluating change from baseline in lumbar spine BMD Z-score, safety and effectiveness were not established hence denosumab should not be used for this indication. In section 5.1 and 5.2 paediatric population "phase 3" replaced with "phase III" C.I.2.a To amend SmPC section 4.4, following the outcome of a PSUSA assessment for the reference product by adding "Treatment discontinuation Following denosumab discontinuation, decrease in bone mineral density (BMD) is expected (see section 5.1), leading to an increased risk for fractures. Thus, monitoring of BMD is recommended, and alternative treatment should be considered according to clinical guidelines." C.I.2.a To amend SmPC section 4.8 to include the risk of Osteonecrosis of jaw. In addition, the MAH has taken the opportunity to update Annex				

	IIIA, on blister content, 5. other Section, and to harmonise with the reference SmPC and the package leaflet by adding the needle image in line with the reference product.				