Anzupgo

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 II /	C.I HUMAN AND VETERINARY MEDICINAL	23/10/2025		SmPC	The efficacy and safety of delgocitinib cream

[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/0000264200	PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 5.1 of the SmPC in order to update efficacy and safety information based on final results from study DELTA FORCE (LP0133-1528).This is a 24-week, randomised, assessor-blinded, active-controlled, parallel-group, phase 3, 2-arm trial to compare the efficacy and safety of delgocitinib cream 20 mg/g twice-daily with alitretinoin capsules once-daily in adult participants with severe chronic hand eczema.				compared to alitretinoin oral capsules was evaluated in a randomised assessor-blinded, 24-week study in adult patients with severe chronic hand eczema in which permanent discontinuation of treatment (35.9% for alitretinoin vs. 13.4% for delgocitinib) and use of rescue medications (8.1% for alitretinoin vs. 4.7% for delgocitinib) were more frequent for patients treated with alitretinoin compared to delgocitinib. Statistically significantly greater improvements (for change in HECSI score from baseline to Week 12, HECSI 90 and IGA CHE TS) were achieved for delgocitinib cream compared to alitretinoin. In addition, greater improvements for delgocitinib cream measured by the mean change in HECSI score compared to alitretinoin, were observed at Week 1 and maintained through to Week 24. For more information, please refer to the Summary of Product Characteristics.
Variation type II / EMA/VR/0000265598	B.I.e.1 Introduction of a new design space or extension of an approved design space for the active substance, concerning: - B.I.e.1.a One unit operation in the manufacturing process of the active substance including the resulting in-process controls and/or test procedures - Accepted	26/06/2025	N/A		
Variation type IB / EMA/VR/0000266470	B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted	17/06/2025		SmPC, Labelling and PL	

PSUR / EMA/PSUR/0000269028	- -				Maintenance