# Adtralza

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 |
|---|---|---|---|---|---|
| IB/0013 | B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation | 27/10/2023 | n/a | | |
| IB/0012 | B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation | 16/10/2023 | n/a | | |

[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).

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

| | | | | | |
|---|---|---|---|---|---|
| X/0007 | Annex I_2.(c) Change or addition of a new strength/potency | 22/06/2023 | 01/09/2023 | SmPC, Labelling and PL | |
| II/0008 | C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data | 31/08/2023 | | SmPC and PL | |
| PSUSA/10937 /202212 | Periodic Safety Update EU Single assessment - tralokinumab | 06/07/2023 | n/a | | PRAC Recommendation - maintenance |
| PSUSA/10937 /202206 | Periodic Safety Update EU Single assessment - tralokinumab | 12/01/2023 | n/a | | PRAC Recommendation - maintenance |
| II/0005 | B.I.e.2 - Introduction of a post approval change management protocol related to the AS | 01/12/2022 | n/a | | |
| II/0001 | C.I.4<br>Update of section 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information with cytochrome P450 and CYP substrates based on final results from study ECZTRA 4 (LP0162-1342). This is an open-label drug–drug interaction trial to investigate the effects of tralokinumab on the pharmacokinetics of selected CYP substrates in adult subjects with moderate-to-severe atopic dermatitis. In addition, the MAH took the opportunity make editorial changes to sections 4.8, 6.5 and 9 of SmPC.<br><br>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance | 20/10/2022 | 01/09/2023 | SmPC | The primary objective of ECZTRA 4 was to evaluate the effects of tralokinumab on the pharmacokinetics of selected CYP substrates (caffeine [CYP1A2], warfarin [CYP2C9], metoprolol [CYP2D6], omeprazole [CYP2C19] and midazolam [CYP3A], in adult subjects with moderate-to-severe atopic dermatitis after repeated administration.<br>No effects were observed for caffeine and warfarin. Small numerical changes, which were not clinically significant, were observed for Cmax of omeprazole, AUC of metoprolol and AUC and Cmax of midazolam (the largest difference being for midazolam Cmax with a decrease of 22%). Therefore, clinically relevant impact of tralokinumab on the pharmacokinetics of concomitant medicines metabolised by the CYP enzymes is not expected and no dose adjustment |

| | | | | | |
|---|---|---|---|---|---|
| | data | | | | is needed.<br>For more information, please refer to the Summary of Product Characteristics. |
| II/0002 | Extension of indication to include treatment of adolescent patients (12-17 years) for Adtralza based on final study LP0162-1334 (ECZTRA 6): a multicentre, randomised, double-blind, placebo-controlled study in adolescent patients 12 to 17 years of age with moderate-to-severe atopic dermatitis to evaluate the efficacy and safety of tralokinumab monotherapy in this population group.As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance.<br><br>C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one | 15/09/2022 | 14/10/2022 | SmPC and PL | Please refer to Scientific Discussion 'Adtralza -H-C-005255-II-0002' |
| PSUSA/10937 /202112 | Periodic Safety Update EU Single assessment - tralokinumab | 07/07/2022 | n/a | | PRAC Recommendation - maintenance |
| IB/0004 | B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation | 12/04/2022 | n/a | | |