Adtralza

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 /		28/05/2026		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/0000343070	Outcome: This was an application for a group of variations. Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted Q.II.f.1 Change in the shelf life or storage - Q.II.f.1.e Change to an approved stability protocol of the finished product - Accepted				
Variation type II / EMA/VR/0000326043	Outcome: This was an application for a group of variations. Q.I.b.1 Change in the specification attribute and/or acceptance criteria of an active substance, starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.1.f) Change outside of the specification acceptance criteria for the active substance - Accepted	16/04/2026			

Renewal - 5 year / EMA/R/0000288404	Outcome: - Renewal - Accepted	29/01/2026	26/03/2026	SmPC, Annex II and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Adtralza in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
Variation type IA / EMA/VR/0000323574	Outcome: This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or	22/01/2026			

	a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted				
Variation type IB / EMA/VR/0000303818	Outcome: B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted	29/10/2025			
Variation type IB / EMA/VR/0000294330	Outcome: B.II.g.5 Implementation of changes foreseen in an approved change management protocol - B.II.g.5.c Implementation of a change for a biological/immunological medicinal product - Accepted	18/09/2025			

Variation type II / EMA/VR/0000254976	Outcome: C.I HUMAN AND VETERINARY MEDICINAL 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 sections 4.8 and 5.1 of the SmPC in order to update clinical efficacy and safety information based on the final clinical trial report of the open-label extension PASS study LP0162-1337 (ECZTEND), listed as a category 3 study in the RMP. This is a phase 3 open-label, single-arm, multi-centre, long-term extension trial to evaluate the safety and efficacy of tralokinumab in subjects with moderate-to-severe atopic dermatitis who participated in previous tralokinumab clinical trials. The RMP has been updated to version 3.0. In addition, the MAH took the opportunity to update the PI according to the updated EU Excipient guideline to include a warning regarding polysorbate as well as to include minor editorial changes and to update the list of local representatives in the Package Leaflet.	04/09/2025	26/03/2026	SmPC, Labelling and PL	The long-term efficacy of tralokinumab was further assessed in an open-label extension study (ECZTEND) in adults (1545 subjects) and in adolescents 12 years and older (127 subjects) with moderate-to-severe AD who had participated for up to 1 year in previous tralokinumab studies. For the total population, the median and maximum exposure time in ECZTEND was 2.6 and 5.1 years; for adolescent subjects, the median and maximum exposure time in ECZTEND was 1.8 and 2.2 years. Efficacy data from ECZTEND indicate that the clinical benefit achieved during initial treatment and maintenance treatment is sustained during long-term treatment with 300 mg of tralokinumab every two weeks (Q2W) and optional TCS as needed. For more information, please refer to the Summary of Product Characteristics.

Variation type II / EMA/VR/0000244619	Outcome: B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.e The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product - Accepted	03/07/2025	26/03/2026	Annex II	
Variation type IB / EMA/VR/0000265489	Outcome: B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.z Other variation - Accepted	27/05/2025	26/03/2026	SmPC and PL	
Variation type IB / EMA/VR/0000265037	Outcome: B.II.f.1.b Extension of the shelf life of the	16/05/2025	26/03/2026	SmPC	

	finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted				
PSUR / EMA/PSUR/0000257863	EURD: PSUSA/00010937/202412 Active substance: tralokinumab Outcome: Maintenance	10/07/2025			Maintenance