



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 April 2021  
EMA/CHMP/202204/2021  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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# Adtralza

## tralokinumab

On 22 April 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Adtralza, intended for the treatment of moderate-to-severe atopic dermatitis.

The applicant for this medicinal product is LEO Pharma A/S.

Adtralza will be available as 150 mg solution for injection. The active substance of Adtralza is tralokinumab, a recombinant human IgG4 monoclonal antibody (ATC code: D11AH07) that works by inhibiting the interleukin-13 signaling.

The benefits of Adtralza are its ability to improve the skin condition as measured by improvements in the Investigator's Global Assessment (IGA) and Eczema Area and Severity Index (EASI)-75 scales and to reduce itching in patients with atopic dermatitis. The most common side effects are upper respiratory tract infections, injection site reactions, conjunctivitis and conjunctivitis allergic.

The full indication is:

Adtralza is indicated for treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy.

Adtralza should be initiated by healthcare professionals experienced in the diagnosis and treatment of atopic dermatitis.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

