



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 September 2022
EMA/CHMP/742227/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Adtralza

tralokinumab

On 15 September 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Adtralza to include treatment of adolescents aged 12 years and older. The marketing authorisation holder for this medicinal product is LEO Pharma A/S.

For information, the full indication for Adtralza will therefore be as follows:²

Adtralza is indicated for the treatment of moderate-to-severe atopic dermatitis in adult **and adolescent patients 12 years and older** who are candidates for systemic therapy.

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

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

² New text in bold

