



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 July 2017
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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Dupixent dupilumab

On 20 July 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Dupixent, intended for the treatment of atopic dermatitis. The applicant for this medicinal product is Sanofi-Aventis groupe.

Dupixent will be available as a 300 mg solution for injection. The active substance of Dupixent is dupilumab, a recombinant human IgG4 monoclonal antibody (ATC code: to be assigned) that works by inhibiting interleukin-4 and interleukin-13 signaling.

The benefits with Dupixent are its ability to improve the skin condition as measured by improvements in the IGA and EASI-75 scales and to reduce itching in patients with atopic dermatitis. The most common side effects are injection site reactions, conjunctivitis, blepharitis, and oral herpes.

The full indication is: "Dupixent is indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy". It is proposed that Dupixent be prescribed by physicians experienced in the 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.

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

