EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 2019
EMA/CHMP/345816/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Dupixent

dupilumab

On 27 June 2019, 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 Dupixent. The marketing authorisation holder for this medicinal product is sanofi-aventis groupe.

The CHMP adopted an extension to one of the existing indications as follows:[2]

> "Dupixent is indicated for the treatment of moderate-to-severe atopic dermatitis in adult**s** ~~patients~~ **and adolescents 12 years and older** who are candidates for systemic therapy."

For information, the full indications for Dupixent will be as follows:

> "Atopic Dermatitis
>
> Dupixent is indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy.
>
> Asthma
>
> Dupixent is indicated in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO (see section 5.1), who are inadequately controlled with high dose ICS plus another medicinal product for maintenance treatment."

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, removed text as strikethrough

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