



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 November 2021  
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Committee for Medicinal Products for Human Use (CHMP)

## Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): dupilumab

Procedure No. EMEA/H/C/PSUSA/00010645/202103

Period covered by the PSUR: 29 September 2020 to 28 March 2021



## **Scientific conclusions**

Taking into account the PRAC Assessment Report on the PSUR(s) for dupilumab, the scientific conclusions of CHMP are as follows:

In view of available data from clinical trials, literature and spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between dupilumab and dry eye is at least a reasonable possibility. The PRAC concluded that the product information of products containing dupilumab should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

## **Grounds for the variation to the terms of the marketing authorisation**

On the basis of the scientific conclusions for dupilumab the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing dupilumab is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.