



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 November 2020  
EMA/43938/2021  
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/00010645/202009

Period covered by the PSUR: 28 March - 28 September 2020



## 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 on keratitis from clinical trials, literature, spontaneous reports including cases with close temporal relationship, positive re-challenge, the PRAC considers that a causal relationship between dupilumab and keratitis is a reasonable possibility at least in atopic dermatitis and asthma conditions.

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 product(s) containing dupilumab is unchanged subject to the proposed changes to the product information

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