EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): secukinumab

Procedure No. EMEA/H/C/PSUSA/00010341/201912

Period covered by the PSUR: 26 December 2018 to 25 December 2019

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Scientific conclusions

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

In view of available data on fatigue, nausea and headache from clinical trials and spontaneous reports including cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between secukinumab and these adverse reactions is at least a reasonable possibility. The PRAC concluded that the product information of products containing secukinumab 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(s)

On the basis of the scientific conclusions for secukinumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing secukinumab 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.