25 July 2019
EMA/521908/2019
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation

Active substance(s): secukinumab

Procedure No. EMEA/H/C/PSUSA/00010341/201812

Period covered by the PSUR: 26 December 2017 - 25 December 2018

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

Based on the review of data presented in this PSUSA, covering the period from 26 December 2017 to 25 December 2018, as well as cumulative data since the European birth date, the PRAC considers that the product information of medicinal products containing the active substance secukinumab should be updated as follows: the section 4.8 of the SmPC is updated to include the adverse reactions “lower respiratory tract infections” and “inflammatory bowel disease” with a frequency uncommon; the package leaflet is updated 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.