15 September 2022
EMA/884594/2022
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): ustekinumab

Procedure No. EMEA/H/C/PSUSA/00003085/202112

Period covered by the PSUR: 01 January 2021 to 31 December 2021

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 ustekinumab, the scientific conclusions of CHMP are as follows:

In view of available data on excretion in breastmilk and use in lactation from the literature and spontaneous reports, the PRAC concluded that the product information of products containing ustekinumab should be amended accordingly.

In view of the available data on cutaneous lupus erythematosus and lupus-like syndrome from spontaneous reports and the literature, including in some cases a close temporal relationship and a positive dechallenge, the PRAC considers a causal relationship between ustekinumab and cutaneous lupus and lupus-like syndrome is at least a reasonable possibility. The PRAC concluded that the product information of products containing ustekinumab should be amended accordingly.

In view of available data on opportunistic infections including reactivation of tuberculosis, opportunistic fungal infections and encephalitis caused by herpes simplex 2 from the literature and spontaneous reports including in some cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC concluded that the product information of products containing ustekinumab 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 ustekinumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ustekinumab 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.