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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): budesonide (centrally authorised products only)

Procedure No. EMEA/H/C/PSUSA/00010664/202101

Period covered by the PSUR: 08 July 2020 to 07 January 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 budesonide (centrally authorised products only), the scientific conclusions of CHMP are as follows:

In view of available data on angioedema risk from clinical trials, literature, spontaneous reports including cases of positive re-challenge and de–challenge and in view of a plausible mechanism of action, the PRAC considers causal relationship between budesonide (centrally authorised products only) and angioedema is at least a reasonable possibility. The PRAC concluded that the product information of products containing budesonide (centrally authorised products only) 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 budesonide (centrally authorised products only) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing budesonide (centrally authorised products only) 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.