25 July 2024
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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 (for centrally authorised products indicated for primary immunoglobulin A nephropathy only)

Procedure No. EMEA/H/C/PSUSA/00011007/202312

Period covered by the PSUR: 15 June 2023 to 14 December 2023

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for budesonide (for centrally authorised products indicated for primary immunoglobulin A nephropathy only), the scientific conclusions of PRAC are as follows:

In view of available data on hypokalaemia from clinical trial(s), one spontaneous report, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between budesonide (for centrally authorised products indicated for primary IgA) and hypokalaemia is at least a reasonable possibility. The PRAC concluded that the product information of products containing budesonide (for centrally authorised products indicated for primary IgA) should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for budesonide (for centrally authorised products indicated for primary immunoglobulin A nephropathy only) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing budesonide (for centrally authorised products indicated for primary immunoglobulin A nephropathy 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.