25 April
EMA/142578/2025
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): loxapine (pre-dispensed inhalation powder)

Procedure No. EMEA/H/C/PSUSA/00010113/202408

Period covered by the PSUR:
20/08/2021 To: 20/08/2024

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for loxapine (pre-dispensed inhalation powder), the scientific conclusions of PRAC are as follows:

In view of available data on drug rash with eosinophilia and systemic symptoms (DRESS) from the literature including a case report with very strong evidence (confirmed DRESS diagnosis with RegiSCAR 6 and a positive skin test for loxapine), the PRAC considers a causal relationship between loxapine (pre-dispensed inhalation powder) and DRESS at least a reasonable possibility. The PRAC concluded that the product information of products containing loxapine (pre-dispensed inhalation powder) 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 loxapine (pre-dispensed inhalation powder) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing for loxapine (pre-dispensed inhalation powder) 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.