EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 February 2025
EMA/164174/2025
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): tobramycin (inhalation powder, capsules)

Procedure No. EMEA/H/C/PSUSA/00009315/202406

Period covered by the PSUR:
01/07/2021 To: 30/06/2024

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for tobramycin (inhalation powder, capsules), the scientific conclusions of PRAC are as follows:

In view of available data on nephrotoxicity from the literature, including in some cases a close temporal relationship and a positive de-challenge, the PRAC considers that a causal relationship between tobramycin (inhalation powder, capsules) and acute kidney injury (AKI) is at least a reasonable possibility. The PRAC concluded that the product information of products containing tobramycin (inhalation powder, capsules) 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 tobramycin (inhalation powder, capsules) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tobramycin (inhalation powder, capsules) 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.