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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): tobramycin (nebuliser solution) (centrally authorised product only)

Procedure No. PSUSA/00010370/202509

Period covered by the PSUR: 3 years to 18 September 2025

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 tobramycin (nebuliser solution) (centrally authorised product only), 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 (nebuliser solution) (centrally authorised product only) and acute kidney injury (AKI) is at least a reasonable possibility.

The PRAC concluded that the product information of products containing tobramycin (nebuliser solution) (centrally authorised product only) 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 (nebuliser solution) (centrally authorised product only) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tobramycin (nebuliser solution) (centrally authorised product 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.