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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): amikacin (centrally authorised product only)

Procedure No. PSUSA/00010882/202509

Period covered by the PSUR: 1 year to 27 September 2025

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for amikacin (centrally authorised product only), the scientific conclusions of PRAC are as follows:

In view of available data on eye irritation, nephrotoxicity and occupational exposure/exposure in caregivers from spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between amikacin (centrally authorised product only) and eye irritation, acute kidney injury, renal failure and blood creatinine increased is at least a reasonable possibility. The PRAC concluded that the product information of products containing amikacin (centrally authorised products 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

On the basis of the scientific conclusions for amikacin (centrally authorised product only) the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing amikacin (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 should be varied.