



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 April 2023  
EMA/155354/2023  
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. EMEA/H/C/PSUSA/00010882/202209

Period covered by the PSUR: 28/09/2021 to 27/09/2022



## **Scientific conclusions**

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

In view of available data on the increased risk of ototoxicity in patients with particular mitochondrial rRNA mutations from the literature and in view of a plausible mechanism of action, the PRAC Rapporteur considers a causal relationship between *amikacin (centrally authorised product only)* and increased risk of aminoglycoside-associated ototoxicity in patients with mitochondrial mutations at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing *amikacin (centrally authorised product only)* should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

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

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(s) 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(s) should be varied.