25 May 2023
EMA/358219/2023
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): tobramycin (nebuliser solution) (centrally authorised product only)

Procedure No. EMEA/H/C/PSUSA/00010370/202209

Period covered by the PSUR: 19/09/2020 to: 18/09/2022

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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 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 considers a causal relationship between tobramycin and an increased risk of aminoglycoside-associated ototoxicity in patients with mitochondrial mutations at least a reasonable possibility. The PRAC concluded that the product information of products containing tobramycin 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 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.