



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 November 2024
EMA/64675/2025
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): spironolactone

Procedure No. EMEA/H/C/PSUSA/00002780/202403

Period covered by the PSUR: 07 March 2021 To: 08 March 2024



Scientific conclusions

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

In view of available data on the literature, and in view of a labelled information in mitotane EU SmPC, the PRAC considers a causal relationship between spironolactone and reduced mitotane plasma levels in adrenocortical carcinoma patients treated with mitotane is at least a reasonable possibility. The PRAC concluded that the product information of products containing spironolactone 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 spironolactone the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing spironolactone 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.