



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): hydrochlorothiazide / telmisartan, telmisartan

Procedure No. PSUSA/00002882/202503

Period covered by the PSUR:
3 years to 31 March 2025

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Scientific conclusions

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

In view of available data on dizziness from clinical trial, literature, spontaneous reports, including in 27 cases with a close temporal relationship, 12 cases with a positive de-challenge, 2 cases with a positive rechallenge and in view of a plausible mechanism of action and class effect, the PRAC Rapporteur considers a causal relationship between telmisartan and dizziness is at least a reasonable possibility. The PRAC concluded that the product information of products containing telmisartan 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 hydrochlorothiazide / telmisartan, telmisartan the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing hydrochlorothiazide / telmisartan, telmisartan 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.