EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 February 2025
EMA/59987/2025
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): sacubitril / valsartan

Procedure No. EMEA/H/C/PSUSA/00010438/202407

Period covered by the PSUR:
01/08/2023 To: 31/07/2024

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Scientific conclusions

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

In view of available data regarding excretion of sacubitril and valsartan in human breast milk from the literature, the PRAC considers that excretion of sacubitril in human breast milk is at least a reasonable possibility.

In view of available data on myoclonus from the literature, spontaneous reports including some cases with a close temporal relationship and a positive de-challenge, the PRAC considers a causal relationship between sacubitril/valsartan and myoclonus is at least a reasonable possibility.

The PRAC concluded that the product information of products containing sacubitril/valsartan 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 sacubitril / valsartan the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing sacubitril / valsartan 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.