30 January 2025
EMA/22169/2025
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): latanoprost / netarsudil

Procedure No. EMEA/H/C/PSUSA/00010905/202406

Period covered by the PSUR: 17 June 2023 To: 17 June 2024

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Scientific conclusions

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

In view of available data from the literature and spontaneous reports, including in some cases a close temporal relationship and a positive de-challenge, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between latanoprost / netarsudil and reticular epithelial corneal oedema is at least a reasonable possibility. Therefore, the PRAC concluded that the Product Information (PI) of products containing latanoprost / netarsudil 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 latanoprost / netarsudil the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing latanoprost / netarsudil 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.