30 May 2024
EMA/375776/2024
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): posaconazole

Procedure No. EMEA/H/C/PSUSA/00002480/202310

Period covered by the PSUR:
25/10/2022 To: 25/10/2023

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## Scientific conclusions

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

In view of available data on interaction with flucloxacillin from the literature and in view a plausible mechanism of action, the PRAC considers that a decrease of plasma posaconazole concentrations due to a drug-drug interaction between posaconazole and flucloxacillin, as well as a causal relationship between posaconazole and photosensitivity reaction to be at least a reasonable possibility. The PRAC concluded that the product information of products containing posaconazole 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 posaconazole the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing posaconazole 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.