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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

Active substance: ingenol mebutate

Procedure no.: EMEA/H/C/PSUSA/00010035/201507

Period covered by the PSUR: 1 February 2015 - 31 July 2015

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for ingenol mebutate, the scientific conclusions of CHMP are as follows:

Following a cumulative review, cases strongly suggestive of hypersensitivity to ingenol mebutate, including cases with features of angioedema, have been documented. It is considered that the product information should be updated to add hypersensitivity including angioedema.

Furthermore, following reports of chemical conjunctivitis and corneal burns on inadvertent contact of ingenol mebutate with the eyes, the product information should be updated to provide prescribers and patients with warnings regarding this risk.

In addition, post-marketing reports of pigmentation change following use of ingenol mebutate have been received, including both hypo- and hyperpigmentation. In some cases the changes remain unresolved more than one year after treatment. Following a cumulative review by the MAH, the PRAC agreed that the product information should be updated to add this adverse event.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considers that changes to the product information of medicinal products containing ingenol mebutate are warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for ingenol mebutate the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing ingenol mebutate is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation should be varied.