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): ingenol mebutate

Procedure No. EMEA/H/C/PSUSA/00010035/201901

Period covered by the PSUR: 31 July 2018 to 31 January 2019

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Scientific conclusions

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

Taking into account the treatment purpose for actinic keratosis, which is prevention of skin malignancy, and considering the number of skin tumour cases reported to ingenol mebutate in clinical trials and post-marketing, the PRAC has serious concerns about the impact of the risk of skin tumours on the benefit risk balance of Picato. The PRAC is of the opinion that a thorough review is needed of the impact of all available data related to skin malignancies, including the results of study LP0041-63, on the benefit risk balance of Picato. Additionally, the product information should be varied concerning ingenol mebutate use and the risk of skin malignancy. The PRAC also agreed that a DHPC is needed in order to mitigate this risk.

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

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for ingenol mebutate the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ingenol mebutate 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.