14 December 2023
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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): tacrolimus (topical formulations)

Procedure No. EMEA/H/C/PSUSA/00002840/202303

Period covered by the PSUR: 1 April 2021 to 31 March 2023

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Scientific conclusions

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

In view of available data on the risk of significant systemic absorption when used off-label to treat pyoderma gangrenosum from cases in the literature, the PRAC concluded that the product information of products containing topical tacrolimus should be amended to add pyoderma gangrenosum to the list of conditions mentioned in the SmPC for which tacrolimus ointment is not recommended.

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 tacrolimus (topical formulations) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tacrolimus (topical formulations) 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.