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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: tacrolimus (topical formulations)

Procedure No. EMEA/H/C/PSUSA/00002840/201503

Period covered by the PSUR: 1 April 2014 – 31 March 2015

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

A study investigating long-term safety of topical calcineurin inhibitors in the treatment of patients with atopic blepharoconjunctivitis was published during this reporting period. The study reported herpes simplex ophthalmic infection in eighteen patients. This is in addition to the cases contained in the marketing authorisation holder safety database, along with the known safety profile of topical tacrolimus. Given the previous signal evaluation of this issue and the known safety profile of tacrolimus, it is considered that this study provides additional evidence of an association of ophthalmic herpes infection with topical tacrolimus treatment, particularly when it is applied near the eyes. In view of the above, it is considered that ophthalmic herpes infection should be reflected as an adverse reaction with frequency unknown in the product information of Protopic.

Therefore, in view of available data regarding Protopic, the PRAC considered that changes to the product information were warranted.

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

Grounds recommending the variation to the terms of the Marketing Authorisation

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 products containing tacrolimus (topical formulations) is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisations should be varied.