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): tacrolimus (systemic formulations)

Procedure No. EMEA/H/C/PSUSA/00002839/202403

Period covered by the PSUR: 31/03/2021 - 31/03/2024

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Scientific conclusions

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

In view of available data on cases of Kaposi sarcoma from clinical trial data, literature and spontaneous reports, including cases with a close temporal relationship and a number of cases with a fatal outcome, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between systemic tacrolimus and Kaposi sarcoma is at least a reasonable possibility. The PRAC concluded that the product information of products containing systemic tacrolimus 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 tacrolimus (systemic formulations) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tacrolimus (systemic 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.