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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): 5-aminolevulinic acid (keratosis)

Procedure No. EMEA/H/C/PSUSA/00010006/201806

Period covered by the PSUR: 15 June 2015 to 14 June 2018

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for 5-aminolevulinic acid (keratosis), the scientific conclusions of the CHMP are as follows:

During the post-marketing phase 20 cases indicative of application site hypersensitivity have been received for Ameluz. In 12 cases the reactions started before illumination. Furthermore, a publication was identified reporting on occurrence of contact dermatitis after treatment with 5-aminolevulinic acid or methyl-aminolevulinic acid. Positive allergy tests were reported in the study. Therefore, it is recommended to include application site hypersensitivity as an adverse drug reaction (ADR) in section 4.8 of the SmPC.

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 5-aminolevulinic acid (keratosis) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing 5-aminolevulinic acid (keratosis) 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.