



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 October 2011
EMA/CHMP/486900/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion¹ (initial authorisation)

Ameluz

5-aminolevulinic acid

On 20 October 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ameluz, 78 mg/g gel intended for the treatment of actinic keratosis. The applicant for this medicinal product is Biofrontera Bioscience GmbH.

They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Ameluz is 5-aminolevulinic acid hydrochloride, a sensitizer used in photodynamic/radiation therapy (L01XD04) that causes damage of cellular components and eventually destroys the target cells.

The benefits with Ameluz are its ability to improve the complete response rate of actinic keratosis lesions. The most common side effects are irritation, erythema, pain, pruritus, oedema, exfoliation, scab and induration at application site.

A pharmacovigilance plan for Ameluz will be implemented as part of the marketing authorisation.

The approved indication is: "Treatment of actinic keratosis of mild to moderate intensity on the face and scalp (Olsen grade 1 to 2; see section 5.1)".

It is proposed that Ameluz is administered under the supervision of a physician, a nurse or other healthcare professionals experienced in the use of photodynamic therapy. Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.



The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Ameluz and therefore recommends the granting of the marketing authorisation.