



20 October 2011  
EMA/CHMP/484377/2011  
Committee for Medicinal Products for Human Use (CHMP)

## CHMP assessment report

### Ameluz

International non-proprietary name: **5-aminolaevulinic acid**

Procedure No. **EMA/H/C/002204**

### Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted

Biofrontera Exhibit 1030  
Biofrontera Inc. et al. v. DUSA Pharmaceuticals, Inc.  
IPR2022-00056



## Product information

<b>Name of the medicinal product:</b>	Ameluz
<b>Applicant:</b>	Biofrontera Bioscience GmbH Hemmelrather Weg 201 D-51377 Leverkusen Germany
<b>Active substance:</b>	5-aminolaevulinic acid hydrochloride
<b>International Non-proprietary Name/Common Name:</b>	5-aminolaevulinic acid
<b>Pharmaco-therapeutic group (ATC Code):</b>	Sensitizers used in photodynamic/radiation therapy (L01XD04)
<b>Therapeutic indication:</b>	Treatment of actinic keratosis of mild to moderate intensity on the face and scalp (Olsen grade 1 to 2; see section 5.1)
<b>Pharmaceutical form:</b>	Gel
<b>Strength:</b>	78 mg/g
<b>Route of administration:</b>	Cutaneous use
<b>Packaging:</b>	tube (alu)
<b>Package size:</b>	1 tube

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## List of abbreviations

%	percent
$\infty$	infinity
$^1\text{O}_2$	singlet oxygen
5-FU	5-fluorouracil
A1	alternative hypothesis
AE	adverse event
AK	actinic keratosis
ALA	5-aminolaevulinic acid
ALAD	aminolaevulinic acid dehydratase
ATP	adenosine triphosphate
BMI	body mass index
$\chi^2$	chi square
C	Caucasian
CCCR	complete clinical clearance rate
CI	confidence interval
cm	centimetre
$\text{cm}^2$	square centimetre
CHMP	Committee for Human Medicinal Products
CR	clearance rate
EC	Ethics committee
e.g. <i>exempli gratia</i> ,	for example
EMA	European Medicines Agency
EU	European Union
F	women
FAS	full-analysis set
g	gram
$\mu\text{g}$	microgram
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
H	hour
H0	null hypothesis
H1	(alternative) hypothesis
HIV	Human immunodeficiency virus
ICH	International Conference on Harmonization
i.e.	<i>id est</i> , that is
ITT	intent-to-treat
J	Joule
kg	kilogram
LOCF	last observation carried forward
M	men
$\text{m}^2$	square meter
mm	millimetre
$\text{mm}^2$	square millimetre
MAL	methyl-aminolaevulinic acid
MedDRA	Medical Dictionary for Regulatory Activities
mg	milligram
$\mu\text{g}$	microgram
mL	millilitre
mW	milliwatt
n	number
N/A	not applicable
nm	nanometre
OR	odds ratio
<i>P</i>	probability
PBG	porphobilinogen
PDT	photodynamic therapy
PK	pharmacokinetics
PP	per-protocol
PpIX	protoporphyrin IX
r	randomized

Resp	Respectively
ROS	reactive oxygen species
sec	second
SCC	squamous cell carcinoma
SD	standard deviation
SK	solar keratosis
SmPC	Summary of Product Characteristics
Target area A	face and forehead
Target area B	bald scalp
TEAE	treatment emergent adverse event
U	unit
UV	ultraviolet
vs.	<i>versus</i> , as opposed to

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