

AMELUZ®
[aminolevulinic acid
HCl] topical gel, 10%
& RhodoLED®

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[Important Safety Information](#)

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ACTINIC
KERATOSIS (AK)

TREAT THE FIELD
WITH PDT

WHY
AMELUZ®?

ACTIVATE WITH A
RHODOLED® LAMP

PHYSICIAN
SUPPORT

ACTIVATE WITH BF-RhodoLED®
Are you RED-y?
Red light activates deeper^{1,2}

Wavelength

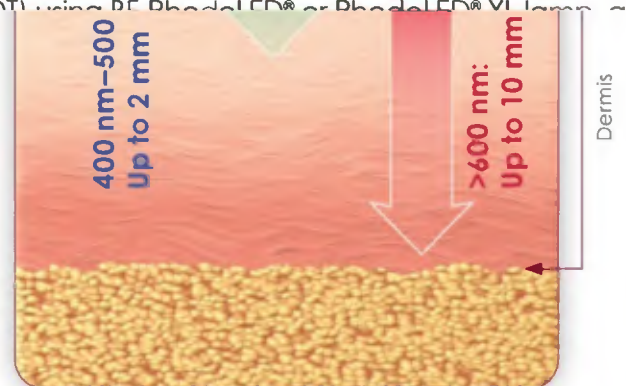


INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

AMELUZ® is indicated in combination with photodynamic therapy (PDT) using BF-RhodoLED® or RhodoLED® XL lamp to treat actinic keratosis (AK) on the face, scalp, and neck. Red light of shorter wavelengths^{1,3}

Activates PpIX, even at the deepest layer of the epidermis.^{1,3}



Estimated depth of light penetration into human skin¹

AMELUZ® (aminolevulinic acid HCl) topical gel, 10% and RhodoLED® lamp portfolio work together

The use of AMELUZ® with nanoemulsion technology, in combination with the red light of BF-RhodoLED® or RhodoLED® XL, enables PpIX formation and activation to treat the field.^{3,4}

RhodoLED® XL



BF-RhodoLED®

- Emits red light at a wavelength of ~635 nm⁴
- Delivers a light dose of approximately 37 J/cm² at a distance of 5-8 cm within 10 minutes⁶

BF-RhodoLED® is composed of four main components⁶:

1

Lamp head with holding bracket including adjustable distance indicator

2

Adjustable scissor arm

3

Storage shelf with control unit (touchscreen monitor)

4

Mobile frame with castors for transport

IMPORTANT SAFETY INFORMATION (SELECTED)

To avoid eye irritation, glare, or injury, protective eye equipment must be used by any person present during the illumination with BF-RhodoLED® or RhodoLED® XL. RhodoLED® XL emits bright light, do not stare into the light source. LEDs are classified in the exempt group according to IEC 62471:2006. Neither the BF-RhodoLED®, RhodoLED® XL nor their power supply units should be exposed to excessive mechanical stress or serviced by unauthorized personnel. Assembly and servicing may only be carried out by Biofrontera authorized personnel. Risk of trapping fingers! Beware of tipping the BF-RhodoLED®! Do not place the lamp on uneven or unstable surfaces. Do not place heavy objects on the storage shelf or use for sitting, leaning or pushing. In order to avoid the risk of electrical shock, the devices may only be connected to a power supply with a grounded connection. BF-RhodoLED® or RhodoLED® XL may not come into contact with water as this may lead to severe damage or electrical shock (exception: cleaning with a damp cloth). AMELUZ® shall not be used by persons who have known hypersensitivity to porphyrins, or other AMELUZ® ingredients (including soybean phosphatidylcholine). AMELUZ® should also not be used for patients who have porphyria or photodermatoses. Hypersensitivity reactions and transient amnesic episodes have been reported with the use of AMELUZ®. Patients should protect treated lesions from sunlight for 48 hours following treatment.

**Schedule a PDT consult to learn more
about the red-light penetration of
RhodoLED® lamp portfolio**

LEARN MORE >>

INDICATION AND IMPORTANT SAFETY INFORMATION**INDICATION**

AMELUZ®, in combination with photodynamic therapy (PDT) using BF-RhodoLED® or RhodoLED® XL lamp, a narrowband, red light illumination source, is indicated for lesion-directed and field-directed treatment of actinic keratoses (AKs) of mild-to-moderate severity on the face and scalp.

IMPORTANT SAFETY INFORMATION

AMELUZ® (aminolevulinic acid hydrochloride) topical gel, 10% with BF-RhodoLED® or RhodoLED® XL lamp

AMELUZ®, containing 10% aminolevulinic acid hydrochloride, is a non-sterile gel formulation for topical use only. Not for ophthalmic, oral, or intravaginal use.

AMELUZ®, in conjunction with lesion preparation, is only to be administered by a health care provider. Photodynamic therapy with AMELUZ® involves preparation of lesions, application of the product, occlusion and illumination with BF-RhodoLED® or RhodoLED® XL. The application area should not exceed 20 cm² and no more than 2 grams of AMELUZ® (one tube) should be used at one time. Lesions that have not completely resolved shall be retreated 3 months after the initial treatment. Refer to BF-RhodoLED® or RhodoLED® XL user manual for detailed lamp safety and operating instructions. Both patient and medical personnel conducting the PDT should adhere to all safety instructions.

AMELUZ® shall not be used by persons who have known hypersensitivity to porphyrins or any of the components of AMELUZ®, which includes soybean phosphatidylcholine. AMELUZ® should also not be used for patients who have porphyria or photodermatoses.

Hypersensitivity reactions have been reported with the use of AMELUZ® prior to photodynamic therapy (PDT). AMELUZ® should be washed off and appropriate therapy instituted. Inform patients and their caregivers that AMELUZ® may cause hypersensitivity, potentially including severe courses (anaphylaxis).

Transient Amnestic Episodes have been reported during postmarketing use of AMELUZ® in combination with photodynamic therapy (PDT). If patients experience amnesia or confusion, discontinue treatment. Advise them to contact the healthcare provider if the patient develops amnesia after treatment.

Eye exposure to the red light of the BF-RhodoLED® or RhodoLED® XL lamp during PDT must be prevented by protective eyewear. Direct staring into the light source must be avoided. AMELUZ® increases photosensitivity. Patients should avoid sunlight, prolonged or intense light (e.g., tanning beds, sun lamps) on lesions and surrounding skin treated with AMELUZ® for approximately 48 hours following treatment whether exposed to illumination or not.

AMELUZ® has not been tested on patients with inherited or acquired coagulation disorders. Special care should be taken to avoid bleeding during lesion preparation in such patients. Any bleeding must be stopped before application of the gel. AMELUZ® should not be used on mucous membranes or in the eyes.

Local skin reactions at the application site were observed in about 99.5% of subjects treated with AMELUZ® and narrow spectrum lamps. The very common adverse reactions ($\geq 10\%$) during and after PDT were application site erythema, pain/burning, irritation, edema, pruritus, exfoliation, scab, induration, and vesicles. Most adverse reactions occurred during illumination or shortly afterwards, were generally of mild or moderate intensity, and lasted for 1 to 4 days in most cases; in some cases, however, they persisted for 1 to 2 weeks or even longer. Severe pain/burning occurred in up to 30% of treatments.

There have been no formal studies of the interaction of AMELUZ® with other drugs. Concomitant use of the following photosensitizing medications may increase the phototoxic reactions after PDT: St. John's wort, griseofulvin, thiazide diuretics, sulfonylureas, phenothiazines, sulphonamides, quinolones, and tetracyclines.

There are no available data on AMELUZ® use in pregnant women to inform a drug associated risk. No data are available regarding the presence of aminolevulinic acid in human milk, the effects of aminolevulinic acid on the breastfed infant or on milk production. Safety and effectiveness in pediatric patients below the age of 18 have not been established as AK is not a condition generally seen in the pediatric population. No overall differences in safety or effectiveness were observed between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Please read the US Full Prescribing Information for AMELUZ® and/or US User Manual of BF-RhodoLED® and/or RhodoLED® XL lamp available together at <https://www.ameluz.com/PI>.

You are encouraged to report side effects of AMELUZ®. Please contact Biofrontera Inc. at [1-844-829-7434](tel:1-844-829-7434) or FDA at [1-800-332-1088](tel:1-800-332-1088) or www.fda.gov/medwatch.

References: 1. Agostinis P, Berg K, Cengel KA, et al. Photodynamic therapy of cancer: an update. *CA Cancer J Clin*. 2011;61(4):250-281. 2. Peng Q, Warloe T, Berg K, et al. 5-Aminolevulinic acid-based photodynamic therapy. Clinical research and future challenges. *Cancer*. 1997;79(12):2282-2308. 3. Reinhold U. A review of BF-200 ALA for the photodynamic treatment of mild-to-moderate actinic keratosis. *Future Oncol*. 2017;13(27):2413-2428. 4. AMELUZ [prescribing information]. Woburn, MA: Biofrontera Inc; 2024. 5. RhodoLED XL User Manual. Version 1.7. Woburn, MA; 2024. 6. BF-RhodoLED User Manual. Version 2.4. Woburn, MA; 2022.

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