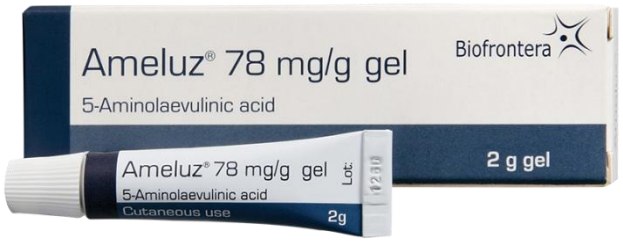
Ameluz

(aminolevulinic acid)



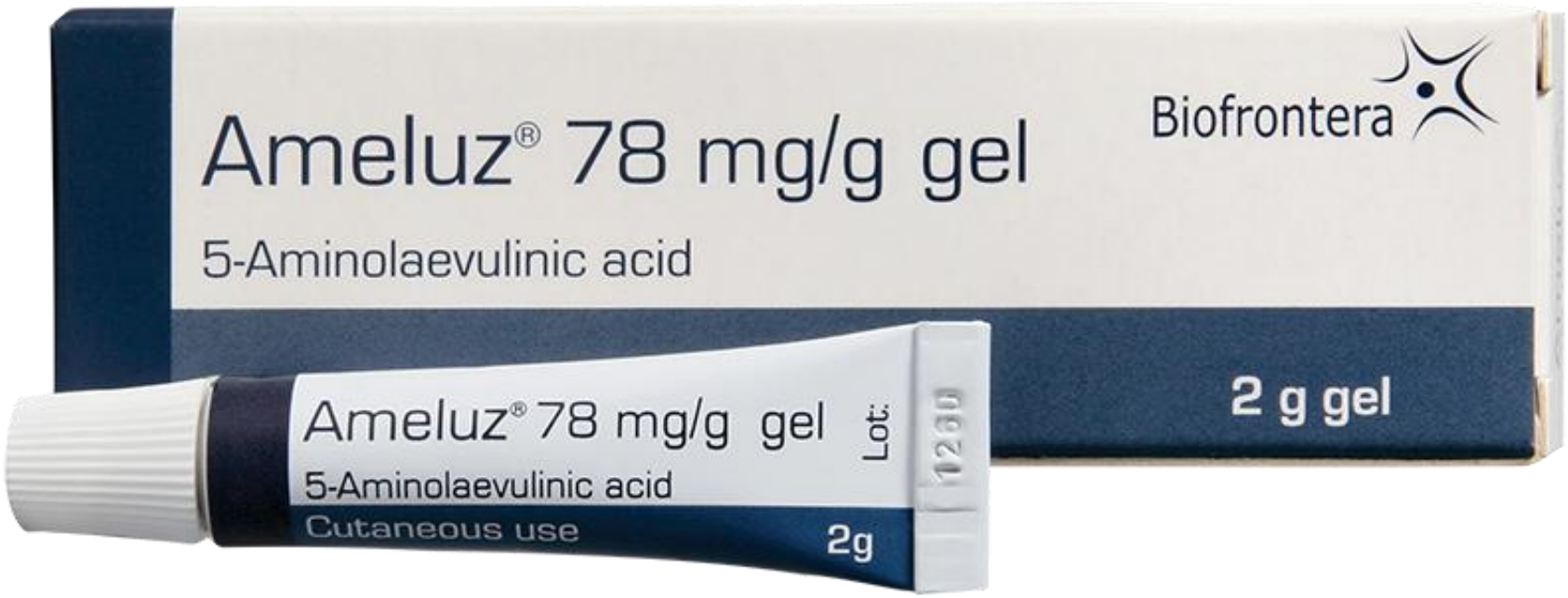
New Product Slideshow

MPR

Introduction

- **Brand name:** Ameluz
- **Generic name:** Aminolevulinic acid HCl
- **Pharmacological class:** Photosensitizer
- **Strength and Formulation:** 10%; gel; contains isopropyl alcohol
- **Manufacturer:** Biofrontera Inc.
- **How supplied:** Gel—2g
- **Legal Classification:** Rx

AMELUZ


Ameluz® 78 mg/g gel
5-Aminolaevulinic acid
Biofrontera
2 g gel
Ameluz® 78 mg/g gel
5-Aminolaevulinic acid
Cutaneous use
2g
Lot:

Indications

- In combination with photodynamic therapy using BF-RhodoLED lamp, for the treatment of **mild-to-moderate actinic keratoses** on the face and scalp

Dosage & Administration

- Clean and prepare all lesions prior to application
- Apply gel approx. 1mm thick and include approximately 5mm of the surrounding skin
- Use sufficient amount of gel to cover lesion(s) and entire area
- Max application area of 20cm^2 and max 2g (1 tube) use at one time

Dosage & Administration

- Cover treated area with occlusive dressing for 3 hours, then remove dressing and any remaining gel; immediately following illumination with red light: see full labeling
- Treated lesions not completely resolved after 12 weeks may be retreated

Considerations for Special Populations

- **Pregnancy:** No available data to inform a drug associated risk
- **Nursing mothers:** Consider benefits and adverse effects
- **Pediatric:** <18 years: not established
- **Geriatric:** No overall differences in safety or efficacy

Warnings/Precautions

- Administered by healthcare provider only
- Not for ophthalmic, oral, or intravaginal use
- **Avoid** sunlight, prolonged, or intense light (eg, tanning beds, sunlamps) on lesions and surrounding skin for 2 days after treatment
- **Avoid** applying to eyes, mucous membranes
- Inherited or acquired coagulation disorders

Interactions

- May **increase risk** of phototoxic reaction to PDT with concomitant other photosensitizing agents (eg, St. John's wort, griseofulvin, thiazides, sulfonylureas, phenothiazines, sulfonamides, quinolones, tetracyclines)

Adverse Reactions

- Application site erythema
- Pain/burning
- Irritation
- Edema
- Pruritus
- Exfoliation
- Scab
- Induration
- Vesicles
- Paresthesia
- Hyperalgesia
- Ophthalmic reactions
- Increased photosensitivity

Mechanism of Action

- Photoactivation occurs when aminolevulinic acid is metabolized to protoporphyrin IX (PpIX), a photoactive compound which accumulates in the skin
- When exposed to red light of a suitable wavelength and energy, PpIX is activated
- In the presence of oxygen, reactive oxygen species are formed which causes damage to cellular components, and eventually destroys the cells

Clinical Trials

- The safety and efficacy of Ameluz in combination with PDT using a narrow spectrum source were evaluated in 3 randomized, multicenter trials (Trials 1, 2, and 3)

- The studies included 212 subjects with 4-8 mild to moderate actinic keratoses lesions on the face/forehead and/or bald scalp

Clinical Trials

- All trials included a follow-up assessment after 6 and 12 months
- The **primary endpoint** for all trials was complete clearance 12 weeks after the last PDT

Clinical Trials

- In **Trial 1**, complete clearance was achieved in 85% of the Ameluz group vs. 13% of the vehicle group
- In **Trial 2**, complete clearance was achieved in 84% of the Ameluz group vs. 13% of the vehicle group
- In **Trial 3**, complete clearance was achieved in 91% of the Ameluz group vs. 22% of the vehicle group

Clinical Trials

- These patients entered a 12-month follow-up period
- Patients who received Ameluz with the narrow band PDT and achieved complete clearance 12 weeks after the last PDT had recurrence rates of:
  - **6 months:** 14%, 11%, and 25%
  - **12 months:** 40%, 22%, and 37%
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/ameluz/drug/34611/