AMELUZ® 78 mg/g gel (5-aminolaevulinic acid) PRESCRIBING INFORMATION

Please refer to the SmPC before prescribing.

Indication: Treatment of actinic keratosis of mild to moderate severity (Olsen grade 1 to 2) and of field cancerization in adults. Treatment of superficial and/or nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment related morbidity and/or poor cosmetic outcome in adults. **Dose and administration:** For cutaneous use under the guidance of a healthcare professional experienced in the use of photodynamic therapy (PDT). **Adults:** *Actinic keratoses (AK)*: One session of PDT administered for single or multiple lesions or entire fields with cancerization. To be performed either utilising natural or artificial daylight (for face and scalp) or red-light lamp (in any body area). *Basal cell carcinoma (BCC)*: Two sessions of PDT with red-light lamp for one or multiple lesions with an interval of about one week between sessions. *All indications*: Evaluate three months after treatment and retreat lesions or fields that have not completely resolved. See SmPC for details of administration. **Contraindications:** Hypersensitivity to active substance, porphyrins, soybeans or peanuts, or to any excipients. Porphyria. Known photodermatoses of varying pathology and frequency, e.g. metabolic disorders such as aminoaciduria, idiopathic or immunological disorders such as polymorphic light reaction, genetic disorders such as xeroderma pigmentosum, and diseases precipitated or aggravated by exposure to sun light such as lupus erythematosus or phemphigus erythemtosus. **Special warnings and precautions**: Transient global amnesia - if observed, discontinue PDT immediately. No experience in patients taking immunosuppressants or with coagulation defects. Any bleeding must be stopped before application of gel. Take special care to avoid bleeding during lesion preparation in patients with coagulation defects. Can cause mucous membrane or eye irritation. May be mildly irritant to the skin. Avoid applying into eyes or to mucous membranes. In case of accidental contact, rinse with water. Success and assessment of treatment may be impaired if the treated area is affected by skin diseases or tattoos; no experience exists with these situations. Intensive lesion preparation, e.g. chemical peel followed by ablative laser, might lead to increased pain. Discontinue UV-therapy before treatment. Avoid sun exposure on treated sites and surrounding skin for approximately 48 hours following treatment. Concomitant use of medicinal products with phototoxic or photoallergic potential such as St. John's wort, griseofulvin, thiazide diuretics, sulfonylureas, phenothiazines, sulphonamides, quinolones and tetracyclines may enhance the phototoxic reaction to photodynamic therapy. See SmPC for further details. **Pregnancy/ Breastfeeding:** Avoid use during pregnancy. Breastfeeding should be discontinued for 12 hours after treatment. **Undesirable effects:** In clinical trials local skin reactions were observed in most subjects treated. *Very common (≥1/10):* At application site: Erythema, pain (including burning pain), irritation, pruritus, oedema, scab, exfoliation, induration, paraesthesia. *Common (≥1/100 to <1/10):* At application site: Vesicles, discharge, erosion, reaction, discomfort, hyperalgesia, haemorrhage, warmth. Headache. *Uncommon (≥1/1,000 to <1/100):* Transient global amnesia (incl. confusion and disorientation) (data from post-marketing period), hypersensitivity (also occurs before illumination)(data from post-marketing period). See SmPC for a full list of undesirable effects. **Legal Category:** POM **Basic UK NHS cost:** £170 per 2g tube. **Market authorization (MA) number:** PLGB 34942/0002. **MA holder:** Biofrontera Bioscience GmbH. Hemmelrather Weg 201. 51377 Leverkusen. Germany. **Date of preparation of PI:** March 2024

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to Biofrontera Pharma GmbH on +49 214 876 32 66