

# Photodynamic Therapy Daylight-Activated

Daylight-Activated Photodynamic Therapy with 5-Aminolaevulinic Acid  
Nanoemulsion Gel (Ameluz®)



**INFORMATION LEAFLET FOR PATIENTS WHO HAVE BEEN  
REFERRED FOR AMELUZ® TREATMENT**

Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

Provided as a service to patients by Biofrontera Pharma GmbH, Leverkusen, Germany. [www.biofrontera.com](http://www.biofrontera.com).  
Additional product information can be found in the leaflet that is included in the pack, which you should be given a copy of. You can also download a copy of this leaflet at [www.medicines.org.uk/emc/product](http://www.medicines.org.uk/emc/product)

**Dear Patient**

**Your Doctor has prescribed daylight-activated Photodynamic Therapy (PDT) for the treatment of your Actinic Keratosis.**

### **What is Actinic Keratosis?**

In Actinic Keratosis or AK, areas of skin have become damaged by the sun over time. The cells in these areas grow more quickly than normal cells and while many may come and go over time, a number have the potential to develop into skin cancer. This is why it is important to treat these lesions. In addition, while some AKs appear as rough or scaly patches on the skin it is quite possible that a number of other non-visible areas of sun damage may exist around that lesion. For this reason, your clinician may have suggested a treating a wider area or a 'field' as they may have called it.

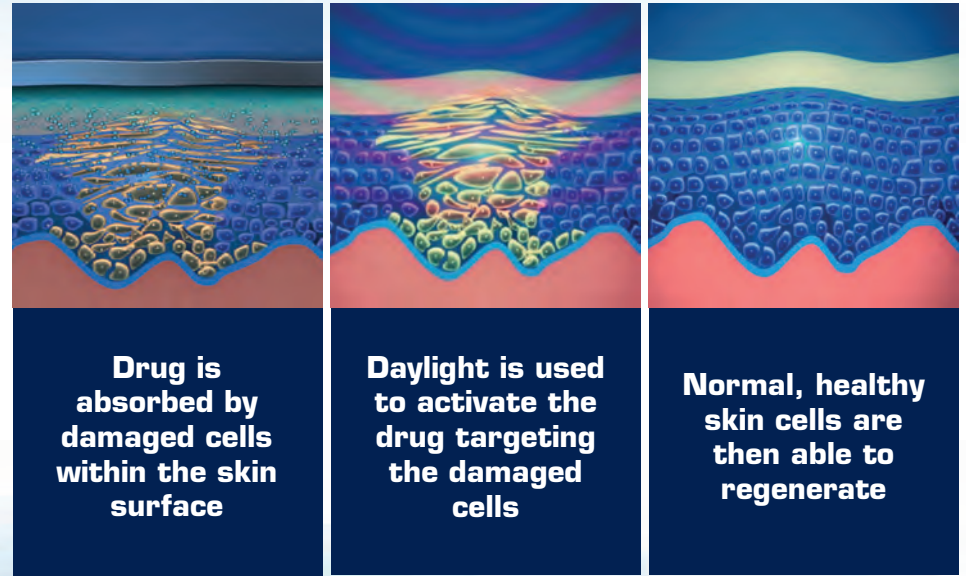
#### **Actinic keratosis lesions in different areas of the skin**



### **What is daylight activated photodynamic therapy?**

This is a treatment for individual Actinic Keratosis lesions or fields of sun damage. It involves the application of a photosensitising gel and then the use of daylight to activate this gel.

The gel starts a process in the damaged cells which helps destroy them while leaving the healthy skin intact.



## What do I need to do before my appointment?

Your doctor or nurse may ask you to apply a moisturiser, daily for the week before your appointment, to the affected area to soften any crusts or scales on your skin.

## What can I expect on the day of treatment?

In total you should expect to be at the hospital or clinic for around 3 hours.

When you arrive at the hospital/clinic, a member of the medical team will explain the procedure and ask for your consent to the treatment.

The first step will be to apply a sunscreen to the area to be treated as well as other exposed areas. It is important to avoid further sun damage but the sunscreen must not contain any physical sun blocks or filters, titanium dioxide for example, which would interfere with the effectiveness of the treatment.



Application of sunscreen:  
SPF 30 or greater  
with no physical filters



Lesion preparation  
(degreasing, roughening  
of the skin)



Application of the drug  
(incubation up to 30 min)



Illumination outdoor  
by natural daylight  
2h:>10°C

The area to be treated will then be cleaned with an alcohol wipe and any remaining crusts/scales will be gently removed. 5-ALA nanoemulsion gel will be applied in a thin layer.

Within the next 30 minutes, you will then be asked to go outside and stay in full daylight for the following 2 hours. Many clinics have a garden or courtyard where you can sit but as long as you remain in daylight the choice is up to you. Remember you don't need full sun, just daylight, so taking some shelter if it's too hot is fine. Bring along some music or something to read. The staff will give you more information on where might be suitable and what time to be back.

During the treatment you may experience some tingling in the sun damaged areas. This is normal and part of the treatment process.

After 2 hours any excess gel should be removed and the treated area covered up. Please keep the treated area covered with a dressing, sunscreen or an article of clothing (e.g. a hat) for the next 24-48 hours.

Your doctor or nurse is also likely to give you some more detailed information on aftercare.

Your clinician will normally ask to see you again in around 3 months to assess the results.



## What happens next

You can expect the treated area to become inflamed and crusty for up to two weeks while the damaged cells are shed and replaced with new healthy ones.



**Crusts and inflammation after treatment indicating where damaged cells have been targeted**



**Normal, healthy skin cells are able to regenerate within weeks**

## Are there any potential side effects of treatment?

Patients treated with PDT commonly experience localised skin reactions such as redness, swelling, itching and irritation. Many of these reactions are simply signs that the treatment is working. However if such symptoms persist or are more serious than you expected, you should not hesitate to contact your doctor or nurse for advice. If you experience adverse events that are not related to the treated areas you should report these to your clinician.

## Where can I find further information?

You can find an up-to-date copy of the Patient Leaflet giving more detailed information regarding 5-ALA nanoemulsion gel (Ameluz®) by searching on the **Electronic Medicines Compendium** website at:

[www.medicines.org.uk/emc/product](http://www.medicines.org.uk/emc/product)

Further information on Actinic Keratosis can be found on the **British Association of Dermatologists** website at:

[www.bad.org.uk/for-the-public/patient-information-leaflets/actinic-keratoses](http://www.bad.org.uk/for-the-public/patient-information-leaflets/actinic-keratoses)

