Fact Sheet – ACTINIC KERATOSIS

Indication

Actinic keratosis (AK) is a frequent form of keratonic disorder with a high burden of disease being the most common precancerous skin lesion.\textsuperscript{1} The prevalence of AKs is up to 60\% in certain populations.\textsuperscript{1}

The typical clinical picture of actinic keratosis shows scaly or keratotic patches, papules or plaques on an erythematous base of a sand paper-like texture.\textsuperscript{1} A common synonym for AK is solar keratosi s, as long-term exposure to the sunlight (UV radiation) is a major risk factor. Therefore AKs are mostly found on sun-exposed areas such as the face, the backs of the hands, the upper torso and the hairless scalp. Fair-skinned people are in particular at risk of developing actinic keratosis. Due to the cumulative sun exposure predominantly elderly people (\textgtr 50 years) are affected – among them more men than woman.\textsuperscript{2} Reasons for the latter are the increased sun exposure due to outdoor occupations like roadwork and a loss of hair by which particularly men are affected.

Between 0.25–16\% of the AK lesions annually progress to invasive cutaneous squamous cell carcinoma (SCC).\textsuperscript{3} Furthermore a recent study showed that SCC can develop from AK out of all degrees of severity.\textsuperscript{4} This changes the paradigm of the sequential model and underlines the importance of an early and effective therapy of AK.

Treatment options

The overall therapeutic goal is the removal of the altered cells – so that they can be replaced with new healthy ones from the deeper skin layers – and to prevent recurrences.


\textsuperscript{4} Fernández-Figueras MT et al. Actinic keratosis with atypical basal cells (AK I) is the most common lesion associated with invasive squamous cell carcinoma of the skin. J EADV. 2015;29:991-7.
Treatment options for actinic keratoses range – depending for example on the size and type of lesion – from topical medication (i.e. gel, cream and ointment) and destructive therapies (i.e. curettage, excision, laser ablation and cryotherapy) to the photodynamic therapy (PDT). A common treatment option for AK is the cryotherapy. This treatment involves the use of liquid nitrogen to ”freeze" the lesion. The correct handling regarding the time of freezing is critical to the effectiveness as well as to the minimization of possible side effects as scarring and pigmentation differences (i.e. Hypopigmentation).

Against this background the photodynamic therapy is a valid alternative. Findings from a meta-analysis showed a better treatment effect for PDT when used on thin actinic keratoses than for cryotherapy leading to consistently good cosmetic results.

Photodynamic therapy is a selective treatment for the local destruction of affected cells and tissue by applying a photosensitiser which is activated by light. The selectivity is based on the fact that the photosensitiser only accumulates in the diseased tissue. When red light is applied, singlet oxygen or other highly reactive species are generated, which induce target cell death.

**Photodynamic therapy (PDT) with the first self-adhesive patch**

Alacare® medicated patches contain the active ingredient 5-aminolevulinic acid (5-ALA) – a precursor of the naturally occurring porphyrin (haem) – in a crystalline form. 5-ALA is accumulated in the affected cells and transformed to Protoporphyrin IX. When the red light is applied during the PDT the Protoporphyrin IX reacts and unfolds its toxic cellular effect limited to the (pre)cancerous cells.

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Alacare® is approved for the single-use treatment of mild AK lesions on the face and hairless areas of the scalp in combination with PDT.

Compared to conventional PDT, with ALA-PDT patches no pre-treatment of the skin is necessary. The patch can be applied directly onto the lesions and is especially suitable for areas like nose or ear. Due to the opaque backing foil of the Alacare® patch, no further light protection is necessary during the application duration of four hours. When removed no cleaning of the treated area is needed as no residues are left and the lesions can directly be exposed to the red light.

**Lower recurrence and better clearance rates with the ALA-PDT patch**

Latest data of a long-term 12 month follow-up study show statistically significantly lower recurrence rates for Alacare® (p=0.011) compared with cryotherapy after 12 months of single treatment. Furthermore the findings proved that the clearance rate on a lesion-basis was statistically significantly superior (p<0.01) to cryotherapy at all visits.8

Another finding was that after 12 months of single treatment the cosmetic outcome was statistically significantly (p<0.001) superior with Alacare® compared to cryotherapy.8 This benefit has been confirmed with regard to the overall satisfaction of patients. Their assessment of the cosmetic outcome of Alacare® treated lesions was significantly more favourable compared to cryosurgery.9

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Fig. 1: Lesion-based CCCR (complete clinical clearance rate) vs. placebo and cryosurgery

Caption: Alacare® significantly improves lesion-based CCCR vs. placebo and cryosurgery

Fig. 2: Recurrence rates vs. placebo and cryosurgery

Caption: Alacare® shows significantly lower recurrence rates vs. cryosurgery
**Fig. 3:** Skin pigmentation after 12 months (single treatment)

Caption:
- Pigmentation of cleared lesions differed significantly between Alacare® and cryosurgery 12 months after single treatment.
- Patient’s assessment of the cosmetic outcome of Alacare® treated lesions was statistically significantly more favourable compared to cryosurgery.

Source: