2. SYNOPSIS

Name of Sponsor: Almirall Hermal GmbH Scholtzstr. 3 D - 21465 Reinbek	***Individual Study Table Referring to Part of the Dossier:*** ***Volume:*** ***Page:***	***(For Authority use only)***
Name of Finished Product: Verrumal® Lösung		
Name of Active Ingredient(s): 5 mg fluorouracil (0,5%) 100 mg salicylic acid (10 %)		

Title of Study: "Clinical trial to investigate clinical efficacy and tolerability of Verrumal® in actinic keratosis (PoC)"

Investigator: [redacted]

Study Center(s): Klinik für Dermatologie, [redacted] Leipzig

Publications (reference): field not pertinent	
Studied period (year): First subject enrolled: 9th April 2007 Last subject completed: 10th October 2007	Phase of development: II

Objectives:
to assess the clinical efficacy and tolerability of Verrumal® (active ingredients: 5-FU, Salicylic acid) in the treatment of actinic keratosis.

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Methodology:
Monocenter, open, single-armed, non-controlled Proof-of-Concept (PoC) to investigate efficacy and tolerability: clinical score, physician global assessment (PGA), patient assessment

Number of subjects planned: *1*5; enrolled: 15; analyzed final visit: 15 ; analysed after follow up: 14 (1 patient lost during follow up)

Diagnosis and main selection criteria:

A group of 15 patients with 1 to 5 actinic keratosis lesions on scalp and/ or hands
male or female subjects aged >18 years

Reference product, dose and mode of administration, batch number: Not applicable
Test product, dose and mode of administration, batch number: Verrumal® Lösung, 80 - 100 mg to be applied to the investigated area of 1 to 5 actinic keratoses on approx 10 -15 cm^2 (acc to the German SmPC of Verrumal DMSO was listed as "active", which has been changes via variation to co-active compound)
Duration of treatment*: 4 weeks*
Criteria for Evaluation: **Primary** variable: improvement in clinical score for AK-lesions **Secondary** variables: tolerability, PGA, patient assessment, compliance
Statistical methods descriptive evaluation
Results efficacy: Overall 66 AKs were treated with Verrumal® Lösung for 4 weeks (3 times per week). After 12 weeks complete response of 47 out of 61 AKs (77%), partial response of 13 AKs (21%) and non response of 1 AK (2%) were achieved.
Results safety: No serious adverse events occurred, treatment with Verrumal ® Lösung was safe and well tolerated. Most patients reported about burning sensations, some pain and itching. Usually adverse reactions lasted for a short time.
Conclusions: Verrumal ® Lösung appeared to be very effective in treating actinic keratoses. The treatment was safe and well tolerated by the patients. The overall satisfaction of the patient with the treatment was good. These preliminary results need to be confirmed in larger clinical trials .