

# NEW COMPLEMENTARY TREATMENT FOR PSORIASIS

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Psoriasis is a common chronic, recurring skin disease. Genetic predisposition as well as provoking factors play a role in its etiology. The clinical presentation is variable. There are multiple topical and systemic treatment options available. In certain clinical presentations the topical therapy is sufficient.

The study of the topical product family was designed to determine whether its natural oil content (the composition and ratio of the natural oils) was able to reduce the psoriatic parakeratosis, inflammation and infiltration.

#### STUDY TYPE - Open

**CONSENT** - Prior to the beginning of the study, the participating patients signed an informed consent and an agreement of voluntary participation.

**OBJECTIVE** - Evaluation of the topical product family in psoriasis, to determine its efficacy, adverse effects and tolerability.

#### CHARACTERISTICS OF THE TESTED PRODUCT

**Triphasic application:** Successive use of a cleansing gel, ointment, and skin conditioner.

##### CLEANSING GEL

**COMPONENTS:** water, coal tar solution, sodium lauryl ether sulfate, coco amido dipropyl betaine, triethanolamine lauryl sulphate, organic acids, fruit acid complex, coconut diethanolamide, carbopol, triethanolamine, methylisothiazolinone, tetrasodium EDTA.

**APPLICATION:** Applied before the use of the ointment.

**Scalp:** Following wetting of the scalp, a small amount of cleansing gel was applied to the plaques. Washed off after 2-3 minutes using lukewarm water.

**Body:** Applied to the psoriatic plaques, washed off with lukewarm water after 2-3 minutes. Not to be applied to the face.

##### ointment

**COMPONENTS:** wheatgerm oil, sweet almond oil, evening primrose oil, pet jelly, zinc oxide, jojoba oil, apricot kernel oil, avocado oil, mineral oil, carrageenun, carrot oil, fruit acid complex, lavender oil, tea tree oil, bergamot oil, sandalwood oil, patchouli oil, pine oil, geranium oil, orange oil, neroli oil, calendula oil, frankincense oil, citronella oil, chickweed extract, chamomile extract, sesame seed oil, myrrh oil, preservatives.

**APPLICATION:** Applied to the psoriatic plaques of the scalp and body after using and washing off the cleansing gel. Ointment was applied only to severely infiltrated plaques on the scalp.

##### SKIN CONDITIONER

**COMPONENTS:** olive oil, sesame seed oil, mineral oil, beeswax, sunflower oil, emu oil, lavender oil, eucalyptus oil, rosemary oil, natural vitamin e, chickweed extract, calendula oil, preservatives.

**APPLICATION:** Applied to the psoriatic plaques two minutes after using the ointment (without washing it off).

**APPLICATION TO THE SCALP WITHOUT OINTMENT:** The conditioner was applied to the scalp at night and washed off in the morning using the cleansing gel. The conditioner was reapplied at night without washing the scalp and washed off again using the cleansing gel in the morning. It was recommended to apply the three component product family twice daily, in the morning and at night.

#### PATIENT EVALUATION

##### INCLUSION CRITERIA

- mild to moderately severe psoriasis without complications
- both genders, age above 18
- no other current anti-psoriatic therapy
- signed informed consent

##### EXCLUSION CRITERIA

- pustular and erythrodermic psoriasis
- systemic, acitretin, cyclosporin, methotrexate, light therapy currently or within the past 3 months
- topical antipsoriatic therapy
- pregnancy, breast feeding
- known hypersensitivity to any of the components of the products
- lack of informed consent
- low compliance

Not to be applied to the face, genitals and flexures.

#### STUDY PROTOCOL

##### TIME FRAME

2 weeks of wash out period. During this phase the patients used only emollients.

Application time of the products:

Total study length: 8 weeks

##### EVALUATION POINTS

-2, 0, 1, 2, 3, 4, 5, 6 week  
Total number of medical evaluations: 8  
Patients included: 62  
Patients excluded: 5  
Patients evaluated, completed: 57  
Application frequency: twice daily

**EVALUATION OF EFFICACY:** The evaluation was based on the Psoriasis Area and Severity Index (PASI) at each of the 8 medical evaluations.

##### EVALUATION OF IMPROVEMENT

Worsened PASI score higher than baseline  
No improvement PASI decrease 0-25%  
Moderate improvement PASI decrease 26-50%  
Good improvement PASI decrease 51-75%  
Outstanding improvement PASI decrease 76-100%

##### RECORDING OF SIDE EFFECTS

The recording of side effects began on week 3. The characteristics of the side effects, their relation to the product and the additional steps taken were recorded on the datasheet.

##### EVALUATION OF SIDE EFFECTS

Evaluation points of side effects: 1, 2, 3, 4, 5, 6 week

##### EVALUATION OF THE RESULTS

**COSMETIC EFFECTS** - tolerability was evaluated at the end of the study based on the statements of the patients.

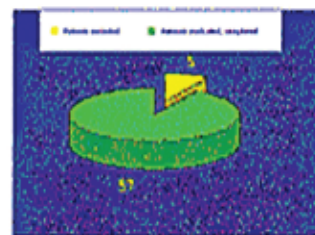
**EFFICACY** was evaluated by the physician at the end of the study using the following descriptors: worsened, ineffective, moderate effect, good effect, outstanding effect. The physician's evaluation was based on the percentage change of the PASI scores.

#### PATIENT CHARACTERISTIC

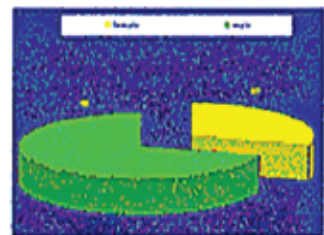
Mean age - 47,48 years (18 - 80)

Mean duration of psoriasis - 16,54 years  
(1 month - 47)

#### DATA OF THE STUDY



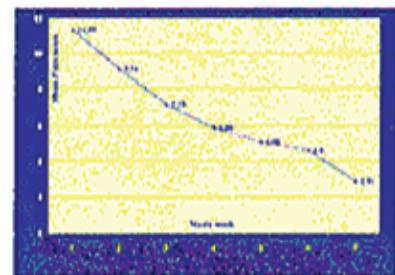
#### GENDER DISTRIBUTION



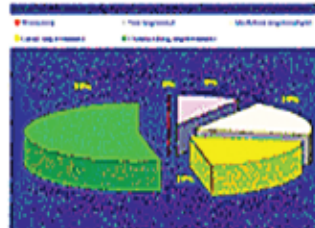
#### PSORIASIS TYPE

Plaque type - mild to moderately severe

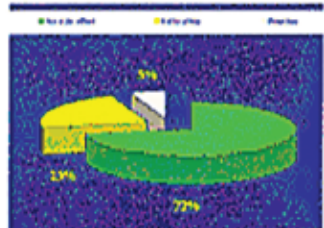
**SUMMARIZED CHANGE OF PASI SCORE IN ABSOLUTE VALUES**  
Number of patients: 57



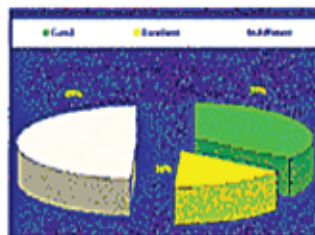
#### CHANGES OF SKIN SYMPTOMS OF THE STUDIED PATIENTS



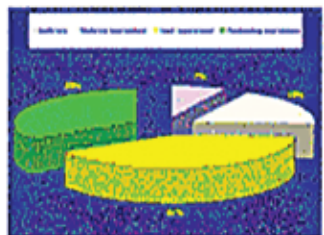
#### SIDE EFFECTS



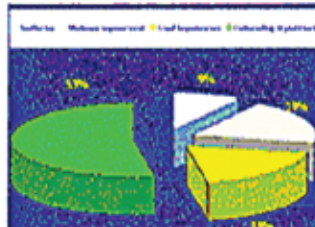
#### COSMETIC EFFECT - EVALUATED BY THE PATIENTS



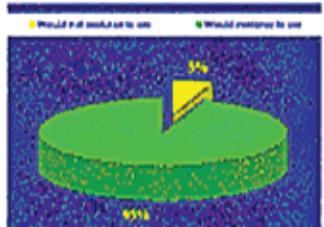
#### SUBJECTIVE EVALUATION OF EFFICACY BY PATIENTS



#### PHYSICIAN'S EVALUATION OF EFFICACY



#### STATEMENT OF PATIENTS REGARDING FUTURE USE OF THE PRODUCT



## SUMMARY

The study was completed in 57 patients. Five patients dropped out four due to lack of compliance and one due to the retraction of informed consent. The patient in the trial had mild to moderately severe psoriasis.

The product proved to be **ineffective** in five of the 57 patients (9%). 11 patients (19%) had **moderate improvement**, 25-50% of the skin lesions cleared up. 11 patients (19%) had **good improvement**, 51-75% of the lesions disappeared. 30 patients (53%) showed **outstanding improvement** with the regression of 76-99% of the lesions.

23% of the patients developed **folliculitis as side effect** that was clearly related to the product family. The folliculitis was noted at a few treated plaques and the surrounding areas on the lower extremities. In all cases the folliculitis regressed upon discontinuation of the application without further treatment. In one case the folliculitis cleared after topical therapy. 5% of the patients developed **pruritus** which regressed without discontinuing the application.

No contact sensitization could be noted, which is probably due to the thorough screening applied during patient selection.

Although this product is a cosmetic, due to the previously described circumstances it was recommended that the patients seek the advice of a dermatologist before starting the application. In case of noticing side effects the patients should consult a dermatologist.

The **cosmetic effect** was evaluated as **indifferent** by 49% of the patients, as **good** by 35% of the patients, and as **excellent** by 16% of the patients.

The **evaluation of the treatment by the patients** differs from that by the **physician**. The physician considered the improvement 'outstanding' in 53% of the cases while the patients considered it 'outstanding' in 33 % of the cases. The differences can be explained by the fact that the physician's evaluation was based on a pre-determined scale and calculation of the percentage changes, while the patient evaluation was entirely subjective. The patients considered the improvement 'good' when it was only moderate based on the calculated scores. However, many patient would only have given 'outstanding' evaluation for complete clearing of the lesions.

95% of the patients stated that they **would continue to use the product**, including those who had only moderate improvement. They argued that they were less concerned about side effects since the product was a cosmetic not a medication.

**BASED ON THE RESULTS OF THIS STUDY,  
THE NEW COMPLEMENTARY TREATMENT  
CAN BE SUCCESSFULLY APPLIED  
IN MILD TO MODERATELY SEVERE PSORIASIS.**