

## **CLINICAL TRIALS - RESULTS OF THE HUNGARIAN, ROMANIAN, RUSSIAN AND AUSTRIAN**

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## **Introduction**

Psoriasis is:

- Inflammatory & proliferative disease
- Results in chronic, sharply demarcated plaques with silvery scales
- Can be very severe – can lead to hospitalization
- Can be itchy
- Non-contagious
- A chronic, recurring skin disease affecting 2-4% of the population
- Genetic predisposition and secondary triggers play a role in its etiology
- Can occur in any age group or gender
- Frequently affected areas of the body include scalp, extensor surfaces of the extremities, skin folds and nails
- Cannot be cured – but can go into remission
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Since psoriasis cannot be cured, it is important to find treatments that are safe and can be used long term. At present topical corticosteroids are the mainstay of therapy for stable chronic plaque psoriasis. Over the past few years, there have been growing concerns about the side

effects of steroid therapy. Patients, the world over, are looking for an alternative therapy which is effective and safe. Herbal remedies are the most common treatment options available, however most of these topicals have not undergone the rigorous testing required by the scientific bodies. Over a twenty year period, Dr. Michaels product family has shown to be both effective and safe, however lacked the independent scientific clinical testing.

## Aims of the Studies

The studies of the Dr Michaels topical product family were designed to determine the efficacy of the preparations in the treatment of cases of psoriasis with differing severity and establish whether these natural oil contents (the composition and ratio of the natural oils) were able to decrease the psoriatic parakeratosis, inflammation and infiltration. Toxicology tests were also carried out .

### Objective

To determine the **efficacy, adverse effects and tolerability** of Dr Michaels topical product family.

## Characteristics of the Tested Products

- **Dr Michaels Scalp and Body Cleansing Gel**

Loose, white-opaque, easily applicable topical preparation

**Effect:** Decreases parakeratosis

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

- **Scalp:** Wet scalp and apply a small amount of cleansing gel. Massage thoroughly and leave for 2-3 minutes. Wash off with lukewarm water. **(Can be applied to forehead but avoid cheek area).**
- **Body:** Wet body. Apply small amount of cleansing gel to the psoriatic plaques. Leave for 2-3 minutes then rinse off with lukewarm water.
- **Active Ingredients:** Organic acids, fruit acid complex.
- **Package: 200ml plastic bottles.**

- **Dr Michaels Scalp and Body Ointment.**

Yellowish-white ointment with characteristic scent.

**Effect:** Decreases inflammation and infiltration.

**Application:** Applied to the psoriatic plaques of the scalp and body after using and washing off the cleansing gel. Only apply to severely infiltrated plaques on the scalp.

**Ingredients:** Vegetable oils (wheatgerm oil, sweet almond oil)

Essential oils (lavender oil, rosemary oil, citronella oil)

**Packaging:** 50g and 200g plastic vials

- **Dr Michaels Skin Conditioner**

**Effect:** Prevent the loss of flexibility and elasticity in the skin.

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

**Application to the scalp without ointment :** The conditioner is applied to the scalp, left on over night and then washed off in the morning using the cleansing gel.

**Ingredients:** A mixture of vegetable and essential oils (olive oil, sesame seed oil, emu oil, lavender oil, eucalyptus oil, natural vitamin E).

**Packaging:** 50ml and 200ml plastic bottles.

- *IT IS RECOMMENDED TO APPLY THE THREE-COMPONENT PRODUCT FAMILY TWICE DAILY, MORNING AND NIGHT.*

## THE TRIALS

### THE HUNGARIAN AND ROMANIAN CLINICAL TRIALS

**The Hungarian and Romanian open trials** involved 57 patients (30 males, 27 females), suffering with mild to moderately severe plaque type psoriasis, between the ages of 18 to 80 years old. The mean age was 45.2 years with a mean duration of psoriasis of 15.3 years. Five patients dropped out due to non-compliance and one due to retraction of informed consent.

The evaluation was based on Psoriasis Area Severity Index (PASI) score at each of the 8 medical evaluations. Evaluated features included erythema, infiltration, parakeratosis and size of affected lesions.

Eight weekly evaluations were done.

The evaluation of improvement was based on the following:

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

The product family proved to be ineffective in 5 of the 57 patients (9%).  
11 patients (19%) had good improvement with 51-75% of skin lesions disappeared.  
30 patients (53%) showed outstanding improvement with the regression of 76-100% of the lesions.

23% of the patients developed folliculitis for a short period as a side effect. The folliculitis was noted on a few plaques of the lower extremities and was insignificant in terms of severity. 5% of the patients developed pruritis, which regressed without discontinuing the application. No contact sensitization was noted, which is probably due to the thorough screening applied during patient selection.

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. Toxicology tests carried out on patients with very sensitive skin, including children, showed a 100% tolerance and passed the requirements of the EU.

The evaluation of the treatment differed from that of 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 percentage changes, while the patients' evaluation was entirely subjective. Many patients would have given outstanding only for complete clearing of the lesions. 95% of the patients stated that

they would continue to use the product family including those who had only moderate improvement. They argued that as the product family was a cosmetic not a medication, they were not considered about safety and bad side effects.

## Conclusion

**Based on the results of these studies, Dr. Michaels new complementary treatment can be successfully applied in mild to moderately severe psoriasis and is well tolerated by all skin types passing all the toxicology tests carried out.**

## THE RUSSIAN CLINICAL TRIAL

**In the Russian clinical examination** there were 30 patients between the ages of 9 to 60 years with psoriasis of different severity. There were 3 girls, 12 boys while the adults consisted of 5 women and 10 men. The severity of the clinical symptoms were evaluated using PASI scores with:-

Mild psoriasis PASI less or equal to 20 (12 patients)

Moderately severe PASI bigger than 21 and less or equal to 50 (9 patients)

Severe PASI bigger than 51 (9 patients)

Four evaluations were done at weekly intervals. 10 patients (84%) in the mild psoriasis group went into clinical remission and 2 patients had no improvement. 4 patients (44%) in the moderately severe group went into remission, 2 had significant improvement, one had improvement and 2 had no effect. In the severe group 2 patients (22%) went into remission, 4 patients had significant improvement, 2 had improvement while one had no effect.

**In the 30 patients treated, 22 patients (73%) had significant improvement or better.**

Dr. Michaels product family is highly effective and in terms of efficacy, it is comparable to the generally used therapeutic regimen, which is based on the application of corticosteroids with fluorid content. Dr. Michaels preparations do not have severe side effects and are user-friendly. They do not have an unpleasant smell and do not stain the underwear. They can be successfully applied in the case of outpatients as well including children **Dr. Michaels preparations have been used successfully on patients with psoriasis exceeding 30% of total body surface area (TBSA), however other parallel applications available CANNOT exceed 30% of TBSA of the patient.**

## Conclusion

**Based on the clinical results Dr. Michaels product family can be used successfully to treat mild to severe forms of plaque and exudative types of psoriasis.**

## THE AUSTRIAN CLINICAL TRIAL

**The Austrian trial** was a "Randomized Controlled double-blind study" involving 34 patients (15 females, 19 males). Evaluation of improvement was based on PASI scores. 14 patients in the verum group (those treated with Dr. Michaels product family) and 10 patients in the placebo group completed the treatment course, 10 patients did not complete the eight week of trial. Before therapy, the mean PASI score of the verum group was 6,8 +/- 2,4 SD, while the placebo group was 5,5 +/- 2 SD. **After the 8 week treatment course, the mean PASI score in the verum group was 1,2 +/- 1,01 SD which is equivalent to a PASI score reduction of 89% +/- 14,9 SD. The respective values for the placebo group were 4,1 +/- 1,7 SD and 22% +/- 28,7 SD.**

**The decrease in PASI scores in the verum is very significant after 8 weeks (P < 0,0001).**

Three patients in the verum group and 3 patients in the placebo group reported mild and transient side effects (irritative dermatitis, folliculitis), which did not require any special therapy or caused the patients to discontinue treatment. The majority of the patients who dropped out came from the placebo group. Results of the toxicology tests carried out fell well within the limits acceptable by the European Union.

## **Conclusion**

**The investigation showed that Dr. Michaels product family is effective and safe for the treatment of stable chronic plaque psoriasis.**

**The results from the clinical investigation were so outstanding that the investigators believed that Dr. Michaels product family must contain corticosteroids or calcipotriol. To qualify these issues the Austrian Health Ministry ordered chemical tests be performed immediately. Tests were carried out using HPLC, DAD, and UV methods for calcipotriol and 104 variations of corticosteroids. All the results showed that Dr. Michaels product family contains NO corticosteroids or calcipotriol. Toxicological tests carried out also showed that Dr Michaels product family can be safely applied even to the most sensitive skin including babies six months old.**

Based on 4 independent clinical investigations involving 121 patients, Dr. Michaels product family has proven to be effective in the treatment of mild to severe plaque and exudative types of psoriasis.

*This document was compiled from the Clinical Reports produced from each of the Investigating Institutions by*

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### **FINAL CONCLUSION**

**In conclusion, the results from all the clinical trials showed that Dr Michaels product family can be used effectively in the treatment of mild to severe types of psoriasis. The toxicology test results also confirmed that the products are safe to use even on the most sensitive skin including babies.**