REPORT OF THE STUDY OF THE "DR MICHAELS" TOPICAL PRODUCT FAMILY IN PSORIASIS

RESULTS OF THE HUNGARIAN, ROMANIAN, RUSSIAN AND AUSTRIAN

CLINICAL TRIALS

Lead investigators:

Hungary:

Prof. Dr. Attila Horváth
Institution: Semmelweis University Budapest
Dept. of Dermato – Venereology
H – 1085 Budapest, Maria utca 41.
Study type: Open.

Romania:

Prof. Dr. Maier Nicolae
Clinica de Dermatologie si Venerologie
Cluj Napoca, Str.Clinicilor nr. 3-5, cod 3400

Russia:

Prof. N.G. Korotky, Doctor of Medical Sciences,
Corresponding Member of the Russian Scientific Academy,
Head of the Department of Dermatology and Venereology of the Pediatric Clinic at the Russian State Medical University

Austria:

Prof. Dr. H. Hönigsmann university professor
Dermatology University Clinic
General Hospital of the City of Vienna
Währinger Grürtel 18-20, A-1090 Wien

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

Since psoriasis cannot be cured, it is important to find treatments that are safe and can be used long term. At present topical corticosteroids at 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

Scanned with CamScanner

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.

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.

Characteristics of the Tested Products

■Dr Michaels Scalp and BodyOintment.

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

Characteristics of the Tested Products

■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.

Scanned with CamScanner

THE 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 s side effect. The folliculitis was noted on a few plaques of the lower extremities and was insignificant in terms if 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.

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.

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)

Scanned with CamScanner

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. **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 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.

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.

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:

Jutka Šibík-Kovács
RICA Pharma s.r.o
Tel: +420 602 290 318
e-mail: skj@ricapharma.cz

Scanned with CamScanner

SEMMELWEIS EGYETEM BUDAPEST
Bőr- és Nemikórtani Klinika

Igazgató:
Dr. HORVÁTH Attila
egyetemi tanár

SEMMELWEIS UNIVERSITY BUDAPEST
Dept. of Dermato - Venereology

Director:
Prof. Attila HORVÁTH
M.D. Ph.D.

Budapest, Mária u. 41. – H-1085 HUNGARY – Tel.: (36) 1 266-0465 – Fax: (36) 1 267-6974

OF THE STUDY OF THE 'DR. MICHAELS' TOPICAL PRODUCT FAMILY

IN PSORIASIS

Lead investigator:	Prof. Dr. Attila Horváth
Institution:	Semmelweis University Dept. of Dermato - Venereology H - 1085 Budapest, Mária utca 41.
Study type:	Open
TÜKEB permit number:	26 / 2002
OÉTI permit number	6060 / 2001
Consent:	Prior to the beginning of the study, the participating patients signed an informed consent and an agreement of voluntary participation.

I. GENERAL POINTS

1. BACKGROUND

Psoriasis is a common (approximate prevalence of 2% in Hungary) chronic, recurring skin disease. Genetic predisposition as well as triggering factors play role in its etiology. The disease can occur at any age without any gender predominance. Although psoriasis can affect any regions of the body there are areas more frequently involved, such as the scalp, extensor surfaces of the extremities, skin folds, nails. The clinical presentation is variable, characterized by infiltration and parakeratosis. There are multiple topical and systemic treatment options available. In certain clinical presentations the topical anti-psoriasis therapy is sufficient.

Scanned with CamScanner

REPORT

OF THE STUDY OF THE 'DR. MICHAELS' TOPICAL PRODUCT FAMILY IN PSORIASIS

Lead investigator:	Prof. Dr. Attila Horváth
Institution:	Semmelweis University Dept. of Dermato - Venereology H - 1085 Budapest, Mária utca 41.
Study type:	Open
TÜKEB permit number:	26 / 2002
OÉTI permit number	6060 / 2001
Consent:	Prior to the beginning of the study, the participating patients signed an informed consent and an agreement of voluntary participation.

I. GENERAL POINTS

1. BACKGROUND

Psoriasis is a common (approximate prevalence of 2% in Hungary) chronic, recurring skin disease. Genetic predisposition as well as triggering factors play role in its etiology. The disease can occur at any age without any gender predominance. Although psoriasis can affect any regions of the body there are areas more frequently involved, such as the scalp, extensor surfaces of the extremities, skin folds, nails. The clinical presentation is variable, characterized by infiltration and parakeratosis. There are multiple topical and systemic treatment options available. In certain clinical presentations the topical anti-psoriasis therapy is sufficient.

Scanned with CamScanner

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

2. OBJECTIVE

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

3. CHARACTERISTICS OF THE TESTED PRODUCT

Triphasic application: Successive use of a cleansing gel (Cleansing Gel – Scalp and Body), ointment (Scalp and body ointment), and skin conditioner (Skin conditioner).

3.1 Dr. Michaels cleansing gel for the scalp and body

Loose, white-opaque, easily applicable topical preparation.

Effect: decreases parakeratosis

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, methylchloroisothiazolinone (and) methylisothiazolinone, tertasodium EDTA.

Application: Applied before the use of the ointment.

Scalp: Applied to the plaques on the scalp together with small amount of cleansing gel after previous wetting of the scalp. Washed off after 2-3 minutes using lukewarm water. Can not be applied to the face.

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

Formulation: 200 ml in plastic bottles

3.2 Dr. Michaels ointment – head and body

Yellowish-white ointment with characteristic scent.

Components: wheatgerm oil, sweet almond oil, evening primrose oil, pet jelly, zinc oxide, jojoba oil, apricot kernel oil, avocado oil, mineral oil, carrageenum, 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.

Scanned with CamScanner

Effect: Decreases inflammation, infiltration.

Application: Applied to the psoriatic plaques of the scalp and body after using and washing off the cleansing gel. On the scalp only recommended to apply to severely infiltrated plaques.

Formulation: 50 g and 200 g in plastic vials.

3.3 Dr. Michaels skin conditioner – head and body

White colored, viscous substance with characteristic scent.

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 is applied to the scalp at night and washed off in the morning using the cleansing gel. The conditioner is reapplied at night without washing the head, and washed off again using the cleansing gel in the morning.

Formulation: 50 or 200 ml in plastic bottles.

It is recommended to apply the three-component product family twice daily, in the morning and at night.

4. PATIENT EVALUATION

4.1 Inclusion criteria

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

4.2 Exclusion criteria

- pustular and erythrodermic psoriasis
- systemic, acitretin, cyclosporin, methotrexate, light therapy currently or within the past 3 months
- topical antipsoriatic therapy

Scanned with CamScanner

- pregnancy, breast feeding
- known hypersensitivity to any of the components of the products
- lack of informed consent
- low compliance

4.3 Can not be applied to the face, genitals and folds

5. STUDY PROTOCOL

5.1 Time frame

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

Application time of the Dr. Michaels products: 6 weeks

Total study length: 8 weeks

Evaluation points: -2, 0, 1, 2, 3, 4, 5, 6 week

Total number of medical evaluations: 8

Patients in the study: 30

Application frequency: twice daily

5.2 Evaluation of efficacy

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

Evaluated features: erythema, infiltration, parakeratosis, size of affected area.

Score	0	1	2	3	4
Erythema	0= none	1= mild	2= moderate	3= severe	4= very severe
Infiltration	0= none	1= mild	2= moderate	3= severe	4= very severe
Parakeratosis	0= none	1= mild	2= moderate	3= severe	4= very severe

Score	0	1	2	3	4	5	6
Area %	0	<10	10<30	30<50	50<70	70<90	90<100

Scanned with CamScanner

6. SIDE EFFECTS

6.1 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.

6.2 Evaluation of side effects: summary evaluation of the side effects was performed after completion of the study.

7. EVALUATION OF THE RESULTS

7.1 Cosmetic effects – tolerability were evaluated at the end of the study based on the statements of the patients.

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

7.3 The patients stated if they would continue to use of the Dr. Michaels product family.

8. SUMMARY EVALUATION

Upon completion the physician conducting the study provides a summary evaluation.

II. DATA OF THE STUDY

Start date:	2/ 4/02
End date:	5/22/02
Patients included:	30
Patients excluded:	3
Patients completed, evaluated:	27

Scanned with CamScanner

PATIENT CHARACTERISTICS

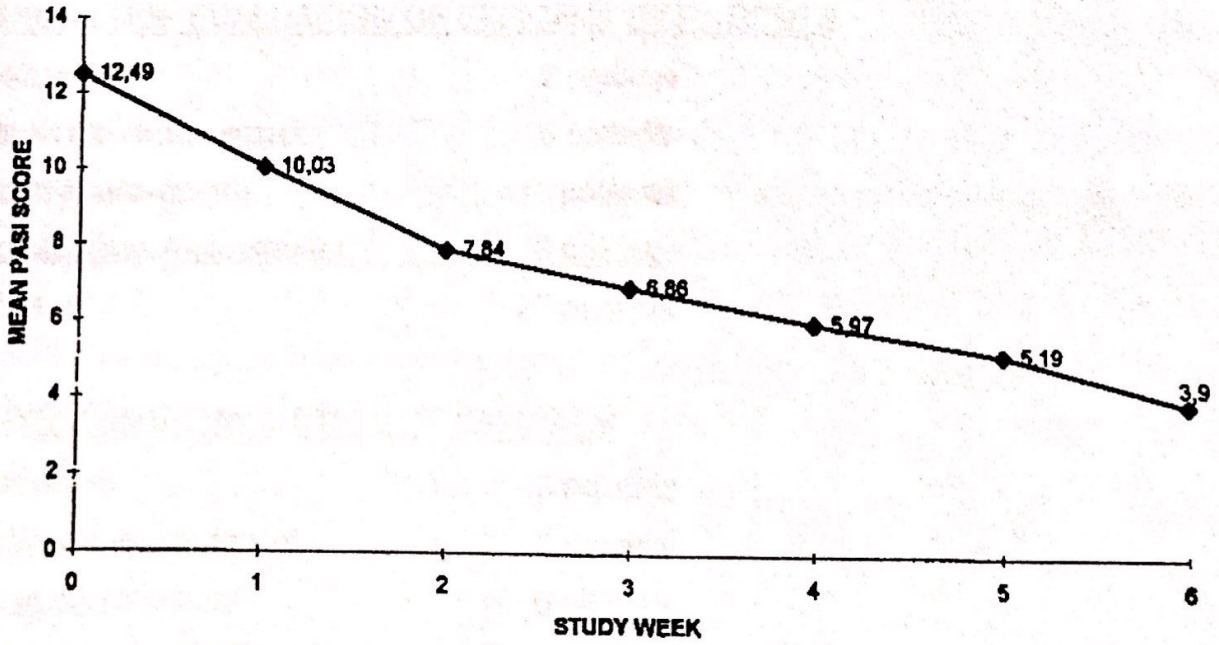
Mean age:	47,26.26 (18-80)
Mean duration of psoriasis:	17.56 years (2-47)
Gender distribution:	male: 18 female: 9
Psoriasis type:	plaque type, mild to moderately severe

EVALUATION OF IMPROVEMENT

Worsened	PASI score higher than baseline
Not improved	PASI decrease 0-25%
Moderate improvement	PASI decrease 26-50%
Good improvement	PASI decrease 51-75%
Outstanding improvement	PASI decrease76-100%

SUMMARIZED CHANGE OF PASI SCORE IN ABSOLUTE VALUES

(Number of patients: 27)



Scanned with CamScanner

CHANGES OF SKIN SYMPTOMS OF THE STUDIED PATIENTS

Worsened	0 patient
Not improved	3 patients
Moderate improvement	5 patients
Good improvement	6 patients
Outstanding improvement	13 patients
Total	27 patients

The percentage values of the improvement fall between 0 - 98, 68 %

SIDE EFFECTS

Evaluation points of side effects:	1, 2, 3, 4, 5, 6 week
Recorded side effect:	folliculitis of lower extremities
	pruritus of the scalp, upper torso
Folliculitis occurrence:	7 total occurrences, 5 males, 2 females
Pruritus occurrences:	1 total occurrence (female)

COSMETIC EFFECT – EVALUATED BY THE PATIENTS

Good	8 patients
Indifferent	19 patients

SUBJECTIVE EVALUATION OF EFFICACY BY PATIENTS

Ineffective	2 patients
Moderate improvement	5 patients
Good improvement	11 patients
Outstanding improvement	9 patients
Total	27 patients

PHYSICIAN'S EVALUATION OF EFFICACY

Ineffective	3 patients
Moderate improvement	5 patients
Good improvement	6 patients
Outstanding improvement	13 patients
Total	27 patients

Scanned with CamScanner

STATEMENT OF PATIENTS REGARDING FUTURE USE OF THE PRODUCT FAMILY

Would not continue to use	2 patients
Would continue to use	25 patients

SUMMARY

The study was completed in 27 patients out of the originally included 30. Three patients dropped out due to lack of compliance in two cases and due to the retraction of informed consent in one case.

We only studied patients with mild to moderately severe psoriasis.

The product proved to be **ineffective** in three of the 27 patients (11.21%). 5 patients(18.52%) had **moderate improvement**, 25-50% of the skin lesions cleared up. 6 patients (22.22%) had **good improvement**, 51-75% of the lesions disappeared. 13 patients (48.14%) showed **outstanding improvement** with the regression of 76-98.86% of the lesions.

7 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 are on the lower extremities. In six cases the folliculitis regressed upon discontinuation of the application without further treatment. In one case the folliculitis cleared after topical therapy.

One patient developed pruritus of the scalp and upper torso which regressed without discontinuing the application.

No contact sensitization could be noted, which is probably due to the thorough screening applied during patient selection. No patient was included in the study with known hypersensitivity to any component of the product. Important that the information material should warn of this and other exclusion criteria. Although we did not notice such effects in this limited study, some of the components of the product may have potential photosensitizing effect.

Patients should be warned about folliculitis as a potential side effect.

Although this product is a cosmetic, due to the previously described circumstances it is 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.

Scanned with CamScanner

The cosmetic effect was evaluated as indifferent by 19 patients, and as good by 8 patients.

The evaluation of the treatment by the patients differs from that **by the physician**. The only identical group is the 'moderately improved' (5-5). There was one more 'not improved' case according to the physician's evaluation compared to the evaluation of the patients (3-2). The patients in 11 the physician in 6 cases considered the improvement 'good'. The distribution of 'outstanding' evaluations is the other way around. The physician considered the improvement 'outstanding' in 13 cases while the patients considered it 'outstanding' in 9 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 percent-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.

25 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.

Because the product family consists of three different components, it is important that the **package insert** should be clear, easy to understand, making the application easy for everyone.

Based on the results of this study, the Dr. Michaels product family can be successfully applied in mild to moderately severe psoriasis when considering the exclusion criteria.

Budapest, Hungary, June 21st 2002.

Prof. Dr. Attila Horváth
professor and chairman, lead investigator

Dr. Margit Berecz
investigator

dr. Péter Holló
independent physician

Scanned with CamScanner

SPECIAL DERMATOLOGY AND ENVIRONMENTAL DERMATITIS DIVISION
Chief surgeon: Dr. H. Hönigsmann university professor
Dermatology University Clinic
General Hospital of the City of Vienna
Währinger Gürtel 18-20, A-1090 Wien

Test report about the clinical efficiency testing of the Dr. Michaels psoriasis treatment products

Introduction

The psoriasis treatment products Dr. Michaels were tested for clinical efficiency by the mandate issued by the Austrian and European distributor company Dr. Michaels RICA-A G.m.b.H. Traiskirchen, Austria. In the case of the dr. Michaels psoriasis treatment products a product family was presented, that included a cleansing gel (Skin Cleanser), a fatting ointment (Aromatherapic Body Ointment) and an after-treatment product (Skin Conditioner), this latter we call herein as skin oil. The products are manufactured in Australia, by TIRSEL PTY LTRD, Frankstone Victoria company, under GMP principles. The manufacturer has produced the full product description, the process certification issued by the Therapeutic Goods Administration, for each product, as well as, the list of ingredients, and the safety data sheets. The testing was accomplished by the general ambulance of the special dermatology and environmental dermatology in the General Hospital of the Dermatology University Clinic of the City of Vienna, Währinger Gürtel 18-20, A-1090 Wien.

Patients included into the study

Male and female patients were enlisted between 18 to 70 years of age, who all suffered in light to medium severe chronic, stable plaque psoriasis. Children, pregnant or stilling women or patients over 70 years of age were not selected. The patients had to abandon any other external and/or other systematic treatment against psoriasis. Any other psoriasis treatment therapy had to be paused by a 2 weeks ban. Also patients taking medication eventually influencing their state to worsen or indeterminable change were excluded. Another counter-indication were the severe, arthropatic psoriasis, psoriasis with inverted presentation, pustuleuse psoriasis and palmoplantary psoriasis. Every patient deposited his/her written statement of approval of the treatment.

Test protocol

For the test we elected a prospective, randomized, placebo controlled double blind test plan. One group of the patients received treatment by the dr. Michaels psoriasis products, the other group received treatment by three skin care products with no effective substance. All products included obtained identical, neutral packing in the institute pharmacy of the General Hospital, Vienna, and they were released by the study supervisor to be used by the patients, at times of the visits.

Both for verum and placebo patients the utilization guide was completely identical. Products denominated to be cleansing gel had to be applied over the lesions of the skin and, after effective time from 3 to 5 minutes be washed off with hand warm water. Following this the ointment was thickly applied over skin areas with psoriasis appearances, and was "sealed" after imbibition by the skin oil. The treatment was repeated twice a day, during the 8 week long treatment period.

Scanned with CamScanner

During the closing testing and every second week the state of the skin disease was judged by a blindfolded specialist. The evaluation was made under PASI principles about the regional and severity index of psoriasis. The patients were prohibited to give information to the controlling person, about the state of medication, during the study. At the control tests the patients received the medication note for the next treatment period. Before the beginning of the treatment, at the controls on the 4th and 8th weeks standardized pictures were made of the typical psoriasis plaques (indication lesions).

Statistical analysis

Mann-Whitney-U Test, with SPSS, in Windows.

Results

We elected 35 (15 men, 19 women) patients to our collective, with lighter and medium severe plaque psoriasis. 14 patients of the verum group (9 w / 5 m) accomplished the 8 weeks long treatment period, in the placebo groups they were 10 (2 w / 8 m). 6 of the placebo patients completed testing before time, because of lack of compliance. Most of the placebo patients ended the study because of lack of true improvement. Also in the verum group 4 patients were quitting because of underrated compliance. These persons explained completion because of the high time demand of the treatment. In the verum group the final PASI values were 6,8 ± 3,4 SD, in the placebo group 5,5 ± 2 SD. The PASI-Score decrease was 89% ± 14,9 SD in the verum group, and indicated 22% ± 28,7 SD in the placebo group, statistically substantially lower ($p < 0,001$). At 50% of the verum and 40% of the placebo patients have shown by-effects. Such unwanted effects were insignificant.

Summary

The psoriasis care products Dr. Michaels are products that resulted in substantial improvement within the present study, in the treatment of stable chronic plaque psoriasis. All the by-effects (follicultis, irritable dermatitis, itching) appeared for short time, only, and in view of severity they can be pronounced to be insignificant. None of these by-effects needed special therapy nor made they the stopping of the treatment mandatory.

The product family Dr. Michaels psoriasis care products offer assured and effective alternative for the treatment of stable plaque psoriasis.

University professor Dr. Herbert Hönigsmann
Chief of Special Dermatology and
Environmental Dermatitis Division

Chief assistant Dr. Harald Maier
study supervisor

Vienna, February 13th, 2004

Seal:

SPECIAL DERMATOLOGY AND ENVIRONMENTAL DERMATITIS DIVISION
Chief surgeon: Dr. H. Hönigsmann university professor
Dermatology University Clinic
General Hospital of the City of Vienna
Währinger Gürtel 18-20, A-1090 Wien

Scanned with CamScanner