SPECIAL DERMATOLOGY AND ENVIRONMENTAL DERMATITIS DIVISION
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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.

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.

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Vienna, February 13th, 2004

Seal:

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