

TEST REPORT

Dermatologically controlled application test with dermatological assessment

Test formulation: DermaNova Active Skin Care Cream

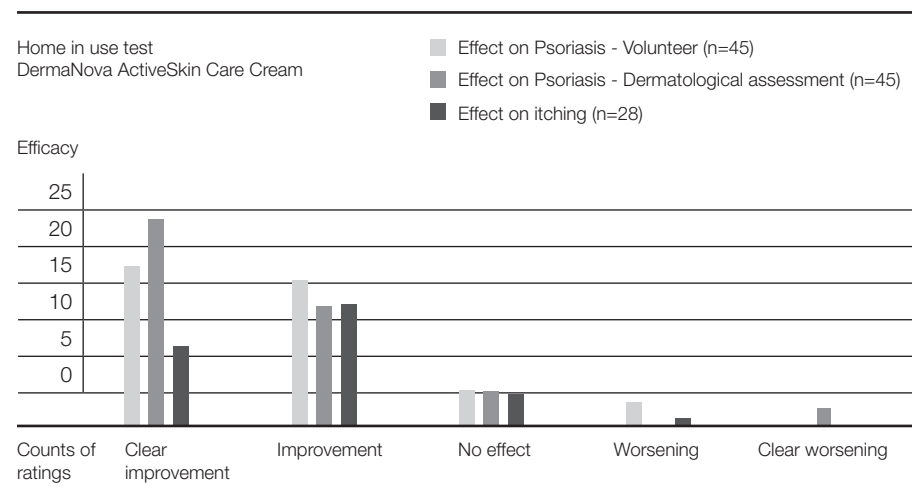
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1. Summary

The DermaNova Active Skin Care Cream formula is tested in a 4 week dermatologically controlled application study on 45 volunteers suffering from psoriasis from slight to moderate grade. The product is investigated regarding its cosmetical acceptance, effectiveness and tolerance. The following graph gives a survey of the mean ratings concerning effectiveness.



Graph 1: Mean ratings of 45 volunteers concerning effectiveness.

Concerning the effectiveness, the test product receives “good” and “very good” results in the volunteers’ ratings as well as in the dermatologist’s assessment. The most positive and obvious effect of the product is the disappearance of the scales often after the first week.

Only two volunteers discontinue the test for tolerance reasons. The occurrence of the irritation, however, is caused by their discontinuation of the former drugs. Otherwise the test product receives “good” mean tolerance ratings in this investigation.

In the total assessment the tested product formula obtains a mean value of 2.00 and accordingly a “good” rating. 29 of 45 (64%) of the testsubjects would without doubt in their mind buy the test product if it was available for sale.

2. Introduction

2.1 GENERAL DATA

Aim of the study:	Assessment of the effectiveness and skin tolerance of the DermaNova Active Skin Care Cream formula in a 4 week dermatologically controlled application study.
Test product:	DermaNova Active Skin Care Cream formula.
Test persons:	45.
Sex:	26 female, 19 male.
Age:	18-80 years.
Region tested:	Body.
Frequency application:	At least once a day.

3. Details of the experiment

3.1 SELECTION OF VOLUNTEERS

A group of 26 female and 19 male volunteers aged from 18-80 years suffering from slight to moderate graded psoriasis take part in the study.

According to the declaration of Helsinki [1] the volunteers must consent to the study in writing. Beforehand they are informed about the study, its objectives, probable benefits, potential risks and troublesome aspects, as well as about rights and responsibilities.

3.2 PERFORMANCE OF THE STUDY

45 female and male volunteers are assigned to use the test product at least once a day over four weeks on the areas affected with psoriasis.

After this application period the volunteers give their ratings on basis of a questionnaire in an examination with the dermatologist and allergologist.

The volunteers are allowed to use their usual cleansing products. Not allowed, however, is to change these products or to use new ones during the period of the study. Besides the test product no other product for the treatment of psoriasis is allowed.

3.3 DOCUMENTATION

Before the study a dermatologist documents the actual skin condition of the volunteers differentiated for face, body and extremities as well as the subjective skin sensitivity. It is stated whether the volunteers suffer from a contact allergy and perhaps can be classified as atopics. The dermatologist describes the skin area affected with psoriasis and localises these areas.

The volunteers name the products they usually apply against psoriasis.

All volunteers name the drugs taken and the disease that occurred during the study.

For the assessment of the cosmetic acceptance of the product the volunteers first judge appearance, consistency and spreadability of the test product. They also judge the absorption of the product. They state whether the product leaves a sticky feeling on the skin.

All parameters are rated on a scale from;

“very good” = 1, “good” = 2, “satisfactory” = 3, “sufficient” = 4, “poor” = 5.

In order to investigate the effectiveness of the test product, the skin care properties are judged by the volunteers. Directly and eight hours after the application the parameters, suppleness, smoothness, dryness, elasticity, firmness and appearance are judged for “improvement”, “deterioration”, or “no change”. The grade of the change is characterised on a scale from 1 = minimal to 5 = extremely.

The effectiveness of the product on the psoriasis is judged by the volunteers as well as by the dermatologist. The assessment scale comprises 1 = distinct improvement, 2 = improvement, 3 = no effect, 4 = deterioration, 5 = distinct deterioration.

Volunteers suffering from itching gave a statement on the products effectiveness on the itching.

For the assessment of the unwanted effects like eye reddening, eye itching, and watering of the eyes as well as skin reddening, itching, flaking, burning, tautness, feeling of warmth and development of papules caused by the test product are noticed. The intensity of the unwanted effects as well as their duration are noted additionally.

Afterwards the volunteers give a total assessment on the product tested. Moreover, the volunteers state which characteristics of the product they like and which they do not like and they give a purchase decision.

From the numerically coded data in the questionnaires mean values and standard deviation are calculated [2]. Otherwise frequency and proportional frequency are stated.

4. Results and discussion

4.1 CHARACTERIZATION OF THE VOLUNTEERS

Three volunteers discontinued the study after three weeks. As these volunteers give a final assessment, there is a total of 45 assessments on the test product after four weeks.

The following table shows the skin condition of the volunteers judged by the dermatologist.

	ACTUAL SKIN CONDITION	NUMBER OF VOLUNTEERS
Face	dry	6
	combination skin	28
	oily	11
	sensitive	0
Extremities	dry	43
	combination skin	2
	oily	0
	sensitive	0
Body	dry	29
	combination skin	15
	oily	1
	sensitive	0

Table 1: Relative frequencies of the respective skin conditions.

Six volunteers (13.3%) describe the actual skin condition of their face as “dry”, 28 volunteers (62.2%) state to have “combination skin” in their face and eleven volunteers (24.4%) describe the skin of their faces as “oily”.

43 volunteers (96.5%) describe the actual condition of their extremities as “dry”. Only two volunteers (4.4%) state to have “combination skin” on their extremities. None of the volunteers stated the skin to be “oily”.

29 volunteers (64.4%) describe the actual skin condition of their body as “dry”, 15 volunteers (33.3%) state to have, “combination skin” and one volunteer (2.2%) describes the skin of the body as “oily”.

	SKIN SENSITIVITY	NUMBER OF VOLUNTEERS
Face	Very sensitive	0
	Sensitive	13
	Normal	32
Extremities	Very sensitive	0
	Sensitive	9
	Normal	36
Body	Very sensitive	0
	Sensitive	9
	Normal	36

Table 2: Relative frequency of the skin sensitivity

13 Volunteers (28.9%) describe the skin sensitivity of their face as “sensitive” and 32 volunteers (71.1%) as “normal”.

9 Volunteers (20.0%) describe the skin sensitivity of their extremities as “sensitive” and 36 volunteers (80.0%) as “normal”.

9 Volunteers (20.0%) describe the skin sensitivity of their body as “sensitive” and 36 volunteers (80.0%) as “normal”.

PERCENT OF THE SKIN AREA AFFECTED	NUMBER OF VOLUNTEERS
10%	4
20%	20
30%	7
40%	6
50%-60%	3
70%	3
80%	1

Table 3: Percent of skin affected with psoriasis

The survey in table 3 shows that most of the volunteers (20) have a psoriasis affected skin area of 20%. 41 of the 45 volunteers use products against psoriasis.

4.2 EFFECTIVENESS PARAMETERS

4.2.1 VOLUNTEERS ASSESSMENT

The following table shows the summarized volunteers' ratings of effectiveness of the test product.

PARAMETER	TOTAL NUMBER	RATING					MEAN VALUE
		1	2	3	4	5	
SKIN CARE	45	6	29	9	1	0	2.11
		distinct improvement	improvement	no effect	deterioration	distinct deterioration	
Effect on Psoriasis	45	20	19	4	2	-	1.73
Effect on itching	29	9	16	3	1	-	1.86

Table 4: Average ratings and number of assessments for the cream by the volunteers.
(Ratings: 1 = very good, 2 = good, 3 = satisfactory, 4 = sufficient, 5 = poor) (n = 45)

PARAMETER	TOTAL NUMBER	RATING				
		Number "better"	Mean Value	Number "worse"	Mean Value	Number "same"
SUPPLENESS						
Direct after application	45	39	3.36	0	-	6
8 hours after application	45	1	2.00	0	-	44
SMOOTHNESS						
Direct after application	45	39	3.36	0	-	6
8 hours after application	45	1	2.00	0	-	44
DRYNESS						
Direct after application	45	39	3.36	0	-	6
8 hours after application	45	1	2.00	0	-	44
ELASTICITY						
Direct after application	45	39	3.36	0	-	6
8 hours after application	45	1	2.00	0	-	44
FIRMNESS						
Direct after application	45	38	3.32	0	-	7
8 hours after application	45	1	2.00	0	-	44
APPERANCE						
Direct after application	45	39	3.33	2	3.00	4
8 hours after application	45	1	2.00	2	4.50	42

Table 4a: Average ratings and number of assessments for the cream by the volunteers.
(Ratings: better, worse, same) (n = 45)

Most of the volunteers (35 volunteers) rate the skin care effect of the test product as “good” respectively “very good”.

Nine volunteers rate the skin care effect of the test product as “satisfactory” and one volunteer as “sufficient”. The reason for the “satisfactory” and “sufficient” assessments are the to slight improvement of the skin condition and the necessity to apply cream relatively often. The skin care effect rated with 2.11.

The observation of the cream formulas effect on psoriasis leads to a “distinct improvement” for 20 volunteers. 19 volunteers assess an improvement, four volunteers cannot realise any effect of the product and two volunteers observe a deterioration. Most statements express that the main effect of the product is the disappearance of the scales covering the affected areas. The daily application of the product leads especially within the first week to a decrease in the psoriatically characteristic flaking of the areas affected.

The product is characterised individually different due to the parameter reddening. For most volunteers the reddening fades in the four week period.

29 of the 45 volunteers in this study complain of itching prior to entering the test. After application of the test product 9 volunteers document a distinct improvement, 16 feel an improvement, three feel no effect and one volunteer feels a deterioration. In most cases the itching is soothed between 1.5 and 6.5 hours after first application. The average period is 3.5 hours.

Directly after application 39 volunteers observe an improved suppleness, smoothness, dryness, elasticity and appearance of their skin. 38 volunteers describe their skin as more firm. Six volunteers do not notice any change of their skin concerning suppleness, smoothness, dryness and elasticity. Seven volunteers do not notice any improvement concerning the firmness of their skin. Four volunteers do not notice any change in the appearance of their skin. A deterioration of the appearance is documented by two volunteers.

Eight hours after the application most of the volunteers describe that their skin is in the initial status again. This means, the majority of the volunteers re-apply the test product after eight hours. Only one volunteer feels the effect of the test product remaining up to eight hours so he assesses the suppleness, smoothness, dryness, elasticity and appearance to be improved after eight hours. A deterioration of the appearance is documented by two volunteers eight hours after application of the test product.

4.2.2 DERMATOLOGICAL ASSESSMENT

TOTAL NUMBER	RATING					MEAN VALUE
	1	2	3	4	5	
45	25	14	4	0	2	1.67

Table 5: Dermatological assessment of the psoriasis after four weeks.

(1 = distinct improvement, 2 = slight improvement, 3 = no change, 4 = slight worsening, 5 = distinct worsening) (n = 45)

After a regular application of the cream for four weeks, the dermatologist states a distinct improvement for 25 of 45 volunteers. For 14 volunteers there is documented a slight improvement. Four volunteers do not show any change and two volunteers show a worsening effect.

Thus the cream achieves a “good” respectively “very good” effect with the majority of the volunteers according to the dermatologist.

4.3 COSMETIC PARAMETERS

The following table shows a summary of the average assessments of the cosmetic parameters.

PARAMETER	TOTAL	RATING					MEAN VALUE
		1	2	3	4	5	
Appearance	45	0	39	6	0	0	2.13
Consistency	45	0	44	1	0	0	2.02
Spread ability	45	0	45	0	0	0	2.00
Soaking	45	0	45	0	0	0	2.00
Stickiness	45	0	45	0	0	0	2.00

Table 6: Average ratings and number of assessments for the cream after four week application. (1 = very good, 2 = good, 3 = satisfactory, 4 = sufficient, 5 = very sticky) (n = 45)

All cosmetic parameters received “good” ratings in the average. The appearance of the product is rated a mean value of 2.13. Six volunteers judge the product only “satisfactory” as they do not like the colour.

The consistency of the product is rated “good” by 44 volunteers. Only one volunteer judges the consistency to be “satisfactory”. All volunteers assess the spreadability as “good”. The same ratings are given for absorption, so this parameter receives a mean value of 2.00. The assessment of stickiness is similar. The product is rated as “not sticky”.

4.4 TOLERANCE PARAMETERS

The following table shows the tolerance problems occurred.

PARAMETER	VOLUNTEER NUMBER	DERMANOVA ACTIVE SKIN CARE CREAM			
		Reaction score	Duration (min.)	% of the volunteers	Total assessment of tolerance
Eye reddening	-	-	-	-	-
Eye itching	-	-	-	-	-
Eye watering	-	-	-	-	-
Skin reddening	24	4	>60	4.4	5
	38	4	>60		
Dryness	-	-	-	-	-
Flaking	-	-	-	-	-
Itching	24	4	>60	2.2	5
Burning	-	-	-	-	-
Tautness	-	-	-	-	-
Papules	-	-	-	-	-

Table 7: Frequency of unwanted effects and caused reactions after application of test product. (Reaction score: minimal = 1 ; strong = 5)
(Assessment of tolerability: very good = 1; poor = 5) (n=45)

Two volunteers discontinued the study after three weeks. The two drop outs are not caused by intolerability, due to a weak effectiveness of the test product in volunteers no. 24. and 38.

Both these volunteers normally use special drugs against psoriasis as “Psorcutan-Salbe” and “Cignolin-Salbe”. Volunteer no. 24 develops a strong skin reddening and itching after treatment with the test product. Both unwanted effects last more than one hour. Volunteer no. 38 develops skin reddening after 10 days, also lasting for more than one hour. Both volunteers used as described above strong drugs against psoriasis before entering the test. Stop taking these drugs caused the strong unwanted effect of the disease due to withdrawal symptoms. These unwanted effects can obviously not be compensated by the test product.

No unwanted effects are documented for the other volunteers. Therefore the compatibility of the test product receives an average mark of 2.00 and thus a “good” tolerability.

5. Literature

- 1 The World Medical Association, World Medical Association Declaration of Helsinki, Fernay, Voltaire, France (1989)
- 2 Hartung Statistik: Lehr- und Handbuch der angewandten Statistik; 4 Auflage, Oldenburg (1985)